

Fetal Research (II): The Nature of a Massachusetts Law

The Commonwealth of Massachusetts has had a law regulating fetal research for 6 months now. It is a criminal statute; violators may be sentenced to as many as 5 years in prison. As yet, no one has been charged under the new law but the fact that it is on the books has made investigators wary. And that changes the relationship of scientists to their research and to their patients. Although this new law is far less restrictive in its existing form than it was in its initial draft, it nevertheless circumscribes a good deal of important physiological and biochemical research on the human fetus. A recent article traced the origins of the law (Science, 24 January). The nature of the law and its potential effect on research is the subject of this piece.

Boston, Massachusetts. The passage in June 1974 of "An act restricting experimentation on live human fetuses" is still thought of as a recent event here, one whose implications are now only barely understood. The fact that this state has any kind of law governing fetal research can be attributed to the efforts of "right-to-life" groups whose influence here—and throughout the country—is not to be underestimated. The fact that the law does not ban every bit of fetal research can be attributed to the counterefforts of a small band of persistent scientists whose initiation into politics came through their participation in the formulation of the law. Chief among them was David G. Nathan, professor of pediatrics at Harvard Medical School.

State Representative William Delahunt, at the behest of "right-to-lifers" among his constituents, last winter introduced a bill that would have brought all fetal research to an uncompromising end. But through a process of intense, and sometimes desperate, negotiation between legislators and scientists, the final draft of the bill that became law on 26 June was very much a product of compromise.

Ever since the bill's passage, researchers have been trying to figure out precisely what it allows and what it forbids. It is not all that easy. Delahunt, who was first seen as something of an ogre but is now viewed in a more charitable light, has been trying to help, interpreting the law as he sees it for scientists at dinners and other gatherings. One day he went to Harvard Medical School to answer questions. Observers there say it was quite a scene. As one nonscientist

present put it: There they were, some of the biggest names at the Harvard Medical School standing up like schoolboys to describe their work and ask, "Please, Mr. Legislator, may I go on with what I'm doing?"

Delahunt foresees the possibility of someday formalizing the role of scientist as petitioner. In a conversation with me during a drive to Boston College Law School, a Jesuit institution in the suburb of Brighton, Delahunt talked about ways investigators could know in advance whether their contemplated research projects are legal. "We have been thinking," he said, "about setting up some kind of board to advise scientists about their research before they get started."

At Boston College we met with James Smith, a lawyer who had written the various drafts of the law and who was very much involved in the negotiations over its final language. As Smith and Delahunt explained the law, a researcher's motivation could play a significant part in determining his culpability in certain situations. "This law does not allow him to take the guinea pig approach," Smith commented. "He must have the interests of the fetus at heart." The emphasis throughout

Recent advances in biomedical science are raising important problems of ethics and public policy. This is one of a series of occasional articles planned for News and Comment on the conflicts involved.

seemed to be on the interests of the particular fetus involved in any given experiment. The idea of doing research for the good of mankind and the health of future fetuses is insufficient justification for experimentation. No research may be performed on any fetus that is the subject of planned abortion; nor may anything be done that might "substantially jeopardize" the life or health of the fetus.

Therefore, Smith said, "Injecting antibiotics or viruses, et cetera, into a mother planning to have an abortion in order to see what effect there is on the fetus is absolutely out. On the other hand, if you give a mother who is not planning an abortion an experimental drug in order to try to help her particular baby, that's OK."

We talked about the use of abortifacients. Again, Smith put the emphasis on the researcher's intent. "If he is giving the mother prostaglandins in order to produce an abortion right away, we don't consider that a fetal experiment but a medical procedure to have an effect on the mother. If his purpose in giving prostaglandins, however, is to see what they do to the fetus, whether they make it convulse or something, then 'No,' such an experiment is definitely not allowed."

It was clear from interviews with several nonscientists that researchers' motives are not universally presumed to be the highest. An indication of the way many laymen see scientists is embodied in the cold legal language of this paragraph in the law:

No person shall perform or offer to perform an abortion where part or all of the consideration for said performance is that the fetal remains may be used for experimentation or other kinds of research or study.

Other attorneys familiar with the law are not sanguine about the importance Smith places on motive and are unhappy that this is a criminal statute. Neil Chayet, who represented scientists in final negotiations with Smith over the wording of the law, believes that it is particularly intimidating and, therefore, bad for research, because it carries criminal penalties. "We don't need any more criminal indictments in this state," he says, referring to the manslaughter indictment of Boston City Hospital (BCH) physician Kenneth Edelin, now on trial (*Science*, 31 January), and the grave-robbing indictments of four other BCH scientists (*Science*, 1 November 1974). Harvard University counsel Daniel Steiner

agrees that the criminal nature of the statute is not desirable. But Smith and Delahunt see it as a protection rather than a threat to fetal researchers.

