Legal Issues in Prenatal Therapy*

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Prenatal diagnosis of a fetal malformation ordinarily presents the mother with a stark choice of having an abortion or having a handicapped child. Recently, medical and surgical treatments of the fetus in utero have become available—treatments of various degrees of safety and efficacy on the continuum from experimental to established therapy. The future is likely to hold even greater power over the preterm fetus. In-vitro fertilization, for example, will make genetic treatments directed at extra-corporeal, preimplantation embryos possible as well.

The availability of prenatal therapy focuses attention on potential conflicts in a clinical relationship that previously had received little scrutiny. What are the rights and duties of the mother and physician to a developing fetus whose conception or continuing gestation has been chosen? What are the rights of the fetus, or rather the child that it will become, in such situations?

The ethical situation is complex. It contains the traditional ethical dilemma in pediatrics—whether the mother may provide or refuse a treatment that may injure but also benefit the child—with two additional considerations. First, the fetus has a controversial legal and moral status. Since the right to have an abortion was recognized legally in Roe v. Wade, the fetus’s interests are deemed secondary to the wishes of the mother up to the point of viability. Yet the possibility of in-utero treatment seems to make the fetus a patient with independent rights and interests. Second, therapies to help the fetus must necessarily invade the body of the mother, a situation not present in pediatrics, thus raising the possibility of conflict with mother’s right to bodily integrity.

The Prenatal Rights of Persons

The legal rights and duties of mothers and physicians in using prenatal therapy derive from a body of law that imposes prenatal obligations of reasonable care toward fetuses that will be born alive. Fetuses have no right to be conceived or, once conceived, to be carried to term unless they have reached the point of viability (estimated at 24 to 26 weeks of pregnancy). However, if they are going to be carried to term, they do have rights against the mother, the doctor, or third parties not to be injured or subjected to unreasonable risk of injury.

Since the fetus’s right to be born as

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healthy as is reasonably possible cannot ordinarily be asserted until after birth, it is clearer to speak of prenatal obligations of mothers and physicians to the unborn child. These obligations are contingent on the live birth of the child, and ordinarily cannot be asserted before birth. If mother or physician violates these prenatal obligations by intentionally injuring the viable fetus or negligently failing to avert injury, then criminal or civil legal action is possible. State law might permit a variety of criminal charges to be brought. If the child is stillborn or dies in utero after the point of viability, the mother and/or physicians could be prosecuted under abortion or feticide laws. If the child is born alive but then dies as a result of prenatal derelictions, a homicide or child abuse prosecution could occur. If the child is born damaged but lives, a charge of child abuse could be lodged against the mother or doctor for prenatal actions.

Civil actions for damages also could be brought. All American jurisdictions recognize a cause of action for reasonably foreseeable and avoidable prenatal and, in some cases, preconceptional actions that cause death or injury to a child born alive. The reasoning of the cases imposing liability for prenatal injuries applies to negligent conduct on the mother’s part as well. A recent case in Michigan shows that previous barriers to such suits, such as doctrines of intrafamilial tort immunity, may no longer apply. In the path-breaking case of Grodin v. Grodin, a suit by a child against his mother for discolored teeth caused by her negligently taking tetracycline during pregnancy was held legally cognizable. Removal of the financial incentives to file such suits by changes in personal liability insurance coverage (in Grodin a broadly stated clause in a homeowners insurance policy was the inspiration for suit) and the other impracticalities of mounting such suits will prevent most children injured by negligent maternal behavior from using their mothers. However, recognition that the law would sanction such conduct does set an important principle.

These legal doctrines clearly limit a woman’s freedom over her body during pregnancy, but they do not limit her reproductive freedom—her constitutional right not to procreate, since they arise in a situation where she has waived that right by choosing not to abort. Recognition of the voluntary nature of pregnancy thus works to strengthen duties to the fetus that a woman chooses to carry to term. Having decided to use her body to procreate, a woman loses some bodily freedom during pregnancy in order to ensure the health of a child that she has chosen to birth. It is against this background of prenatal duties to children that the rights and duties of mothers and physicians regarding fetal therapy emerge.

**Experimental Prenatal Therapies**

Because the experimental or established status of a therapy affects the legal rights and duties of parents and physicians, we must at the outset distinguish between the legal and ethical issues that arise when prenatal fetal therapies are innovative and experimental and those that arise when they become established and accepted therapy.

