Fetal Research: The Question in the States

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In 1977, the authors of a leading work on human experimentation stated: “Of all research discussed in this book, experimentation with fetuses is perhaps the most controversial.”1 It had not always been thus. Before the 1973 Supreme Court decision legalizing abortion in Roe v. Wade,2 fetal research had been conducted with little public concern.3 Some have suggested that opposition to fetal research is largely a rearguard action by opponents of the Roe decision who do not want medical benefits from fetal research to impede their antiabortion efforts.4 But the timing of the controversy can be explained in other ways as well.

Three months after the Roe decision, the Washington Post published a series of articles (April 10 and 13, 1973) that focused public attention on the ethical questions raised by fetal experimentation. The Post reported disturbing experiments in other countries with longer-standing liberal abortion policies such as Great Britain.

In July 1974, a congressional moratorium was imposed upon federal funding of fetal research until the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research promulgated guidelines governing it.5 In the summer of 1975, the Commission issued its final recommendations,6 which were partially codified as federal regulations.7

Meanwhile, a great deal of legislative action was occurring at the state level. In 1973, statutes regulating some forms of fetal research were passed in four states: California, Indiana, Minnesota, and South Dakota.8 In 1974, five more states were added: Kentucky, Massachusetts, Montana, Ohio and Utah.9 In 1975, two: Arizona and North Dakota.10 In 1976, California and

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2 410 U.S. 113 (1973).
7 40 FR 33528, Aug. 8, 1975, as amended at 40 FR 51638, Nov. 6, 1975; 45 C.F.R. SS 46.201 – 46.211.
Massachusetts amended their statutes. In 1977, Indiana amended its statute and three states passed new ones: Maine, Nebraska, and Wyoming. In 1978, Louisiana and Oklahoma passed statutes. In 1979, activity peaked when Nebraska amended its statute and new statutes were passed in five states: Florida, Illinois, Missouri, New Mexico, and Tennessee. Since then, new statutes have been limited to one each year: Michigan in 1980, Rhode Island in 1981, Pennsylvania in 1982, and Arkansas in 1983. However, there were also two amendments: Florida in 1980 and Louisiana in 1981. At this writing, twenty-five states have statutes explicitly regulating fetal research.

Some of these statutes seem to have only symbolic value. There were probably no research facilities in states such as Wyoming or Montana set up to engage in fetal research. On the other hand, the impact of such statutes in states with major research institutes, such as California and Massachusetts, is real. And the potential price to be paid is considerable.

Even those who take a cautious position regarding fetal research must admit that much medical benefit may be gained from certain sorts of studies. Studies on dead fetuses may be valuable for the same reasons as autopsies on dead adults. If recently deceased, the fetus may offer living organs to be transplanted or living tissues which can aid studies of developmental genetic problems, growth regulation, and discovery of the early antecedents of human disease.

Fetuses in utero that are scheduled for abortion provide opportunities for perfecting and practicing diagnostic techniques such as amniocentesis, fetoscopy, and chorionic villus biopsy without risk of inducing injury or abortion to a wanted fetus. They also provide opportunities for research into other forms of fetal diagnosis and therapy, for research into methods of improved therapy, and for placental transfer studies that may improve medical care for expectant mothers and their wanted fetuses. And research upon nonviable but still living abortuses can produce data on fetal physiology and metabolism or develop new methods for prolonging neonatal life, which could improve techniques for saving the lives of prematurely born infants.

Clearly the great promise and grave threat of fetal research present our society with a painful dilemma. In many ways, the dilemma is the same as that presented by abortion: we are here too weighing the life, dignity, and comfort of the fetus (or abortus) against the lives, dignity, and comfort of others. On the other hand, there are important ways in which the dilemmas differ. With rare exceptions, we are not faced in the case of fetal experimentation with the mother’s claim to reproductive autonomy. (Two exceptions may be: those cases where fetal experimentation may be indicated for the purpose of diagnosing problems in the mother that implicate future childbearing; and those cases where fetal experimentation may enable an

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unwanted abortus to become an unwanted child.)  Even if a woman has a right to be free of an unwanted pregnancy, she does not necessarily have a right to determine what shall be done to the fetus before, during, or after its removal from her body. ¹⁷

Perhaps as a result, we are presented with another difference – a legal one.  Thus far, there is no Supreme Court decision constitutionally restricting fetal research laws in the way that Roe restricts abortion laws.  Consequently, federal and state legislative bodies have felt free to develop substantive laws reflecting each jurisdiction’s notion of the appropriate compromise for the competing values involved.

