

News & Comment

IVF Research Moratorium to End?

The Department of Health and Human Services has taken the first step toward ending a de facto moratorium on federal support for research involving in vitro fertilization, but it is moving slowly

FOR THE PAST 8 YEARS, the Administration has used a bureaucratic Catch-22 to maintain a moratorium on federal funding for research involving human in vitro fertilization. Federal regulations require that all such research be reviewed by an ethics advisory board in the Department of Health and Human Services (HHS) before government funds can be made available; but the ethics board was disbanded in 1980 and it has not been reconstituted since. No board, no funds.

Last week, after receiving numerous requests from officials at the National Institutes of Health and pressure from Representative Ted Weiss (D-NY), the department announced that it is finally going to resurrect the board. But it is doing it in a way that will delay decisions on specific proposals for months—almost certainly until the next Administration.



Robert Windom: *The ethics board is being reestablished, but will not get going until 1989.*

Robert Windom, the assistant secretary for health, made the announcement on 14 July in testimony before the House subcommittee on human resources and intergovernmental relations, which Weiss chairs. He said that because so much time has passed since the department last reviewed the ethics of in vitro fertilization research, the advisory

board should be reconstituted entirely afresh and it should take another look at the issues. This will require publishing its proposed charter in the *Federal Register*, allowing 60 days for public comment, revising the charter in light of those comments, and appointing the members. As a result, Windom acknowledged that the board will not be in operation before 1989. "Isn't this just a way of passing the buck to the next Administration?" wondered Weiss.

Nevertheless, Windom's decision at least paves the way for resumption of federal funding of research in this area—something that has been advocated by NIH and various professional groups for years. "It does what we've asked," says Duane Alexander, director of the National Institute on Child Health and Human Development, which is the chief source of federal funds for fertility research.



Representative Weiss: *"Isn't this just a way of passing the buck to the next Administration?"*

Research involving in vitro fertilization has always presented ethical problems for the federal government because of opposition from some religious and right-to-life groups who oppose a technique that results in destruction of some fertilized ova. In 1975, HHS issued regulations requiring that all proposals involving federal funds for

such research be reviewed by an ethics advisory board. A board was established in 1978—a few months before the birth in England of the first child conceived by in vitro fertilization—and its first task was to recommend guidelines for the types of research that the department could support.

The board set out a number of recommendations in 1979 that would have permitted funding of in vitro fertilization research under certain conditions, including a requirement that no embryos be sustained beyond the stage normally associated with implantation—usually 14 days after fertilization. Although the recommendations prompted a vigorous public response—some 13,000 comments were sent in, most of them postcards expressing opposition to any such research—they were adopted as department policy. This set the stage for the government to begin funding proposals.

The next year, however, a bureaucratic snafu developed. Congress created a presidential bioethics commission but appropriated no money for its operations. Patricia Harris, then the secretary of HHS in the Carter Administration, decided that because the department's own ethics advisory board and the presidential commission would overlap to some extent, the board could be disbanded and its budget transferred to the commission. The move left no properly constituted body to carry out the department's own regulations for funding in vitro fertilization research.

In the past 6 years, professional organizations, including the American Fertility Society, the National Advisory Child Health and Human Development Council, and the AAAS, have formally requested that the board be reconstituted. And 2 years ago, Alexander sent a memo to HHS officials pointing out that "it is difficult for the Department 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." Although Edward Brandt, Windom's predecessor, did recommend in 1982 to then HHS secretary Margaret Heckler that the board be reestablished, no action was taken.

In the meantime, in vitro fertilization has become accepted medical practice. According to a recent study by the Office of Technology Assessment (OTA), some 170 medical teams in the United States are now offering the technique. The success rate (15%) remains dismally low and the costs (about \$4000 per attempt) are staggeringly high, however.

Much of the debate about federal support for in vitro fertilization research has taken place in something of a vacuum because, until recently, no proposals had been submitted. (A proposal was submitted in 1976, but it was never funded because of the lack of a mechanism to approve it.) NIH officials believe that the dearth of proposals stems from the existence of the de facto moratorium. Last year, the child health institute estimated that perhaps 100 proposals would have been submitted by now if the moratorium had not been in place.

In the absence of federal funding, much of this potential research "probably is not being done," says Alexander. The OTA reported that some clinics and pharmaceutical companies are supporting limited research on in vitro fertilization techniques, but the volume is small.

