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NEWS AND COMMENT

Fetal Research: Ethics Commission Votes to End the Moratorium

The "four month" moratorium on research on the living human fetus, which legally has been in effect since 12 July of last year,* should be lifted to allow such research to go on under carefully circumscribed circumstances. This, in essence, is the recommendation that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research has sent to the Secretary of the Department of Health, Education, and Welfare (HEW).

After studying and debating the ethical, legal, and scientific issues relevant to research involving live fetuses, the commission has adopted a position that can be described as being moderately liberal. For example, the commission voted unanimously to allow experimentation on fetuses in anticipation of abortion and, with only one dissent, implicitly acknowledged that there are situations in which one would want to single out for studies fetuses that are scheduled to be aborted rather than jeopardize those that will go to term.

Although it is likely that the Secretary will adopt the commission's recommendations generally as written, it is less certain that biomedical scientists, intimidated as they were by the very fact that Congress demanded a moratorium on fetal research, will rush forward with proposals for studies involving live human fetuses.

The commission, created under a section of the National Research Act of July 1974, was given a mandate to investigate a number of areas of research involving human subjects, but was instructed by law to deal with fetal research first. A commission staff paper recognizes that the priority given fetal research in the law is indicative of "the concern of an overwhelming majority of the members of Congress that unconscionable acts involving the fetus might have been performed in the name of scientific inquiry."

By design the 11 members of the commission were chosen to represent a variety of points of view and religious persuasions, as indeed they do. Five months elapsed between the time the commission was created and its members were actually appointed, during which time every special interest group one can think of lobbied the Secretary to appoint its favored candidates. Then, when the commissioners were finally named in December (*Science*, 27 December 1974), charges were made that the body was top-heavy with Roman Catholics and that it was stacked with persons who were antiscience. It appears, however, that those allegations cannot be supported. In spite of the conservative nature of many commissioners, their recommendations seem calculated neither to please the Pope nor to call a halt to fetal experimentation. Generally, their recommendations are entirely reasonable.

The commission covered a lot of territory in its deliberations on research on live fetuses. It contracted with Maurice Mahoney of Yale University for studies of the extent, nature, and purposes of fetal research worldwide, during the past 10 years. His survey revealed 3000 papers on the subject and showed that less than 1 percent of the research involved living fetuses after delivery. It contracted for a study of available medical technology for preserving the life of fetuses born at an early gestational age, as part of its efforts to define what a "viable" fetus is. The study, headed by Richard Behrman of Columbia University, was summarized by the commission staff in a brief paper which concluded that "On an empirical basis the current limits of viability are clear: an infant born weighing less than 601 grams at a gestational age of 24 weeks or less has never survived."

The commission solicited papers from legal scholars, as well as from ethicists and philosophers. It held a day of hearings at which public witnesses testified. And, it consulted its own expertise—the commissioners themselves are medical researchers, lawyers, and ethicists—in arriving at its conclusions.

From the start, commission chairman J. Kenneth Ryan† of Harvard Medical School, was committed to the idea of achieving consensus on these recommendations about fetal research, which may be the most sensitive and difficult the group will have to make. Particularly because fetal research is so closely tied in many persons' minds to the abortion conflict, it seemed evident that the force of the recommendations would be seriously diluted were they to be accompanied by very many minority reports. Throughout the day-long session during which they voted on recommendations, Ryan urged commission members to first handle those portions of issues on which they could agree and then tackle areas of disagreement. As a result,

*For all practical purposes, there has been a ban on research on living fetuses since April 1973, when officials of the National Institutes of Health promised a contingent of Roman Catholic schoolgirls that they would not support such experimentation.

†Ryan was elected chairman by the commissioners themselves after their first meeting.

he got consensus on most of the 16 recommendations.

During the months that the commissioners probed issues pertinent to fetal research, they had in mind not only the fact that they were going to have to make concrete recommendations but also the fact that they would want to express the ethical and logical foundations that would underlie them. As commissioner Albert R. Jonsen of the University of California School of Medicine, San Francisco, observed, one of the most significant, and certainly most unusual qualities of this body is that it is deliberately and consistently trying to apply philosophical principles to public policy.

It is no surprise that 11 individuals from diverse backgrounds would have trouble agreeing completely on questions of ethics and morality. Ryan, realizing that no amount of discussion would resolve certain fundamental conflicts, nevertheless suggested that the commissioners might be able to agree on their recommendations even if their reasons for endorsing them were different. And, convinced that no amount of philosophical dialogue would make them totally of one mind, he strongly, repeatedly—and successfully—urged the commissioners to meet the 1 May deadline for submitting their recommendations rather than seek an extension. (The law required the commission to complete its investigation of fetal research within 4 months of the date of its first meeting.)

