Fetal Research: HEW Rules Depart from Commission's Recommendations

Is it ethical to maintain the vital functions of a fetus for research purposes if there is every reason to believe that the fetus is about to die? According to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, which Congress created to study such difficult questions, the answer clearly is No. According to regulations recently issued by the Department of Health, Education, and Welfare (HEW),* the answer is Yes. The HEW position seems to be based on a scientific judgment rather than an ethical one. In justifying its departure from the commission's recommendations on this point, HEW says in a statement accompanying the regulations: ". . . the Secretary is persuaded by the weight of scientific evidence that research performed on the nonviable fetus ex utero has contributed substantially to the ability of physicians to bring viability to increasingly small fetuses. The Secretary perceives that it is in the public interest to continue this successful research and accordingly an exception is made to the Recommendations of the Commission. . . ."

There are two matters for consideration here. One is the validity of the secretary's position about the "weight of scientific evidence," which certainly is debatable. The other is the bureaucratic process by which the recommendations of a federal advisory body are, or are not, transformed into law by government employees. In this instance, a significant change in the commission's recommendations was initiated by a group of middle-level HEW staffers who felt that valuable research would be prohibited if the commission's view were adopted. None of them will claim individual credit or blame for the decision.

The exception taken to the commission's recommendation about research on nonviable fetuses—there are a couple of other exceptions—is particularly substantive, going to the heart of the debate about whether scientific practicality or ethical tenets should prevail in governing experimentation. It may mark the first test of the commission's moral authority over the legal authority of a federal department. It is almost surely going to be an issue at the commission's next meeting in mid-October.

Technically, the ethics commission, which is considering all aspects of human experimentation, is an advisory committee like any other; it has no authority to write regulations, merely to recommend. But practically, the commission has, or should have, an extra measure of clout, expressly granted to it by a Congress that decided in advance to preclude the possibility of the commission's work being lost in the maze of the executive branch. To that end, the legislators wrote into law a provision that the HEW secretary must publish in full whatever the commission recommends and that he must either comply with its recommendations or explain why not, in public, in writing. Thus, the very nature of the terms under which the commission advises and the secretary receives advice demands an openness that is unprecedented in administrative policy-making. Nevertheless, it was not until mid-September that most of the commissioners became aware of the changes that were wrought in their recommendations and, even now, most of them know neither how nor why they came about.

The decision to allow artificial maintenance of vital functions of nonviable fetuses emerged from discussions by a number of staff people, including NIH lawyers and Charles U. Lowe, the executive director of the commission itself. The regulations, incorporating this and other changes, then went to the assistant secretary for health, Theodore Cooper, who approved them on 17 July, and finally to Caspar W. Weinberger, who signed them on 29 July in one of his last acts before his resignation as secretary took effect.†

Lowe declares that he had nothing to do with initiating any change in the commission's recommendations. In a telephone interview, he asserted that in his dual role as executive director of the commission and an employee in the office of the assistant secretary for health, it is his duty only to "interpret" the wishes of the commission to the department. He added that it put him in a delicate and difficult position.

The process of getting regulations through the HEW bureaucracy is a labyrinthian one requiring that individuals in many divisions of the department have a chance to comment and suggest, or insist upon, change. In this case, the process began at the National Institutes of Health (NIH); its origins can be traced back a couple of years. Lowe, a pediatrician, was among the first individuals to express concern about the rights of children, born and unborn, in human experimentation. In 1972, when he was scientific director of the National Institute of Child Health and Human Development, he organized an ad hoc group that met privately off the NIH campus to talk about the issue. Then, in 1973, former NIH director Robert Q. Marston appointed an official committee to study human experimentation and make recommendations for guidelines. The ad hoc group disbanded, the NIH committee recommended guidelines, and lawyers and legislative analysts took it from there. On 16 November 1973, the *Federal Register* carried a set of regulations that was technically described as a preliminary draft of proposed rule-making. That draft said of the nonviable fetus, ". . . vital functions of the abortus will not be maintained for purposes of research."

