

January 1984

Legal Implications of Human In Vitro Fertilization for the Practicing Physician in North Carolina

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Roger B. Bernholz and G. Nicholas Herman, *Legal Implications of Human In Vitro Fertilization for the Practicing Physician in North Carolina*, 6 *CAMPBELL L. REV.* 5 (1984).

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Campbell Law Review

Volume 6

Spring, 1984

LEGAL IMPLICATIONS OF HUMAN IN VITRO FERTILIZATION FOR THE PRACTICING PHYSICIAN IN NORTH CAROLINA

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and
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I. INTRODUCTION

This article discusses the legal implications of human *in vitro* fertilization (IVF) and embryo transfer with a particular focus for the medical practitioner in North Carolina. While IVF is now recognized as an acceptable medical technique to absolve some of the problems of infertility, the procedure is still considered relatively novel and is practiced in only few jurisdictions in this country. Unlike the generally rapid advancements of medical science and application, the development of applicable law is slow and uncertain. This is so not because the judicial system is conscientiously dilatory, but because the courts can only be responsive at such time that actual controversies are brought before them and, in many instances, it is rightly ruled that appropriate legislative enactments should be awaited prior to judicial decision.

This poses a major caveat to any definitive discussion of the legal implications associated with IVF practice at the present time. As there has been only one judicial case in this country concerning IVF practice, any analysis of its legal implications must be drawn from a confluence of existing law in all jurisdictions of this country that is essentially analogous but not directly "on point." In this context, there is, understandably, a particular paucity of North Carolina law that can be related to the subject.

With this caveat in mind, discussed in this article is the current federal and North Carolina law that bears upon IVF, the potential criminal and tort liabilities that should be of concern to the IVF practitioner, and the recourses available to the IVF practitioner for protection against liability in the course of this practice. In appropriate circumstances, the law of other American jurisdictions is drawn upon.

II. IVF PROCEDURE, APPLICATION AND RISKS

Human *in vitro* fertilization (IVF) generally refers to the process whereby fertilization of the female ova with the male sperm is accomplished in the laboratory, and the early embryo is subsequently transferred to the uterus of the female for continued development. After various medical and social evaluations, the process usually begins by treating the woman with hormones to stimulate production of eggs in the ovary. A laparoscopy is then conducted whereby a needle is surgically passed through the wo-

man's navel and, by visual sighting, mature ova are located and withdrawn. The ova are placed in a dish containing blood serum and nutrients to which sperm is added for fertilization. After fertilization by the sperm, the early embryo is transferred to another laboratory medium where it divides, forming a cluster of cells called a blastocyst. The blastocyst is then implanted into the uterus of the female for continued embryo development.¹

The most basic application of human IVF occurs where an infertile wife, by obstructed or missing Fallopian tubes, has one of her eggs fertilized in the laboratory with her husband's sperm (or perhaps the sperm of another male), after which the blastocyst is implanted into her uterus. If the wife is incapable of producing normal egg cells but can otherwise carry a fetus to term, she may be the recipient of a fertilized egg from a donor woman which has been fertilized *in vitro* with the sperm of the wife's husband (or possibly of an egg fertilized *in vivo* in the uterus of a donor woman by artificial insemination with the sperm of the wife's husband) after which the early embryo is removed from the donor woman's Fallopian tube and implanted into the wife's uterus.²

Considerably more controversial is the situation where a woman with healthy tubes and ovaries either would be endangered by pregnancy or simply does not want to go through pregnancy and thus has her egg, whether fertilized *in vitro* or *in vivo*, implanted into another woman who carries the fetus to term, after which this "surrogate mother" gives the infant back to its genetic mother. Finally, it has been envisioned that IVF may eventually be applied where a woman may choose among a variety of prepackaged embryos with particular genetic characteristics and have the selection of her choice implanted into her uterus.³

Despite a significant growth in human IVF research since the early 1970's and the first birth of an IVF child in 1978,⁴ IVF tech-

1. See, *Ethics Advisory Board of the Department of Health, Education, and Welfare, Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer*, 44 Fed. Reg. 35,034 (1979) [hereinafter cited as *EAB Report*]; Shettles, *Human Blastocyst Growth In Vitro in Ovation Cervical Mucus*, 229 NATURE 343 (1971); Edwards, Bavister & Steptoe, *Early Stages of Fertilization in Vitro of Human Oocytes Matured in Vitro*, 221 NATURE 632 (1969).

2. See *EAB Report*, *supra* note 1.

3. See Rorvik, *The Embryo Sweepstakes*, N.Y. TIMES MAGAZINE 17, 50 (Sept. 15, 1974).

4. Louise Brown, born in England in July, 1978, was the first child conceived

nique still remains experimental. As of the end of 1980, it was reported that of the total number of IVF embryos transferred to women recipients, the rate of pregnancy was 10.7%, and the probability of having a child, computed in relation to the number of embryos transferred, was 5.4%.⁵ However, these percentages are actually much higher as compared to the success rates calculated on the basis of the number of women monitored. Thus, out of 210 women participating in IVF and embryo transfer programs, 6 became pregnant (2.8%) and 3 delivered normal infants (1.4%).⁶ Finally, with respect to *in vivo* fertilization, it is estimated that only 2-5% of the attempts to fertilize ova have been successful.⁷

The potential risks of IVF and embryo transfer in causing birth defects in offspring or injury to the implanted woman have received some discussion in the scientific literature without clear conclusion. A 1979 review of the literature cites four potential sources of damage to the early embryo: (1) superovulation, sometimes used prior to IVF, may be correlated with an increased incidence of chromosomal abnormality in embryos; (2) the sperm fertilizing the ovum *in vitro* may be inferior to the quality of sperm fertilizing the ovum *in vivo*, since the female Fallopian tube selects against some types of abnormal sperm; (3) the high concentration of sperm subjected simultaneously *in vitro* to the ovum may result in a polyploid embryo; and (4) freezing techniques used to preserve gametes or embryos may produce mutations.⁸ The potential sources of risks to women donating ova or receiving a blastocyst include: (1) the use of hormonal treatments prior to IVF to induce superovulation which may result in ovarian hyperstimulation or ovarian cysts; (2) the possibility of repeated laparoscopies under general anesthesia; (3) the potential danger of ectopic pregnancy if the embryo fails to implant in the uterus; (4) the use of amniocentesis in monitoring pregnancy; and (5) the possibility of a higher-than-average rate of embryo loss or spontaneous abortion.⁹

Despite the potentiality of these risks, the scientific community has not developed a clear consensus about their certainty and

through the IVF process. See *All About That Baby*, NEWSWEEK at 66 (Aug. 7, 1978); *The First Test-Tube Baby*, TIME at 58 (July 31, 1978).

5. Lopata, *Successes and Failures in Human In Vitro Fertilization*, 288 NATURE 642 (1980).

6. *Id.*

7. 1979 RPTR H.R.L. II-B-9.

8. See *EAB Report*, *supra* note 1.

9. *Id.*

gravity, particularly insofar as they have been postulated from limited data and thus remain essentially hypothetical.¹⁰ Nevertheless, the mere "potentiality" of special risks incident to IVF procedure and application must be particularly recognized in understanding the legal implications of the practice.

III. FEDERAL AND STATE LAW APPLICABLE TO IVF

A. Federal Law

The only federal law currently applicable to IVF exists in the form of administrative regulations promulgated by the Department of Health and Human Services (DHHS).¹¹ The regulations apply to any IVF research, development and related activities conducted by DHHS or funded by DHHS grants or contracts.¹² The principal regulation provides that "[n]o application or proposal involving human (*in vitro*) fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advise as to its acceptability from an ethical standpoint."¹³

The DHHS regulations, however, do not address standards for research with IVF embryos prior to implantation, although the regulations are applicable after implantation under the rules governing research on the fetus and pregnant women. This is so because "fetus" is defined as "the product of conception from the time of implantation,"¹⁴ and "pregnancy" is defined as "the period of time from confirmation of implantation . . . until expulsion or extraction of the fetus."¹⁵ The inapplicability of the DHHS regulations to IVF prior to implantation is noteworthy insofar as many problems associated with IVF may occur prior to embryo transfer.

With respect to the regulations governing research on the fetus and pregnant women, detailed rules are set forth.¹⁶ The Secretary of DHHS is to appoint one or more Ethical Advisory Boards to render opinions on ethical issues or establish classes of applica-

10. See Schlesselman, *How Does One Assess the Risk of Abnormalities from Human In Vitro Fertilization*, 135 Am. J. Obstet. Gynecol. 135 (1979).

11. 45 C.F.R. §§ 46.101-46.211 (1982).

12. *Id.* at § 46.201(a).

13. *Id.* at § 46.204(d).

14. *Id.* at § 46.203(c).

15. *Id.* at § 46.203(b).

16. *Id.* at §§ 46.201-46.211.

tions when requested by the Secretary,¹⁷ and any public or private entity or agency proposing to conduct research is to establish an Institutional Review Board to assure and monitor compliance with the regulations.¹⁸ No research grant may be made until the appropriate reviewing boards certify that adequate consideration has been given to the manner in which potential subjects of research will be selected and that they have given informed consent.¹⁹

The particulars and process for obtaining informed consent are quite comprehensive.²⁰ Among the most important information that should be provided to each research subject include: identification of any procedures which are experimental,²¹ a description of any reasonable foreseeable risks (or unforeseeable risks to the embryo or fetus),²² a disclosure of appropriate alternative procedures or courses of treatment,²³ and an explanation as to whether any compensation and any medical treatments are available if injury occurs during research involving more than minimal risk.²⁴ Finally, no informed consent, whether oral or written, may include any exculpatory language or release the researcher from liability for negligence.²⁵

All fetal research is subject to general limitations.²⁶ Studies on animals and non-pregnant individuals must first be conducted.²⁷ Except where the purpose of the research is to meet the health needs of the mother or fetus, the risk to the fetus must be minimal and, in all cases, be the least possible risk for achieving the research objectives.²⁸ Research may have no part in any decision as to the timing, method, and procedures used to terminate the pregnancy or in determining the viability of the fetus at the termination of pregnancy.²⁹ No procedural changes may be introduced into the procedure for terminating the pregnancy solely in the interests of research where such changes may cause greater than minimal

17. *Id.* at §§ 46.204(a)-(c).

