Fetal Research: The Case History of a Massachusetts Law

During the last year or so, several states adopted legislation regulating fetal research. And Congress enacted a moratorium on experiments on live fetuses. These laws inevitably alter the relationship of a scientist to his research and to his patient by placing legal sanctions on courses of action that previously were his alone to determine. Massachusetts is one of the states to pass a fetal research law. The origin of that law is the subject of this article. A second article will discuss the kinds of experiments that are permitted or forbidden under that law, as well as the reaction of the scientific community to it.

Boston, Massachusetts. Massachusetts State Representative William Delahunt, like so many of his colleagues in politics, entered the Statehouse knowing virtually nothing about science or research. But that did not stand in his way when he drafted his—and his state's—first bill to ban fetal research. Delahunt knew he did not know much about biomedical experimentation, but he thought he knew all he needed to know about cruelty to the unborn.

Delahunt's interest in fetal research developed in response to the concerns of some of his constituents. In a conversation about the origin of the Massachusetts bill, Delahunt recalled that members of "right-to-life" groups, many but not all of whom were Roman Catholics like himself, came to him for help. They told him tales of researchers jabbing needles into unborn fetuses and experimenting on fetuses that had been kept alive deliberately after abortion. They said that sometimes researchers perform abortions just to get their hands on the fetuses. They told him the story about a team of scientists who cut off fetuses' heads and kept blood circulating through them.

These were grisly accounts, and Delahunt, who did not number scientists among his friends, saw a situation that was black and white. What we need, he thought, is a law.

To draft a bill, Delahunt teamed up with lawyer James Smith of Boston College Law School, a Jesuit institution in the suburb of Brighton. Smith, who has a reputation for being especially concerned with the protection of the weak and defenseless says, "A fetus scheduled for abortion should not be the subject of experiments because there is no one to look after its interest." Delahunt and Smith wrote a bill that banned all research on fetuses, living or dead, which were the subjects of planned abortions. It appeared likely to pass the lower house of the state legislature easily. It was not until then that anyone at Harvard Medical School knew what was going on downtown in the Statehouse.

One afternoon in late March 1974, Jack Ewalt, the school's senior associate dean for clinical affairs, learned there was to be a hearing the next day. "I felt we should try to get the bill modified, or clarified at least," Ewalt remembers, "so I tried to get some Harvard people to go down there and testify. I must have called eight or ten people between four and six o'clock that afternoon, but most of them were too busy to go down on such short notice." But Arthur Hertig, a senior scientist who had worked with John F. Enders on experiments leading to the discovery of polio virus, was available. Hertig had obtained fetal tissues that were essential for Enders' studies and he testified at the hearing that research with human embryonic and fetal tissue is vital to medical advances. In addition to his own testimony, Hertig went armed with written statements from Enders, who won the Nobel Prize in 1954, and Thomas Weller, also of Harvard, who shared in the 1954 prize. Harvard was hoping that the Nobel connection would be immediately persuasive to the legislators. It was not. Nor was the testimony of one lone scientist against numbers of "right-to-lifers" who favored a ban on fetal research. However, it did let legislators know, apparently for the first time, that there was opposition to the proposed law, and it paved the way for compromise legislation.

Arrangements were made for a meeting of Delahunt's committee, House Speaker David M. Bartley, Smith, and others. Ewalt attended. So did Weller and Kenneth Ryan,* chairman of obstetrics and gynecology at Harvard, whom the dean's office had picked to negotiate for Harvard. Others from Harvard were there this time too. House member Lois Pines, apparently the only representative who had understood how damaging the bill would be to research, had called Franz J. Ingelfinger, editor of the *New England Journal of Medicine*, to alert him to the problem. Ingelfinger got in touch with individuals whom he thought should know what was going on. One of them was David G. Nathan, professor of pediatrics at Harvard and chief of hematology and oncology at Harvard-affiliated Children's Hospital Medical Center.