Draft Rules Written Last Year

Public comment on the draft rule-making was solicited and the public, including many scientists, spoke up. HEW received about 450 responses in all, which were considered before draft regulations were subsequently written. It was during this time that the act creating the ethics commission was passed and the political process of choosing its members was going on. By the fall of 1974, NIH and HEW found themselves locked in debate about whether or not to publish those draft regulations according to the normal schedule, which would have meant they would have come out only a couple of months before the commission began its deliberations on the same subject. Some argued it would be helpful to the commission; others said it would look as if the department were trying to take the wind out of its sails. The draft regulations were put in a drawer.

By 21 May of this year, the commission completed its study of fetal research and sent its recommendations for regulations to the HEW secretary, along with a recommendation that the moratorium on research on living human fetuses, which had been in effect since July 1974, be lifted. At that point, the commissioners, exhausted by 4 months of intense activity to get their recommendations in within the time required by law, turned their attention to other matters.

*The commission's recommendations and the HEW regulations on fetal research are published in the 8 August *Federal Register*, part III.

†Weinberger is now a vice president of the Bechtel Corporation, an engineering and construction firm. His office is in San Francisco.

Senate Bill Would Redo Commission

A bill that would dissolve the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research as it currently exists and then reconstitute it with additional members and powers is expected to be introduced in the Senate within a couple of weeks. Initiated by staffers for Senator Edward M. Kennedy (D–Mass.), the bill would transform what is now a Health, Education, and Welfare (HEW) advisory body into a presidential commission and invest it with authority to probe the ethics of human experimentation in the military and the Central Intelligence Agency (CIA). Added to its membership of 11 citizens would be 4 members of the House, 4 members of the Senate, and the heads of HEW, the Veterans Administration, the Department of Defense, and the CIA. The language of the bill is still being negotiated, but the point of it all apparently is to devise some way of enabling the commission to gain access to classified information. Two plans are being considered. One would be to have the add-on members, who already have security clearances, form a subcommittee of the commission, responsible for military and CIA investigations. The other would be to get clearances for all 11 commissioners. The proposed legislation, to be sponsored by Kennedy and Senators Jacob K. Javits (R–N.Y.) and Richard S. Schweiker (R–Pa.), would also extend the life of the 2-year commission indefinitely.

In ways, the draft Senate bill represents a position that that house of Congress has had for a couple of years. Kennedy and others originally wanted the ethics commission to be a permanent, presidential body with jurisdiction over the entire government rather than HEW alone. In early 1974, when the bill establishing the commission was being written, the House disagreed with the Senate on these positions. It may do so again.—B.J.C.

At this stage of the process, NIH and HEW staffers entered the picture as weeks of regulation writing began. The first thing they did was pull their draft regulations from the previous year out of the drawer. Those regulations included a ban against artificially sustaining a nonviable fetus. And the commission's feelings on the subject were clearly stated in its recommendations. It would permit no experiments that would alter the life of the fetus. And it would allow no nontherapeutic research at all on a nonviable fetus unless it is fewer than 20 weeks of gestational age. Under this provision, you could not put a nonviable fetus on a respirator, for instance, but you could draw blood for biochemical analysis. The latter type of experiment might include research to determine whether a specific enzyme is present in a very young fetus.

In arriving at this position, the commission was careful to delineate different categories of fetuses and different types of research. What it would forbid in this instance is nontherapeutic research on a nonviable fetus, that is, research that is not intended to be of any possible benefit to the particular fetus being studied and a judgment has been made that the fetus is too immature to survive on its own no matter what. The commission, concerned with the dignity of the fetus, felt that one could not experiment on a nonviable fetus just because it was about to die. To do so would be, as Commissioner Robert E. Cooke put it, to use the fetus as a laboratory animal.