**Duty to Employ Procedures**

Few fetal therapies have been established as safe and effective. As of January 1985, fewer than 100 fetuses have been treated surgically, and no full-scale reviews of these cases or clinical trials have been published. When intrauterine surgery is experimental and innovative, it offers a possible benefit to the fetus by providing an alternative to abortion. However, parents or physicians are not obligated to try this alternative. Under the Supreme Court decision in Roe v. Wade, a mother is free to abort through the end of the second trimester and even beyond if the state has not pro-
hibited abortion after viability. Since this right exists even if the fetus is normal and would be born healthy, the possibility of correcting a congenital defect in utero with an experimental therapy would not prevent the mother from choosing abortion.

If the mother decides against abortion, she still has no legal or moral duty to have an experimental procedure done. Because reasonable people could differ over whether the benefits of experimental therapy outweigh the risks, it is clearly the mother's prerogative to decide about the use of an experimental therapy. The mother would have no greater duty to employ an experimental therapy with a fetus than she would with a child. Parents, for example, are free to refuse experimental chemotherapy for treatment of their child's leukemia, even though they could not refuse an established therapy or treat with an unproven drug such as Laetrile instead.

The experimental status of fetal therapy also affects the legal duties of the obstetrician. The physician may offer to try an experimental intrauterine technique but must defer to the mother. If the mother refuses, the physician would have no obligation to take steps to override her decision, as he or she might if the therapy were established as safe and effective.

Discretion to Employ Procedures

Although mothers and physicians are not obligated to use prenatal surgery to correct a congenital anomaly, the more crucial question at this stage of development is whether they may choose to do so and which procedures must be followed if they do. This question is important because experimental intrauterine therapy may pose risks that could harm the fetus and mother to a greater degree than doing nothing. Intervention could induce premature labor and death when the fetus might have survived if nothing had been done, or it could cause greater damage than if no intervention occurred, as would result if the doctors were mistaken in their diagnosis and prognosis. Finally, the intervention might allow the fetus with a lethal lesion to survive in a severely handicapped state. Since one of the patients to be helped or hurt by the experimental procedure—the unborn child who does not yet exist except in fetal form—is incapable of consent, can the mother decide to subject the fetus to these risks? May the physician go along with her?

In most situations a mother may legally allow experimental procedures to be performed in utero. As long as the mother is competent and has been fully informed of the unproven status of the therapy, the risks to her and the fetus, and the risks and benefits of the alternatives, she is legally free to undergo some medical risk in order to bring a healthy baby into the world. Although the procedure poses risks to the fetus, doing nothing may impose even higher risks of death or disability. In such circumstances, consent to an experimental procedure may be a reasonable course of action. Even if the therapy leads to the child's being more damaged than if the surgery had been postponed until delivery, or if the surgery prevents death but leads to the child's surviving in a damaged state when it would not otherwise have been born at all, use of the experimental therapy still may have been a reasonable course of action. A poor outcome that resulted from a series of clinical judgments that were reasonable at the time would not justify legal sanctions.

The legal duties of the physician mirror those of the mother, with some important differences. Since intrauterine therapy involves specialized knowledge and skills, obstetricians should have the training and experience to do it skillfully. If they have the requisite training and experience, they may legally use experimental techniques to benefit the unborn child as long as the mother has been fully informed and freely
consents. Trying an unvalidated procedure with the mother’s consent for the purpose of benefiting a fetus that would otherwise die or be severely disabled would not, if there are grounds for thinking it would help, be so reckless or unreasonable as to constitute actionable negligence. However, a physician should be careful not to oversell the benefits of what is still a speculative and risky procedure.

The physician employing intrauterine surgical techniques may have additional duties, according to whether the procedure is seen as research or as an innovative, unproven therapy. If the physician is conducting research with the fetus and mother as subjects, then approval of an Institutional Review Board (IRB) may be required, whatever the source of the funding. An IRB reviewing experimental intrauterine therapy in accordance with Department of Health and Human Services regulations for research on fetuses may approve such research. The regulations permit research on fetuses and pregnant women when “the purpose of the activity is to meet the health needs of the mother or the particular fetus.” If the physician has no research intent and perceives the unproven procedure to be innovative therapy, there may be no legal obligation to obtain IRB review, though it is an advisable course of action.

**Legal Issues with Established Procedures**

The rights and duties of mothers and physicians change significantly when prenatal therapies are established as safe and effective for their intended purpose.

**Termination of Pregnancy**

The mere fact that a congenital defect is treatable prenatally does not alter the mother’s right under *Roe v. Wade* to terminate the pregnancy. The right to abort depends on the wishes of the mother and the stage of pregnancy, not on the health or prospects of the fetus. Just as a normal fetus may be aborted, so may a defective though treatable one. In the 20 states that have not prohibited abortion after viability, termination and death in utero would be lawful at any point in the pregnancy. If the state has prohibited postviability abortions, then abortion of a viable fetus with a congenital defect may be prohibited. In that case, a mother might be required to have the prenatal fetal therapy or be subject to criminal and civil penalties for not taking reasonable steps to protect the child that she has chosen to bring into the world.