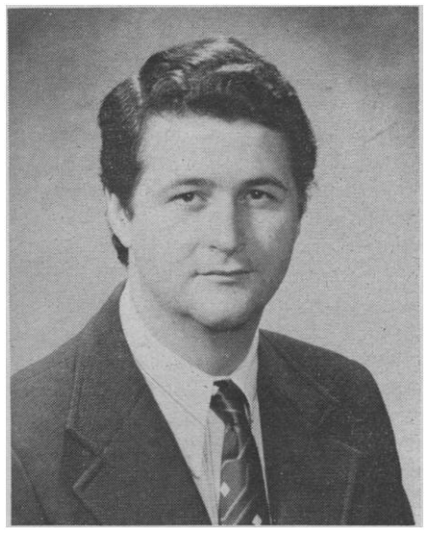
Ewalt recalls that "They, Ryan and Weller, hammered out some changes to allow amniocentesis and to permit studies on living fetal tissues. We came up with a compromise bill that everyone seemed happy with at the moment."

Nathan, who notes that at the meeting he and some other researchers "each stood up before the legislators and gave our own little Gettysburg address for fetal research," was not happy, however. In fact, he recalls, "I was in a rage. I felt we were selling out."

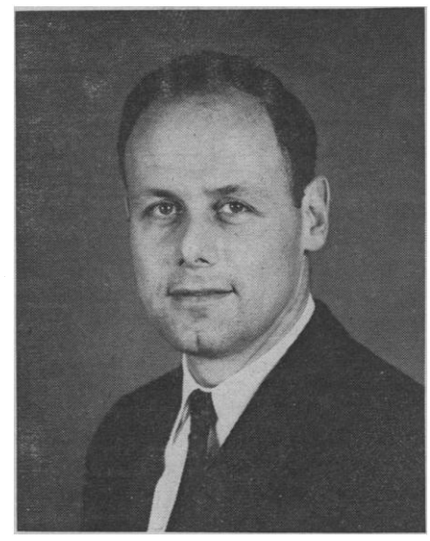
Nathan, who had never heard of the pending legislation until 4 May, shared the general feeling of most researchers that fetal experimentation is a necessity, but his interest in the bill went deeper than that. For years he had been trying to identify certain hemoglobin disorders in utero and was on the verge of successful antenatal diagnosis of beta-thalassemia, an inherited disease that primarily occurs in persons of Mediterranean ancestry (*Science*, 10 November 1972). Biochemical studies were going well and, because of progress in the development of the amni-

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.

* Ryan was recently elected chairman of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, the group that must decide whether to continue the present federal ban on research on live fetuses (*Science*, 27 December 1974).



William Delahunt



David Nathan

oscope, a new device for visualizing a fetus by inserting a tiny cannula with a lens at its tip in the mother's womb, it was becoming possible to obtain samples of fetal blood for analysis. The compromise bill would have made Nathan's research illegal. He decided to fight to save it. In so doing, he ventured into areas of internal medical school politics and state politics where he had not been before.

The compromise bill no longer carried a prohibition against research on dead fetuses and made provision for the study of a live fetus while still in its mother's womb, thereby permitting amniocentesis, as long as the fetus is not the subject of a planned abortion *"at the time of"* [emphasis added] the procedure and as long as the procedure does not "substantially jeopardize the life or health of the fetus." But the same language that sanctions amniocentesis, a procedure now recognized as part of routine medical practice, would block research with the experimental amnioscope.

Nathan points out that one cannot yet say that use of the amnioscope to visualize the fetus poses no substantial risk; it is too early to know. Therefore, he argues, until the procedure is further refined, it is all the more important to test it on fetuses slated for abortion. "Personally, I'm not in favor of abortion, but I'm less in favor of practicing on a fetus we are trying to save." Nathan believes that, in situations such as this, it is both sensible and moral to experiment with a fetus that will be aborted.

Nathan recalls that he tried on his own to get through to Delahunt and Smith to effect a change in the bill. "I had to convince them," he said, "that, if I could diagnose sickle cell anemia [something he hopes to be able to do before long] and thalassemia and other disorders in utero, I'd be preventing more abortions than they ever could. We have women who have an abortion because they don't want to risk having an afflicted child. With antenatal diagnosis, I could tell them, three times out of four, to go ahead and have the baby." They listened but were not persuaded.