The commission did not recommend a ban on therapeutic research on a "possibly viable fetus." Therefore, in its view, if you have a fetus that stands a chance of surviving, it is perfectly all right to take experimental measurers to sustain its life in the hope that it will then be able to make it on its own. According to Cooke, a pediatrician and a conservative on the abortion issue that underlies much of the debate on fetal research, there are large numbers of possibly viable fetuses on which to do therapeutic research that will ultimately lead to improvement in physicians' abilities to save very tiny fetuses. In his view, which he describes in this case as being based on scientific rather than ethical considerations, the "weight of scientific evidence" that such research on nonviable fetuses is essential is actually against the HEW position. Commissioner Robert H. Turtle, a lawyer, says that from the testimony he heard before the commission, he concludes that nontherapeutic research on nonviable fetuses may be expedient but not necessary. "Perhaps," he said, "the secretary has some information that we have not received."

Obviously, NIH and HEW staffers found the commission's stand on nontherapeutic research too restrictive. Richard Riseberg, legal counsel to NIH who actually wrote the regulations in their final, technical language, recalls discussions about whether the commission's prohibition was "too categorical," and about whether it would preclude certain types of research. The issue was discussed, he says, by "many people," including Lowe, commission staffers, and NIH officials responsible for overseeing guidelines on human experimentation. "All of us had in our minds the feeling that this was too categorical, at least that was my feeling, that is what was in my notes when I wrote the regulation," Riseberg says. The work of two scientists—Richard Behrman of Columbia University and Maurice Mahoney of Yale University—who prepared reports on fetal research at the request of the commission are said to have been part of the information that supported the final decision. However, it is equally possible to interpret their data the other way. Mahoney, for example, reported that experimentation on the nonviable fetus has never occupied a prominent place in fetal research.

In another significant departure from the commission's recommendations, the staff rule-makers introduced a provision that would allow the secretary, after consultation with a national ethical advisory review board, to waive the regulations in certain unspecified circumstances. The commission wanted a national review body that would interpret the regulations in complicated cases but said nothing about waiving them. Commissioner Karen A. Lebacqz told *Science* that this is the departure that troubles her most.

As the process of moving the regulations through the HEW bureaucracy took its course, the commissioners were not kept informed of changes that were being made, nor did they ask to be. The commission had said that the moratorium on fetal research should be lifted and the legal experts in the department knew that could not be done until regulations governing that research were in place. Foremost in their minds, according to Riseberg, was getting the regulations ready to go as expeditiously as possible. And, considering the way things sometimes work, they did well to get the regulations out and the moratorium lifted by 8 August.

When the 8 August *Federal Register* came out, most of the commissioners assumed it contained only their recommendations and, knowing them practically by heart, simply put the *Register* aside. But scientists in the field, anxious to see what the commission had to say, read the volume with care. One of them was David G.

Nathan of Harvard Medical School who met commissioner Albert R. Jonsen in August at a meeting on birth defects sponsored by the National Foundation–March of Dimes. Nathan expressed surprise at the regulation allowing artificial maintenance of vital functions of the nonviable fetus, in part because it is so liberal and in part because a provision immediately following it seemed to be saying that once you put a nonviable fetus on a respirator, for example, you cannot then do anything to terminate its life. It seems to raise the possibility of fetuses being kept "alive" for unpredictably long periods.

Jonsen turned out to be just as surprised as Nathan. He was carrying the *Register* in his briefcase but had not got around to reading it. He did so that night, and the next day he discarded prepared remarks about the general operation of the commission to speak about the regulations. He was upset by the changes and about the fact that the commission seemed to have been reduced to nothing more than an ordinary advisory body.

This latter point has been a source of mild tension throughout the commission's short existence. It thinks of itself as being more authoritative than the usual advisory committee although it knows it has no legal power. HEW staffers tend to think of it as being advisory only, and legally they are correct to do so. Certainly, HEW has the responsibility of reviewing and the right to change the commission's recommendations.