On the federal level, fetal experimentation is governed by the regulations that were promulgated upon the recommendation of the National Commission.  They apply only to “all research involving human subjects conducted by the Department of Health and Human Services or funded in whole or in part by a Department grant, contract, cooperative agreement or fellowship.”  On the one hand, these regulations go beyond the power of the states in that they regulate “research conducted or funded by the Department of Human Services outside the United States.”  On the other hand, they do not regulate fetal research in the various states that is not funded or conducted by the Department. ¹⁸  Moreover, even regarding fetal research that is so conducted or funded, the regulations provide that “[n]othing in this subpart shall be construed as indicating that compliance with the procedures set forth herein will in any way render inapplicable pertinent State or local laws bearing upon activities covered by this subpart.”

Informed consent is routinely required from both father and mother, except for certain instances where the father’s consent will not be required: “(1) the purpose of the activity is to meet the health needs of the mother; (2) his identity or whereabouts cannot be reasonably ascertained; (3) he is not reasonably available; or (4) the pregnancy resulted from rape.”  In addition, the risk to the fetus may not be higher than certain thresholds specified.  Those thresholds fall into a small number of classes, which are determined by: (1) whether the experimental procedure is therapeutic to either the mother or the fetus; and (2) whether the fetus is in utero or ex utero, living or dead, viable or nonviable.

Where the experiment is upon a pregnant woman, it may proceed if it is for the purpose of providing therapy to the mother or “the risk to the fetus is minimal.”  Where it is upon a fetus in utero, it may proceed if it is for the purpose of providing therapy to the fetus or the risk is minimal and “the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.”

If the fetus is ex utero, experimentation standards depend on whether it is living and, if living, whether it is viable.  If it is viable, it is considered a “premature infant” and entitled to the protections of other portions of the regulations.  If it is not viable, experimentation may be done even if the risk is more than minimal if “the purpose of the activity is the development of

¹⁸ Except to the extent that a funded research institution must gain approval of “A statement of principles governing the institution in discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of source of funding.”  45 C.F.R. S 46.103 (b)(1).
important biomedical knowledge which cannot be obtained by other means” and if the research will neither artificially maintain vital functions nor purposely terminate the fetus’ heartbeat or respiration. If it is not yet clear whether the fetus is viable or not, experimentation may proceed if it is for the purpose of providing therapy to the fetus or “there will be no added risk to the fetus resulting from the activity and the purpose of the activity is the development of important biomedical knowledge which cannot be obtained by other means.” If the fetus is dead, regulation of experimentation upon it is left entirely to applicable state law.

The Uniform Anatomical Gift Act

Supplementing the federal regulations are the twenty-five state statutes and the Uniform Anatomical Gift Act (UAGA), which was passed in all of the fifty states from 1969 through 1973. The UAGA governs research on dead fetuses along with dead humans generally by including within its definition of a “decedent” any “stillborn infant or a fetus.” As a result, it serves as a backdrop against which all the later state statues have been written. Its provisions allow for the gift of “all or part of the …body” of a dead fetus to be used for research or therapeutic purposes. Such gift may be made by “either parent” and must take the form of a “document signed by him or made by telegraphic, recorded telephonic, or other recorded message.”

The act prescribes respectful treatment for the decedent’s remains. And it provides that “the time of death shall be determined by a physician who tends the donor at his death, or, if none, the physician who certifies the death. The physician shall not participate in the procedures for removing or transplanting a part.” No sanctions are imposed for any violations of the terms of the act, and it provides that “a person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another state or a foreign country is not liable for any damages in any civil action or subject to prosecution in any criminal proceeding for his act.”

Variability in the States

The various provisions of the state statutes passed since 1973 are anything but uniform. Indeed, six of these statutes—those passed in Arizona, Illinois, Indiana, Louisiana, Ohio, and Oklahoma—undermine the uniformity provided by the provisions of the UAGA by placing serious restrictions or prohibitions on the use of dead fetuses for research. And they range from the very strict to the very liberal. Perhaps the strictest statute is one passed in Arizona in 1975:

“A person shall not knowingly use any fetus or embryo, living or dead, or any parts, organs or fluids of any such fetus or embryo resulting from an induced abortion in any manner for any medical experimentation or scientific or medical investigation purpose except as is strictly necessary to diagnose a disease or condition in the mother of the fetus or embryo and only where the abortion was performed because of such disease or condition.”