Then Nathan and others interested in further modifications of the proposed ban on fetal research met with the Senate leadership. But, as Nathan remembers the outcome of that meeting, they still were not successful. "The Senate leadership listened," he says, "but it was no go for us. They said the bill was going through."

Nathan next arranged a meeting with members of the Governor's staff. He was going to ask that the Governor make a change in the bill to allow antenatal diagnosis, particularly amnioscopy. But by then, others were involved in what was known to many as the "fetus fight" and Nathan's meeting, when it took place, did not come off quite as originally planned.

Wider Implications

Boston lawyer Neil Chayet had been consulted about the bill and was advising the scientists to fight to get the whole thing scrapped, not just modified. Because of what he considered its loose legal language, he feared that if it passed, researchers would be vulnerable to innumerable types of suits. Chayet wanted a press conference to generate publicity against the bill.

Howard Hiatt, dean of the Harvard School of Public Health, was anxious to see the bill changed or killed and agreed to make facilities available for the press conference. He talked to Nathan by telephone the night before. "Howie's call really made me stop and think about what I was fighting for," Nathan recollects. "He said, 'Dave, I'm behind you because I know you are doing this for all of our patients, not just to save your amnioscope.'" From then on, Nathan recounts, he knew that saving antenatal diagnosis was not enough. "I really always knew it," he says, "but that call brought it home."

Nathan realized that by calling a press conference and getting in touch with the Governor he was riling the medical school brass. Ewalt, who believed chances of getting the Governor of this Catholic state to kill the bill were zero, thought the Harvard "militants should keep still." But by this time, they could not be quieted.

The press conference was held on 6 June. To the scientists' surprise, Delahunt showed up, along with George McMahon of House Speaker David M. Bartley's office.

Delahunt commented to me on his reason for attending. "Even after attempts to negotiate the language of the bill with the doctors, they still refused to support it. I wanted to figure out why." Apparently he did.

After the press conference, Delahunt talked with Frederic D. Frigoletto, at Boston Hospital for Women and one of Nathan's chief collaborators in research. Nathan reports that "Frigoletto finally got through. He got Delahunt to understand what we were doing and why antenatal diagnosis is a procedure that allows babies to be born who would otherwise be aborted."

The following day, the meeting Nathan had scheduled with the Governor's staff took place but there was no promise of a veto. Instead, staff members, sensing that an acceptable compromise might still be possible, urged the two sides to try again.

That weekend, there were intensive negotiations over the language of the bill, with Chayet acting as principal negotiator for the scientists.

The premise of the bill as written by Delahunt and Smith was that no research should be performed on any fetus that is the subject of a *planned* abortion. What would happen, then, if a woman who said she did not intend to have an abortion were to subse-

quently change her mind? Chayet got the following sentence written into the bill. "In any criminal proceeding, the fetus shall be *conclusively presumed* [emphasis added] not to be the subject of a planned abortion if the mother signed a written statement that at the time of the study she was not planning to have an abortion." Some investigators have criticized that portion of the bill, saying it invites deceit, but Chayet points out that it nevertheless protects the researcher.

A section of the bill defining a "live fetus" as one with movement or heart or respiratory activity was amended, and more vague language about the "best medical judgment of a physician" was substituted.

The law requires the written consent of the mother before any experiment can be lawfully performed on a dead fetus. Keeping in mind the pending case of four Boston City Hospital investigators charged with grave robbing for moving bodies of dead fetuses without maternal consent (*Science*, 1 November), Chayet inserted a provision to protect scientists in the future. Written consent to allow researchers to use a dead fetus also constitutes consent for its "transfer" from one hospital or laboratory to another.

These compromises were agreed to relatively easily, but the language of paragraph two of the bill, a single sentence, turned out to be harder to negotiate. The sentence has to do with diagnostic and remedial procedures, including amnioscopy. By telephone over the weekend, Smith and Chayet drafted a paragraph that said, "This section shall not prohibit or *relate to* [emphasis added] diagnostic or remedial procedures the purpose of which is to determine the life or health of the fetus involved or to preserve the life or health of the fetus involved or the mother involved."