18. *Id.* at §§ 46.102(c); 46.103-46.115.

19. *Id.* at §§ 46.205(a)(2); 46.205(b).

20. *Id.* at §§ 46.116, 46.117.

21. *Id.* at § 46.116(a)(1).

22. *Id.* at § 46.116(a)(2); 46.116(b)(1).

23. *Id.* at § 46.116(a)(4).

24. *Id.* at § 46.116(a)(6).

25. *Id.* at § 46.116.

26. *Id.* at § 46.206.

27. *Id.* at § 46.206(a)(1).

28. *Id.* at § 46.206(a)(2).

29. *Id.* at § 46.206(a)(3).

risk to the fetus or the pregnant woman.³⁰ Finally, no inducements, monetary or otherwise, may be offered to terminate the pregnancy for the purposes of the research.³¹

The regulations specify conditions under which research may be conducted toward fetuses *in utero*.³² Such research is permissible only when its purpose is to meet the health needs of the particular fetus and the fetus will be placed at risk only to the minimum extent necessary to meet such needs, or when the risk to the fetus imposed by the research is minimal and its purpose is the development of important biomedical knowledge which cannot be obtained by other means.³³ Where such research is permissible, it may only be conducted if the mother and father have given their informed consent, except that the father's consent is not required if his identity or whereabouts cannot reasonably be ascertained or he is otherwise not reasonably available, or the pregnancy resulted from rape.³⁴

With respect to research directed toward fetuses *ex utero*, until it has been ascertained whether such a fetus is viable, research is permissible if there will be no added risk to the fetus resulting from the research and its purpose is to develop important biomedical knowledge which cannot be obtained by other means, or the purpose of the research is to enhance the possibility of survival of the fetus to the point of viability.³⁵ Research on a nonviable fetus is permissible as long as the vital functions of the fetus will not be maintained artificially, research activities that would terminate the heartbeat or respiration of the fetus will not be employed, and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means.³⁶ If the fetus *ex utero* is found to be viable, research is permissible to the extent it accords "with the requirements of other subparts of this part."³⁷ In addition, all of the foregoing research may only be conducted with the informed consent of the mother and father as required for research on *in utero* fetuses.³⁸

30. *Id.* at § 46.206(a)(4).

31. *Id.* at § 46.206(b).

32. *Id.* at § 46.208.

33. *Id.* at § 46.208(a).

34. *Id.* at § 46.208(b).

35. *Id.* at §§ 46.209(a)(1)-(2).

36. *Id.* at §§ 46.209(b)(1)-(3).

37. *Id.* at § 46.209(c).

38. *Id.* at § 46.209(d).

Finally, the regulations prescribe that research involving a dead fetus or fetal material shall only be conducted in accordance with applicable state or local laws.³⁹

The DHHS regulations, while leaving the propriety of IVF research to the Ethical Advisory Board, do not promulgate any requirements or standards to guide the Board's decisions.⁴⁰ In response to a 1977 application for IVF research and the announcement of the first birth of a baby following IVF in England in 1978, the Secretary of the then Department of Health Education and Welfare (HEW), Joseph Califano, Jr., asked the Ethical Advisory Board (EAB) to undertake its consideration of the pending application along with a study of the scientific, ethical, legal and social issues surrounding IVF.⁴¹ The EAB Report, published in 1979, indicated future approval of funding for IVF research in light of the following conclusions: (1) HEW should consider increased support of IVF and embryo transfer on non-human subjects to better assess the risks and efficacy (efficiency of procedure) of IVF; (2) research involving human IVF and embryo transfer is acceptable from an ethical standpoint (in the sense of being ethically defensible but still legitimately controverted) provided that with respect to IVF research without embryo transfer the research is primarily designed to establish the safety and efficacy of embryo transfer and to obtain important scientific information toward that end not reasonably attainable by other means, that gametes used in such research be exclusively obtained from persons giving informed consent, and that no embryos will be sustained beyond 14 days after fertilization; and, with respect to research involving embryo transfer after IVF, such transfer will only be attempted with gametes obtained from lawfully married couples and the recipient of the transfer will be the woman whose ova was used for the IVF; (3) HEW finds it acceptable from an ethical standpoint to support the foregoing human IVF research under the conditions specified; (4) the National Institute of Child Health and Human Development and other agencies should collect, analyze and disseminate information derived from world research involving IVF and embryo transfer; and (5) a model law should be developed to clarify the

39. *Id.* at § 46.210.

40. A possible exception is a regulation that requires that "[a]ppropriate studies on animals and nonpregnant individuals have been completed." 45 C.F.R. § 46.206(a)(1); See 45 C.F.R. § 46.201(a) (where *in vitro* fertilization is made applicable).

41. See *EAB Report*, *supra* note 1.

legal status of children conceived through IVF.⁴²

Shortly after the EAB Report on *in vitro* fertilization was published, a second Report was released by the EAB concerning *in vivo* fertilization.⁴³

The *in vivo* Report concluded that the ethical aspects of any proposed research in this area should be carefully reviewed prior to funding by the Department, and indicated that such a review would be made when research proposals on *in vivo* fertilization are submitted.⁴⁴ The Report recommended that the then existing HEW regulations governing *in vitro* research be amended to provide that "[n]o application or proposal involving the collection or laboratory study of human ova fertilized *in vivo* may be funded by the Department or any of its components until it has been reviewed by the Ethics Advisory Board, and the Board has advised the Secretary as to its acceptability from an ethical standpoint."⁴⁵ To date, this regulatory recommendation has not been adopted.

Since 1979, both the EAB Reports on *in vitro* and *in vivo* fertilization have remained dormant. Patricia Harris, the successor to Joseph Califano, Jr. as Secretary of HEW, had extended until at least January 8, 1980 the time for public comment on the EAB *in vitro* fertilization Report.⁴⁶ Nothing has happened since. Inasmuch as the current DHHS regulations leave discretion to the Secretary to appoint and dictate the responsibilities of Ethical Advisory Boards,⁴⁷ any further developments, absent congressional action, must likely await renewed initiative from the Secretary.

B. State Law

The DHHS regulations that constitute the current federal law applicable to IVF explicitly state that nothing in the regulations shall be construed as rendering inapplicable pertinent state or local laws.⁴⁸ Neither the North Carolina Constitution nor the State's statutory law specifically deals with the practice of IVF. However, two North Carolina statutes are worthy of some discussion insofar as they may be potentially pertinent to IVF practice and research.

42. *EAB Report*, *supra* note 1, at 35,057.

43. *See* 1979 RPTR H.R.L. II-A-3.

44. *Id.* at II-B-9 and II-B-10.

45. *Id.* at II-B-10.

46. *Id.* at II-A-3.

47. *See* 45 C.F.R. § 46.204.

48. 45 C.F.R. § 46.201(b).

The first of these statutes is the Uniform Anatomical Gift Act (UAGA).⁴⁹ Most of the provisions of this Act set forth procedures by which a "decedent," defined to include a stillborn infant or fetus, may donate his body or any part of it for the purposes of research or transplantation.⁵⁰ In the case of a fetus, the authorizing donor would be either parent.⁵¹ Whether the Act's application to a "fetus" would encompass an *ex utero* blastocyst is unlikely but not absolutely clear. Because the basic thrust of the Act is to provide for gifts donated after death, it would appear strained to presume that the Act contemplates donations of unimplanted blastocysts for research or transplantation.

On the other hand, within the same Article in which the UAGA is published, there is a separate provision stating that:

[t]he procurement, processing, distribution or use of . . . human tissues . . . for the purpose of injecting, transfusing or transplanting any of them into the human body is declared to be, for all purposes, the rendition of a service by every person or institution participating therein and, whether or not any remuneration is paid therefor, is declared not to be a sale of such . . . human tissues, for any purpose . . . No person or institution shall be liable in warranty, express or implied, for the procurement, processing, distribution or use of said items but nothing herein shall alter or restrict the liability of such person or institution in negligence or tort in consequence of said service.⁵²

The language of this provision is arguably a sanction of IVF and embryo transfer to the extent that a blastocyst can be equated with human tissue. Again, however, such a construction would be severely strained. It seems inconceivable that in enacting this provision in 1971 the legislature had IVF in mind. Moreover, while not *exclusively* defining "human tissue," the provision refers to "[w]hole blood, plasma, blood products, blood derivatives, and other human tissues such as corneas, bones or organs."⁵³

The second North Carolina statute that may be pertinent to IVF relates to the legal status of a child born as a result of artificial insemination. That statute provides that "[a]ny child or children born as the result of heterologous artificial insemination shall

49. N. C. GEN. STAT. §§ 90-220.1 through 90-220.9 (1981).

50. *Id.* at § 90-220.1(2); *See id.* at §§ 90-220.2 through 90-220.7.

51. *Id.* at § 90-220.2(b)(3).

52. *Id.* at § 90-220.10.