At the other extreme are a statue passed in South Dakota in 1973:

20 Ariz. Rev. Stats. S 36-2302 A.
“Experimentation with fetuses without written consent of the woman shall be prohibited.”

and one passed in Tennessee in 1979:

“(a) It shall be unlawful for any person, agency, corporation, partnership or association to engage in medical experiments, research, or the taking of photographs upon an aborted fetus without the prior knowledge and consent of the mother.

(b) No person, agency, corporation, partnership or association shall offer money or anything of value for an aborted fetus; nor shall any person, agency, corporation, partnership or association accept any money or anything of value for an aborted fetus.

(c) It is the express intent of the general assembly that nothing in the provisions of this section shall be construed to grant to a fetus any legal right not possessed by such fetus prior to July 1, 1979.”

However, the vast majority of the statues fall between these extremes; despite their great variety, they can be described in terms of a few helpful classifications.

Only New Mexico’s 1979 statute follows the federal model, and even it differs in many of its substantive provisions. However, most of the criteria employed by the federal regulations find their way into the state statutes as well. The difference is in the way that they combine necessary and sufficient conditions, their varying importance, and the extent to which they are supplemented by additional criteria. Typically, the state statutes give less importance to maternal consent and a weighing of the costs to the fetus against the benefits to medical science. Instead, they tend to ban all nontherapeutic research on the living product of conception.

There are two very common and interesting limitations. First, they most often prohibit such experimentation only upon fetuses that are planned to be or have been aborted. Second, at least eight statutes do not explicitly prohibit research on the fetus in utero, but focus exclusively upon use of the living abortus. Presumably, one reason for this is the pragmatic and ad hoc nature of state legislation of this sort. In the wake of Roe and the revelations of experiments on the living abortus, some legislatures concerned themselves solely with that acute problem. Where they did consider research upon fetuses in utero, they again focused only upon the plight of the fetus whose natural protector, the mother, had decided on an abortion. Moreover, as some

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22 Tenn Code Ann.§ 39-4-208.
24 Exceptions are the statutes in Minnesota, New Mexico, South Dakota, and Tennessee.
25 Exceptions are the statutes in Louisiana, Maine, Massachusetts, Michigan, Minnesota, Montana, New Mexico, North Dakota, Pennsylvania, Rhode Island, South Dakota, Tennessee, and Utah.
26 The statutes are those passed in Arkansas, California, Indiana, Kentucky, Montana, Nebraska, Ohio, and Wyoming.
pro-choice advocates have suggested, the legislators may also have focused upon cheating medical science of any benefits that might flow from Roe.

Yet another difference from the federal regulations is a frequent prohibition regarding trafficking in live abortuses. This may also be explained as a legislative ad hoc response -- this time to post-Roe rumors that such trafficking had reached disturbing proportions in other countries. In two states, Kentucky and Wyoming, only trafficking in fetuses is prohibited. There is no direct prohibition of research.

Despite the lack of uniformity in the precise language of the various statutes, there is a sense of development around certain issues and a repetition of concepts and words of art. But in only one instance has a state statute been used as a model and adopted by other states in either unchanged or modified form. That one model is the statute adopted by Massachusetts in 1974.\textsuperscript{27} In 1975, it was adopted in North Dakota with only one minor addition.\textsuperscript{28} In 1980, the statute, this time with important improvements in language, was adopted by Michigan.\textsuperscript{29} Finally, in 1981, Rhode Island adopted the statute in its original form.\textsuperscript{30}

How do these state statutes add restrictions to the federal regulations?

First, twenty-five states have no restrictions. They have only the enabling provisions of the UAGA concerning dead fetuses.

Second, two (South Dakota and Tennessee) permit fetal research of all sorts so long as maternal consent is obtained.

Third, of the remaining twenty-three: nine (Kentucky, Maine, Minnesota, Missouri, Montana, Nebraska, New Mexico, Utah, and Wyoming) permit research on dead fetuses under the terms of the UAGA. An additional eight (Arkansas, California, Florida, Massachusetts, Michigan, North Dakota, Pennsylvania, and Rhode Island) permit research upon dead fetuses under the terms of the UAGA with very slight modifications. The remaining six (Arizona, Illinois, Indiana, Louisiana, Ohio, and Oklahoma) do not permit nontherapeutic research on even dead fetuses if they are the product of a therapeutic abortion.

