chapter 13

Legal Considerations:

Artificial Insemination, In Vitro Fertilization, Embryo Transfer, and Gamete Intrafallopian Transfer

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This chapter reviews the legal rights and duties related to a variety of the infertility treatment and circumvention techniques discussed in this assessment. In many cases, the techniques are so new that little or no guidance is available on how the law will be applied. There is, however, a great deal of speculation in the legal literature, along with a wealth of inadvertently and peripherally related legislation and case law based on principles that may have some application in the area of new noncoital reproductive techniques.

The established medical and surgical techniques for treating infertility do not raise unusual legal problems. They fall squarely within the larger area of medical and public health laws, which encompass questions of informed consent and professional standards of practice. Noncoital reproductive technologies, however, challenge traditional legal thinking by introducing two novel factors into human reproduction: the extracorporeal embryo and the child of up to five parents: genetic mother, gestational mother, rearing mother, genetic father, and rearing father.

The conflicting interests of the many parties in noncoital reproductive technologies are difficult to adjudicate. First, some techniques separate the concept of '(biological mother," traditionally a unitary term, into two component parts: the genetic mother and the gestational mother. Existing legal models of the role of the purely genetic connection between parent and child have been worked out in the context of fathers, not mothers. For example, a genetic connection between a man and a child will render him legally and financially responsible for the child, absent a formal legal intervention such as adoption (17,38). The intentions of the man to produce offspring or not are irrelevant.

This legal outcome protects the interests of the child, and explains the one general exception to this rule, i.e., that a child born to a married woman is presumed to be the child of the woman's husband, regardless of the genetic realities of the situation. This "presumption of paternity" is common in State legislative codes (9,45). Provided that the child has two parents, the law will then consider other interests, such as sanctity of marriage, when adult responsibilities for child care are allocated. Note that the emphasis on genetic relationships with men is based on the self-evident fact that men are incapable of any other sort of "biological" relationship.

Similarly, a fairly coherent body of law outlines the rights of "biological" versus "rearing" mothers in the context of adoption (17). Never before, however, have the component rights and responsibilities associated with gestational versus genetic relationships been delineated, let alone balanced against those of social mothers and fathers. Models of responsibility based on male biological linkages may well be inadequate to cover the complexities of female biological linkages, which can entail a gestational relationship as well as one based on genetics.

A second problem is that many of these techniques involve extracorporeal gametes or embryos. The still imperfect national consensus on the status of unborn children affects reproductive technologies, as questions arise concerning the management of unimplanted embryos. Whereas the abortion issue is complicated by the right of an adult woman to control the physical state of her body, the extracorporeal fertilized egg raises the narrower issue of embryo rights. If such rights are found to exist by virtue of ***the U.S.*** Constitution or are created by legislative action, then the course of reproductive biology research and treatment will be profoundly affected by limitations on actions that might harm an embryo.

Finally, new reproductive technologies raise a host of issues that are familiar to the law, but that rarely have been seen in such a tangled combination. These include equal access to reproductive services by the poor, the unmarried, and the homosexual; the rights of children with respect to their biological and social parents; the use of contractual arrangements to govern parental relationships; and the role of governmental and commercial interests in areas typically viewed as private. The arrangements facilitated by noncoital reproductive techniques invite a fresh consideration of the legal significance of genetic and social connections between parent and child, and also invite a review of the legal obstacles to the formation of nontraditional family groupings.

This chapter summarizes the legal issues raised by the use of artificial insemination, in vitro fertilization (IVF), embryo transfer, and gamete intrafallopian transfer (GIFT). These techniques have in common the possibility of an extracorporeal embryo or the use of sperm or egg donors. Situations in which a woman gestates a child with the intention of relinquishing her parental rights at birth are examined in chapter 14. Overarching constitutional issues concerning the right to procreate, personal autonomy, the commercialization of procreation, and nondiscriminatory access to noncoital reproductive techniques are discussed in chapter 12.

STRUCTURE OF APPLICABLE LAW

Both Federal and State law will affect the status of noncoital reproductive technologies. The Federal Government has limited powers, i.e., only those powers granted by the U.S. Constitution, with all residual powers falling to the States or the people (Ioth Amendment), As a result, States generally have the authority by judge-made law (also known as common law) or by State legislation to protect the public health, safety, and morals. It is on this basis that States have the authority to regulate familial relations, including marriage, divorce, adoption, inheritance, and parental duties.

In addition, contracts are generally regulated by State statute. Thus, contracts to arrange for a surrogate mother would be subject to State law rules governing interpretation or enforceability of the agreement. As each State is free to write its own laws, a contract may have differing degrees of enforceability from State to State (32). Some States may consider certain contractual arrangements as entirely void because they are contrary to public policy, such as, for example, a contract of marriage between an adult and a minor. Another State might consider the contract voidable, i.e., the contract may be voided upon request of one of the parties. In many cases, the request to void a contract may come only from the vulnerable party to the transaction, in this case the minor. Finally, some States may find no public policy reason to treat a contract in any special way, and therefore hold the contract enforceable according to the general laws of the State.

The distinctions made among void, voidable, and enforceable contracts are important in the context of surrogate motherhood arrangements, which may offend public policy in some States. Others might view either the surrogate mother or the infertile couple as a particularly vulnerable party who may initiate an action to void the contract. Thus, the enforceability of these contracts will likely vary around the country. Even with a definitive statement from the Federal courts that part or all of these transactions are constitutionally protected, individual State regulations may differ considerably.

Another applicable section of State law is known as torts, which governs most noncontractual situations in which someone harms another. The two most important areas of tort law cover intentional harms-e.g., intentionally touching someone's body without consent—and unintentional harms. Often the latter are caused by negligence, which occurs if someone behaves in an unreasonable way that breaches a duty of care owed to someone else, and thereby causes harm, A relevant example would be a physician mistakenly removing a healthy ovary rather than a diseased ovary scheduled for removal. After having the dis-

eased ovary removed, the woman could sue for damages to compensate for the additional surgery, for the resulting infertility, and for her pain and suffering.

Federal law can touch on some of these same issues if the activity involved is partly or wholly funded by Federal monies. A hospital, for example, though regulated by a State Department of Health, may also be subject to conditions on any Federal money it receives through Medicare or Medicaid. These conditions on the receipt of Federal money are a kind of Federal regulatory mechanism. The Federal Government also has the power to regulate interstate commerce. A physician may be subject to State licensure and discipline laws, but if the physician opens up a nationwide business with many offices, the business itself may be subject to Federal regulations. This commerce power of the Federal Government has been interpreted liberally in recent years, and can serve as the basis for extensive regulation when an activity is interstate in nature, or when it has an effect on interstate commerce (76).

Not only can Federal regulatory powers affect the operation of a State activity, but Federal constitutional protections may affect the structure of State laws. For example, a State law regulating adoption may specify that single-race homes are to be given preference to mixed race homes when placing children. Federal constitutional guarantees of equal protection under the laws, however, may void such a requirement as unreasonably discriminatory (76), This and other aspects of Federal constitutional law affecting the limits of permissible State legislation concerning reproductive technologies are discussed in chapter 12.

In general, Federal constitutional law is superior to Federal statutory law, which in turn is generally superior to State statutory or common law if there is a direct conflict (33). State constitutions, however, can go further than the Federal constitution in their protections, and thus forma separate basis for attacking a State law as discriminatory, even if the Federal constitutional interpretations find the law nondiscriminatory (76).

A lawsuit based on an area of State law, such as contract, tort, or family law, will generally be heard in a State court. However, if the parties to the litigation come from different States and if more than $15,000 is at stake, a Federal court may hear the case (33). This does not mean that Federal law will be applied to the case; Federal common law on these topics generally does not exist (31). Rather, the Federal court will determine which State's laws ought to apply, using the principles of "choice of law" (4i'). The decision is not a trivial one, as certain activities maybe governed in entirely different ways in one State or another. For example, the practice of surrogate motherhood is now interstate in nature, with surrogates and intended social parents often coming from different States. In the event that one State were to explicitly legalize surrogate motherhood and another to forbid it, choice~of-law principles might determine the outcome of a Federal court's decision with respect to a surrogacy contract.

ARTIFICIAL INSEMINATION BY HUSBAND

Artificial insemination by husband commonly refers to artificial insemination in which the semen is provided by the recipient's partner, whether or not she is married to him. This form of insemination is relatively uncomplicated legally because no third party is involved; the sperm donor is the intended parent of the child. Nevertheless, certain problems can arise, for example, with respect to disposition of sperm left frozen after a man's death. Furthermore, artificial insemination by husband may be subject to State law requirements that a physician perform the insemination. Finally, cryopreservation of semen may lead to physician or laboratory liabilities when storage facilities are not properly managed.

Improper Handling of Sperm

Negligent handling of sperm can give rise to professional liability if it causes harm. Further, to the extent that sperm are the property of a man, with a physician storing or using them as

per the man's directions, a physician could be viewed as a bailee, i.e., someone charged with the responsibility of caring for the property of another (59). In this capacity, the physician once again must be reasonably careful. Damages, however, are likely to be quite small for any loss of sperm or sperm viability, as the sperm can be replaced at little expense and without dangerous or invasive procedures.

One exception is the loss of irreplaceable sperm -e.g., sperm stored prior to irreversible sterilization. In 1987, suit was brought by a couple whose frozen sperm was damaged during transit from the cryobank to the site of insemination. The husband, who had stored the sperm before undergoing radiation and chemotherapy, could not replace the semen, and sued for his irrevocable loss of ability to genetically parent a child (81).

If the sperm is lost after the death of the husband, and the widow seeks damages for the loss, the damages might also be high, as the loss is again irrevocable. In this case, however, the widow would have a right to recovery by virtue of her entitlement to her husband's property; if sperm are not considered '(property, " she may have no right to recover at all.