53. *Id.*

be considered at law in all respects the same as a naturally conceived legitimate child of the husband and wife requesting and consenting in writing to the use of such technique."⁵⁴ Although this provision does not address the legal status of an IVF child, the statute may be significant to a court in this State faced with the issue of legitimacy of such a child. This is so because "heterologous" artificial insemination, whereby the sperm of a third party donor is used to impregnate the mother, is closely analogous to the IVF procedure whereby the ovum of a wife is fertilized by third party semen because of the husband's sterility, and the resulting blastocyst is implanted into the wife.⁵⁵ Thus, a North Carolina court might conclude that even though the legislature had not specifically addressed the legal status of an IVF child, since legitimacy is accorded to children born from heterologous artificial insemination, there would seem to be no reason for concluding that the legislature would intend a lesser status for an IVF child.

It should be noted that with respect to "homologous artificial insemination," whereby the semen of the husband is impregnated to fertilize the ovum of the wife, there would seem to be no legal problems regarding the legitimacy of a child born from such circumstances since the child is essentially the natural product of the husband and wife.⁵⁶ While North Carolina has no statute on homologous artificial insemination, it seems likely that this State would treat an IVF child as "legitimate" when it was conceived by the implantation of an embryo into the wife that was created from the husband and wife.⁵⁷

C. Summary

Neither federal law nor North Carolina statutory law prohibits the practice of IVF. The detailed regulations imposed by DHHS relate solely to the propriety of research involving IVF after embryo transfer where such research is either conducted by DHHS or funded by the Department through grants or contracts. The North Carolina statutes that might be considered potentially pertinent to

54. N. C. GEN. STAT. § 49A-1 (1976).

55. See Flannery, Weisman, Lipsett, and Braverman, *Test Tube Babies: Legal Issues Raised by In Vitro Fertilization*, 67 Geo. L.J. 1295, 1319 (1979).

56. See *In re Adoption of Anonymous*, 74 Misc. 2d 99, 345 N.Y.S.2d 430 (Sup. Ct. Kings Co. 1973); *C.M. v. C.C.*, 152 N.J. Super. 160, 377 A.2d 821 (Juv. & Dom. Rel. Ct. 1977).

57. See Flannery, Weisman, Lipsett, and Braverman, *supra* note 55.

IVF practice are essentially inapplicable insofar as they were not drafted by a legislature that had any contemplation of IVF.

For the IVF practitioner, whether seeking federal funding for research or not, the DHHS guidelines on informed consent are particularly worthy of note insofar as they amplify the federal government's particularly protective disposition towards humans exposed to relatively new or experimental medical applications. The North Carolina UAGA Statute is important to the IVF researcher in that any research conducted upon a non-living IVF conceptus would seem to require the consent of at least one parent. Finally, in view of North Carolina's statute on the legal status of children born by heterologous artificial insemination, it would seem wise for the IVF practitioner to have the subject husband and wife expressly request and consent to IVF in writing so that any child born from them as a result of IVF would be considered "legitimate" at law.

IV. CRIMINAL LIABILITY

It is to be expected that incident to the practice of IVF there will be a significant number of "terminations" of blastocysts prior to implantation. In addition, in at least some cases, it may be necessary or otherwise desirable for the mother to have an abortion subsequent to implantation. Accordingly, it is important to clarify any possible criminal liability for the physician involved in these circumstances.

The crime of "feticide," a species of homicide, has been defined as the destruction of the fetus whether *in utero* or *in vitro*.⁵⁸ After the United States Supreme Court decision in *Roe v. Wade*,⁵⁹ it seems that the deliberate termination or destruction of an unimplanted blastocyst would not constitute feticide. The *Wade* decision held unconstitutional feticide statutes that proscribed abortion during all stages of pregnancy since such statutes violated the due process clause of the fourteenth amendment and a mother's right to privacy which encompasses her decision whether or not to terminate her pregnancy.⁶⁰

This right, however, is qualified. For the stage of gestation prior to the end of the first trimester, the decision to terminate the fetus rests with the attending physician in consultation with his

58. See GRAD, *New Beginnings in Life — A Lawyer's Response*, THE NEW GENETICS AND THE FUTURE OF MAN 72 (M. Hamilton ed. 1972).

59. 410 U.S. 113 (1973).

60. *Id.* at 154.

patient.⁶¹ During the second trimester, the State may regulate abortion procedure in ways reasonably related to maternal health.⁶² For the stage subsequent to "viability" (when the fetus is potentially able to live outside the mother's womb, albeit with artificial aid, and presumably has the capability of meaningful life outside the mother's womb),⁶³ a State may regulate as it chooses or even proscribe abortion except where it is necessary to preserve the life or health of the mother.⁶⁴ Thus, under the *Wade* decision, there can be no crime for the destruction of a fetus before the third trimester. This rule would seem to logically extend to preimplantation embryos.

North Carolina's abortion statutes make it a felony for any person to wilfully administer to any woman who is "pregnant with a child that is quick,"⁶⁵ or prescribe for any such woman, or advise or procure any such woman to take any medicine, drug or other substance, or use any instrument or other means with the intent to destroy such child.⁶⁶ A child is "quick" when the woman herself has felt the child alive within her.⁶⁷ Similarly, regardless of whether the child is quick,⁶⁸ it is a felony to administer to any pregnant woman, or prescribe for such woman, or advise or procure such woman, to take any medicine, drug or other substance, with the intent to procure the miscarriage of such woman.⁶⁹

These statutory provisions, however, are not applicable during the first 20 weeks of a woman's pregnancy so long as the abortion or miscarriage procured is undertaken by a licensed physician in North Carolina in a hospital or clinic certified by the State Department of Human Resources to be a suitable facility for the performance of abortions.⁷⁰ The procurement of an abortion or miscarriage is not unlawful after the 20th week of a woman's pregnancy if there is substantial risk that continuance of the pregnancy would threaten the life or gravely impair the health of the woman.⁷¹

61. *Id.* at 163.

62. *Id.*

63. *See id.* at 160-61, 163-64.

64. *Id.* at 163-64.

65. *State v. Green*, 230 N.C. 381, 383, 53 S.E.2d 285, 287 (1949).

66. N.C. GEN. STAT. § 14-44 (1981).

67. *State v. Forte*, 222 N. C. 537, 539, 23 S.E.2d 842, 844 (1943).

68. *State v. Mitchner*, 256 N.C. 620, 124 S.E.2d 831 (1962).

69. N.C. GEN. STAT. § 14-45 (1981).

70. *Id.* at § 14-45.1(a).

71. *Id.* at § 14-45.1(b).

On their face, the abortion statutes would not appear to warrant particular attention by IVF practitioners beyond that of pediatric physicians generally. However, to the extent that the risks of IVF procedure may encompass an increased incidence of chromosomal abnormalities or other defects in embryos, the limitation on procuring an abortion or miscarriage after the 20th week of pregnancy to circumstances where "[t]here is substantial risk that continuance of the pregnancy would threaten the life or gravely impair the health of the woman"⁷² is especially important. While there has been no judicial interpretation of this provision to date, the Attorney General of North Carolina issued a terse opinion in 1979 that it would be unlawful to procure the abortion of a post 20-week-old fetus where it has been diagnosed, without more, that the fetus is genetically abnormal and will be severely mentally retarded and/or not survive beyond the first year of life.⁷³ Thus, careful monitoring of the IVF fetus for the first 5 months of pregnancy would seem to be of heightened importance such that the option of abortion or induced miscarriage would not be foreclosed by the discovery of an unexpected abnormality after the statutory period has run.

V. TORT LIABILITY

Various causes of action may be advanced against a physician who causes injury as a result of negligence in the practice of IVF. If an unimplanted blastocyst is negligently or deliberately terminated or destroyed, the genetic parents may have a cause of action for wrongful conversion of their property and intentional infliction of emotional distress. If birth defects result in an IVF child from negligence during the process of embryo transfer or during a stage of *in utero* gestation, a cause of action may exist on behalf of the child for prenatal injuries. Preconception injuries might serve as a basis for a defective child's cause of action where there is negligence in the extraction of ova or application of semen, or in treatment of the mother prior to embryo transfer. If the IVF child dies due to either prenatal or preconception injuries, a cause of action might exist on its behalf for wrongful death. If a physician negligently advised or directed the selection of defective ova or semen or the implantation of a defective blastocyst, an IVF child born with defects may have a cause of action for wrongful life. Similarly,

72. *Id.*

73. 48 N.C. Att'y Gen. Rep. 136 (1979).

the parents of a defective child might seek to recover for wrongful birth as where there was negligence in giving medical advice or a decision to proceed with IVF.

The succeeding parts of this Section, beginning with a brief discussion of the general standard of care in medical practice, examine in detail the various causes of action that may be brought against a negligent IVF practitioner.

A. *The Standard of Care in Medical Practice*

North Carolina provides by statute the standard of care owed by medical practitioners to their patients as follows:

In any action for damages for personal injury or death arising out of the furnishing or the failure to furnish professional services in the performance of medical, dental, or other health care, the defendant shall not be liable for the payment of damages unless the trier of the facts is satisfied by the greater weight of the evidence that the care of such health care provider was not in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities at the time of the alleged act giving rise to the cause of action.⁷⁴

As a general rule, once the physician-patient relationship is established, the physician is under the duty in the treatment of his patient to apply his skill in a careful and prudent manner.⁷⁵ This means that the physician must exercise reasonable care and diligence in the application of this knowledge and skill to the patient's care, and he must use his best judgment in the treatment and care of his patient.⁷⁶ The requirement of care and knowledge extends to the physician's selection and use of drugs in the treatment of the patient and to his knowledge of the dangers, if any, inherent in their use.⁷⁷ Since a physician is not an insurer of his diagnosis or the success of treatment to his patient, so long as he acts according to his best judgment after a careful and proper examination of his patient's condition, he cannot be found liable for mere error of judgment, opinion or theory.⁷⁸

74. N.C. GEN. STAT. § 90-21.12 (1981).

75. See *Kennedy v. Parrot*, 243 N.C. 355, 358, 90 S.E.2d 754, 756 (1956).

76. *Dickens v. Everhart*, 284 N.C. 95, 106, 199 S.E.2d 440, 443 (1973); See *Wiggins v. Piver*, 276 N.C. 134, 139, 171 S.E.2d 393, 396 (1970).