The commissioners considered research on living human fetuses in a variety of circumstances, tailoring their recommendations to each one. In every case, however, they emphasized the need for careful evaluation of a proposed experiment for both its medical and ethical soundness. And, in every case, they demanded informed consent.

Among their recommendations are the following, selectively noted here:

▶"Nontherapeutic* research directed toward the pregnant woman" must be evaluated for any side effects it might have on her fetus and "special care" must be taken to be sure she is informed of any possible risk and has given her informed consent (adopted unanimously).

The question of the father's consent, championed by commissioner Robert Turtle, a Washington, D.C., attorney and the father of four children, was a matter of debate with respect to this recommendation on nontherapeutic research on a pregnant woman, and to a couple of others. The question was not so much whether the father's consent were needed as whether his active objection must be honored. In cases in which the fetus is going to term, the commissioners voted 8 to 1 that a father's objection must be respected. When abortion is planned, the father still has a right to veto nontherapeutic research, the commissioners decided, by a vote of 5 to 4.

▶"Nontherapeutic research directed toward the fetus in utero (other than research in anticipation of, or during, abortion)" is to be allowed provided, in addition to requirements for consent, etc., that animal studies, where appropriate, have been conducted first and the point of the research is to gain knowledge that cannot be obtained any other way (adopted unanimously).

▶"Nontherapeutic research directed toward the fetus in anticipation of an abortion . . ." The commission approved this category of research provided that it meets with the requirements established for research on a fetus that is not scheduled for abortion, including one that says, "Minimal or no risk to the well-being of the fetus will be imposed by the research," (adopted unanimously).

Arriving at that recommendation was not easy for the commission. Taking the next step was even more difficult. Can experiments be done on fetuses about to be aborted *because* they are about to die anyway—experiments potentially too risky to be ethically allowable on a fetus that would come to term? Some of the commissioners clearly answered "Yes," to that. Others had trouble. A compromise was reached. "Such research presenting special problems related to the interpretation or appli-

*Therapeutic research is research that might benefit the actual subject of an experiment. Nontherapeutic research is not intended to benefit the individual subject but rather to gain information that might help others in the future.

"Freedom of Information" Can Work

One of the most remarkable things about the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research is that it has not attempted to duck the requirement that it conduct its business in public. It stands as a testament to the fact that the idea of "freedom of information" can work.

At the commission's first meeting last December (*Science*, 27 December 1974), its executive director, Charles U. Lowe, and staff director, Michael S. Yesley, told the commissioners in no uncertain terms that the law said they would have to do their job with everybody watching. There would be no clandestine nighttime meetings in hotel rooms where the "real" business of the commission would be done. There would be no secret pieces of paper for the commissioners' "eyes only." All reports to the commission would be public—even draft reports—whether they came from outside consultants or from the staff.

At first, the notion of such total public exposure struck many commissioners as an impossibility. (It has in other situations struck other scientific advisory bodies the same way and has prompted them to seek all manner of ways around freedom of information laws.) How could draft documents be exposed to the public? How could the commissioners speak their minds freely on sensitive and potentially devisive matters? How could they argue with one another with the press in the room? And how could they work out compromises if people could see what they were doing?

The answer, on all counts, is "Very well." The commissioners quickly adapted to working in a fishbowl. There is no evidence that anyone has kept still on matters of importance. There seems to have been no grandstanding for the press, either; no cases in which a commissioner deliberately makes flamboyant statements just to see them repeated in the morning paper. Quite the contrary, some observers believe that the presence of the public has had a beneficial effect, indirectly encouraging each commissioner to be as thoughtful and reasonable as possible.

The public availability of all commission documents likewise has not proved to be troublesome. Among other things, it has precluded the necessity of journalists or other members of the public importuning commissioners for leaked copies. Therefore, no purloined document has become the object of exaggerated attention.

The commission staff has helped a great deal by making public access to public documents easy. One is not put off by stories about there not being enough copies of this or that or about the copier breaking down. Documents are available to the press as soon as they are available to the commissioners.

Of course there has been controversy among the commissioners, and there will be more, but there have been few, if any, headlines declaring "Commissioners fight over fetal research." Honest differences of opinion, openly and reasonably expressed, do not lead to that.

The commission seems to be what freedom of information is all about. It is something that is not seen very often in Washington.—B.J.C.

cation of these guidelines may be conducted if supported by the Secretary, HEW, provided such research has been approved by a national ethical review body," is what the second half of this particular recommendation says. What it means is that an investigator, who has a good case for selectively experimenting on fetuses about to be aborted, can circumvent the more stringent requirements if a national review body can be convinced that the circumstances warrant it (adopted by a vote of 8 to 1).