In a criminal situation, they observed, the real burden of proof is on the person bringing an accusation. "You have to prove motive in a criminal case and that is very hard. You would not have to in a civil case, just that someone, in this case the fetus, had been harmed. The scientists may be better off with the law as it is," Delahunt noted.

It remains to be seen who is right.

Perhaps the most restrictive aspect of the Massachusetts law is the prohibition on experimentation with fetuses scheduled for abortion. It is that prohibition that is most likely to significantly retard research.

David Nathan, who says he has personal reservations about abortion, is, nevertheless, one of the many, many fetal researchers who believe it is morally justifiable to do research on fetuses before abortion. His own research on antenatal diagnosis of blood diseases, particularly sickle cell anemia and thalassemia, is a case in point. Research on the effects of virus vaccines on the fetus is another.

Nathan frequently sees parents who elect to abort a pregnancy rather than risk having a baby with sickle cell anemia or thalassemia, also known as Cooley's anemia. They base their decision on statistical considerations. In the case of either disease, if both parents carry the gene for it, there is a one in four chance that each baby they conceive will be afflicted. So, many parents decide not to take the risk. Nathan is among many scientists in this country who are working to change that situation by developing techniques for antenatal diagnosis of the disorders. That way, they would be able to tell parents each time whether their baby would be diseased. "This," says Nathan, "would lead to a decreased number of sick babies while allowing these parents to have as many well children as they want. In the end, we'd be preventing more abortions than we'd encourage."

It is not yet possible to detect sickle cell anemia in the early months of pregnancy but thalassemia can be identified, though the techniques for doing so are so very sophisticated that it is not likely they will be widely available for some time. However, real progress is being made in the antenatal detection of both diseases, progress which de-

pends upon the study of fetuses scheduled for abortion.

There are certain genetic disorders that can be diagnosed in utero through the comparatively simple process of obtaining cells from amniotic fluid by amniocentesis and culturing them for 3 weeks or so. Thalassemia poses a more complicated problem. The disease is basically a defect in the ability to synthesize a form of hemoglobin, in this case, beta-hemoglobin, and it is first of all necessary for the diagnostician to get a sample of fetal blood, which is not very easy to do.

When inserting any kind of instrument into the uterus, one must obviously be careful not to injure the fetus. To this end, investigators concluded that they need to literally see what they are doing. For the past few years, work has been going on to develop and perfect the amnioscope, a device that provides a view inside the uterus.

The idea is to insert the amnioscope into the uterus and withdraw fetal blood from a fetal vein in the placenta without sticking the fetus with the needle. While Nathan has been working on biochemical techniques for analyzing the blood once it is in hand, his colleague Fredric D. Frigoletto has been concerned with improving the amnioscope. He talked about some of the problems that have to be solved.

Amnioscopy Is Risky

"Work with the amnioscope is going very slowly, and it should," Frigoletto says, explaining that amnioscopy is a difficult and risky procedure that must be handled cautiously. Existing amnioscopes, he notes, have a very restricted field of vision. They are very small, about 1.7 millimeters in diameter, so the lens at the end takes in a narrow view. Once inside the uterus it is hard to become oriented, a circumstance complicated by the fact that the fetus is inconveniently moving around rather than holding still as if to have its picture taken.

Another limitation is that present amnioscopes are too rigid. Although inserted by a flexible cannula, the scope itself is a glass rod. "We'd like it to be flexible and controllable, like a snake's head," says Frigoletto. So, what researchers need is an amnioscope that is flexible and has a wide-angle lens. Meanwhile, they are doing the best they can.

Although experimentation to date indicates that the amnioscope is useful,

indeed essential for getting fetal blood, there are virtually no data on its safety. Nathan reports that as far as he knows amnioscopy has been used only once in a "save the baby situation" and that was recently on one of his own patients. That pregnancy is not yet complete but physicians are hopeful that the procedure caused the fetus no harm.

Because of the risk involved, Nathan, Frigoletto, and others believe that it is entirely moral to experiment on consenting women who have decided to have an abortion. The "right-to-lifers" and the Massachusetts law as it now stands do not agree.

As questions about the ethics of fetal research receive more and more attention, the matter of doing experiments on animals rather than people comes up. In this regard, two things seem to be happening. One is that many investigators are conceding that some human experimentation could be done validly on animals and are thinking more in that direction. Another is that researchers are coming up with examples of situations in which animal studies would be insufficient. One such case has to do with Rubella vaccine. According to Nathan, commenting on work done by others, Rubella vaccine does not enter the monkey fetus, although it does enter and damage the human fetus. He is apprehensive about what the prohibition against drug and vaccine studies in fetuses scheduled for abortion will mean for future research.

The situation in Massachusetts is in many ways representative of what is going on, or can be expected to go on, in other states. To reduce the debate about research ethics to one between "right-to-life" or antiabortion forces versus "enlightened" scientists is, clearly, to oversimplify the case. However, it is apparent that the research community is in danger of losing control of its own destiny as it is forced again and again to cope with the demands of people on the outside.