**Duty to Employ Established Prenatal Fetal Therapy**

Although there is no duty to use experimental prenatal therapies, parents and physicians may have a duty to use prenatal procedures that are accepted by reasonable practitioners as safe and effective. In such a case the benefit to the unborn child from the intervention clearly outweighs the risks of the intervention, and thus the procedure may appropriately be done with maternal consent and without IRB review.

The key legal issue that arises when fetal therapies are medically established is whether the mother can refuse them. If prenatal therapies are medically acceptable or indicated in a clinical situation, a physician who fails to employ them or to inform the parents of the need for them and their availability elsewhere could be liable under traditional malpractice standards for wrongful death, or if the child is born in a damaged condition, liable to the parents and child for the costs of care and the pain and suffering involved.

The most difficult question concerns the scope of the mother’s duty to the unborn child. If the mother elects not to abort, she may be legally obligated to employ available medical procedures that will prevent the child from being born damaged or in an avoidable unhealthy state. If the child is likely to be born alive, she takes on a legal
duty to take all reasonable measures, including employing established intraterine therapies, to minimize damage to the child. The parents' duty to children to provide necessary medical care thus includes the duty to provide essential prenatal therapy when a live birth is expected. Depending on the jurisdiction, refusal of an established therapy could be prosecuted under feticide, homicide, or child abuse/neglect statutes if the viable fetus died in utero or after birth or was born in an avoidably damaged or handicapped state. In theory a child in a state that no longer recognizes intrafamilial tort immunity could also sue the parents for failing to employ low-risk in-utero therapy that would have prevented the child from being born injured. While, practically speaking, such suits may be rare, they could arise if the parents have personal liability coverage or if they divorce.

The possibility of criminal or civil action against the mother for prenatal negligence that harms the child carried to term also raises the question of the obstetrician's duty under child abuse-reporting laws to report maternal neglect to child welfare authorities. If the mother has prenatal obligations to prevent harm to unborn children, then presumably physicians, nurses, and other persons covered by child abuse-reporting laws do as well. Although no case or action against a physician on this basis has occurred, the logic of the situation would allow the imposition of such a duty on the physician, illustrating once again how prenatal therapies clarify (and complicate) a relationship that had previously escaped close scrutiny.

Direct Seizures and Coerced Treatment

The most troubling ethical and legal issue is whether prenatal therapy may be directly imposed on the mother against her wishes. May child welfare authorities informed that a mother's prenatal conduct is likely to harm the offspring obtain a court order compelling the mother to undergo in-utero treatment? In the typical pediatric situation, an established treatment could clearly be ordered over the parents' wishes, since parental autonomy ordinarily cannot override the child's interest in life or health. When the child is unborn, however, treating the child over the mother's wishes necessarily invades her body. With fetal therapy, the issue is whether the mother's interest in bodily integrity is great enough to override the unborn child's well-being.

State law could authorize judges to order prenatal treatment in certain cases. (Whether this power should be used is another matter.) Bodily intrusions without a person's consent for the sake of another are highly disfavored, but they are not unknown to the law.² The state may force people to have blood drawn or even undergo surgery to produce evidence of crimes. Compulsory vaccination and military service are well-established traditions. Prisoners may be forcibly fed or treated for the sake of prison discipline. Courts have sometimes ordered Jehovah's Witness parents with young children to receive blood transfusions.

Given some precedent for violating bodily integrity when a very important interest is at stake, it is likely that legislation authorizing courts to order parents to undergo a simple blood test, donate a pint of blood, or even give bone marrow if it were necessary to preserve the child's life would be found constitutional. As the degree of harm and intrusion to the parent increases, as in the case of a forced kidney donation, the state's power to override bodily integrity weakens, and it is less likely that courts would order bodily intrusion for the child's sake. While the loss of a kidney is not itself life threatening, the burden of forced nephrectomy is considerably greater than the burden of forced blood or marrow donations. But the factor that makes forced nephrectomy hard to justify is the degree of harm and
not the fact of coerced bodily intrusion. When the harm is less substantial, bodily
intrusions essential to the child’s health could be constitutionally ordered.

