FETAL TISSUE RESEARCH

THREATENED BAN COULD AFFECT SOME COMPANIES

WASHINGTON, D.C.—Officials in the White House are considering a broad ban on research involving the use of human fetal tissues. Such a ban would have a wide-ranging impact—affecting clinical researchers who are studying tissue transplant methods to treat conditions such as diabetes and Parkinson's disease. The ban would also affect scientists who are using fetal cells to develop model systems for the study of viral diseases.

At the request of Assistant Secretary of Health Robert Windom, a special panel of consultants was convened by the National Institutes of Health (NIH, Bethesda, MD) to evaluate the specific use of human fetal tissue in transplant experiments. Although unable to complete its discussions in September, the panel appeared to recommend that such research on fetal tissues—including material obtained from legal abortions—continue.

The panel was responding to narrow questions about transplant experiments, but White House officials have been considering a broad ban on all research using human fetal tissues. Such basic biomedical experiments have used human fetal tissues for decades—to understand normal and abnormal cellular development and to study particular genetic diseases (such as sickle cell anemia), viral diseases (such as polio), and diseases affecting newborns (such as respiratory distress syndrome). In fact, NIH spent more than $11 million on such research in 1987.

The panel of consultants was convened following an unusual exchange between senior officials at NIH and the Department of Health and Human Services (HHS). In late 1987, NIH scientists were preparing to transplant human fetal brain tissue into patients with Parkinson's disease. NIH director James Wyngaarden asked HHS approval before beginning the procedures. Seeking such approval is highly unusual, but NIH "elected to ask...to permit the maximum review of this sensitive area of research."

The panel includes biomedical researchers, members of the clergy, representatives of special interest groups, such as the right-to-life movement, and attorneys and other specialists with expertise in laws and regulations governing biomedical research practices and ethics. During several days of discussion, the panel was informed about the status of current research—with summaries of the laws, regulations, and ethical standards that govern it—and also about various organizations' positions.

The panel was particularly sensitive to private sector involvement in obtaining and studying fetal tissues. This sensitivity arises from several concerns, including fears expressed by some panel members that payments for such tissues could be used to induce women to have abortions. Ethical constraints, federal regulations, and laws such as the Uniform Anatomical Gift Act, however, prohibit for-profit sale of organs and tissues recovered from cadavers.

Representatives from several non-profit U.S. organizations described the current practices for recovering and distributing fetal tissues for research. Numerous safeguards are in place to ensure that tissues are obtained and used properly, says Leatrice Ducat, president of the National Disease Research Interchange (Philadelphia, PA). The Interchange was founded in 1980 to serve approximately 400 biomedical researchers who use fetal and adult tissues to study some 80 different diseases.

In addition to such non-profit organizations, companies such as Hana Biologics, Inc. (Alameda, CA) are developing technologies for culturing specialized cells, including cells from fetal tissues. Like biomedical researchers in academic institutions and at NIH, scientists at Hana are studying diseases—such as diabetes and Parkinson's—that someday may be treatable by transplantation techniques, according to vice president for research and development Fred Voss. He says that the company complies with all "legal and ethical norms."

Several panelists seemed uneasy that Hana anticipates making profits from such efforts. Currently Hana pays clinics for their services in providing tissues, and the company plans to charge fees based on the techniques it develops to maintain, improve, and deliver cell lines, Voss says. "Our [legal] analysis...is that it's appropriate to charge a fee for [this] service, just as Federal Express can charge for delivering a heart for transplant surgery," he says.

—Jeffrey L. Fox

Dr. Fox is helping the panel draft its report.

INTERNATIONAL TRANSPLANTATION SOCIETY

CAN FETAL CELLS CURE DIABETES?

SYDNEY, Australia—Exactly one month before Fred Voss faced the concerned individuals convened by the National Institutes of Health (NIH, Bethesda, MD), he presented his clinical trial data to an audience unquestionably more receptive—scientific peers attending the 12th International Congress of the Transplantation Society, held here in August. In those trials, 25 diabetic patients received transplants of human fetal pancreatic pre-islet cells—potentially capable of secreting insulin. Voss is not the only scientist conducting such experiments, but his company—Hana Biologics (Alameda, CA)—is the lone private-sector concern intent on profiting from the technique. While NIH ponders banning such transplants—and the White House considers an end to any and all work with human fetal cells—research scientists are still trying to determine if fetal-cell transplants will actually work in humans. (For a discussion of government concerns, see Jeffrey Fox's article on this page.)

Hana's Phase I clinical results at least indicate that it is safe to transplant pre-islet cells (first proliferated in culture), says Voss. The 25 diabetics who participated in this study all required kidney transplants—some received pancreatic islet grafts at the same time as the kidney, others about six months later. There were no controls (patients receiving only a kidney). None of the patients reacted adversely to the pancreatic pre-islet-cell graft and their transplanted kidneys functioned: all 25, however, remained insulin-dependent (from 25–140 days post-graft). Nine patients actually required less insulin (5–29 percent) than they had before—an encouraging result. For 14 of the 16 remaining patients, however, "the change in insulin requirement was 100 percent or greater." That the majority required more insulin may be only a consequence of the kidney transplant—a fairly common response. These results are too preliminary, Voss claims, for meaningful conclusions beyond safety issues.

It is customary to monitor transplant recipients for several years following the procedure. The data emerging from earlier trials, conducted by Kevin Lafferty (Barbara Davis Center for Childhood Diabetes, Denver, CO), demonstrate that grafted fetal tissue "will grow and has the