IVF research may yet receive federal funding

- US Department of Health to end moratorium
- White House opposition anticipated

Washington

THE US Department of Health and Human Services (HHS) has taken the first steps to end an eight-year *de facto* moratorium on federal funding of research on human *in vitro* fertilization (IVF). Robert Windom, Assistant Secretary for Health, last week announced that the department would reestablish its Ethics Advisory Board (EAB), a body required by department regulations to approve all research grants for IVF, but whose charter lapsed in 1980.

The decision to create an ethics board goes back to 1974, when the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. In 1979, the EAB produced a report concluding that it was ethically acceptable to conduct research involving human IVF and embryo transfer under certain conditions.

According to Charles McCarthy, now director of the Office for Protection from

sion for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. But without approval from an ethics board, NIH could award no grants for IVF research.

In 1980, NIH officials began a campaign to reestablish the EAB, but these efforts got nowhere within the Reagan administration. President Reagan has been extremely sympathetic to the so-called pro-life lobby, and there was little enthusiasm for research that might upset a strong political constituency. The failure to provide a new charter has proved frustrating for NIH officials. In a 1986 memorandum to the office of the assistant secretary for health, Duane Alexander, director of the National Institute of Child Health and Human Development, criticized the HHS's failure to follow its own regulations by failing to reestablish an ethics board.

It is difficult for the HHS to maintain the respect of the research community when it insists that its regulations for protecting human subjects and animals be followed strictly by its grantees, yet ignores the parts of its own regulations that impose requirements on itself. Earlier this year, NIH tried a new tack. NIH director James Wyngaarden suggested in a memo to HHS in January that research proposals could be approved on the basis of the EAB's earlier recommendations. Receiving no reply, Wyngaarden sent a second memo in April proposing approval of a specific grant request from Washington University in St Louis to improve the culture medium used to nourish the early fertilized ovum and improve the success rate of the procedure. HHS has decided to postpone approval of the Washington University grant.

But the decision to reestablish the EAB, announced at a House of Representatives committee hearing, nonetheless came as a welcome surprise.

Aware that the decision might raise hackles at the White House, HHS took pains to maintain a low profile until the announcement was made publicly. HHS plans to publish a new charter for its Ethics Advisory Board in the *Federal Register* within 30 days, and a 60-day comment period will follow.

Choosing the board's membership will certainly take several additional months, so it will undoubtedly fall to a new White House administration to get the EAB up and running.

Joseph Palca

Research Risks at the National Institutes of Health (NIH), but formerly the staff director for the EAB, one of the conditions was that the sperm and eggs come from married couples only. In addition, the EAB concluded that IVF research that did not involve implantation of embryos could proceed so long as the research was designed to establish the safety and efficacy of embryo transfer, that the donors were informed of the nature of the research, and that no embryos were sustained *in vitro* for more than 14 days, the period normally associated with complete implantation.

The EAB report was controversial. HHS received some 13,000 comments, most of which merely stated opposition to IVF and embryo transfer research. When its charter expired in 1980, the EAB was dissolved, and its budget given to the newly formed President's Commis-

NIH's ethics panel

THE US National Institutes of Health last week announced that a panel to investigate the moral, legal and ethical aspects of using human fetal tissue from induced abortions for therapeutic purposes will meet on 14–16 September.

The panel was created at the request of Assistant Secretary for Health Robert Windom, who last March ordered a temporary moratorium on research involving the transplantation of such fetal tissue pending a report of the newly created panel. Arlin Adams, a retired judge of the US Court of Appeals will chair the panel. Dr Kenneth Ryan of Harvard University Medical School and Dr LeRoy Walters of Georgetown University will chair scientific and ethical sessions during the September meeting.

J.P.

■ The fetus and pain. See this week's Correspondence, page 190.

New genome money

THE National Institute of General Medical Sciences has awarded the first round of grants from the \$17.2 million appropriated by Congress for gene mapping. Although the NIH reckon they spend nearly \$300 million annually on research related to gene mapping and sequencing, the new awards are the first from what will ultimately be a separate project office at NIH. The largest award (\$723,160) goes to David Schlessinger of Washington University in St Louis for human genome analysis using the yeast artificial chromosome technology developed by Maynard Olson. The next largest (\$540,410) is to Frederick Blattner at the University of Wisconsin for determining the complete genome sequence of *Escherichia coli*.

The current awards represent the first year of grants that will last from three to five years. The next round of grants will be announced in September.

J.P.

Hoechst wins battle

AFTER a three-year struggle, the West German company Hoechst AG has finally overcome local opposition to its DM50-million human insulin production facility in Frankfurt. The facility will use bacteria incorporating recombinant DNA to produce the insulin, a procedure that has been used since 1982 in other countries.

A decision by the *Land* (state) of Hesse on 8 July to allow a two-year test phase of the facility included concessions to environmentalist groups which fear the release of recombinant DNA into the environment. But the chief opponents of the plant, the citizens' initiative 'Höchster Schnüffler und Maagucker,' is considering a further court appeal.

Only one other company, Boehringer Ingelheim, produces pharmaceuticals in West Germany using recombinant techniques. They make the heart drug TPA (tissue plasminogen activator).

S.D.