Disposal of Sperm After Husband's Death

No State statutes specify whether frozen sperm remaining after a man's death are to be considered property of the estate, thereby passing to heirs by his will or by State law. Nor are sperm clearly considered property of the widow, to be used for impregnation or destroyed, per her request, or as abandoned property reverting to the institution or the State. In the only case to date on this subject, a French woman successfully sued in French courts to recover her late husband's sperm in order to bear a child of his. The court declined to consider the sperm as an object of a commercial contract, or as a donated organ subject to existing French regulations. Rather, it said that sperm deposition created an obligation for conservation and restitution, and that the widow's family established "without equivocation the formal will of Corinne's husband to make his wife the mother of a common child, whether the conception of this child happened while he was living or after his death" (26).

Assuming that a woman uses the frozen sperm of her late husband in order to have a child by him, a problem develops with respect to the '(after-born" child-one born after the death of his or her parent. Ordinarily, after-born children are the legal offspring of the deceased parent, entitled to inherit along with the rest of his children. In this case, however, the child is not only born but conceived after the death of its genetic father. Considering such children as the legal offspring of the deceased father creates a number of trust and estate difficulties, most of which are purely internal aspects of State law and beyond the scope of this report (49,75).

One obvious problem is that it makes ambiguous the typical language "to my children" as used in wills. The possibility of an after-conceived child would make this class of children open to additions much longer than the current 9 months following death, thus making it impossible to probate a will expeditiously. Similar problems could arise with respect to frozen embryos, with the death of one or both genetic parents no longer an insuperable obstacle to bringing the child to term.

Louisiana law, which touches on the subject of inheritance rights of IVF embryos, states that the embryo will have such rights at the time of its birth. The law places no time limit on this right, and so opens the way for inheritance rights in children whose fathers have died many years before they were brought to term.

ARTIFICIAL INSEMINATION BY DONOR

Sperm donation—the oldest of noncoital techniques–has existed as a therapeutic option in the United States since about 1950 and has resulted in statutes in some 30 States (see table 13-1). Of these, eight appear to be modeled on the Uniform Parentage Act. Others share some common lan-

Table 13-1.—State Statutes—Artificial Insemination

State	Has laws on artificial insemination	Physician must inseminate	Refers only to married women	Mentions husband consent	Legitimates offspring	Requires recordkeeping	Limits number offspring per donor	Requires screening for disease
Alabama	x	x	x	x	x	x		
Alaska	x		x	x	x			
Arizona								
Arkansas	x	x	x	x	x			
California	x	x		x	x	x		
Colorado	x	x			x			
Connecticut	x	x		x	x	x		
Delaware								
District of Columbia								
Florida	xx			x	x			
Georgia		x			x			
Hawaii								
Idaho	xx			x		x		x
Illinois		x		x	xx			
Indiana		x						
Iowa								
Kansas	x			x	x	x		
Kentucky								
Louisiana	x				x			
Maine								
Maryland	x		x	x	x			
Massachusetts								
Michigan	x		x	x	x			
Minnesota	x	x			x			
Mississippi								
Missouri								
Montana	x	x	x	x	x	x		
Nebraska								
Nevada	x	x	x	x	x	x		
New Hampshire								
New Jersey	x	x			x			
New Mexico	x	x		x	x	x	x	
New York	x	x	x	x	x			
North Carolina	x			x	x			
North Dakota								
Ohio	x	x		x	x	x		x
Oklahoma	x	x		x	x	x		
Oregon	x	x		x	x	x		x
Pennsylvania								
Rhode Island								
South Carolina								
South Dakota								
Tennessee	xx		xx	x	x			
Texas				x	x			
Utah								
Vermont								
Virginia	x		x	x				
Washington	x	xx		x	xx	x		
West Virginia								
Wisconsin	x	x		x				
Wyoming	x	x		x	xx	x		

SOURCES: Ala. Code. Sec. 26-17-21 (Supp. 1986); Alaska Stat. Sec. 25.20.045 (1983); Ark. Stat. Ann. Sec. 61-141 (c) (1971); Cal. Civil Code Sec. 7005 (West 1983); Cal. Penal Code Sec. 270 (West Supp. 1987); Col. Rev. Stat. Sec. 19-6-106 (1986); Conn. Gen. Stat. Ann. Sec. 45-69 (f-m) (West 1981); Fla. Stat. Ann. Sec. 742.11 (West 1986); Ga. Code Ann. Sec. 43-34-42 (Michie 1984); Ga. Code Ann. Sec. 19-7-21 (Michie 1982); Idaho Code Secs. 39-5401 to 39-5408 (1985, Supp. 1986); Ill. Ann. Stat. ch.40, paras. 1452-1453 (Smith-Hurd 1987); Kan. Stat. Ann. Secs. 23-128 to 130 (1981, Supp. 1986); La. Civ. Code Ann. art. 188 (West Supp. 1987); Md. Est. & Trusts Code Ann. Sec. 1-206b (1974); Md. Health Gen. Code Ann. Sec. 20-214 (1987); Mich. Comp. Laws Secs. 333.2824 to 700.111 (West 1980); Minn. Stat. Ann. Sec. 257.56 (1987); Mont. Code Ann. Sec. 40-6-106 (1985); Nev. Rev. Stat. Sec. 126.061 (1985); N.J. Stat. Ann. Sec. 9:17-44 (West Supp. 1987); N.M. Stat. Ann. Sec. 40-11-6 (1986); N.Y. Dom. Rel. Law Sec. 73 (West 1977); N.C. Gen. Stat. Sec. 49A-1 (1984); Ohio Rev. Code Ann. Secs. 3111.30-.38 (Page Supp. 1986); Okla. Stat. Ann. tit. 10. Secs. 551-553 (West Supp. 1985); Or. Rev. Stat. Secs. 109.239-.243, and 109.247 (1985); Or. Rev. Stat. Secs. 677.355-677.370 (1985); Tenn. Code Ann. Sec. 68-3-306 (1987); Tex. Fam. Code Ann. Sec. 12.03 (Vernon 1986); Va. Code Ann. Sec. 64.1-7.1 (1986); Wash. Rev. Code Ann. Sec. 26.26.050 (1986); Wis. Stat. Ann. Sec. 767.47 (West 1981); Wis. Stat. Ann. Sec. 891.40 (West Supp. 1987); Wyo. Stat. Sec. 14-2-103 (1986).

guage, but vary widely in their precise wording, ranging from a detailed code to a terse statement of their intended legal effect.

Despite the variation in wording, all artificial insemination by donor statutes make clear that the offspring of donor sperm shall be treated as the legal offspring of the consenting husband for legitimacy, inheritance, and support purposes (28,40,41,57). Sometimes the legal implications are directly specified; in other cases they arise by implication from designation of the offspring as the natural or legitimate child of the consenting husband. Sometimes this effect is certain only if the precise statutory conditions are satisfied, leaving open the consequences if statutory conditions concerning physician, marital status, and the like are not met, The result is that many questions are not answered by clear statutory language, leaving the parties to act on legal predictions of varying certainty.

The artificial insemination by donor laws appear to follow and implement a contractual approach to offspring status when donor, recipient, and recipient's husband agree that the husband shall assume all rearing rights and duties and the donor none. It maybe that this model will be followed for donor sperm transactions that do not follow all statutory specifications, for artificial insemination by donor in States without specific legislation, and for egg and embryo donation as well, though this will depend on court interpretation and future legislation.

Although these statutes operate to legitimate offspring of donor sperm, they fail to grapple with a number of potential problems discussed in this section, such as limiting the number of offspring per donor, screening for infectious and genetic diseases, clarifying the legal consequences of use by a single woman, and maintaining adequate records.

Physician Requirement

Twenty-one' of the thirty artificial insemination by donor statutes provide that offspring are the legitimate children of the consenting husband when the insemination is done by a "licensed physician," "certified medical doctor," or person "duly authorized to practice medicine. "

In States with this specification, the legal effect of insemination by someone other than a physician, such as husband, lover, donor, friend, family member, or even medical technician, nurse, or physician's assistant, may be uncertain. States such as Ohio avoid this confusion by tating explicitly that failure to have insemination performed under the supervision of a physician will not prevent the child from benefiting from the law's legitimization provisions. This would probably be the result obtained by judicial decision in States without such clarifying language (48).

Ambiguities in the statutes raise questions as to whether inseminations done without the required physician supervision have different legal consequences (43). For example, in the ***Jhordan C.*** case, the lack of physician-supervised insemination was one factor that persuaded the court to permit the sperm donor to have visitation rights. That case was complicated, however, by the fact that the mother was unmarried but living with another woman who also was to have visitation rights.

In the nine States that do not specify physician insemination, State laws against the unauthorized practice of medicine might nevertheless make it criminal for third parties to inseminate. In Georgia, Florida, and Idaho it is specifically a crime for someone other than a physician to do the artificial insemination. Nevertheless, these laws would not affect the enforceability of the parties' agreement concerning rights and duties toward the offspring.

The reasonableness of State laws that directly or indirectly require a physician to perform artificial insemination is questionable. The technique itself can be quickly learned and needs no special equipment. Limiting vendors who screen semen from anonymous donors to those with medical expertise may be easily justified (see ch. 9); similarly limiting those who use this screened semen for themselves alone is more difficult to rationalize.