77. 284 N.C. at 106, 199 S.E.2d at 443.

78. *Id.*; *Belk v. Schweizer*, 268 N.C. 50, 56, 149 S.E.2d 565, 570 (1966).

Apart from the aforementioned standards, North Carolina's statute⁷⁹ contemplates that the physician possess and exercise the professional competence and care customary in similar communities among physicians engaged in his field of practice.⁸⁰ A physician who holds himself out as having special knowledge and skill in a particular treatment is required to bring to the discharge of his duty to a patient employing him as such specialist, not merely the average degree of skill possessed by general practitioners, but that special degree of skill and knowledge possessed by physicians similarly situated who devote special study and attention to the particular treatment.⁸¹ In this connection, regard is to be given to the state of scientific knowledge existing at the time the treatment is rendered.⁸²

These standards of care are particularly important to the IVF practitioner. Because IVF is still considered a new technique and, to a certain extent, even experimental, it is clear that its practice is a specialty. Accordingly, the practitioner will be held to a heightened standard of skill and knowledge in the context of exercising reasonable care to his patients. Exactly what "community" standard will be applicable to IVF is uncertain. Since the practice is quite limited in American jurisdictions, the applicable "community" would seem to encompass at least this country as a whole and perhaps even certain international sectors.

B. *General Civil Liability*

It is a novel question whether any civil liability exists for the deliberate termination or destruction of an unimplanted blastocyst. It would seem that no liability would attach to an IVF practitioner or researcher where the destruction was consented to by the persons whose ova and sperm were used to create the blastocyst. This conclusion would follow from analogy to abortion law, which under *Roe v. Wade*⁸³ accords a mother a right of privacy that encompasses her absolute discretion to decide whether or not to beget a child up to the point of viability. Thus, the question of potential liability is narrowed to the circumstance where an unimplanted embryo is terminated or destroyed by a third party

79. N.C. GEN. STAT. § 90-21.12 (1981).

80. 284 N.C. at 106, 199 S.E.2d at 443.

81. 268 N.C. at 55, 149 S.E.2d at 569.

82. *Id.* at 56, 149 S.E.2d at 569-70.

83. 410 U.S. 113 (1973).

absent the authorization or consent of the genetic parents.

To date, the only authority on this point is the New York case of *Del Zio v. Presbyterian Hospital*.⁸⁴ In this unpublished case, a husband and wife brought a \$1.5 million damage suit against Manhattan's Columbia-Presbyterian Medical Center and its Chief of Obstetrics and Gynecology for deliberately destroying an IVF conceptus prior to implantation. The husband and wife had sought the Center's services for IVF because the wife's Fallopian tubes had been blocked and partially destroyed by disease. The blastocyst destroyed was the product of the husband's sperm and the wife's ovum.⁸⁵

The wife claimed that terminating the conceptus without the consent of her or her husband denied them their last opportunity to have a child, damaged her physically and psychologically, and jeopardized her marriage. The action called for damages for infliction of mental and physical anguish and wrongful conversion of the couple's property. The trial judge allowed both the claims for mental distress and wrongful conversion of the blastocyst to go to the jury. While denying any damages for wrongful conversion, the jury awarded \$50,000 to the wife for emotional distress and the husband received nominal damages.⁸⁶

It is somewhat questionable to what extent the *Del Zio* case has value as precedent for future rulings insofar as the case was never brought up for appeal and thus was never subject to judicial scrutiny and analysis. Nevertheless, the case must be considered a signal to warn against indiscriminate terminations or destructions of unimplanted blastocysts absent authorization or consent by the genetic parents.

C. Prenatal and Preconception Injuries

Since 1946 there has been a rapid trend in American law recognizing tort liability for prenatal injuries.⁸⁷ As a general rule, this type of action may be brought on behalf of a child only if it is born alive.⁸⁸ The right of action also appears to belong to the child alone, and thus a number of courts have expressly denied a cause

84. 74 Civ. 3588 (S.D.N.Y. April 12, 1978).

85. *Id.*

86. *Id.*

87. See Annot., 40 A.L.R.3d 1222 (1971).

88. See Prosser, *Law of Torts*, § 55 (4TH ED. 1971) (CATALOGING CASES); RESTATEMENT (SECOND) OF TORTS § 869 (1977).

of action brought by the child's parents.⁸⁹

North Carolina recognizes a child's cause of action for prenatal injuries at least where those injuries were inflicted upon the child when it was *en ventre sa mere* (viable). In dictum, the Court in *Gay v. Thompson* said: "[s]ince the child must carry the burden of infirmity that results from another's tortious act, it is only natural justice that it, if born alive, be allowed to maintain an action on the ground of actionable negligence."⁹⁰ This statement was expressly adopted as authoritative in *Stetson v. Easterling*.⁹¹ In *Cardwell v. Welch*, the Court made it certain that "[t]his State now recognizes, as do virtually all American Jurisdictions, a right of action in a child to recover for its prenatal injuries caused by the tortious act of another."⁹²

These decisions, however, recognize the child's cause of action subject to the limitation that the prenatal injuries were inflicted when the child was viable.⁹³ This limitation is rejected by the more recent cases in other jurisdictions which allow a cause of action for negligently inflicted prenatal injuries incurred at any time after conception so long as the child is born alive.⁹⁴ One or more of three rationales have been adopted to reach this result.⁹⁵ First, under biological theory, an unborn child is separate from its mother from the time of conception, and thus an injury inflicted at any time before birth should impose a conditional liability upon the tortfeasor which ripens into a cause of action when the child is born and hence becomes a legal person. Second, it is argued that a claim for an injury inflicted prior to viability is no less meritorious than a claim for an injury sustained afterward, since whether viable nor not at the time of injury, the child sustains the same harm after birth. And third, the viability rule is impossible to apply practically since there is no real way of determining in a borderline case whether a fetus was viable at the time it was injured.

It is not clear whether the North Carolina courts will maintain the viability limitation in future cases. One scholar has noted that

89. See Annot., *supra* note 87, at 1254.

90. 266 N.C. 394, 399, 146 S.E.2d 425, 429 (1966).

91. 274 N.C. 152, 156, 161 S.E.2d 531, 534 (1968).

92. 25 N.C. App. 390, 391, 213 S.E.2d 382, 383 (1975).

93. See, e.g., *Stetson v. Easterling*, 274 N.C. 152, 154, 161 S.E.2d 531, 534 (1968).

94. See 62 AM. JUR. 2D, *Prenatal Injuries* § 5 (1972); Annot., 40 A.L.R.3d 1222, 1230 § 3(a) (1971).

95. See 62 AM. JUR. 2D, *Prenatal Injuries* § 6 (1972).

“[w]hen actually faced with the issue of decision, almost all jurisdictions have allowed recovery even though injury occurred during the early weeks of pregnancy, where the child was neither viable nor quick.”⁹⁶ Neither, the *Gay*, *Stetson* nor *Cardwell* cases that pronounced the viability limitation involved an action brought by or on behalf of a child born alive. Accordingly, North Carolina has not yet been actually faced with the issue of decision.

With respect to the right of a child to bring an action for the consequences of injuries inflicted prior to conception, the few existing cases are in conflict. In *Renslow v. Mennonite Hospital*,⁹⁷ an Illinois Court recognized a cause of action on behalf of a child who was born with severe injuries allegedly as a result of improper blood transfusions given to the child’s mother eight years before the child’s birth. Although it was not alleged that the child was viable when the injuries occurred, the Court rejected viability as a criterion to bringing a common law action for prenatal injuries. Noting that medical science has developed techniques which can alleviate a child’s prenatal harm, the Court declared that there is a right to be born free from prenatal injuries foreseeably caused by a breach of duty to the child’s mother and that sound social policy required a finding of legal duty in this case.⁹⁸ In *Bergstresser v. Mitchell*,⁹⁹ the Court held under Missouri law that a child stated a cause of action for injuries sustained as a result of physicians’ negligence in performing a Caesarean section upon the child’s mother several years prior to his birth which caused his mother to suffer an occult rupture of the uterus which, in turn, necessitated his own premature emergency Caesarean delivery during the course of which he suffered anoxia and resultant brain damage.

However, in *Morgan v. United States*,¹⁰⁰ the Court in applying Pennsylvania law denied a cause of action on behalf of a child who was allegedly damaged as a result of a negligent blood transfusion given to the mother prior to conception. The Court’s decision rested in part on the fact that when the tortious conduct occurred, the child had been neither *en ventre sa mere* nor even conceived.

There is no case in North Carolina dealing with this type of action. It would seem, however, that unless the viability limitation

96. PROSSER, *supra* note 88, at 337; *See* Annot. 40 A.L.R.3d 1222, 1230 (1971).

97. 67 Ill. 2d 348, 367 N.E.2d 1240 (1977).

98. *Id.*

99. 577 F.2d 22 (8th Cir. 1978).