Eight (Arkansas, California, Indiana, Kentucky, Montana, Nebraska, Ohio and Wyoming) of the twenty-three states place no restrictions on research with fetuses in utero. An additional two allow research upon fetuses in utero if “no significant risk to the fetus is imposed by the research activity” (New Mexico) or if “verifiable scientific evidence has shown [it] to be harmless to the conceptus” (Minnesota). The remaining thirteen (Arizona, Florida, Illinois, Louisiana, Massachusetts, Michigan, North Dakota, Oklahoma, Pennsylvania, Rhode Island, Utah, Maine, and Missouri) will not allow nontherapeutic research upon the fetus in utero if it is the subject of a planned abortion.

\textsuperscript{28} N.D.Cent. Code SS 14-02. 2-01 and 02.
\textsuperscript{30} R.I. Gen. Laws SS 11-54-1 and 2.
Two states (Arkansas and Utah) seem to place no restrictions on medical research on live abortuses. Two states allow research on live abortuses if it poses no significant risk to the abortus (New Mexico) or if it is harmless to the abortus (Minnesota). The remaining nineteen states (Arizona, California, Florida, Illinois, Indiana, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Missouri, Montana, Nebraska, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, and Wyoming) allow no nontherapeutic research on live abortuses.

**Rule Making in a Pluralist Society**

It might well be argued that this complicated, patchwork-quilt of legislation presents us with the worst of all possible worlds. In more than half of the American jurisdictions, defenders of the rights of the fetus have lost all protection for the fetus beyond those of the federal regulations; in many other jurisdictions they have been cheated of numerous protections that they might want. On the other hand, opportunities for important research are lost to the medical and scientific communities in those states that have restricted statutes, and in all fifty states medical researchers must follow the federal regulations which cover all federally funded research.

And where is justice? If it is “right” to conduct research on abortuses or fetuses under certain circumstances, then it should be permissible to conduct research on them under those circumstances in every jurisdiction. If it is “wrong,” then research should be prohibited in every jurisdiction.

There is no fast and easy route to uniform “right” rules in a democratic society, especially one that is a federation of fifty sovereign states. To whom shall we look for such rules? The medical community? As expert in the field of medical science as its members may be, they are not experts in morals and statecraft. They are also, like all other mortals, capable of judging state questions from a viewpoint more narrow than that of the public good – more narrow even then their perception of the public good. As one Harvard researcher recently admitted: “I share in a common guilt to which all of us within academic medicine must admit, an ambitious hunger for new discoveries. While we do truly labor for the common good, we also strive for personal recognition; our own egos bob embarrassingly to the surface of swelling altruism.”

Shall we look then to religious leaders or philosophers to lay down uniform rules of right conduct here? Even if we did, we would not find such leaders and thinkers speaking with one voice. And, even if they did, we would still have to ask ourselves whether we agreed, after reflection, with the rules they endorsed unless we were ready, for some reason, to delegate decision-making power to them.

In a majoritarian democracy, the buck stops with the voters. And we are still in the process of making up our minds about how we collectively feel about fetal research. Of course, under our Constitution, there are methods for cutting short the slow democratic process of consensus building. These methods were employed in *Roe* to cut short the process as regards

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abortion. And there are those who would like to see these methods employed as well regarding fetal experimentation.

The great merit of the federal regulations is that they take into account not only the stage of development and viability of the fetus, but also the risk to the fetus weighed against the need for and value of the medical benefits to be obtained through the proposed research. Moreover, they have built-in processes for constantly refining the rules on the basis of individual research applications. Not only do Institutional Review Boards, with diverse memberships, judge specific research applications for their compliance with the regulations, but an Ethics Advisory Board (if the Department of Health and Human Services recreates one) has the power to modify the regulations when a specific research application warrants it. As a result, the opportunity for rule-making on the basis of all of the relevant factors presented by actual cases is maximized.

In contrast, the vast majority of the state statutes are defective; they lay down blanket prohibitions largely based only upon the status of the fetus or abortus. However, unlike decisions based upon the Constitution, they do not eliminate the opportunity for refining rules on the basis of argument, experience, and negotiation.

Legislation is only as strong as the majority it commands in a current legislature. If the medical community in a given jurisdiction believes that extraordinarily valuable medical research is being stifled, it may present those facts to the legislature and the public in an effort to win a majority. And opponents of fetal research are always free to present their own opposing facts and arguments. Such debates may go on for many years before a societal consensus begins to develop. In the process, opposing advocates may not only educate and persuade legislators and their constituents, they may educate and persuade each other. At least, opponents may learn to compromise for the good of society as a whole.