It has been suggested that parents of children born with various genetic defects and other disorders might be molded into an effective lobby against restrictive legislation. Many of them are already joined together in groups to lobby for research money for their special causes. It is not inconceivable that they could be persuaded to expand their activities, but as far as is known no one has tried.

Another approach to rational law-making and the protection of scientific research is exemplified by an advisory commission that has been established recently in Massachusetts. The commission, of which Nathan is a member, was set up by Delahunt as a body to advise the legislature on bills that

would influence research. It has not been in business long enough for anyone to evaluate its performance but, on the face of it at least, it seems to be a useful step in the direction of giving scientists a voice that they have not really had before.

And, if laws governing the conduct

of research continue to come into being, as is likely, the time may come when the idea of establishing some sort of quasi-legal board to advise scientists about the legality of their proposals will be one that will have to have serious consideration.

—BARBARA J. CULLITON

NIE: Beleaguered Institute Has a Stormy Past, a Cloudy Future

The National Institute of Education (NIE), the Nixon Administration's idea for laying a solid research and development base for federal education support activities, has lead a precarious and tortured life throughout the 3½ years of its existence. Last fall it appeared to be headed for extinction, but now survival for the institute seems assured, although by no means in the form or dimensions originally envisaged for it.

The institute, conceived by the then White House intellectual Daniel Moynihan, was created by Congress in the Higher Education Act of 1972. The underlying vision was that it would be a sort of NIH (National Institutes of Health) for the world of education, essentially apolitical, whose purpose would be to bring together some of the best minds in the country to orchestrate a program of research that would lead to educational reform and, as Nixon's speech on the subject emphasized, to "make educational opportunity truly equal." Even Democrats were willing to regard this as one of Nixon's better domestic ideas; many people were starting to agree with him that "throwing money at problems" would not solve all of them. There was no solid research base for many of the expensive Great Society programs of the Lyndon Johnson era, such as Head Start, that had failed to achieve the desired ends. It seemed time to pull back and regroup. In education, this meant calling on the resources of creative thinkers who were not necessarily part of the constituency of the Office of Education (OE), the "school people." OE's role, despite the fact that it had a research component, has been mainly to react

to the needs of its constituency; NIE was to be free to be innovative and initiate its own projects. Nixon's idea was that NIE within a decade of its birth would have a budget of some \$1.2 billion a year and a staff of up to 1000. Well, the legislation did get passed, in large part owing to the efforts of Representative John Brademas, (D-Ind.), chairman of an education subcommittee of the House Committee on Education and Labor. NIE was made separate from but equal to OE, both being within the Division of Education in the Department of Health, Education, and Welfare (HEW). And it was given a broad mandate—to advance education as an "art, science, and profession," to strengthen education's scientific and technological foundations, and to build "an effective educational research and developmental system."

Numberless problems have hindered achievement of the grand design. First of all, Congress resented being asked for funds for a fancy new R & D program, particularly one with the Nixon imprimatur, at a time when R & D money in other areas was being cut back by the Administration. The institute has been faced from the beginning with dilemmas about whether to concentrate its resources on pork barrel-tinged programs inherited from OE that seemed to have most direct relevance to present and pressing problems, or to antagonize the "practitioners," as teachers and school administrators are called, as well as Congress, by pushing into innovative enterprises that had no clear or direct application to those problems.

As yet, it has hardly had a chance

to choose. After 3 years, it is still trying to pull itself together. It suffered from the fact that Nixon was preoccupied with his own survival long before the magnitude of Watergate became known. Its director, Thomas K. Glennan, was not appointed until 5 months after the institute was created; and the 15-member policy board (the National Council on Educational Research), modeled along the lines of the National Science Board of the National Science Foundation, was not appointed until July 1973. Relations with Congress were dreadful. Glennan, formerly an economist at the Office of Economic Opportunity (OEO) who left NIE last November, found himself in a double bind with Congress. On the one hand, he was being asked for specifics on what the institute intended to accomplish and how it was going to do it; yet according to the law he was not supposed to enunciate programs and policies that had not been approved by the then nonexistent board. Furthermore, the institute was caught off balance because it had been led to expect a 3-year "honeymoon" of sorts before being called to account. By the time the board was appointed, it seemed that a lot of damage had already been done. Social science research has a checkered reputation, and educational research is generally held to occupy the bottom rung in terms of quality and prestige. So Glennan, with only generalizations to go on, sounded to Congress rather fuzzy, and his organization came across as surly and even arrogant. This circumstance, combined with the worsening economic picture, resulted in appropriations far below what might have been expected from the initial 3-year authorization of \$355 million. The fiscal 1973 appropriation of \$110 million permitted NIE to move into a new "field-initiated" grants program despite the fact that \$90 million of the funds were tied up in obligations transferred from OE. Appropriations for fiscal 1974 suffered a drop to \$75 million, largely owing to dissatisfaction