100. 143 F. Supp. 580 (D.N.J. 1956).

recognized in *Gay*, *Stetson*, and *Cardwell* is rejected, this State would not allow a child a cause of action for the consequences of injuries inflicted prior to conception.

D. Wrongful Death

As applied to the context of prenatal injuries, a cause of action may exist for wrongful death where a child is stillborn or is born alive and subsequently dies from the prenatal injuries. A majority of the states now permit the administrator of the estate of an unborn child to recover damages from the tortfeasor who causes the child's wrongful death.¹⁰¹ North Carolina, however, by judicial construction of its Wrongful Death Statute,¹⁰² refuses to permit a wrongful death action on behalf of a child at least where it does not survive birth.

The leading case in this jurisdiction is *Cardwell v. Welch*.¹⁰³ There, the administrator of the estate of a stillborn child sought to recover under the Wrongful Death Statute on behalf of the child who allegedly died as a result of the defendants' negligence in causing the mother to be injured in an automobile collision. The Court held that because the child, by not having been born alive, was not a "person" within the meaning of the Statute, there was no cause of action.¹⁰⁴ In its analysis, the Court said:

The wrongful death statute was enacted in this State in 1855 We think it highly unlikely that the Legislature which enacted it, or any which has been concerned with it since, intended to create a cause of action for the death of an unborn fetus. Had such an intention existed, it could easily have been clearly expressed. The greater probability is that by speaking of the death of a "person" and by creating a cause of action to be brought by "the executor, administrator or collector of the decedent," the Legislature was thinking solely in terms of and intended to create a cause of action only for the wrongful death of one who by live birth had attained a recognized individual identity so as to have become a "person" as that word is commonly understood. Certainly, in common understanding a "person" is one who has a separate identity as such, and to become a "decedent" one must first have been born.

Practical considerations also favor this construction. It is

101. See Annot. 84 A.L.R.3d 411 (1978).

102. N.C. GEN. STAT. § 28A-18-2 (1976).

103. 25 N.C. App. 390, 213 S.E.2d 382 (1975).

104. *Id.* at 392, 213 S.E.2d at 384.

true, of course, that the parents of an unborn child may suffer intense anguish if through the tortious act of another the child is stillborn. To say, however, as some courts have, that an action lies for the death if the child was viable at the time of its injury and death but that no action lies if the child was not yet capable of existing apart from its mother's womb does not solve but merely relocates the problem. From the moment of conception onward there must be some cutoff point, and to place this at the moment of live birth has at least the merit of providing some degree of certainty to an otherwise highly speculative situation

Accordingly, we construe the word "person" in our wrongful death statute to mean one who has become recognized as a person by having been born alive. If it be deemed desirable that a cause of action exist to recover for the wrongful death of an unborn fetus, that result would be accomplished more appropriately by legislative action than by strained judicial construction of an ancient statute.¹⁰⁵

Thus, failing a future legislative enactment that gives an unborn child a cause of action under the Wrongful Death Statute, there is no reason to suppose that the North Carolina courts will depart from the *Cardwell* ruling. The *Cardwell* decision was found dispositive one year later in barring a very similar cause of action brought in *Yow v. Nance*.¹⁰⁶

It is presently not clear in North Carolina whether a cause of action for wrongful death would be invalid where a child is born alive but subsequently dies as a result of prenatal injuries. The most recent case on the issue is *Stetson v. Easterling*,¹⁰⁷ wherein the administrator of a deceased child brought a wrongful death action on its behalf alleging that the child died after only living a few months due to the negligence of physicians who caused the child to suffer from prenatal brain injuries on account of lack of oxygen during birth.

The *Stetson* court applied North Carolina's Wrongful Death Act as written prior to its most recent amendments in 1969.¹⁰⁸ For damages recoverable for wrongful death under the pre-1969 Act "[t]he plaintiff in such action may recover such damages as are fair and just compensation for the pecuniary injury resulting from such

105. *Id.* at 392-93, 213 S.E.2d at 383-84.

106. 29 N.C. App. 419, 224 S.E.2d 292 (1976).

107. 274 N.C. 152, 161 S.E.2d 531 (1968).

108. N.C. GEN. STAT. §§ 28-173, 28-174. The current Act was amended in 1969 and renumbered as § 28A-18-2 in 1973.

death.”¹⁰⁹ In construing this statutory language, the Court denied the administrator’s cause of action because the complaint made insufficient allegations to show that the child’s estate suffered pecuniary loss on account of the death.¹¹⁰ The *Stetson* court relied primarily on its decision in *Gay v. Thompson*,¹¹¹ wherein it was said that “[n]egligence alone, without pecuniary injury resulting from such death, does not create a cause of action,” and “[d]amages may not be assessed on the basis of sheer speculation devoid of factual substantiation.”¹¹² Because the child in *Stetson* was afflicted by severe brain damage after birth “[i]t would be ‘sheer speculation’ to attempt to assess damages as of the time of the alleged negligently inflicted fatal injuries.”¹¹³

The *Stetson* Court boldly stated, however, that “[w]e are advertent to the fact *the result* reached here is in conflict with *the result* reached in decisions elsewhere.”¹¹⁴ Yet it distinguished the rulings of other jurisdictions by pointing out that the Wrongful Death Act (pre-1969) “[d]oes not provide for the assessment of punitive damages, nor the allowance of nominal damages in the absence of pecuniary loss.”¹¹⁵ Finally, the Court noted that “[n]o questions are presented or determined on this appeal with reference to whether the mother has a cause of action and, if so, the basis and extent thereof, or as to whether a parent has a cause of action for money expended and liability incurred in the care and treatment of [the child] during the months he was alive.”¹¹⁶

In light of the extensive 1969 amendments to North Carolina’s Wrongful Death Statute, it seems likely that when the issue for decision is next raised, the *Stetson* case will be reversed in part and this jurisdiction will permit a wrongful death action on behalf of a child who was born alive but later died due to prenatal injuries, at least where those injuries were inflicted upon the child when it was in a viable stage of gestation. In contrast to the pre-1969 Act, the current Wrongful Death Statute provides for nominal damages and punitive damages, the latter being recoverable where there is maliciousness, willful or wanton injury, or gross neg-

109. N.C. GEN. STAT. § 28-174 (1976).

110. 274 N.C. at 156, 161 S.E.2d at 534.

111. 266 N.C. 394, 146 S.E.2d 425 (1966).

112. *Id.* at 398, 146 S.E.2d at 428.

113. 274 N.C. at 157, 161 S.E.2d at 534.

114. *Id.*, (emphasis in original).

115. *Id.*

116. *Id.* at 157.

ligence.¹¹⁷ In addition, damages recoverable include expenses for care, treatment and hospitalization incident to the injury resulting in death, compensation for pain and suffering of the decedent, reasonable funeral expenses, and the present monetary value of the decedent (to those who would be beneficiaries of the decedent under North Carolina's Intestate Succession Act), including but not limited to compensation for the loss of the reasonably expected net income of the decedent, services, protection, care, and assistance of the decedent, and the society, companionship, comfort, guidance, kindly offices and advice of the decedent.¹¹⁸

Thus, the rationales of the *Stetson* case as they focus strictly on the showing of pecuniary injury to the estate of the deceased child and the absence of statutory provisions allowing for nominal or punitive damages (or other damages) without regard to pecuniary loss, are nullified by the 1969 amendments to the Wrongful Death Act. Also, given the express proviso under the new Act that "expenses for care, treatment and hospitalization incident to the injury resulting in death"¹¹⁹ are recoverable, it is clear that a parent(s) paying for such services who also otherwise qualify as beneficiaries under the Act would be compensated for such expenses.

Notwithstanding the view that this State would probably now recognize a wrongful death action brought on behalf of a child born alive but who subsequently dies as a result of prenatal injuries, such an action would likely be limited to circumstances where the injuries causing the death were inflicted upon the child when it was in a viable stage. Despite the rulings of some jurisdictions that impose no such limitation,¹²⁰ North Carolina is likely to impose it in light of its decisions that recognize a cause of action for prenatal injuries inflicted only when the child was *en ventre sa mere* and was born alive.¹²¹ For similar reasons, the limitation would also seem to apply where the wrongful death action is brought alleging that the child's death subsequent to birth was a consequence of injuries inflicted prior to conception.

117. See N.C. GEN. STAT. § 28A-18-2 (1976).

118. *Id.*

119. *Id.* at § 28A-18-2(b)(1).

120. See 62 AM. JUR. 2D, *Prenatal Injuries* §§ 12-13 (1972).

121. See, e.g., *Stetson v. Easterling*, 274 N.C. 152, 154, 161 S.E.2d 531, 534 (1968).

E. *Wrongful Life and Wrongful Birth*

In contrast to the cause of action for prenatal injuries where it is alleged that the defendant's tortious conduct intervened in the process of gestation and caused the unborn child to die or be born defective or disabled, wrongful life and wrongful birth actions take the form of contentions that the defendant could have prevented or made possible the prevention of any birth at all, and that his failure to do so resulted in the birth of a child with defects or disabilities so severe that no human existence would be preferable to life with such defects or disabilities.¹²² The principal distinction between wrongful life and wrongful birth actions rests upon who it is that is seeking to be compensated. For wrongful life the cause is brought by or on behalf of the child, whereas in wrongful birth cases the cause is brought by the parent(s).