'Alabama, Arkansas, California, Colorado, Connecticut, Georgia, Idaho, Illinois, Minnesota, Montana, Nevada, New **Jersey, New Mexico, Ohio, Oklahoma, Oregon, Virginia, Washington, Wisconsin, Wyoming.**

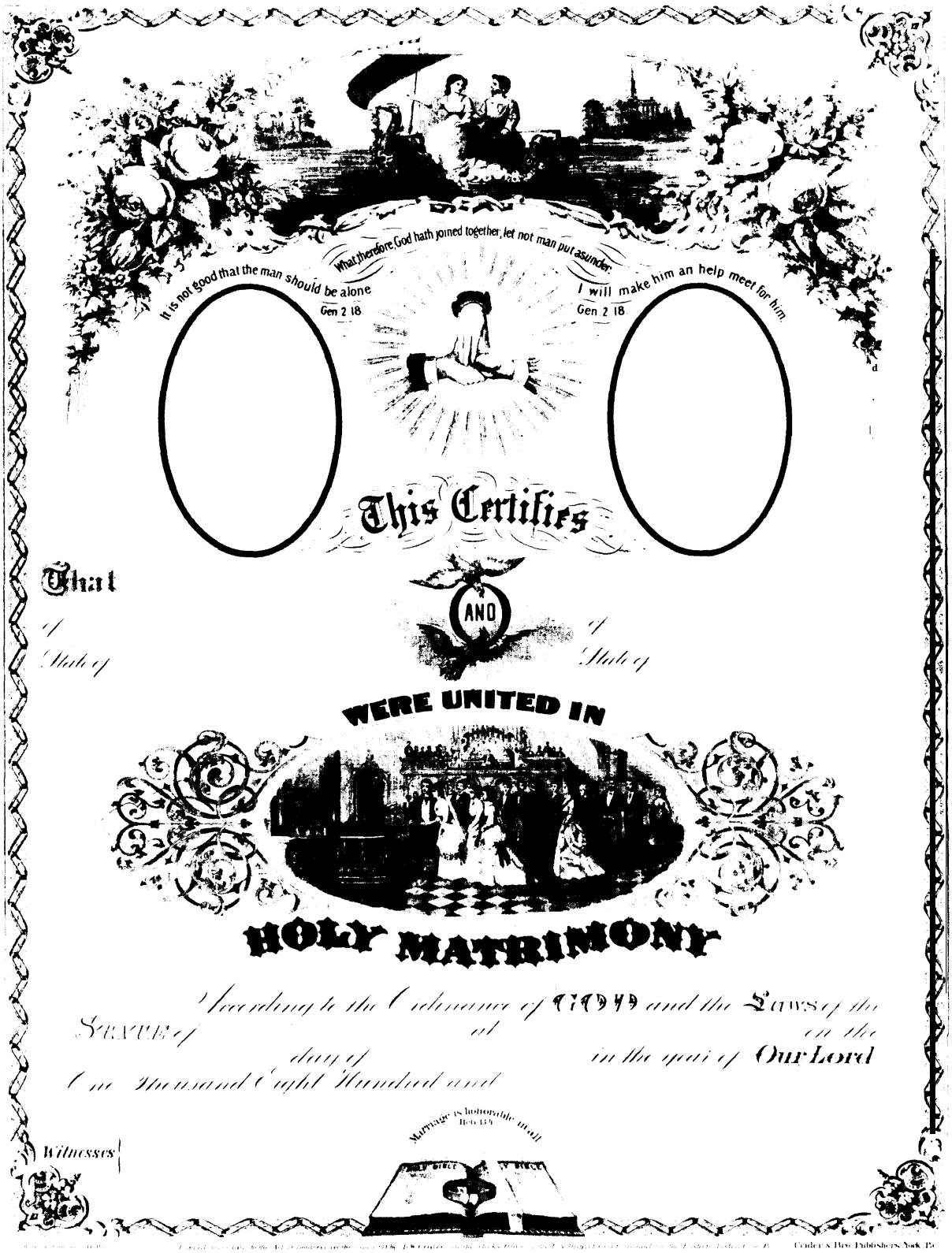


Photo credit: Library of Congress

Nineteenth Century Marriage Certificate

Marital Status of the Recipient

No statute explicitly makes it illegal for an unmarried woman to be artificially inseminated. However, most State artificial insemination by donor laws, directly or by implication, address the status of offspring where the husband consents to the insemination, thus leaving open the question of how the statutory provisions will have effect if there is no husband. when a consenting husband is present, these statutes cut off the sperm donor's rights of fatherhood and grant them instead to the consenting husband. Not all statutes are as clear as that of Ohio, which provides that even if no husband is present, sperm donor's rights and responsibilities will be cut off automatically. Another question is whether the sperm donor may sue to have these rights and responsibilities reinstated. Donors known to the recipients have successfully sued for rights of fatherhood when no husband is present (20,43).

Requirements for Consent of Recipient's Husband

All the statutes require that the husband consent for the offspring to be treated as his legitimate or natural child and for him to take on rearing rights and duties. Some States specify that the consent be in writing, four require that it be signed by both husband and wife (Alabama, California, Illinois, Ohio), and several States require that it be filed confidentially with the State health department. The penalty for failure to obtain the husband's consent is often unclear.

Husband's Rights and Duties to the Child

The only possible exceptions to the husband being the legal father of the resulting child may be in situations in which the recipient failed to obtain her husband's consent, as previously discussed, or when the recipient is in fact planning to relinquish the child to the genetic father (i.e., the recipient is a surrogate mother). In the latter case, a contractual agreement ordinarily purports to rebut the presumption of paternity or to exempt the parties from the statutory legitimation of the artificial insemination by donor laws. Whether such a contractual effort works will depend on the particular laws of the States in which the parties reside, and whether surrogate parenting contracts will be recognized by those State courts (see ch. 14).

Legal Status of Resulting Children

The offspring's status as the natural or legitimate child of the consenting husband brings into play the State law concerning rights and duties that fathers owe their natural or legitimate children, and affects the offspring's right to support and inheritance. With artificial insemination by donor, this status means that the consenting husband is listed on the birth certificate and has rearing rights and duties. The offspring inherits through him either by will or intestacy laws and not through the donor, The donor loses explicitly or by implication of law the usual rights and duties of a natural father.

Requirements for Consent of Donor's Wife

None of the 30 artificial insemination by donor statutes require a man to obtain his wife's consent before donating sperm, and thereby committing an act intended to produce offspring outside the context of his marriage. This stands in contrast to the requirement that a wife obtain her husband's consent before undergoing artificial insemination, required by every statute (9). One rationalization for the distinction is that the sperm donor will probably not be legally or financially responsible for the offspring, at least if he does not subsequently seek recognition as the father of the child.

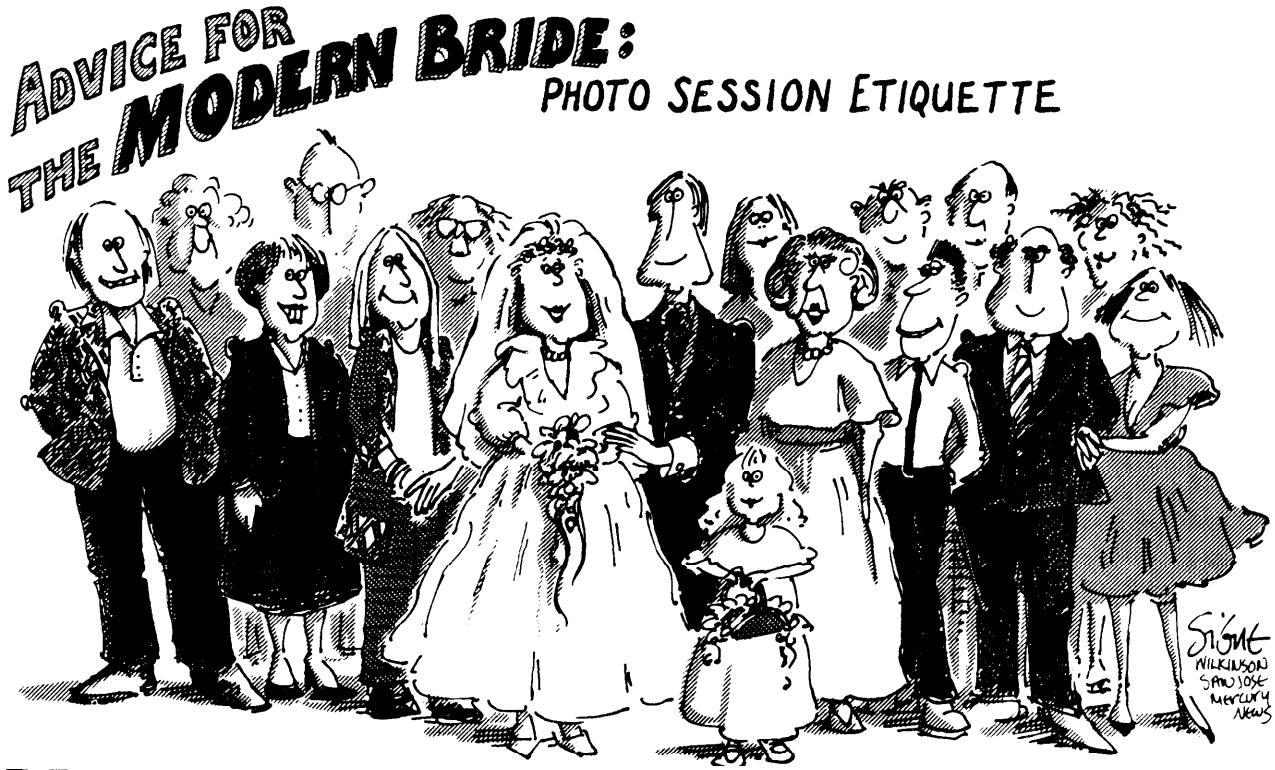
Sperm Donor's Rights and Duties to the Child

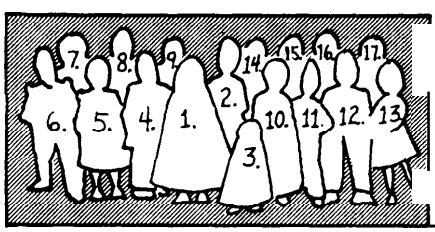
By direct statement or clear implication, all 30 State artificial insemination by donor laws remove from the donor any rearing rights and duties to the offspring when the statutory provisions are met. Sometimes this is stated directly; sometimes it occurs by clear implication from recognition of the consenting husband as legitimate or natural father. Presumably this is the donor's wishes

in those cases as well, thus implementing the contractual agreement among the parties. This arrangement helps to ensure an adequate supply of donors, for otherwise each would be subject to an unknown number of claims on his financial and emotional resources at some indeterminate time in the future.