Last year, however, a group at Washington University in St. Louis did submit a proposal to NIH, and it has turned into something of a test case. The research would involve studying fertilized and unfertilized ova (obtained from clinics) that are unsuitable for clinical use. The objective of the research would be to try to improve the culture medium used to nourish early fertilized ova, which in turn could lead to improvement in the success rate of the procedure. The proposal received an outstanding priority score of 126 from a peer-review committee, and it was endorsed in January by the child health institute's advisory council.

Three days before the advisory council endorsed the proposal, NIH director James Wyngaarden sent a memo to Windom urging the department to reconstitute the ethics advisory board. On 6 April, Wyngaarden followed up with another memo enclosing the Washington University proposal, in which he noted that the discussion is no longer hypothetical.

Weiss then planned public hearings on the issue. Two days before they took place, HHS secretary Otis Bowen approved the reestablishment of the ethics board.

The debate is not yet over, however. Publication of the board's charter in the *Federal Register* is sure to ignite fresh opposition—as well as an opportunity for researchers to state their case.

■ COLIN NORMAN

West Germany Moving to Make IVF Research a Crime

Bonn

In spite of heated opposition from scientific groups, the West German Bundestag is expected to approve legislation in the next few months that would make it a crime to conduct research on human embryos. Under a so-called embryo protection bill that is currently under consideration, the intentional in vitro fertilization of a human egg for research purposes would be punishable by up to 5 years in prison.

"Our primary concern is the protection of human dignity" says Jürgen Schmidt, a spokesman for the West German Ministry of Justice, which is developing the legislation. "We don't want to have to regulate after the damage has been done. There is no need for human embryo research at the moment. Should the time come when it is necessary, we will consider new legislation."

The issue is a particularly sensitive one in West Germany because of the abuse of human experimentation by the Nazis in World War II, and all the major political parties are in favor of the legislation. But many scientists argue that the proposed law goes too far. The legislation is far more restrictive than regulations on reproductive research imposed in any other country.

"It's national hysteria," says Walter Doelfler, director of the Cologne Institute of Genetics. "Embryology and genetics have a bad reputation in West Germany. It's not clear to many people just how well the self-control mechanism of science works. We don't need a law. We could use a review board which has control over what experiments are done, but this law amounts to a criminalization of science."

Research workers say the law will have a prohibitive effect on research in areas of reproductive medicine and embryology. "This area of research is still developing," notes Dieter Krebs, of the Clinic of Gynecology at the University of Bonn. "There are areas of prenatal diagnosis, where further human embryo research is a possibility. There is no way to tell now when and by which experiment therapeutic medical advancement can be expected."

"It took years of research with embryos in many countries—including West Germany—to make in vitro fertilization and embryo transfer possible," says H. Beier, director of the Department of Anatomy and Reproductive Biology in Aachen. "Today, 10% of the couples who can't have children for medical reasons can be helped." According to Beier, further research could determine the best conditions for obtaining and fertilizing intact ova, while minimizing the strain and danger to the patient. The same applies to in vitro cultivation and conservation of embryos in early stages of division before they are implanted.

The German Research Foundation (DFG), West Germany's largest research funding organization, has openly criticized the proposed law. Notes Dieter Husken, a spokesman for the DFG, the legislation would not permit exceptions of any kind. Experiments even under the strictest conditions would not be possible. As a result, Husken says, embryo research in West Germany would be brought to an end. "It will isolate West Germany," Husken says. "Biomedical research has become largely international. We should adhere to guidelines of the European Medical Research Council and not try to go it alone."

Indeed, in what is widely seen as an effort to head off the proposed legislation, both the Max Planck Society and the DFG have suggested that a voluntary moratorium be instituted.

Many West German scientists accept that research on embryos should be regulated, but argue that it should be regulated by experts who set the conditions under which certain experiments can be carried out. "Freedom of research" notes Karsten Vilmar, president of the West German Medical Association "leaves scientists with a special responsibility to society. If human life is the object of their research, scientists must recognize their limits and act accordingly."

"Science accepts this research as ethically responsible," notes DFG spokesman Eberhard Buchborn, "it serves to alleviate human suffering, protect life and health. It will be difficult to make it clear to a life scientist or doctor why such research is a punishable crime."

■ DON KIRK

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