(To some extent, the commission is passing the buck by laying decisions at the feet of a national review body, particularly in as much as no such body now exists. However, one of the commission's recommendations to the Secretary is that he create a national ethical review body to handle situations that cannot be dealt with adequately by local ethical review groups which must be established in every research institution. Although commission members are reluctant to call it an appellate court, it would certainly serve that function. A provision that its activities be public has satisfied some commissioners that it would be a basically conservative body. There is no telling how much red tape it would add to the already complicated process of conducting research.)

Unlike so many federal advisory bodies that write reports that are not read and offer advice that is not taken, this commission's activities are expected to have a very real impact on federal regulations. The Secretary of HEW, for example, must implement them or else explain in writing, in public, why not.

Chances are that the fetal research guidelines proposed by the commission will not please everybody, but there is no reason to think any other group could do any better.—BARBARA J. CULLITON

Strip Mining Legislation: The Tug of War Continues

For several years now, on the question of strip mining regulation as well as on other issues, coal industry lobbyists and environmental lobbyists have been tugging hard at opposite ends of the legislative rope. And, although Congress sent a strip mining bill to the President on 7 May, the tug of war between the lobbyists is not yet over. The Surface Mining Control and Reclamation Act of 1975 has been pronounced as unacceptable by the industry lobbyists, and they are demanding a presidential veto. The environmental lobbyists, while they view this bill as in part a congressional cop-out in favor of the mining interests, nevertheless much prefer it to no bill at all.

These conflicting reactions were predictable in light of the dilemma Congress has faced in wanting to encourage the rapid expansion of coal production while at the same time protecting the environment of the eastern and western coal regions. If President Ford vetoes the bill it will be because he has been persuaded by advisers in the Federal Energy Administration (FEA) and the Department of the Interior that the economic costs imposed by the measure would be too great. Frank Zarb, administrator of the FEA, told Congress in April that the proposed strip mining legislation could result in "locking up" between 12 to 72 billion tons of coal, or up to 53 percent of all domestic coal recoverable by surface mining.

Zarb emphasized that to impede coal production in the face of the need to reduce dependence on foreign oil would be folly. He said also that, by forcing up the price of electricity from coal-fired generating stations, the legislation could have an inflationary impact; and, finally, that up to 36,000 jobs might be lost as numerous small strip mining operations in Appalachia and elsewhere were forced out of business by mining restrictions and reclamation requirements.

The validity of these objections to the bill is in much dispute, and Representative Morris Udall (D–Ariz.), the bill's chief sponsor in the House, has accused administration officials of playing a "shabby numbers game."

As finally passed, the strip mining bill reflects some concessions to Administration criticisms, but probably not enough to gain either the support or the benign neutrality of officials such as Zarb. Last December Zarb opposed a bill similar to the present one, and President Ford vetoed it.

The National Coal Association (NCA), the industry lobbying group, has repeatedly voiced the same objections that Zarb has. Indeed, to judge from its record, the NCA would prefer no bill at all.

The environmental lobbying for a strong strip mining bill has been led by Louise C. Dunlap and John McCormick of the Environmental Policy Center, a Washington-based group. Dunlap acknowledges that if the strip mining bill becomes law, it would do a lot of good overall. But she and her associates are still indignant at actions by the House-Senate conference which removed from the bill some things they put great store by—which is itself evidence that the bill is not designed to impede strip mining.

As Dunlap and other environmentalists recognize, the bill would bring a much needed uniformity of standards to strip mining regulation. Heretofore, apart from some conditions attached to federal coal leases, such regulation has been left to the states. But while a few states have imposed stringent reclamation requirements, most have not. Under the measure now on the President's desk, regulation would remain in state hands but would be subject to federal oversight and certain minimum standards. For instance, land that has been stripped of its coal would be returned to its "approximate original contour," a term of art to be applied flexibly enough to allow open pit mining in relatively level areas as well as "contour" mining on steep mountain slopes.

The fact that contour stripping would be allowed to continue under the bill represents a major concession to the coal industry, although this particular issue was settled at the outset of congressional deliberation about strip mining several years ago. This controversial mining practice is in bad odor even among some of the major coal companies.

For instance, the Pittsburg and Midway Coal Mining Company (a subsidiary of the Gulf Oil Corporation), in a recent brochure said, "This mining method has been widely used by irresponsible coal operators who have left environmental disasters over large areas of Appalachia." It added that, inasmuch as only a small percentage of domestic coal is produced by contour mining, the practice probably should be stopped altogether, at least pending development of acceptable reclamation practices. This is a remarkable position for a company whose president, James A. Borders, sits on the board of the NCA, a group which holds