The situation can be different, however, in the case of a known sperm donor. In the New Jersey case of C.M. v. C. C., a man provided sperm to his still virginal fiance'e, who desired a child by him prior to marriage. After the birth, the engagement was broken off. The father sued for visitation rights, which were contested by the mother. The court held that in the absence of another male parent for the child, and in light of conflicting evidence of the parties' original intentions, it was in the best interests of the child and of the State to preserve a two-parent arrangement, even if the parents were unmarried (20).

Decisions such as these demonstrate the strength of the judicial interest in ensuring two legal parents to a child born as a result of artificial insemination. They also explain, however, the reason for the demand for anonymous artificial insemination by donor among single and lesbian women. Obtaining sperm from a friend rather than from an anonymous donor means that there always exists the possibility of continued involvement by this friend in the lives of the mother and child, or even of a custody battle (43). Yet for these women the very reason for using artificial insemi-





1. Bride 2. Groom 3. Groom's daughter from **first** marriage 4. **Bride's mother 5. Bride's mother's current lover 6.** Bride's sperm donor father **7.&8.** Sperm donor's parents **who sued for visitation rights to bride 9. Bride's mother's lover at time of bride's birth 10. Groom's mother 11. Groom's mother's boyfriend 12.** Groom's father **13. Groom's stepmother 14. Groom's father's third wife 15. Groom's grandfather 16. Groom's grandfather's lover 17. Groom's first wife**

SOURCE: Signe Wilkinson, Philadelphia Daily News (from San Jose Mercury News),

nation by donor is to avoid such entanglements. Thus, use of sperm banks and anonymous donors remains the surest way for such women to achieve pregnancy without requiring a sustained involvement with a man. This fact brings into focus why physician reluctance to provide artificial insemination by donor services to singles and lesbians poses such a troubling dilemma to these women.

An important question left open by most artificial insemination by donor laws is whether parties may actually agree in advance that the donor will have rearing rights and duties toward the offspring. This will be of special importance when the donor is providing the sperm as part of a surrogate arrangement, whereby the donor and his partner will have a child to rear who is genetically related to the donor. One Arkansas statute does provide for this eventuality (see ch. 14). It will also be important when the recipient is unmarried and wishes to share parenting rights and duties to some limited extent with the donor.

Although most statutes do not provide for the latter contingency, New Jersey, New Mexico, and Washington specifically allow the donor and recipients to provide that the donor will have such rights and duties as the parties agree on. However, it is not clear that the parties will be able to change legitimacy and inheritance implications of artificial insemination by donor when a consenting husband is present, even if they may agree not to omit the donor altogether from rearing rights and duties. Even the New Mexico statute has some ambiguity, as it does not directly address the possibility that the recipient in this case is married, with a consenting husband who wishes to share in recognition of the child.

Professional Responsibility for Screening Sperm

Only 3 of the 30 State statutes address donor screening. Idaho and Oregon have statutes directed at the donor, making it a violation or crime for a man to become a donor if he knows he has a venereal or genetic disease. Ohio's statute requires a full physical examination and a medical and genetic history, and includes a list of suggested tests for specific infectious and genetic diseases. Generally, however, the artificial insemination by donor statutes do not address a physician's duty to screen donors to prevent transmission of venereal or genetic diseases to the recipient and to offspring. Only Idaho and Ohio require physicians to quarantine frozen semen and to screen the donors for human immunodeficiency virus (HIV). .

A 1978 survey indicated that many physicians were inadequately screening donor sperm for genetic and sexually transmitted diseases (23). This survey sparked a flurry of journal articles and conference discussions on ways to improve screening practices and to avoid liability for poor screening (6,7,8,13,14,51)65). Physicians and sperm banks have somewhat improved their screening practices, particularly with respect to sexually transmitted diseases (80). For example, the vast majority of sperm banks now quarantine sperm while doing followup testing on a donor (64,80). This is important for identifying donors who are seropositive for HIV antibodies, as such results may show up months after the donor was capable of transmitting the virus through his semen (see ch. 9).

In general, physicians are held to reasonable standards of care in their screening for genetic and sexually transmitted diseases. "Reasonable" is a flexible term in the law, and in this case would reflect that level of care common among similarly situated professionals. Failure to exercise such care would be malpractice, and could leave the physician liable for the physical and emotional harm resulting from the transmission of the disease (see ch. 9). For example, in 1987 a California woman brought suit claiming that she suffered from cytomegalovirus (CMV), a mild disease in adults but one that can cause birth defects in children, as a result of using semen from a sperm bank that screened for many infectious diseases but not for CMV (15,83). A court would be free to evaluate whether the sperm bank's screening protocols were "reasonable."

The American Association of Tissue Banks and the American Fertility Society (AFS) have issued guidelines on gamete donation and operation of sperm banks (1,3)5), and the American College of Obstetricians and Gynecologists endorsed the AFS guidelines (2). Such guidelines are voluntary, but

may be considered strong evidence of at least a minimal level of professional responsibility for screening, should a court consider a malpractice claim on these grounds. However, adherence to these standards is not necessarily evidence of reasonably prudent practice of medicine; courts have at times found that an entire industry or professional group has been failing to meet such a standard (see ch. 9).

The AFS guidelines, for example, did not until 1988 recommend that all use of fresh sperm be discontinued, even though only frozen, quarantined sperm can be eventually judged certain to be incapable of transmitting HIV. Instead, the 1986 AFS guidelines proposed a series of careful steps to be taken to help judge whether a donor poses any risk. The AFS guidelines are periodically reviewed, and were amended in early 1988 to express a preference for the use of frozen, quarantined semen only (58); past guidelines made no such recommendation. Should someone have contracted acquired immunodeficiency syndrome (AIDS) from fresh semen donated in accordance with the previous AFS standards, a court would be free to evaluate whether those procedures were in keeping with then-common practice and reasonably prudent. This determination could well be affected by recent reports that at least two sperm banks have had donors "seroconvert" during the quarantine period—i.e., donors tested positive for exposure to HIV soon enough after having donated sperm that it is possible they were infectious at the time of donation (66,69,83) (see ch. 9).

In early 1988, the Centers for Disease Control, coordinating with the Food and Drug Administration, recommended that all donor semen should be frozen and quarantined, so that donor testing for HIV could take place both at the time of donation and 6 months later (see ch. 9). A physician's failure to comply with this Federal recommendation would probably be considered negligent by a court. Compliance would not necessarily preclude a finding of negligence (see ch. 9), but would be strong evidence of reasonable practice.

A sperm donor who fails to report a genetic or infectious disease that might harm the recipient or child may well be violating a common-law duty of care to these parties. The general lack of recordkeeping in current artificial insemination by donor practices makes it impossible for most recipients to trace their donors in order to complain of such behavior, but should that situation change, sperm donors might conceivably find themselves responsible for deliberate or negligent misrepresentation of their health. For example, in the California suit over CMV infection via artificial insemination, the plaintiff sought a court order to open the sperm bank's records in order to identify the sperm donor, who has been included as a defendant in her suit. Although the California court hearing the case denied the request, similar suits could be brought in other jurisdictions.

Recordkeeping and Confidentiality

Fourteen[z] State artificial insemination by donor statutes specify that the written consent of the recipient and her husband be filed with the State health department, to be kept confidential except in response to a court order. A few States, such as Ohio, require the physician to keep the signed consent forms sealed and confidential rather than file them with the State. In some cases the registration requirement applies only after the birth of the child. The inseminating physician is required to file the forms only if the physician is aware of the birth, which may not occur if another physician delivers the baby. Thus some States make clear that failure to follow the recordkeeping provisions does not affect the allocation of rearing rights and duties otherwise recognized in the statute.

Adoptees have argued that a person has a right to know the identity of his or her biological parents (60), claiming that issuing birth certificates with adoptive parents' names unconstitutionally discriminates against adoptees, and violates their right to privacy (see ch. 12). Their arguments have been unsuccessful, so it seems unlikely that children conceived with anonymous donor sperm will have any more success objecting to procedures to guard the identity of their genetic

[z] Alabama, California, Connecticut, Idaho, Kansas, Montana, New Mexico, Nevada, Ohio, Oklahoma, Oregon, Washington, Wisconsin, Wyoming.

fathers. Further, identification of the donor's identity may discourage many men from offering to become sperm donors, thus reducing the supply of semen for artificial insemination. However, many States have passed legislation to provide adoptees with nonidentifying information concerning the health, interests, and ethnic background of the biological parent (61), and such statutes could be held to apply or be extended to cover children of sperm donor fathers.

IN VITRO FERTILIZATION

Although used in an estimated 169 programs nationwide, little statutory regulation exists on IVF. Only two State statutes, those of Pennsylvania and Louisiana, explicitly address therapeutic IVF. Fetal research statutes do not appear to have much of an impact, despite broad language in some that might be deemed to apply to embryos (see apps. C and F). There seem to be no statutory restrictions on IVF with egg and sperm provided by the intended social parents. Couples probably have a legal right to resort to IVF or to donate embryos to others, and, except in Louisiana, to discard unwanted embryos. They also appear to face no legal barriers, other than restrictions on research, to freezing their own embryos for later use by themselves.