There is currently a split in authority as to whether a cause of action exists for wrongful life. Those courts rejecting the action have done so based on a variety of rationales including that the legal right not to be born is alien to the public policy of the state to protect and preserve human life,¹²³ that the law is not equipped to make a comparison between life in an impaired state and non-existence upon which a calculation of damages depends,¹²⁴ that the propriety of such a cause of action should be left to the legislature,¹²⁵ and that to recognize such a cause of action would produce vast legal implications and a possibly staggering social impact.¹²⁶ Thus, as examples, the courts have denied wrongful life actions where a child was born with Tay-Sachs disease after negligent testing,¹²⁷ where a child was born with Down's Syndrome after the physician failed to warn a 37-year-old mother of the risks associated with conceiving after 35 years of age,¹²⁸ where a child was

122. See 62 AM. JUR. 2D, *Prenatal Injuries*, § 10 (1972).

123. See *Becker v. Schwartz*, 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978).

124. See *id.*

125. See *Stewart v. Long Island College Hosp.*, 35 App. Div. 2d 531, 313 N.Y.S.2d 502 (1970); *Dumer v. St. Michael's Hosp.*, 69 Wis. 2d 766, 233 N.W.2d 372 (1975); *Zepeda v. Zepeda*, 41 Ill. App. 2d 240, 190 N.E.2d 849 (1963).

126. See *Zepeda v. Zepeda*, 41 Ill. App. 2d 240, 190 N.E.2d 849 (1963), *cert denied*, 379 U.S. 945 (1964).

127. *Gildiner v. Thomas Jefferson Univ. Hosp.*, 451 F. Supp. 692 (E.D. Pa. 1978).

128. *Becker v. Schwartz*, 46 N.Y. 2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978).

born after the negligent performance of an abortion,¹²⁹ and where a child suffered birth defects due to rubella.¹³⁰

The first case recognizing a child's cause of action for wrongful life was the California decision of *Curlender v. Bio-Science Laboratories*.¹³¹ In *Curlender* it was alleged that medical laboratories were negligent in performing and interpreting tests that were designed to reveal whether the parents carried genes which would result in their children being born with Tay-Sachs disease. The parents subsequently had a child born with the disease and the action was brought on behalf of the child for damages for pain and suffering, costs of medical care, and punitive damages. In upholding the child's wrongful life claims, the Court addressed the issue of damages as follows:

The circumstance that the birth and injury have come hand in hand has caused other courts to deal with the problem by barring recovery. The reality of the "wrongful life" concept is that such a plaintiff both exists and suffers, due to the negligence of others. It is neither necessary nor just to retreat into meditation on the mysteries of life. We need not be concerned with the fact that had defendants not been negligent, the plaintiff might not have come into existence at all. The certainty of genetic impairment is no longer a mystery. In addition, a reverent appreciation of life compels recognition that plaintiff, however impaired she may be, has come into existence as a living person with certain rights.¹³²

In addition, the Court rested its decision on the public policy of encouraging proper medical practice in the field of genetic counseling, and the principle that for every wrong committed there should be a remedy.¹³³

The California Supreme Court in *Turpin v. Sortini*¹³⁴ reaffirmed the decision in *Curlender* but clarified that in a wrongful life action the child may not recover general damages for being born impaired as opposed to not being born at all, though the child may (like his or her parents) recover special damages for expenses necessary for medical treatment.¹³⁵ The State of Washington re-

129. *Stills v. Gratton*, 55 Cal. App. 3d 698, 127 Cal. Rptr. 652 (1976).

130. *Gleitman v. Cosgrave*, 49 N. J. 22, 227 A.2d 689 (1967); *Stewart v. Long Island College Hosp.*, 35 A.D.2d 531, 313 N.Y.S.2d 502 (1970).

131. 106 Cal. App. 3d 811, 165 Cal. Rptr. 477 (1980).

132. 106 Cal. App. 3d at 829, 165 Cal. Rptr. at 488.

133. *Id.*

134. 182 Cal. Rptr. 337, 643 P.2d 954 (1982).

135. *Id.* at 348, 643 P.2d at 966.

cently adopted the *Turpin* holding in *Harbeson v. Parke-Davis, Inc.*¹³⁶

However, the *Curlender* decision and its progeny have not succeeded in persuading many other jurisdictions to recognize wrongful life actions. For example, in *Eisbrenner v. Stanley*,¹³⁷ the Michigan Court of Appeals denied the wrongful life claim of a child who was born defective as a result of alleged negligence on the part of a physician in failing to diagnose that the mother had contracted rubella during her pregnancy and in failing to advise her of the risks of birth defects in time for her to obtain an abortion. In rejecting the reasoning in *Curlender*, the *Eisbrenner* Court restated the view of other jurisdictions that the comparison between nonexistence and deformed life is impossible to make, and that to recognize the child's cause of action "[w]ould turn the courts into forums for pure gambling events, since damage awards could range from zero to millions of dollars based on essentially the same evidence."¹³⁸ Notwithstanding the view taken in California and Washington, six other states have rejected a cause of action for wrongful life.¹³⁹

Despite the general reluctance of courts to recognize wrongful life claims, most jurisdictions are willing to uphold wrongful birth actions brought by a parent. Thus, in the *Eisbrenner* case, while denying the child's wrongful life claim, the Court found no difficulty in allowing the parents to seek damages for both medical expenses and mental distress.¹⁴⁰ Similarly, other cases have recognized the parents' cause of action for wrongful birth (1) where a child was born with Down's syndrome due to the negligence of physicians in informing the mother of the availability of amniocentesis testing which would have revealed genetic defects so the mother could choose to have an abortion,¹⁴¹ (2) where a child was born defective as a result of a physician's negligence in failing to diagnose rubella during the first trimester of the mother's preg-

136. 98 Wash.2d 460, 656 P.2d 483 (1983).

137. 106 Mich. App. 351, 308 N.W.2d 209 (1981).

138. 308 N.W. 2d at 213.

139. *Elliott v. Brown*, 361 So.2d 546 (Ala. 1978); *Berman v. Allan*, 80 N.J. 421, 404 A.2d 8 (1979); *Becker v. Schwartz*, 46 N.Y.2d 401, 386 N.E.2d 807, 413 N.Y.S.2d 895 (1978); *Phillips v. United States*, 508 F. Supp. 537 (D.S.C. 1980); *Jacobs v. Theimer*, 519 S.W.2d 846 (Tex. 1975); *Dumer v. St. Michael's Hosp.*, 69 Wis. 2d 766, 233 N.W.2d 372 (1975).

140. 106 Mich. App. 351, 308 N.W.2d 209 (1981).

141. *Berman v. Allan*, 80 N.J. 421, 404 A. 2d 8 (1979).

nancy and advise her of the risks to the unborn child,¹⁴² and (3) where a child was born mongoloid because physicians failed to advise the mother of risks of pregnancy and the availability of amniocentesis testing when they knew of the mother's age, thyroid condition, and that she previously had given birth to a deformed child.¹⁴³

To date, no North Carolina case has dealt with a wrongful life claim.¹⁴⁴ However, in *Pierce v. Piver*,¹⁴⁵ the Court recognized a cause of action that can be considered as having all the features of a "wrongful birth" claim, although the opinion never used the phrase.

In *Piver*, a husband and wife alleged that the wife engaged a physician to remove a tumor from her left ovary and to perform a bilateral tubal ligation at the same time so that she would not again become pregnant. Just one year after the operations, she gave birth to a child. The wife sought damages against the physician to compensate her for expenses, loss of services stemming from the pregnancy, and for the costs of raising and providing for the child until the age of emancipation. The trial court sustained the defendant's motion to dismiss the action and the Court of Appeals reversed.¹⁴⁶

In so ruling, the Court of Appeals tersely said: "[t]he action is basically one for medical malpractice, sounding in negligence and breach of contract. Plaintiff's complaint adequately stated a claim for relief cognizable under existing legal principles of this jurisdiction."¹⁴⁷ Without citing any North Carolina authority for the "legal principles" to which the Court was referring, it went on to list three cases from other jurisdictions for authority.¹⁴⁸ None of these cases were denominated "wrongful birth" actions, but involved claims brought for "malpractice" under "contract" or "warranty" theories. Thus, the *Piver* decision would seem to suggest that re-

142. *Jacobs v. Theimer*, 519 S.W. 2d 846 (Tex. 1975).

143. *Karlsons v. Guerinot*, 57 App. Div. 2d 73, 394 N.Y.S. 2d 933 (1977).

144. The issue, however, may be decided for the first time by *Azzolino v. Dingfelder*, No. 8351SC1292 now pending in the North Carolina Court of Appeals.

145. 45 N.C. App. 111, 262 S.E.2d 320 (1980).

146. *Id.* at 112-13, 262 S.E.2d at 321-22.

147. *Id.*

148. *Id.* at 113, 262 S.E.2d at 322 citing: *Jackson v. Anderson*, 230 So.2d 503 (Fla. App. 1970); *Martineau v. Nelson*, 311 Minn. 92, 247 N.W.2d 409 (1976); *Vaughn v. Shelton*, 514 S.W. 2d 870 (Tenn. App 1974).

ardless of a parent's particular styling of the action (whether "wrongful birth," "malpractice," or "breach of contract"), North Carolina might recognize damages on the parent's behalf where the negligence of a physician results in the birth of an unwanted child.