While the courts have not yet addressed the constitutional authority of the state
of force tissue or blood donation from a parent to a child, there are two cases that
uphold coerced medical treatments on the mother for the sake of an unborn child. In
a hospital unsuccessfully petitioned a trial court to order blood transfusions on a
23-year-old Jehovah’s Witness who was eight months’ pregnant and in danger of
severe hemorrhaging. The New Jersey Supreme Court, reversing the trial court,
held that “the unborn child is entitled to the law’s protection” and ordered blood
transfusions to the mother if the physicians determined that they were necessary.

Then in 1981, the Georgia Supreme Court ordered a cesarean section to be per-
formed on a woman to save her unborn child. The case, *Jefferson v. Griffin Spalding
County Hospital Authority*,7 involved a woman in the 39th week of pregnancy who had a
complete placenta previa. The doctors claimed that neither she nor the child
would survive if a vaginal delivery oc-
curred. When the mother refused the sur-
gery on religious grounds, the state child
welfare agency petitioned the juvenile
court for temporary custody of the unborn
child and for an order requiring the
mother to submit to the cesarean section.
The Georgia Supreme Court affirmed the
juvenile court order that the mother sub-
it to a cesarean section if “considered
necessary by the attending physician to sus-
tain the life of this child” on the ground
that “the intrusion involved into the life of
[the mother] is outweighed by the duty of
the State to protect a living, unborn human
being from meeting his or her death be-
fore being given the opportunity to live.”

If resolution of the fetal–maternal con-

flict in *Raleigh-Fitkin* and *Jefferson* in favor
of the near-term fetus over the mother’s
interest in bodily integrity is followed, then
the state may have a far-reaching power to
intrude on the mother’s body and freedom
of action for the benefit of the unborn
child. In addition to the results seen in the
court cases just discussed, this reasoning
would support state policies compelling
many different kinds of maternal behav-
or. A women might be prohibited from
using alcohol or other substances harmful
to the fetus during pregnancy or be kept
from her workplace because of toxic ef-
effects on the fetus. She might be ordered to
take drugs such as insulin for diabetes,
medications for fetal deficiencies, or intra-
uterine blood transfusions for fetal Rh
isoimmunization. Prenatal screening and
diagnostic procedures, from amniocentesis
to sonography or even fetoscopy, could be
made mandatory. If established as safe and
effective, fetal surgery to shunt cere-
broventricular fluids from the brain to relive
hydrocephalus or to relieve the ure-
thal obstruction causing bilateral hydron-
ephrosis also could be ordered. Indeed,
even extraterine fetal surgery, if it be-
comes an established procedure, could be
ordered, if the risks to the mother were
small and if it were a last resort to save
the life of or prevent severe disability in a
viable fetus.8

An important limit on coercing treat-
ment or other behaviors for the sake of the
fetus is the risk presented to the mother.
Society’s preference for the viable fetus
and unborn child over the mother’s bodily
autonomy is authorized by *Roe v. Wade* only
where protection of the fetus does not
threaten “the life or health of the
mother.” The boundaries of this limit,
however, are vague, for health interests can
range from relatively minor emotional
harm to major, permanent physical in-
juries, and the Supreme Court has not in-
dicated how substantial the threat to health
must be. It is likely that minimal or non-
substantial health risks posed by an intervention to save the fetus will be insufficient to give the mother priority over the viable fetus. Many types of fetal therapy, such as forced medication or intrauterine transfusions, for example, may carry very small health risks and thus be required of the unwilling woman. Invasive prenatal diagnostic techniques, such as amniocentesis or even fetoscopy, also involve relatively minor risks to the mother. Even intrauterine surgery performed through fetoscopy may not be so risky as to outweigh a societal interest in preserving the life or health of a viable fetus. Of course, the mother would be free to undergo medical procedures necessary for her health (e.g., radiation for cervical cancer) even if they risked harm to an expected unborn child.

The hardest case for imposing treatment against a mother’s wishes will arise with procedures involving general anesthesia and major surgery, such as extrauterine fetal surgery, and, more commonly, cesarean section. The court in Jefferson was able to avoid this issue since the mother’s health was also threatened. The risks to the mother of the surgery must be weighed and balanced against the benefit to the unborn child. The decision will depend on the medical condition and risks to the mother in each case. A Colorado trial court, for example, has found that the health risks to the mother of a cesarean section under general anesthesia are not so great as to prevent the state from preferring the interests of the fetus and ordering the surgery.8

This discussion is not intended as a recommendation that all legally available means should be used to modify the behavior of pregnant women. Bodily seizures or intrusions ordered by the state raise basic questions of civil liberties and should be used, if ever, only as a last resort to avoid very great harm. There is also the need to proceed cautiously in curtailing the behavior of pregnant women, to avoid scapegoating a relatively powerless group, at a time when more effective prenatal health programs are being cut back. However, the constitutional authority of the state to intervene with postbirth sanctions or even direct bodily intrusions should be recognized.