Control Over Disposition of Embryos

States with laws regulating fetal research use terms such as "embryo," "product of conception," and "unborn child" that could be read to include preimplantation embryos (see table 13-2), raising the question of whether the statutory use of these terms might restrict clinical use of IVF and any of its variations. Further, five States have now adopted laws aimed specifically at IVF research or therapeutic applications (see box 13-A). At issue is whether any legal constraints prohibit couples:

- from using basic IVF to initiate pregnancy,
- from deciding not to transfer all the embryos to a uterus,
- from cryopreserving and thawing embryos for later transfer, or
- from donating embryos to willing recipients.

Fetal research statutes, many of which address questions of research with aborted fetuses, do not generally speak to these issues. For example, they do not appear to prohibit clinical use of IVF. First, most apply only to aborted embryos or fetuses, and not to preimplantation embryos. Second, they ban research or experimentation, not nonexperimental therapeutic applications of techniques that aim at bringing healthy offspring into being. (See ch. 9 for discussions of the status of IVF as experimental or therapeutic, and of State and Federal limits on embryo research.) Nor would the statutes clearly ban cryopreservation of embryos, as enabling embryos to be transferred during a later cycle may fall within the statutory exceptions for research done to benefit or avoid harm to embryos.

Finally, the validity of fetal research statutes remains to be determined; in the only challenge to date, a Louisiana ban on experimentation with fetuses obtained from induced abortions was struck down for vagueness (50). In its decision, the Court focused on the fact that it is difficult to distinguish between experimentation on the fetus, and tests on the fetus that are necessary for ensuring maternal health. As a result, physicians would be unsure of whether their actions were banned by the statute. Adoption of this reasoning by other courts would make it unlikely that statutory bans on fetal experimentation, unless quite narrowly drawn, could survive constitutional challenge.

A concurring opinion in this case focused on the unsubstantiated distinction between fetal tissue obtained by induced abortion and fetal or otherwise human tissue obtained from different sources. (A concurring opinion is a separate opinion written by a judge of the court who agrees with the outcome of the case, in this case, striking down the Louisiana statute, but who prefers alternative reasoning.) Finding no rational reason to ban experimentation on fetal tissue derived from induced abortion while at the same time allowing experimentation on corpses and fetal tissue derived from miscarriages, the concurring opinion concluded that the statutory ban was part

Table 13-2.—State Statutes—Fetal Research

State	Restricts fetal research	Prohibits sale of fetus or embryo	Mentions preimplantation embryos[a]	May restrict research with pre-embryos[b]
Alabama				
Alaska				
Arizona	X		X	X
Arkansas	X	X		X
California	X		X	X
Colorado				
Connecticut				
District of Columbia				
Delaware				
Florida	X	X		X
Georgia				
Hawaii				
Idaho				
Illinois	X		X	X
Indiana	X			
Iowa				
Kansas				
Kentucky	X			X
Louisiana	X[c]		X	X
Maine	X		X	X
Maryland				
Massachusetts	X		X	X
Michigan	X		X	X
Minnesota	X		X	X
Mississippi				
Missouri	X			
Montana	X			
Nebraska	X			
Nevada				
New Hampshire				
New Jersey				
New Mexico	X		X	
New York				
North Carolina				
North Dakota	X		X	X
Ohio	X	X	X	X
Oklahoma	X	X	X	X
Oregon				
Pennsylvania	X		X	X
Rhode Island	X		X	X
South Carolina				
South Dakota	X			X
Tennessee	X	X		
Texas				
Utah	X	X	X	X
Vermont				
Virginia				
Washington				
West Virginia				
Wisconsin				
Wyoming	X			X

[a]By terms such as "embryo," "product of conception," "conceptus," or "unborn child."
[b]Statute could be interpreted as prohibiting some pre-embryo research.
[c]Louisiana statute found unconstitutional in *Margaret S. v. Edwards,* 794 F.2d 994 (1986).

SOURCES: Ariz. Rev. Stat. Ann. Sec. 36-2302 (1986); Ark. Stat. Ann. Secs. 82-436, 442 (Supp. 1985); Cal. Health & Safety Sec. 25956 (West 1984); Fla. Stat. Ann. Secs. 390.001(6), 873.05 (1987); Ill. Ann. Stat. ch.38, paras. 81-26, 32 (1987); Ind. Code Ann. Sec. 35-1-58.5-6 (West 1986); Ky. Rev. Stat. Sec. 436.026 (1985); Ky. Rev. Stat. Sec. 311.720 (1983); La. Rev. Stat. Ann. Secs. 14:87, 121-133 (1987); Me. Rev. Stat. Ann. tit.22, Secs. 1593-95 (1980); Mass. Gen. Laws Ann. ch.112, Secs. 12J,K (1983); Mich. Comp. Laws Secs. 333-2685-2692 (1980); Minn. Stat. Ann. Secs. 145-421,422 (Supp. 1986); Mo. Rev. Stat. Secs. 188.015,037 (Vernon 1983); Mont. Code Ann. Sec. 50-20-108 (1987); Neb. Rev. Stat. Sec. 28-346 (1985); N.M. Stat. Ann Secs. 24-9A-1 to 6 (1979); N.D. Cent. Code Sec. 14.02.2-01 (1981); Ohio Rev. Code Ann Sec. 2919.14 (Page 1987); Okla. Stat. Ann. tit. 63, Sec.1-735 (1984); Pa. Stat. Ann tit. 18, Secs. 3203, 3216 (1983); R.I. Gen Laws Sec. 11-54-1 (Supp. 1987); S.D. Cod. Laws Ann. Sec. 34-23A-17 (1986); Tenn. Code Ann. Sec. 39-4-208 (1982); Utah Code Ann. Sec. 76-7-310 (1978); Wis. Stat. Ann Sec. 51.61 (Supp. 1986); Wyo. Stat. Sec. 35-6-115 (1977).

Box 13-A.—Summary of State Laws That Specifically Address In Vitro Fertilization

Kentucky.–Kentucky mentions IVF in its adoption statutes, only to say that nothing in a statute prohibiting adoption in certain instances prohibits IVF.

Illinois.—Illinois' fetal research statute specifically says that it is not intended "to prohibit the performance of in vitro fertilization," when it says that nontherapeutic experimentation on a "fetus produced by the fertilization of a human ovum by a human sperm" is prohibited.

Louisiana.—Louisiana passed a law in 1986 concerning "in vitro fertilized" ova, thereby seemingly excluding embryos created in vivo, whether or not subsequent lavage and transfer were contemplated. The law forbids the purposeful creation of an in vitro embryo solely for the purpose of research or sale. The law also expressly prohibits the sale of a human ovum.

The Louisiana law is novel in that it expressly grants the status of "juridical person" to the fertilized ovum, until such time as it is implanted in a uterus, when presumably its status is governed by State law applying to products of conception in utero. As a juridical person, the fertilized ovum may sue or be sued, and may not be considered property. Instead, the gamete donors are considered its parents, and if they are unidentifiable, the medical facility is considered guardian of the fertilized ovum. The gamete donors may allow another couple to adopt the embryo. Inheritance rights do not attach until birth, and then attach to the birthing or adopting parents, rather than the genetic parents. No person, including the gamete donors, may intentionally destroy an in vitro embryo that appears capable of normal development. IVF facilities are particularly noted as having a direct responsibility for the safekeeping of the embryo. Further, while such facilities and their personnel are protected from strict liability claims by the embryo, they are not so protected from strict liability claims brought by other interested parties.

The law restricts IVF practice to those facilities complying with the personnel qualification and physical plant guidelines of the American Fertility Society or the American College of Obstetricians and Gynecologists.

New Mexico.–New Mexico defines IVF and then states that '(clinical research" is to be construed "liberally to embrace research concerning all physiological processes in man and includes research involving human in vitro fertilization, but shall not include human in vitro fertilization performed to treat infertility; provided that this procedure shall include provisions to insure that each living fertilized ovum, zygote or embryo is implanted in a human female recipient, and no physician may stipulate that a woman must abort in the event the pregnancy should produce a deformed or handicapped child" [Sec. 324-9 A-1 (D)].

The restrictions on research thus do not apply to IVF conducted to treat infertility, even if they are experimental or unproven in some sense. Thus this law's effect on IVF does not appear to be significant.

Pennsylvania.—Pennsylvania defines IVF as "the purposeful fertilization of a human ovum outside the body of a living human female" (Sec. 3203). It then requires that all persons conducting or experimenting in IVF "file quarterly reports with the department which shall be available for public inspection and copying. " The reports must include the names of the persons conducting or experimenting in IVF, the locations, the sponsor of the research, number of eggs fertilized, number destroyed or discarded, and number transferred ("implanted") in a woman. The names of the persons or couple providing the gametes are not required to be reported. Failure to file a report is subject to a fine of $50 a day.

A telephone call to the State official in charge of these records in 1985 revealed that reports are filed by many programs, though no effort to monitor programs to see if they are complying with the law has occurred. Nor is it clear what purpose collection of these data now serves, since they do not appear to have been used for any regulatory purpose or sought by researchers.

SOURCE: Office of technology Assessment, 1988

of an attempt to discourage the use of abortion (other aspects of the statute were found to have this purpose), and for that reason was unconstitutional. If this latter reasoning were adopted by other courts, it would increase the possibility that general bans on experimentation with fetal tissue, regardless of source, could survive constitutional scrutiny because they would no longer make the unjustifiable distinction between fetal tissue obtained by abortion and that obtained by miscarriage.

Discretion over discard of embryos does not generally appear to be considered by fetal research statutes. Almost all address what can be done with the product of abortion, but do not address restrictions on abortion itself. Thus, they would not appear to affect the decision to discard an embryo. Even the four States that would arguably prevent research on discarded embryos (see table 13-2) do not address the legality of discard itself.

Discretion over discard of embryos is specifically addressed, however, by Louisiana's IVF law, which states that even the gamete donors may not discard a viable embryo. Instead, they may preserve it for later use or donate it (without compensation) to another couple. Physicians and IVF facilities are directed to take every precaution to preserve the viability of the IVF embryo.