At the beginning of the week, everyone went to the House Speaker's office to complete the negotiations and participate in a press conference announcing that differences had been resolved. But there was unanticipated trouble, Nathan remembers. "The negotiations had been conducted through a series of hysterical phone calls. No one had had time to reflect." Smith, who had not seen the final peace document in writing, said he would not buy "relate to" but wanted all of paragraph two deleted. "For a while," says Nathan, "I thought the whole deal was going to fall through. There we were with lots of reporters waiting in a room upstairs and suddenly we had no agreement. I was ready to cave in but Fred Frigoletto wouldn't let me. 'Don't give an inch,' he said."

Speaker Bartley, Nathan declares, then saved the day. "He calmly told everyone to take his time about working things out and said he would just tell the press to go home, which he did." So, the two sides went back to negotiating and each side gave a little. The scientists agreed to the substitution of "regulate" for "relate to," and Smith agreed to the rest of the para-

Briefing

Greetings from Holifield National Laboratory

The folks at Holifield National Laboratory wish everyone a happy new year, but they ask you not to jot down the name in your address book just yet. It may be but a short-lived phenomenon.

Who? Where? Well it's that big energy and biological research center down in the hills of Tennessee that used to go by the name of Oak Ridge National Laboratory or ORNL for short. As a little holiday surprise, some friends of Representative Chet Holifield (D–Calif.) thought it would be a nice idea to memorialize the retiring congressman for his more than 30 years of staunch and distinguished service on behalf of nuclear energy. And what better way than to append his name to an institution nurtured on the billions of dollars Mr. Holifield helped channel into nuclear research?

The idea of renaming ORNL apparently was cooked up by staffers on the House Government Operations Committee (of which Holifield was chairman as well as being a major power on the Joint Committee on Atomic Energy since the 1940's). A bill to enact the change slipped through the House and Senate on 18 and 19 December and, amid the rush to adjourn, aroused no objections. President Ford signed it a few days later and only then did the word get around Oak Ridge.

The result was a chain reaction of displeasure, from the Chamber of Commerce (Holifield, Tennessee?) to researchers and administrators at the laboratory. Everyone, it seems, deeply appreciates Holifield's efforts and thinks a memorial of some sort would be just fine. But the whole laboratory seemed a bit much. As the local *Oak Ridger* editorialized, "Rep. Holifield has long been a special friend of Oak Ridge and Oak Ridge National Laboratory . . . [But] where does it begin, where does it end? With the nuclear scientific pioneers like Einstein, Fermi, Compton? With the military men who led the Manhattan Project? . . . This is the kind of bill that congressmen tend to introduce and vote 'yes' on willy-nilly. Who wants to insult a fellow congressman? And, who knows, the next laboratory they name may be your own."

Community leaders and laboratory administrators alike are concerned about a loss of identity, for the town as well as the laboratory. "I recognize the role Holifield's played," says Howard I. Adler, director of ORNL's biology division. "But the name ORNL has worldwide significance and recognition that can't be tossed aside lightly. We lose more than Holifield gains."

Now that the new name has been cast into law the Tennessee congressional delegation has started hearing from its constituents. An aide to Senator Howard Baker (R–Tenn.) says that office has received "literally hundreds" of protesting telegrams and letters. Baker is working with Representative John J. Duncan (R–Tenn.) to devise a pacifying compromise. Two possibilities are a hyphenated name (like Oak Ridge-Holifield National Laboratory) or dedicating ORNL's headquarters building to Holifield.

Laboratory officials, however, are miffed at not having been consulted before or since the name change.

Possibly they can take heart from the residents of Cape Canaveral (briefly Kennedy), who won their identity back in 1973. Or from Caltech's Jet Propulsion Laboratory, which two years ago found itself rebaptized in honor of H. Allen Smith, not the humorist but the local congressman who, by coincidence, had periodically voted to cut the space budget. Before long Mr. Smith's name was attached to the administration building and JPL has been just plain JPL ever since.—R.G.

graph which gives researchers considerable leeway in the kinds of studies they can conduct. The law does not regulate diagnostic or remedial research but it relates to it nevertheless, making scientists legally accountable for clear-cut violations.

On 26 June, Massachusetts Governor Francis W. Sargent signed the bill which had passed both houses of the legislature without debate.