**Resolving Conflicts Over Refusal of Established Prenatal Therapy**

Compelling prenatal medical interventions on a woman to protect a viable fetus represents a drastic step that should be taken only after the need for it is clearly established. Indeed, the dilemma is not likely to arise often, for most mothers will want their child to survive in the healthiest state possible. When conflicts do arise and the mother refuses an established procedure, the physician will face a dilemma. If the physician accedes to the mother’s refusal and the fetus dies or is born defective, the physician could be criminally liable for feticide or child abuse or could be civilly liable to the child for failing to fulfill obligations to a fetus likely to be born alive. On the other hand, if out of fear of legal liability or concern for the unborn child, the physician insists on the surgery, he or she may face civil or criminal charges for assault and battery on the mother.

To be sure that the physician’s actions are legal, hospital administration, lawyers, child welfare authorities, and the courts must be involved. A judicial hearing at which a guardian ad litem would represent the unborn child (and a separate lawyer would represent the mother) should be conducted to determine whether the benefit to the fetus from the intervention outweighs the harm to the mother of the coerced intrusion. If the court ordered the therapy, there would be a problem of patient compliance. A patient who did not fear arrest and incarceration for contempt of court could simply leave the hospital against medical advice. In some cases the hospital might have to exercise physical restraint and place physicians in the un-
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enviable position of treating a recalcitrant patient.

A less troubling alternative in cases in which the mother has resisted a safe and effective prenatal treatment would be to rely on postbirth criminal or civil sanctions to induce compliance. If the mother has knowingly refused a low-risk procedure necessary for offspring welfare, or knowingly has engaged in behaviors that harm offspring, she may have violated state laws against child abuse or child neglect. Prosecution in such cases may serve the social policy goal of encouraging appropriate prenatal maternal behavior, without incurring the risks of state-ordered surgery on pregnant women. However, any state coercion of pregnant women raises serious issues about the role of government in reproduction, which need careful attention before such policies are implemented.

Genetic Alteration of Embryos

Although genetic therapy on embryos is still several years away, some mention should be made of legal issues that would arise with genetic alteration of extracorporeal preimplantation embryos. The logic of fetal therapy—treatment prior to birth before the disease manifests itself—would extend to gene alteration of extracorporeal embryos once the ability to diagnose and alter the genetic structure of embryos is established.

The legal structure of rights and duties described above for fetal therapy would also apply to genetic alteration of embryos. As long as embryo therapy is experimental, parents may be free to employ it but are under no obligation to do so. When a procedure is established as safe and effective, parents who wished to transfer the embryo to a uterus would have an obligation to have gene alteration occur, unless an alternative prenatal or postnatal therapy were available. Indeed, the mother’s interest in refusing prenatal therapy is considerably weakened by the extracorporeal location of the embryo to be treated. In this case treatment can occur without the intrusion into her body that is necessary with fetal therapy. Of course, an accepted genetic therapy would not require treatment and transfer of embryos to the mother’s uterus, since she is free to refuse embryo transfer to herself.

In general, embryo status does not alter the array of rights and duties one has regarding future persons. Actions or omissions regarding embryos that may be transferred to a uterus must take account of the interests of potential offspring, just as actions after implantation must. However, an argument for different treatment might be made where genetic therapy on the preimplantation embryo would affect germ cells and hence possibly alter the genes of later generations as well. Although the issue of germline therapy is controversial, an effective genetic therapy that will allow the birth of healthy offspring should not be prohibited merely because the germ cells would also be affected.10

Conclusion

The development of prenatal fetal therapies is rightly heralded as an important step in obstetrics, clinical genetics, and perinatology. While intrauterine surgery poses some novel ethical and legal problems, the law does not present a barrier to further development and diffusion of these techniques. With a few exceptions, the problems are no different from those that arise in pediatric practice. Doctors and mothers acting in good faith may use experimental prenatal fetal therapies when the fetus would be at great risk without them, but they are not legally or morally obligated to do so. When the therapy is established, a mother’s refusal of the intervention in principle may be penalized or overridden by the courts. Of course, the circumstances in which refusal of an estab-
lished therapy should be punished or lead to direct intervention will be controversial, and probably rare. If limits are placed on a woman's freedom, however, they will be limits on her right of bodily integrity rather than her right not to procreate. Once a woman decides not to abort, she has an obligation to take reasonable steps to ensure the birth of a healthy child. The same considerations will apply to gene alteration of preimplantation embryos when that technology is developed.

References

5. 45 C.F.R. 46. 206(a)(2).