Although some prosecutorial authorities have indicated that they will not prosecute IVF programs under their fetal research laws if all embryos are transferred to a uterus, it is not clear they have a statutory basis for such a position. Further, transfer of grossly abnormal embryos resulting in miscarriage might be a violation of a physician's duty to the patient.

Juridical Status of the Extracorporeal Embryo

There are mixed indications of whether the preimplantation embryo will be treated as the property of the gamete donors. Some commentators have written about viewing sperm and ova as property, and have speculated about the extension of this concept to embryos (42). Judicial decisions have begun to wrestle with the question as well. For example, in a challenge to the Illinois IVF law, a court accepted the notion that an IVF patient is pregnant as of the moment her egg is fertilized, even though the fertilization is extracorporeal (71). The implication is that any decision concerning disposal, particularly destruction, must be made with the woman's consent, as is done for any form of pregnancy termination. In such a case, it is unclear whether this privilege is based on notions of control of property.

On the other hand, a couple successfully sued for $50,000 in damages when their preimplantation embryo was deliberately destroyed after an IVF treatment was canceled by the clinic (24). Nevertheless, the trial-level case set no precedent outside its own district; further, it awarded damages for intentional infliction of emotional distress, rather than for conversion or trespass to chattel, which are causes of action for interference with the property rights of another (59).

The Louisiana IVF law defines the extracorporeal in vitro fertilized ovum as a "juridical person, " specifically stating that the gamete donors have parental rather than property rights with respect to the embryo. It further states that the extracorporeal embryo is able to sue and be sued, implying that actions adversely affecting its viability or its health upon birth are subject to legal consequences. In many States, persons have the right to sue for injuries sustained prenatally (10,44,63), but the Louisiana law goes further, granting to the embryo the right to sue for injuries, rather than having these rights accrue upon birth. Granting rights of personhood to an embryo, extracorporeal or in utero, could conflict with the U.S. Supreme Court ruling in Roe v. ***Wade,*** which stated explicitly that the unborn are not "persons" within the meaning of the 14th Amendment's due process and equal protection clauses (62). However, the Louisiana law has not yet been tested in court.

Later Implantation for Same Couple

The physician or institution providing the in vitro service will be responsible for adequate storage of any frozen embryos being kept for later use by the same couple. Failure to exercise rea -

sonable care could leave the service provider open to liabilities stemming from medical malpractice, negligence, intentional or negligent infliction of mental distress, interference with property, or breach of contract. Such a case could arise, for example, where a malfunctioning incubator damages stored embryos.

Not every embryo loss would leave the provider liable; the technology of embryo freezing and storage is still too undeveloped to offer any guarantee that the embryos will all survive. Yet, failure to operate a storage facility that meets the average standards of practice of the industry certainly would be strong evidence of negligence (53). Furthermore, any deliberate destruction of the embryo, such as took place in the case mentioned in the preceding section, would almost certainly leave the provider liable. The Louisiana IVF law specifically prohibits the physician or institution from destroying the embryo. It absolves the' phy - sician and institution from strict liability for screening, fertilization, preservation, and transfer of the ovum, but only with respect to actions brought on behalf of the fertilized ovum. Thus, strict liability might be applicable in a suit by the gamete donors. Further, it absolves the physician and institution from any liability to the embryo if actions were taken in "good faith," but fails to clarify whether a well-intentioned but negligent action would be covered.

"Strict liability" is a legal doctrine generally applied to either ultrahazardous or unnatural activities with a great propensity for harm regardless of how carefully undertaken. Under this doctrine, in order to collect damages a plaintiff need only show that the defendant's actions harmed the plaintiff. It is unnecessary to show that the defendant was negligent. In essence, the doctrine places financial responsibility for harm on those who choose to undertake these activities, regardless of their efforts to be careful or their good intentions. The activities that might qualify for strict liability have been the subject of much discussion, a number of cases, and several efforts by the American Law Institute's codifications of case law, known as "Restatements" of the law. In light of the high rate of early embryo loss in both natural and in vitro fertilization, it is difficult to predict whether IVF would ever become subject in any particular State to strict liability principles.

Calculating the damages from the loss of an embryo would be difficult as this is an unsettled area of law. One calculation could focus on the cost of obtaining a replacement embryo. Another could be the calculation of the net value of the potential child that was lost (35).

Trusts and Estates

Problems regarding trusts and estates are raised by the prospect of frozen embryos left unimplanted after the death of one or more of the genetic parents, as occurred in the Australian case of the Rios embryos (see box 11-A in ch. 11). Controversy developed over whether the embryos should be discarded, given to another couple to gestate and raise as theirs, or given to another to gestate and raise as the orphaned children of the Rioses. Although the embryos were genetically related only to Mrs. Rios, the intended rearing father (her husband) had consented to the use of donor sperm, a fact that would have made him the legal father of the embryos upon birth. This last scenario could conceivably have made the offspring heir to the considerable Rios fortune, and explains in part the international attention that was focused on these frozen embryos (70).

Further, in other areas of trusts and estates Iaw, the validity of certain legacies is determined by whether the beneficiaries will be completely identifiable within a certain period of time, This period of time depends partly on identifying those "lives in being" at the time the legacy is created (16). Although clearly frozen extracorporeal sperm are not lives in being, the same cannot be stated as categorically for a frozen embryo, although constitutional decisions holding that the unborn are not "persons" under the 14th Amendment may prevent States from defining frozen embryos as "lives in being" (62).

The Louisiana IVF law grants inheritance rights to the embryo at the time of birth. Further, the resulting child would inherit from the woman who gives birth (and her husband, if any), rather than from the gamete donors. The provision is

unclear, however, with respect to a number of problems. For example, if the woman giving birth were unmarried, it is unclear whether the child could inherit from the genetic father if his sperm were used as that of an anonymous sperm donor rather than an intended rearing parent. Further, if the genetic father is deceased but his wife, the genetic mother, gives birth many years later by bringing to term a previously frozen embryo, it would appear necessary to reopen probate of the father's will in order to account for this new child. With no time limit specified for inheritance purposes, such events pose real problems for the orderly disposition of estates. The ambiguities in the Louisiana effort to account for inheritance rights of extracorporeal embryos simply point out some of the many complexities of trusts and estates law in this area, a topic beyond the scope of this report.

GAMETE INTRAFALLOPIAN TRANSFER

Gamete intrafallopian transfer involves transfer of ova and sperm by catheter to the fallopian tubes, where fertilization may take place (see chs. 7 and 15). As both donor sperm and donor eggs can be used, GIFT can raise all the same questions of relative rights and responsibilities among gamete donors and gestators as are raised by IVF. In one sense, GIFT simplifies the legal issues raised by noncoital reproductive technologies, because it eliminates the presence of the extracorporeal embryo. This avoids the difficulties posed when embryos are left frozen after the death of the genetic parents, and also avoids the possibility of commercial cryobanking of embryos.

EMBRYO TRANSFER

This section considers the situation in which a child will be raised by a gestational mother and her husband or partner, using an embryo that was donated. Embryos may be donated in one of two ways. First, embryos may be donated by couples who have embryos left over from an IVF procedure. In this situation, the gestational mother will rear a chiId to whom neither she nor her husband are genetically related. The genetic parents of the embryo are referred to as embryo donors. Although this can occur with fresh embryos, problems of synchronizing the recipient's cycle make it more likely to occur as cryopreservation of embryos becomes more common.

Second, a woman may deliberately undertake to donate an ovum to another. For example, she may undergo laparoscopy or sonography-guided egg retrieval so that the recovered eggs can be fertilized in vitro before being implanted in another woman's womb. In this situation, the gestational mother's husband usually donates the sperm to be used for the fertilization, and the term ovum donor is used to refer to the woman undergoing egg retrieval.

A variation on this method for donation is for the ovum donor to become pregnant by artificial insemination with the intended gestational mother's husband's sperm, in order to have the fertilized egg washed from her uterus by lavage and then donated to the gestational mother. Since the lavage removes an embryo from the uterus before it has implanted, it probably cannot be considered an abortion; use of an intrauterine device may also induce the removal of a fertilized ovum before implantation, but is not viewed under the law as equivalent to an induced abortion. Nevertheless, the precise classification of artificial insemination followed by uterine lavage remains somewhat ambiguous. Embryo donation by artificial insemination and lavage, or by egg retrieval and IVF with the intended rearing father's sperm, is quite rare and may remain uncommon (see ch. 15).

The situation in which an embryo is carried to full term by a gestational mother and then returned to the gamete donors for rearing—gestational surrogate motherhood—is considered in chapter 14.

Existing Legislative Controls

With the exception of Louisiana and Kentucky, no State has statutes specifically addressing embryo donations of any type. The tendency or practice of some persons to speak of embryo donations as "embryo adoptions" can be misleading legally, since State adoption laws have always involved transfer of rearing rights and duties in a live-born infant rather than in an unimplanted embryo.

Fetal research statutes generally cannot be read to prevent the donation of embryos created in vitro or by artificial insemination followed by lavage. In five States,[3] however, prohibitions on donating fetuses for research or experimentation might be interpreted to include embryo donation for gestation, if the definition of fetus were extended to include embryos and the transfer process were viewed as experimental. In Nebraska and Wyoming, this same conclusion might be drawn if, in addition, the embryo resulted from an abortion, arguably true in the case of artificial insemination followed by lavage for the purpose offertilized ovum donation (4).

By contrast, the Louisiana IVF law (which applies only to ova fertilized in vitro rather than by artificial insemination) specifically preserves the possibility of donating the embryo, but does not permit any compensation for the donation. It allows gamete donors to renounce their parental rights, at which time the embryo can be donated to another. The drafting of the statute makes it unclear, however, whether only married couples may accept the donated embryo. It is also unclear from the drafting whether the IVF facility can limit donations to persons meeting criteria it specifies.