Delahunt, who calls the fetal research law as it currently stands a "modern statute," is the first to admit that his original version of the bill would have been disastrous for research. And Smith says, "Most doctors in fetal research see it as a benefit rather than a burden. It gives them assurance to go on without fear of criminal charges."

The lawmaker and the lawyer overstate the case somewhat—virtually no one in the scientific community is completely happy with the present law—but there is no doubt that, because of their willingness to listen to what Nathan and his conferees had to say, the law is more enlightened than it might have been. Nevertheless, the law is restrictive in ways that scientists find hard to live with, and efforts are under way to amend it.

For Delahunt the experience with the fetal research law has been broadening, instructing him in the ways of science and scientists. His relationship with the scientific community is one he intends to continue, and he has established a state advisory commission to work with the legislature on bills that would affect researchers. Nathan is a member.

The confrontation between the scientists and the lawmakers has been equally illuminating for the scientists who, as Delahunt puts it, "have learned that we in the Statehouse do not have horns." In fact, the individuals involved in the struggle to save fetal research consistently say, still with surprise in their tone, that Delahunt is a very "reasonable, rational" fellow, as are the other public officials they got to know. But the process was a trying one.

Nathan, like many researchers, is jealous of his time in the laboratory and clinic, and he quickly found out from experience what he knew to be true anyway; involvement in controversial political issues is a full-time job. And, like many researchers, especially those in medicine, Nathan was trained to respect authority. He did not regard himself as a rebel and found it hard to go against the dean. He wonders whether he would have had the nerve to do so had he not had the security he does as a tenured professor and researcher of established reputation. But, looking back on the most trying of days, he is satisfied. "We have a better Act, and we have Bill Delahunt and people in the Speaker's office on our side. I'm glad I did what I did, but now I keep waiting for someone to take my place so I can go back to research."

From a scientist's point of view, this is a story with a reasonably happy ending. The Massachusetts law is regarded as more liberal than those of some other states. If efforts to amend the law succeed, it may have an even happier epilogue. But it was a close call.—BARBARA J. CULLITON

Air Force R&D Policy: More for Basic Research, Universities

Last June, Barry Goldwater, Senator from Arizona and Air Force Reserve Major General (Ret.), wrote a "Dear Jim" letter to Defense Secretary James R. Schlesinger expressing the view that a "steady erosion of Defense sponsored research may already have affected our future." At the same time Goldwater made it known that he was shocked because the Air Force had cut back on research even more than the other services.

Goldwater's complaint was not an isolated one. On Capitol Hill there has been growing criticism of the Pentagon for paring the R & D budget, including barbs on reducing support of basic research carried out in the universities. In recent months, Defense Department (DOD) policy-makers have taken steps to reverse the trends, and the question of basic research performed in the universities seems to be getting special attention from the Air Force officials.

The problems of military R & D (RDT & E is Pentagonese for research, development, testing, and engineering) are multiple. Inflation is a major and obvious factor. In the basic research sector, where contracts with university researchers have traditionally played an important role, the effects of antimilitary feeling generated in the universities by U.S. involvement in Vietnam linger on, although basic research funded by the military continued at a relatively high level even during the peak periods of campus opposition to the war.

Since 1969, the so-called Mansfield amendment (*Science*, 13 March 1970), which requires that basic research funded by defense agencies have a direct and demonstrable link to military missions, has exerted a drag on basic research funding, although some qualified observers argue that the caveat has had much less practical effect than budgetary factors.

Within the defense establishment, as the competition for funds sharpened, there were shifts within the RDT & E budget generally benefiting applied research and exploratory development at the expense of basic research, and, in the basic research category, favoring DOD, in-house R & D laboratories over outside research institutions—universities and nonprofit labs. These trends applied generally to DOD and were specifically true of the Air Force.

In October, Air Force Secretary John L. McLucas sent a memo to the Air Force chief of staff setting guidelines for research policy in coming years. The memo itself has not been made public but its contents have been discussed fairly widely. The McLucas memo declared that research funding should be protected from encroachment from development and procurement programs. He said that priority in the Air Force research program should be given to preserving and increasing university contributions both to knowledge useful to the Air Force and to the training of young scientists in fields crucial to the Air Force. Specifically, he asked that research fund-