For the most part, however, the HEW regulations and the commission's recommendations are in accord. In the HEW report accompanying the regulations, there is the following statement, made with respect to the recommendations about research on fetuses in utero:

> The Department notes that the Commission was created to represent the best judgment of the community, and to make recommendations following an intensive study of the issues. All of the arguments which were submitted to the Department were considered by the Commission in its deliberations, and it is therefore reasonable to accept the findings of the Commission as the best possible judgment on the matter.

It can be said fairly that the commissioners represent a wide spectrum of views. These 11 men and women representing science, ethics, and law were not handpicked by HEW or NIH to see that research got the best possible shake. They are the survivors of an intensely political process in which the biases of congressmen, scientific societies, antiabortion groups, minority interests, and others came to bear. Indeed, their philosophical outlooks are so different that some people were amazed that they themselves could reach as close agreement as they did on their recommendations.

When the commission met last in September, Jonsen called the issue of the regulations and recommendations to the attention of his colleagues, most of whom were hearing about it for the first time. The commission staff is now at work on a detailed analysis of the situation and will report at the October meeting. Then the commissioners will have to decide whether they will stand firm behind their recommendations and put pressure on the secretary to amend the regulations or whether they will let this challenge pass.

—BARBARA J. CULLITON

Peer Review: NSF Faces Changes, the Question Is How Extensive

When the House Science and Technology Committee's oversight hearings on the National Science Foundation's (NSF's) peer review system ended in July (*Science*, 15 August) there were no signs that the congressmen were appalled by what they had learned. Neither, however, did they give NSF a resounding vote of confidence on peer review.

The hearings do seem to have convinced subcommittee chairman James W. Symington (D–Mo.) and his colleagues that peer review raises complicated questions and that changing the system requires a deliberate approach. The hearings record is expected to emerge from the Government Printing Office in the next few weeks and a report should follow, indicating the general lines of corrective action—if any—the panel will recommend. The likely timetable would put any such action in the next cycle of authorization legislation, which will begin after the Congress convenes for its second session in January.

Since the end of the hearings, however, several things have happened to keep the peer review pot boiling:

- Most recently, NSF's constant critic in the House, Representative John B. Conlan (R–Ariz.) has introduced legislation (H.R. 9892) which would drastically revise the NSF review system and grants management generally. Senator Jesse Helms (R–N.C.) has introduced a generally similar version (S. 2427) in the Senate.
- In mid-September, NSF got what amounted to a negative peer review of its peer review system from Philip Handler, president of the National Academy of Sciences (NAS). Handler suggested that NSF adopt a review system which relies "systematically" on advisory panels to replace the present mixed system, which uses both advisory panels and mail reviews from individual scientists (*Science*, 6 June).
- NSF is taking a number of internal actions aimed at improving the present peer review system. The effect, essentially, will be to amplify the array of checks and balances in the system.
- NSF's policy-making body, the National Science Board (NSB), which is considering the major policy question of whether to make names of reviewers available in certain circumstances, has decided to conduct an opinion survey to elicit a more comprehensive answer to the question of how scientists react to a possible change in NSF policies on confidentiality.

In a statement accompanying the introduction of his bill, which he read into the *Congressional Record* on 29 September, Conlan said that "The main purpose of the bill is to establish a grants award and management system at the Foundation which is fair, open and accountable to the scientific community and to the Congress."

He called the present peer review system "secret and arbitrary" and charged that "Recent statistics show that NSF funding is restricted primarily to a small group of preferred institutions in a few states, with special preference to an elite corps of academic institutions heavily represented on the Foundation's advisory committees."

Conlan's criticism of peer review seems to have been triggered by NSF's refusal to comply with his requests for peer review material and the identification of reviewers in connection with NSF-funded social science course improvement projects. Conlan's bill calls for establishment of a "Peer Review Office" in NSF to administer the