But we need not talk about the potential virtues of the legislative process in this area entirely in the abstract. They are amply illustrated by the Massachusetts experience as reported in a two-part series in *Science* magazine. Following the decision in *Roe* and the *Washington Post* articles, Massachusetts State Representative William Delahunt decided to introduce legislation regulating fetal experimentation: “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.” Together with Professor James Smith, of the Boston College Law School, he drafted legislation that would have banned all research on fetuses, living or dead, if they were the subject of planned abortions.

Learning at the last minute of public hearings, Dean Jack Ewalt of the Harvard Medical School began to involve the Massachusetts medical community in an effort to kill or modify the bill. He arranged for Arthur Hertig, a scientist who had provided John Enders with fetal tissue that proved essential to the discovery of polio virus, to attend the hearings. Delahunt, Smith and

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others arranged to begin meeting with an expanding number of representatives of the medical research community. Among the new researchers brought into the process was David Nathan, professor of pediatrics at Harvard and chief of hematology and oncology at Children’s Hospital Medical Center.

Nathan began as one of the most intransigent advocates for fetal research. When other researchers seemed ready to settle for a compromise, which would have permitted experimentation on dead fetuses, studies on living fetal tissues, and amniocentesis on fetuses that were not scheduled for abortion, he objected. “In fact,” he recalls, “I was in a rage. I felt we were selling out.”

Nathan was on the verge of a breakthrough with a method of antenatal diagnosis of beta-thalassemia and sickle-cell anemia that depended upon sampling fetal blood by means of fetoscopy. Because use of the fetoscope was still sufficiently experimental that it might pose a substantial risk to a fetus, it would be prohibited by compromise legislation. “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… and thalassemia and other disorders in utero, I’d be preventing more abortions than they ever could.’ They listened but they were not persuaded.”

But Delahunt, Smith, and members of the state legislature were persuaded to yield on other points. In a series of negotiating sessions covering several weeks, further compromises where worked out in the scope and the language of the legislation that was enacted in June 1974. At the end, Delahunt was “the first to admit that his original version of the bill would have been disastrous for research.” He reported that his “experience with the fetal research law has been broadening, instructing him in the way of science and scientists.” In order to continue the relationship between the legislature and the scientific community, he established a state advisory committee on medical research of which David Nathan was made a member. And “[t]he confrontation between the scientists and the lawmakers [had] been equally illuminating for the scientists who, as Delahunt puts it, ‘have learned that we in the State House do not have horns.’ In fact, the individuals involved in the struggles 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 that they got to know. But the process was a trying one.”

David Nathan never did get the permission he wanted to make the breakthrough he was seeking in antenatal diagnosis of thalassemia and sickle cell anemia. However, he continued to work with James Smith, who had become a respected friend, on possible compromise legislation until Smith died in the fall of 1982. Together they did get the legislature to enact in 1976 an amendment that added procedures for obtaining advance rulings on the legality of fetal research activities so that pioneering efforts were not made at the risk of after-the-fact criminal prosecutions.  

Nathan’s research requiring fetoscopy was brought to fruition by researchers in London, England and New Haven, Connecticut, where the law is more favorable to fetal research. He and his colleagues have developed alternative methods using amniocentesis an analysis of DNA to make the antenatal diagnosis he was after in three-out-of-four cases in his clinic. The other cases he refers to physicians in New Haven for blood sampling by means of fetoscopy.

And he still speaks of his experience with Smith, Delahunt, and the legislative process with great enthusiasm. He said recently, “At one point when the fetal experimentation furor was at its height, I had Jim Smith come to speak at a meeting of the Harvard Medical Society. They thought they would make mincemeat of him. When he was finished with their questions, he had just destroyed their arguments. They really learned something.”

Even the greatest medical researchers count as only one when it comes time to vote. If their influence is to be any greater, it will have to come through the power of the facts and ideas that they share with the rest of society. And in order to share those facts and ideas, they have no choice but to enter an arena in which one may not only inform but also be informed, not only persuade but also be persuaded, and not only gain way but also give it.

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35 Interview with Professor David G. Nathan, Chief, Hematology and Oncology, Children’s Hospital Medical Center and Sydney Farber Cancer Institute, Boston, in Boston, March 27, 1984.