Finally, it should be noted that Judge Wells, concurring in the *Piver* opinion, stated that "[t]o the extent to which the majority opinion recognizes plaintiff's claim for relief for recovery of fees paid to defendant, expenses incurred due to pregnancy and the delivery of the child, and for pain and suffering to the feme plaintiff due to the pregnancy and birth, occasioned or contributed to by defendant's negligence or breach of contract, I concur."¹⁴⁹ This statement indicates that North Carolina would recognize damages encompassing pregnancy-related expenses and pain and suffering but maybe not the costs of raising and providing for the child until emancipation.¹⁵⁰

F. Summary

The causes of action for prenatal or preconception injuries, wrongful death, and wrongful life or wrongful birth have generally received only limited treatment by the American courts and hence without consistent application. With the exception of the *Del Zio v. Presbyterian Hospital*¹⁵¹ case, wherein claims for wrongful conversion and infliction of emotional distress were permitted to go to the jury against defendants who destroyed an unimplanted blastocyst, no cases have involved a lawsuit against an IVF practitioner. Accordingly, the potential theories by which tort liability may be asserted for negligence in IVF practice can only be speculated from analogy to the limited number of decisions that have applied these theories in other contexts.

A large number of jurisdictions, including North Carolina, recognize tort liability for prenatal injuries. This State, however, would seem to allow such a cause of action only where it is shown that the injuries were inflicted upon the child when it was in a viable stage of gestation. As for tort liability for preconception injuries, while some other jurisdictions have recognized this cause of action, North Carolina would probably not recognize it due to its case law establishing the viability limitation.

The recognition of tort liability for wrongful death of an un-

149. 45 N.C. App. at 113, 262 S.E.2d at 322.

150. See LEE, NORTH CAROLINA FAMILY LAW, § 287 p. 93 (1981).

151. 74 Civ. 3588 (S.D.N.Y. April 12, 1978).

born child is subject to judicial interpretation of the state's applicable Wrongful Death Statute. Because the North Carolina decisions do not accord an unborn child the status of a "person" within the meaning of the State's Statute, no wrongful death recovery is permitted for such a child. However, North Carolina would probably now recognize a cause of action for wrongful death of a child who is born alive but subsequently dies as a result of negligently inflicted prenatal injuries.

With the exception of California and Washington, no other jurisdiction currently recognizes a cause of action for wrongful life brought by or on behalf of a defective child. However, most jurisdictions recognize an action for wrongful birth brought by the parents of a defective or abnormal child. North Carolina has decided only one case which appears to permit wrongful birth claims, at least where they are styled under general malpractice or breach of contract principles.

VI. PROTECTION FOR THE PHYSICIAN

A. *The Doctrine of Informed Consent*

A brief discussion of the importance and elements of the "doctrine of informed consent" is necessary to provide a background from which available legal methods for protecting the physician can be detailed.

Generally, this doctrine refers to the legal duty imposed upon the physician to sufficiently apprise his patient of all material elements and risks of a proposed treatment or procedure such as may affect the patient's consent to the particular treatment or procedure.¹⁵² The failure to comply with this duty may subject the physician to either criminal¹⁵³ or tort liability. Insofar as the doctrine applies prior to the physician's rendering of treatment to his patient as distinguished from the standards of care owed to a patient during treatment, it is to be considered a particular species of medical malpractice law. The doctrine is important to the physician in that it may protect him from liability so long as the patient gives informed consent and the physician is not otherwise negligent in the performance of the treatment or procedure to which

152. See 61 AM. JUR. 2D, *Physicians, Surgeons, etc.* § 187 (1981).

153. See, e.g., *Brigham v. Hicks*, 44 N.C. App. 152, 156, 260 S.E.2d 435, 437 (1979) (suggesting a possible action for assault against a physician if he performs a surgical procedure on a person without properly informing that person of the risks involved so that an informed consent can be given).

the patient has consented.

North Carolina addresses the doctrine of informed consent by a 1975 statute which states:

(a) No recovery shall be allowed against any health care provider upon the grounds that the health care treatment was rendered without the informed consent of the patient or the patient's spouse, parent, guardian, nearest relative or other person authorized to give consent for the patient where:

(1) The action of the health care provider in obtaining the consent of the patient or other person authorized to give consent for the patient was in accordance with the standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities; and

(2) A reasonable person, from the information provided by the health care provider under the circumstances, would have a general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments which are recognized and followed by other health care providers engaged in the same field of practice in the same or similar communities; or

(3) A reasonable person, under all the surrounding circumstances, would have undergone such treatment or procedure had he been advised by the health care provider in accordance with the provisions of subdivisions (1) and (2) of this subsection.

(b) A consent which is evidenced in writing and which meets the foregoing standards, and which is signed by the patient or other authorized person, shall be presumed to be a valid consent. This presumption, however, may be subject to rebuttal only upon proof that such consent was obtained by fraud, deception or misrepresentation of a material fact.

(c) A valid consent is one which is given by a person who under all the surrounding circumstances is mentally and physically competent to give consent.

(d) No action may be maintained against any health care provider upon any guarantee, warranty or assurance as to the result of any medical, surgical or diagnostic procedure or treatment unless the guarantee, warranty or assurance, or some note or memorandum thereof, shall be in writing and signed by the provider or by some other person authorized to act for or on behalf

of such provider.¹⁵⁴

Those North Carolina cases that have described the physician's duty under the doctrine have done so in very general terms. For example, it has been said that if there is some danger peculiar to a surgical procedure of which the patient is not aware, it is the duty of the physician to warn the patient of the danger.¹⁵⁵ A surgeon should make "reasonable disclosure" of the risk involved in a proposed operation if the operation involves "known risk."¹⁵⁶ A duty exists on the part of a physician to warn his patient of the "possible or probable" injurious effects of a drug so that an informed election can be made by the patient in deciding whether to use such drug.¹⁵⁷

The key provisions of the statute make clear that the physician must sufficiently inform his patient such that he has "[a] general understanding of the procedures or treatments and of the usual and most frequent risks and hazards inherent in the proposed procedures or treatments."¹⁵⁸ Both the extent of disclosure and the particular information to be disclosed is to be governed by "[t]he standards of practice among members of the same health care profession with similar training and experience situated in the same or similar communities."¹⁵⁹ Even if the physician fails to make any disclosure at all, he will not be liable to his patient for this failure if the jury finds that a reasonable person in the patient's position would have undergone the treatment or procedure had he been appropriately informed about it.¹⁶⁰ Because of the relatively general pronouncements in North Carolina case law on this subject, reference to some rulings from other jurisdictions may provide some additional content to the doctrine.

In a number of circumstances the courts have tempered the physician's duty of disclosure such that disclosing risks or hazards and obtaining consent are not required at all. Examples¹⁶¹ of these circumstances include where the risks are not reasonably foresee-

154. N.C. GEN. STAT. § 90-21.13 (1981).

155. *McPherson v. Ellis*, 53 N.C. App. 476, 478, 281 S.E.2d 94, 96 (1981).

156. *Watson v. Clutts*, 262 N.C. 153, 159, 136 S.E.2d 617, 621 (1964).

157. *Koury v. Follo*, 272 N.C. 366, 375, 158 S.E.2d 548, 555 (1968).

158. N.C. GEN. STAT. § 90-21.13(a)(2) (1981).

159. *Id.* at §§ 90-21.13(a)(1)-(2).

160. *See id.* at § 90-21.13(a)(3).

161. *See Holt v. Nelson*, 11 Wash. App. 250, 523 P.2d 211 (1974) (summarizing cases); *Annot.*, 69 A.L.R.3d 1235 (1976); 61 AM. JUR. 2D, *Physicians, Surgeons, etc.* § 191 (1981).

able and not inherent in the procedure,¹⁶² where the disclosure of risks or consequences may have a detrimental effect on the physical or psychological well-being of the patient, where the patient has specifically requested that he not be informed, where the risk is that of the improper performance of an appropriate procedure, where an emergency makes it impractical to obtain consent,¹⁶³ where the risks have no apparent materiality or relationship to the patient's decision, where the physician may assert the defense that the patient would have proceeded whether or not he had been informed of the risks,¹⁶⁴ and where the risks are actually known to the patient or are so obvious as to justify presumption of such knowledge.

The types of risks and hazards that should be disclosed depend upon the particular medical problem, the procedures or treatments in question, the individual patient, and the general standard of disclosure provided by physicians engaged in the same or similar field of practice. In connection with the disclosure of risks and hazards, a number of courts have emphasized the importance of informing the patient of alternative treatments or procedures and their comparative risks so that, in an appropriate case, the patient can choose among the alternatives.¹⁶⁵ This principle would seem particularly important where innovative procedures are used and there is the element of unknown risks. Thus, while it has been said that it is not necessary to disclose each infinitesimal, imaginative, or speculative element that may bear upon known risks,¹⁶⁶ where innovative practice is involved it may nevertheless be necessary to disclose that there may be inherent risks that as yet have not been identified.

Clearly the most vexing problem in the area of informed consent is the applicable standard of disclosure required of the physician as defined by the standards of practice among members of the health care profession engaged in the same or similar practice in the same or similar communities. In new clinical techniques such as IVF, the relevant "community" would at least extend nationwide and perhaps even to some other countries where the proce-

162. See also N.C. GEN. STAT. § 90-21.13(a)(2) (1981).

163. See also N.C. GEN. STAT. § 90-21.13(a)(3) (1981).

164. *Id.*

165. See, e.g., *Jacobs v. Theimer*, 519 S.W.2d 846 (Tex. 1975); *Holt v. Nelson*, 11 Wash. App. 230, 523 P.2d 211 (1974); *Shack v. Holland*, 89 Misc. 2d 78, 389 N.Y.S.2d 988 (1976).