Kentucky Revised Statutes Section 199.590, which prohibits payment in connection with adoption, was revised in 1984 to read:

> Nothing in this section shall be construed to prohibit in vitro fertilization. For the purposes of this section, in vitro fertilization means the process whereby an egg is removed from a woman, then fertilized in a receptacle by the sperm of the husband of the woman in whose womb the fertilized egg will thereafter be implanted.

Subsequent court dictum in the 1986 Kentucky case ***Surrogate Parenting Association*** interpreted the section to mean that embryo donation is permitted when the gestational mother and genetic father are married to one another and intend to raise the child themselves (74). ("Dictum" is commentary that is not strictly necessary to the decision on the case before the court; it is used by judges to explain their reasoning and to draw analogies to other fact situations. Although dictum has no precedential value, it can be persuasive to other courts, and can provide a clue as to future judicial decisions in related areas of law.) However, no case has arisen in Kentucky to test this interpretation or to determine legal maternity in the event of a dispute between a genetic and a gestational mother.

The Kentucky statute addresses embryo transfer involving an ovum donor who undergoes egg retrieval so that the ova may be fertilized with the gestational mother's husband's sperm, but it does not address the question of the more common form of embryo donation, which involves the transfer of "surplus" embryos from one couple to another. By its terms, the Kentucky statute cannot apply to this situation, as the gestational mother's husband would not be the genetic father of the resulting child. However, there is nothing in existing Kentucky law that prohibits such transfers either.

No other State statutes address embryo transfer. Nor can the State artificial insemination by donor laws be easily interpreted to extend **to male** and female gametes alike, since they use the term "sperm" or "semen. " It is likely that courts would give legal effect **to** the agreement between the parties to an embryo donation if it paralleled sperm donation—i.e., if an ovum donor has no rearing rights and duties and the consenting embryo recipient (who will also gestate) and her partner (who will be the genetic father) assume them. Yet, embryo donation entails greater risk **to the** ovum donor than does sperm donation.

The risks of ovum donation depend on a number of factors, including the method by which the ova are recovered. Laparoscopy involves the risks

[3]Maine, **Massachusetts, Michigan, North Dakota, Rhode Island.**

of abdominal surgery, such as infection and anesthesia. Sonography-guided vaginal retrieval also poses a risk of infection, and both egg recovery techniques may be used in conjunction with drugs to stimulate ovulation, thus posing the risk of side effects. Artificial insemination followed by uterine lavage and embryo retrieval risks unintended or ectopic pregnancy, as well as the transmission of infectious disease by the semen used for the insemination.

These risks may strongly influence the development of paid ovum donation, as professional societies such as the American Association of Tissue Banks recommend that their members not accept tissues if it entails "undue risk" to the donor. The difference in risk associated with these forms of embryo donation as opposed to sperm donation might be used by professional societies and lawmakers to justify regulation or prohibition of paid embryo donation, at least when it is undertaken solely to earn money and not in conjunction with a therapeutic or diagnostic procedure needed by the ovum donor herself.

Some restrictions on commercial embryo donations do exist. Payment for a human embryo is specifically banned in Louisiana and Florida, and some of the State fetal research statutes prohibit the sale or transfer of embryos for experimental purposes. Eleven States that prohibit selling fetuses for experimentation use language potentially broad enough to affect the sale of embryos conceived in vivo (10, I1,12).

Professional Responsibility

Professionals who facilitate embryo transfer have responsibilities with regard to ensuring that there is informed consent by all parties to the procedure, that the sperm and ova are properly screened, and that the resulting embryo is preserved as well as current technology permits.

Ensuring informed consent is difficult when the risks of a procedure are still poorly understood. Under these circumstances, physicians are generally required to err on the side of caution and to present even those risks that seem quite remote (34). Relatively unexplored procedures, such as artificial insemination followed by lavage, pose just this dilemma.

There are no State laws on recordkeeping and confidentiality with respect to embryo donation. As these donations require a medical procedure, however, hospital or at least office records are likely to exist for each donor. Such records are ordinarily held in confidence, but are subject to disclosure upon court order or at the request of the patient herself (39).

No legal constraints on techniques for ovum screening exist, although professional guidelines have been issued by the American Fertility Society, in addition to those issued with regard to sperm donation. Further, there are no statutory requirements that physicians screen fertilized ova for morphological indications that they are not viable, but it is nevertheless a common practice at IVF clinics. Even so, some clinics transfer embryos that may have little chance of implanting and coming to term, both because the dearth of embryo research has made it difficult to predict with certainty which embryos will implant successfully and because of a desire to avoid the ethical issues raised by the deliberate discard of fertilized eggs (84).

Responsibility for storage of a cryopreserved embryo will always fall on the institution providing the service. But the party to whom the institution is liable in the event of negligence may change, depending on who is considered the "owner" of the frozen embryo and who intends to raise the resulting child. If an embryo has been donated to another couple, and this donation is evidenced by some sort of written or oral agreement, the intended recipients might be viewed as the "owners, " at least with respect to control over decisions concerning disposition of the embryo. This scenario has not yet been tested in any court of law.

Embryo Donor's Rights and Duties to Child

Using the analogy of the sperm donor's rights and duties to his genetic offspring, a couple donating an embryo to another would presumably have no rights or duties to the child. As only the donors are familiar with their own genetic backgrounds, however, they might have a duty to warn the recipient of potential genetic problems in the off-

spring, If the resulting child is in fact born with a genetic problem that could have been identified if the donors had warned the recipient of its possibility, there might be two causes of action. First, the recipient might sue to recover the extra costs of raising a child with these problems. Second, the child might sue the donors. If the problem would have been correctable, then the suit would be for the pain and suffering of living with the disease. If the problem were unavoidable except by abortion, the child might sue for '(wrongful life)" alleging that nonexistence would have been preferable to diseased existence.

Such wrongful life suits have met with limited success in U.S. courts, but as the number of identifiable genetic disorders increases, they might become more common (19,21)56)63). Usually they are directed at the physician or genetic counselor who failed to properly advise the parents of the condition. In this situation, both the parents and the gamete donors have a role in identifying the disorder, and thus may be liable to the potential child. A suit against the gamete donors is somewhat analogous to a suit against the genetic counselor, as in both cases a duty exists to disclose information that is uniquely held by that person.

When these suits are directed at the child's rearing parents, it appears at first to be a futile attempt to move funds from the parents' pockets to the child's. In fact, however, the purpose may simply be to obtain funds from the parents' insurer. To date, courts and legislatures have not shown a willingness to countenance such suits against a child's parents (30)67)68). Should this reaction change, however, insurance coverage for such liabilities may be an important factor in the growth of these particular lawsuits. Another key factor would be the development of recordkeeping practices that allow identification of the embryo donors; if they are kept anonymous, then the child and the child's rearing parents would be unable to bring suit. Such anonymity has been a factor in restricting analogous suits against sperm donors.

Requirements for Consent of Ovum Donor% Husband

A husband may have an interest in his wife's decision to be artificially inseminated for subsequent lavage and recovery, There is, however, no common law or statutory duty for a physician to obtain the consent of an ovum donor's husband. Using the analogy of sperm donation, if the ovum donor has no legal rights or responsibilities to the child, it is unlikely that a consent requirement will be developed. There is a key distinction, however, between being an ovum donor and being a sperm donor that might affect consent requirements: the former may inadvertently become pregnant. If she does, and if she chooses to sustain the pregnancy, then her husband could become legally responsible for the child.

Embryo Recipient's Rights and Duties to Child

As the embryo recipient is the intended rearing parent, her responsibilities will probably be identical to those of any mother. Her rights, however, are less clear. As a "gestational mother," she is not clearly recognized in law as the sole woman with claim to be recognized as the "legal" mother. Analogies to date have been limited to questions surrounding fatherhood, in which genetic relationship is generally determinative of parentage (37).

One major exception, however, is the presumption of paternity, which is designed both to protect the needs of the child to have two parents and to preserve the institution of marriage. Similar policies might come to be used to justify a State policy favoring a gestational mother or an intended rearing parent's primacy in any conflict with the genetic mother over custody to the child. In the only two court cases to date, however, prebirth uncontested petitions to have the genetic mothers (rather than gestational mothers) recognized as the legal mothers of the children were granted, subject to postbirth confirmation (72)73). The cases, however, were from lower courts, and so have limited precedential value even within the States in which the courts were sitting. A ruling on a similar case in Virginia is expected in early 1988 (27).

It should be noted, too, that embryo donation will be made by a woman who has undergone an IVF procedure and who has had several embryos left over after the procedure. In other words, the embryo results from an invasive sur-

gical laparoscopy done on a woman who herself was having trouble conceiving. If such a woman subsequently finds that she is unable to have a child, perhaps because she is unable to carry to term, there may be an emotional demand for custody of any child that resulted from one of the embryos, regardless of the gestational mother's own attachment after pregnancy. There is no tested law at all on this subject, and as yet no established principles to predict the outcome in the event of such a controversy.

With regard to the embryo recipient's husband, no statutory requirement for his consent exists when a woman seeks an embryo transfer from an ovum donor, despite the analogy to artificial insemination. Physicians can be expected to individually require such consent if they know that the woman is married, just as many have in the context of artificial insemination. Absent legal constraints, however, such consent is not required. Nevertheless, the presumption of paternity will probably render the husband the legal father of the child, even if his sperm were not used to inseminate the ovum donor nor his consent obtained.

RESTRICTING OR REGULATING THE SALE OF GAMETES OR EMBRYOS

Most States do not prohibit the sale of blood, plasma, semen, or other replenishing tissues if taken in nonvital amounts (55,79), although the prohibitions on organ sales in three States are conceivably broad enough to cover semen sales as well (12). Florida, however, outlaws the sale of human embryos: "No person shall knowingly advertise or offer to purchase or sell, or purchase, sell or otherwise transfer, any human embryo for valuable consideration" [Fla. Stat. Ann. Sec. 873.05(1)]. Similarly, Louisiana's IVF law prohibits paid transfers of fertilized ova.

State laws usually characterize these paid transfers as provision of services rather than sale of commodities, either in the State's version of the Uniform Anatomical Gift Act or in their version of the Uniform Commercial Code (UCC), which governs various commercial transactions, including contracts for the sale of goods. The primary reason for this characterization is to avoid liability for defective products under either general product liability principles or the UCC'S implied warranty provisions (18,22,36). In addition, services are not subject to the UCC'S specific performance provisions.

Product liability is the name given to the area of law involving the liability of suppliers of goods or products for the use of others, and their responsibility for various kinds of losses resulting from defects in those products. Four possible theories of recovery are available under product liability law:

- strict liability in contract for breach of an express or implied warranty,
- strict liability in tort largely for physical harm to persons and tangible things,
- negligence liability in contract for breach of an express or implied warranty that the product was designed and constructed in a workmanlike manner, and
- negligence liability in tort largely for physical harm to persons and tangible things (59).

Generally, negligence liability may exist with respect to both products and services, but strict liability is applicable only to products, Thus, characterization of blood and semen sales as services enables blood and semen banks to avoid liability if a specimen is contaminated or infected, provided that the bank was not negligent (46).

If sales of gametes and embryos were to be treated as those of goods as opposed to services, then UCC warranties would apply. The UCC provides that commodity contracts (but not service ones) are subject to:

- the implied warranty of merchantability, which requires goods to be of "fair average quality" within the description provided by the seller and fit for the ordinary purposes for which such goods are used (UCC Sec. 2-314), and

- the implied warranty of fitness, which requires goods to be suitable for the buyer's particular purpose to the extent this purpose is known by the seller (UCC Sec. 2-315).

The merchantability warranty only applies to sales by "merchants," defined by the UCC as those who regularly supply the product (e.g., hospitals, tissue banks), but not by occasional sellers [UCC Sec. 2-104(1)]. The fitness warranty applies equally to regular dealers and occasional sellers (UCC Sec. 2-315).

If these transactions were treated as sales of commodities, these implied warranties could result in substantial liability for injuries resulting from transfusion or insemination with a specimen capable of transmitting hepatitis, AIDS, or another contagious disease. Insemination with sperm containing a genetic defect could also result in substantial liability. Since the suit would be based on strict liability for breach of warranty rather than negligence principles, careful examination of specimens for contamination or a genetic flaw would not entitle the providing entity to avoid liability if an injury occurred.

If exchanges involving human gametes and embryos are treated like those involving blood–i.e., if such exchanges are considered to be transactions for services rather than commodities—then certain types of liability may similarly be avoided by tissue and cell banks, research institutions, hospitals, and companies. Although liability would continue to exist for negligence (e.g., failing to use an available and appropriate test to screen suppliers for viral infections), there would be no liability for imperfect specimens in the absence of negligence. Avoiding the concept of an imperfect specimen with respect to embryos might also help avoid some of the ethical questions raised by treating embryos as traditional articles of commerce.

The Federal Government has the authority to enter this area to regulate gamete and embryo sales by virtue of the interstate commerce clause (see ch. 9). The ultimate regulation of interstate commerce might be to ban the sale of an article altogether. Of course, the Food and Drug Administration does this implicitly for all drugs and medical devices that have not been proven safe and effective. But Congress has also indicated its willingness to ban the purchase and sale of human body parts, and could certainly ban the interstate sale of human embryos, as well as sperm and ova. In 1984, for example, Congress passed the National Organ Transplant Act. Although most of the act is aimed at promoting organ transplantation in the United States, Title III is directed exclusively toward prohibiting organ purchases:

> It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce. For the purposes of this act, "human organ" is defined to mean "the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin. . . ." Violation carries a five year maximum prison sentence, and a $50,000 fine [Public Law 98-507 (1984)1.

Thus, the statute bans the profitable sale of organs, although not the recompense of expenses incurred by the donor. The statute's organ sale prohibition was based primarily on congressional concern that permitting the sale of human organs might undermine the Nation's system of voluntary organ donation (77). It was also driven by concern that the poor would sell their organs to the rich, to the detriment both of poor people who might feel economically coerced to become organ suppliers and those who need but cannot afford transplantable organs. It may also reflect congressional distaste for sales of human body parts generally.

These considerations may or may not apply to the sale of gametes and embryos (29). Semen sales, in particular, involve no physical risk to the donor and have long been tolerated in the United States. Ova sales involve risk to the donor, as she may well be prescribed drugs to induce superovulation, undergo laparoscopy for retrieval of the eggs, or be impregnated by artificial insemination and risk ectopic pregnancy from the lavage technique used to recover the fertilized ovum. Embryo sales may involve the risks of ovum donation, and also raise ethical considerations not present in the sale of gametes (see ch. 11).

MODELS OF STATE POLICY

The approaches taken by State legislatures to the oversight or regulation of noncoital reproduction may be broadly grouped into five categories: static, private ordering, inducement, regulatory, and punitive (25,82). These models are of interest both because they reflect the variation in proposed State legislation and because they serve as an informative guide to Congress, should it choose to consider legislation in this field. Further, constitutional challenges to these State laws could illuminate the boundaries of the right to procreate.

The static approach, one of State legislative inaction, leaves the resolution of familial relationships to case-by-case consideration by the courts. For example, in the District of Columbia and the 20 States without legislation on the topic of artificial insemination, challenges to the legitimacy or legal status of the resulting child could be brought, and judicial determinations would be made based on the effect of any general State legislative presumptions of paternity, the best interests of the child, the understanding of the parties to the insemination, the existence (if any) of an underlying contractual agreement, and other pertinent facts. This nonlegislative approach can be indicative of a lack of consensus among State legislators, or a temporary absence of legislative leadership while courts are given an opportunity to consider several test cases. Alternatively, it could be an expression of hostility to an activity altogether. By failing to provide legislative guides to resolving possible disputes, the legislature can effectively decrease the frequency of the activity within the State by making it a more legally risky venture for the participants.

Private ordering approaches allow the State to validate private arrangements by recognizing underlying agreements or contracts to allocate familial roles to those who participate in artificial insemination by donor or the transfer of embryos for IVF, Artificial insemination statutes that identify the recipient's husband as the legal father of her child only if he consented to the insemination follow this model. others allow participants to specify that a sperm donor may have a continuing parental role for the child. Legitimizing these choices by State statute and enforcing them by judicial action places the State in the role of facilitating individual choices of all sorts.

By contrast, inducement approaches only validate the parties' underlying intentions or agreements if their actions meet certain legislative conditions. For example, many of the State artificial insemination statutes contemplate only those inseminations done by a physician. The physician requirement can be premised on a number of policies, such as ensuring the physical and genetic health of both sperm donor and recipient, maintaining artificial insemination as a form of medical practice despite the ability of laypersons to perform the procedure, encouraging the use of anonymous donation only, or facilitating the role of physician as a gatekeeper who screens out socially unacceptable recipients and donors. Such a law can encourage conformity to State-sanctioned procedures by denying nonconforming artificial insemination participants the advantage of certain legitimation of the resulting child under State paternity law, or by denying a recipient the advantage of knowing that the sperm donor is unable to reenter her life with a request to be acknowledged as the father of her child. The case of ***Jhordan C. (43)*** in California exemplifies the results of the inducement approach, as the lack of physician-supervised insemination allowed the court to fashion a unique distribution of parental rights and responsibilities that precisely followed neither the parties' original intentions nor those set forth under the California artificial insemination by donor statute.

A prominent example of a regulatory approach is the Louisiana IVF law, which specifies that IVF be done in accordance with the standards of practice suggested by prominent medical professional societies. This translates into legalization of clinics staffed and equipped to the levels identified as desirable by groups such as the American Fertility Society or American College of obstetricians and Gynecologists, and implicitly makes illegal those clinics that fail to meet these guidelines. Further, the Louisiana law attempts to specify a variety of rights held by an embryo in vitro and

responsibilities or limits on discretion for the physicians and gamete donors involved. The permissible limits of such State regulation may be subject to constitutional challenge, as would any State effort to take a punitive approach by outlawing a technique entirely. The Louisiana and Florida bans on the sale of embryos exemplify this appreach. These bans have not yet been challenged, and so an explicit determination of their constitutionality has not yet been made.

SUMMARY AND CONCLUSIONS

The use of noncoital reproductive technologies raises questions concerning the relative rights and responsibilities of gamete donors and rearing parents. In many cases, these questions are so new that there is little or no guidance as to how the law will be applied. Legal literature and analogies drawn from other areas of law are available in the meantime, to guide participants and courts in their analyses of the rights and duties created by these techniques.

With several configurations of parents available, it is probably not practical to draw an inflexible rule generically stating that all gamete donors are the legal parents of their progeny, or that all intended rearing parents have sole rights and responsibilities to their children. Case-by-case consideration of the parties' intentions, however, would probably yield a collection of rules. To date, the courts have not been presented with the full range of these situations, and thus have been restrained by the Constitution from making pronouncements on all possible parental configurations.

Legislation, which is prospective rather than retrospective in nature, could be drafted to clarify these relationships and to safeguard the interests of the children born as a result. Legislation, too, could fill in the gaps concerning the status of children born to single women using artificial insemination, the control over the disposition of ex-tracorporeal embryos, and the maintenance of records documenting the genetic parentage of children born by these techniques.

Absent legislative directives, courts will continue to decide cases that come before them, and to develop rules that help make the legal implications of these parental relationships more predictable. But as the courts in the District of Columbia and each of the 50 States are free to come to their own conclusions concerning these rules, there may long be significant State-to-State variations in the law.

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