166. See, e.g., *Charley v. Cameron*, 215 Kan. 750, 528 P.2d 1205 (1974).

cedure has been performed. Even assuming that there presently exists a recognized "standard of practice" for obtaining informed consent of IVF patients, it is certainly to be expected that changes will occur in that standard as the technique is medically refined and better understood. This poses a special responsibility for the IVF practitioner to keep abreast of new developments in his practice, such that under the doctrine of informed consent he will be protected from liability by appropriately adjusting his disclosure practices as medical advancements dictate.¹⁶⁷

B. Considerations for Consent Forms

While the doctrine of informed consent may serve as a sword to an injured party against a physician, the doctrine may also serve as a shield for the medical practitioner in protecting him from liability in innovative practice such as IVF. Crucial to this protection is the use of a comprehensive consent form. Because particular protocols for IVF procedure and technique may vary and, with medical advancements, new risks may be identified and others abolished, it is not possible or advisable to suggest a "boilerplate" consent form for IVF practice as a whole. However, given below are some basic considerations for provisions in IVF consent forms in light of the existing federal and state law discussed throughout this article.

Where IVF is to be accomplished with the ova of the wife and sperm of the husband, and the early embryo is to be transferred into the uterus of the wife, the following considerations are suggested for a consent form:

- (1) A basic description of the IVF process should be provided such that the husband and wife have a general understanding of the procedures and treatments associated with the process.¹⁶⁸
- (2) A statement summarizing the current medical opinions on the success of IVF procedure should be provided.¹⁶⁹
- (3) Alternatives to IVF procedure, if any, should be fully explained.¹⁷⁰

167. See, e.g., *Failure to "Keep Up" as Negligence*, 224 J.A.M.A. 1461 (1973).

168. See N.C. GEN. STAT. § 90-21.13(a)(2) (1981).

169. *Id.*

170. See *Statement of the American Medical Association to the Ethics Advisory Board of the U.S. Department of Health, Education, and Welfare*, 1979 RPTR H.R.L. at II-B-14. [hereinafter cited as *AMA Statement*].

(4) The physician should be authorized to employ such other assistants or health care providers as in his discretion may be necessary to undertake the IVF procedure.¹⁷¹

(5) A general description of the usual and most frequent risks and hazards inherent in IVF procedure should be provided,¹⁷² including for example: the possibility of genetic abnormalities in embryos,¹⁷³ the risk of a polyploid embryo,¹⁷⁴ the risk of ectopic pregnancy if the embryo fails to implant in the uterus,¹⁷⁵ any risks associated with ovulation inducing drugs,¹⁷⁶ the risk of higher-than-average embryo loss or spontaneous abortion,¹⁷⁷ and the risk of having twins or triplets.

(6) A general description of the usual and most frequent risks and hazards inherent in surgical or other treatments incident to IVF should be provided,¹⁷⁸ including for example: any risks associated with amniocentesis,¹⁷⁹ risks associated with repeated laparoscopies under general anesthesia,¹⁸⁰ any risks of wound infections or discomforts from surgical procedures, and risks involving the use of particular drugs.¹⁸¹

(7) The husband and wife should be made aware that they may incur mental anguish or distress in connection with the IVF process.¹⁸²

(8) Specific consent should be obtained for performing laparoscopy or amniocentesis.¹⁸³

(9) It should be stated that there may be other risks associated with IVF that as yet have not been identified.

(10) It should be stipulated that the physician does not guarantee, warrant, contract, or otherwise assure any particular result of

171. See 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:84 (1971).

172. See N.C. GEN. STAT. § 90-21.13(a)(2) (1981).

173. See *EAB Report*, *supra* note 1.

174. *Id.*

175. *Id.*

176. *Id.*

177. *Id.*

178. See N.C. GEN. STAT. § 90-21.13(a)(2) (1981); *McPherson v. Ellis*, 53 N.C. App. 476, 478, 281 S.E.2d 94, 96 (1981); *Watson v. Clutts*, 262 N.C. 153, 159, 136 S.E.2d 617, 621 (1964).

179. See *EAB Report*, *supra* note 1.

180. *Id.*

181. See *Koury v. Follo*, 272 N.C. 366, 375, 158 S.E.2d 548, 555 (1968).

182. See *Del Zio v. Presbyterian Hosp.*, 74 Civ 3588 (S.D.N.Y. April 12, 1978); *Evans and Dixler, Human In Vitro Fertilization, Some Legal Issues*, 245 J.A.M.A. 2326 (1981).

183. See *McPherson v. Ellis*, 53 N.C. App. 476, 478, 281 S.E.2d 94, 96 (1981); *Watson v. Clutts*, 262 N.C. 153, 159, 136 S.E.2d 617, 621 (1964).

the IVF process, or the result of any surgical or diagnostic procedure or treatment.¹⁸⁴

(11) An explanation should be provided as to the availability of treatment if injury results in the course of IVF procedure, and whether financial assistance would be available for such treatment.¹⁸⁵

(12) It should be stipulated that any unimplanted blastocyst is the sole property of the physician, or that the husband and wife expressly consent to the termination of an unimplanted blastocyst in the sole medical discretion of the physician.¹⁸⁶

(13) A description should be given of the extent to which monitoring of the fetus and mother will be provided during the first 5 months of pregnancy so as to preserve any necessary option of abortion.¹⁸⁷

(14) It should be explained that termination of the fetus by abortion or induced miscarriage can only be undertaken prior to the expiration of the 20th week of pregnancy, and that thereafter such termination can only be undertaken if there is a substantial risk that continued pregnancy would gravely impair the mother's health or threaten her life.¹⁸⁸

(15) The husband and wife should stipulate that they have been informed of the usual and most frequent risks and hazards inherent in IVF as well as such risks and hazards in the procedures and treatments incident to the process, and that they have had an opportunity to ask questions and are satisfied by the explanations given to them.¹⁸⁹

(16) It should be stated that the physician will seek to preserve the confidentiality of both the husband and wife.¹⁹⁰

(17) It should be agreed that with respect to the IVF procedure and treatments incident to it the law of North Carolina shall govern.¹⁹¹

(18) The husband and wife should state that they are lawfully

184. See N.C. GEN. STAT. § 90-21.13(d) (1981); *Pierce v. Piver*, 45 N.C. App. 111, 262 S.E.2d 320 (1980).

185. See 45 C.F.R. § 46.116(a)(6) (1982).

186. See *Del Zio v. Presbyterian Hosp.*, 74 Civ. 3588 (S.D.N.Y. April 12, 1978); *Evans and Dixler*, *supra* note 182.

187. See 48 N.C. Att'y Gen. Rep. 2 (1979).

188. See N.C. GEN. STAT. § 14-45; *Roe v. Wade*, 410 U.S. 113 (1973); 48 N.C. Att'y Gen. Rep. 2 (1979).

189. See N.C. GEN. STAT. § 90-21.13(a)(2) (1981).

190. See *AMA Statement*, *supra* note 170, at 1979 RPTR H.R.L. at II-B-12, II-B-13.

191. See *Evans and Dixler*, *supra* note 182, at 2327.

married,¹⁹² that they are over 18 years of age and are of sound mind and body,¹⁹³ and they should both request and expressly consent in writing to the IVF procedure.¹⁹⁴

(19) The husband should expressly state that he recognizes any IVF child born of his wife as his natural child.¹⁹⁵

If IVF is conducted under circumstances where the wife is impregnated with a blastocyst fertilized either by the sperm of a donor male with the wife's ova or by the sperm of the husband with a donor woman's ova, some additional considerations are suggested for consent forms:

(1) The husband and wife should expressly request and consent in writing to the IVF procedure where the semen or ova of a donor is used.¹⁹⁶

(2) The husband and wife should agree that the physician has sole discretion in selecting qualified donors.¹⁹⁷

(3) The husband and wife should stipulate that they will not require that the name of the donor be divulged to them or anyone else, and that they waive all rights as to the identity of the donor.¹⁹⁸

(4) The husband and wife should be advised, and acknowledge that they have been advised, of the potential psychological implications that IVF procedure involving a donor may have on their marriage and any child born from the procedure.¹⁹⁹

(5) Both the husband and wife should expressly acknowledge that any child born from IVF using donor sperm or ova will be considered in all respects their natural child.²⁰⁰

(6) The donor should stipulate that the identity of any recipient will not be divulged by the physician to the donor, and that the physician will not reveal the donor's identity to any recipient.²⁰¹

(7) The donor should state the extent to which he/she has suf-

192. *Id.* at 2326.

193. See N.C. GEN. STAT. § 90-21.13(c) (1981).

194. See N.C. GEN. STAT. § 49A-1 (1976).

195. See Evans and Dixler, *supra* note 182, at 2326.

196. See N.C. GEN. STAT. § 49A-1 (1976); 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:84 (1971).

197. See 10 AM. JUR. FORMS SUPP., *Physicians and Surgeons*, § 10:1525.1 (1983); 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:84 (1971).

198. *Id.*

199. See 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:86 (1971).

200. *Id.* at § 202:85.

201. See 10 AM. JUR. FORMS SUPP., *Physicians and Surgeons*, § 10:1525.2 (1983); 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:87 (1971).

ferred from any physical or mental impairment or disability (whether inherited or as a result of any disease or ailment), the extent to which he/she has ever been afflicted with syphilis or any other venereal disease, the extent to which his/her grandparents, parents, brothers, sisters or children, if any, or their lineal descendants have ever been afflicted with emotional illness or any inherited mental or physical disabilities or disease; and state that he/she is in good health and has no communicable disease.²⁰²

(8) The donor should consent to a comprehensive physical examination by the physician.²⁰³

(9) The wife or husband of the donor (as the case may be) should expressly consent to the donor's services, agree not to attempt to discover the identity of the IVF recipient, acknowledge the truth of the donor's statements respecting medical history and condition to the best of his/her knowledge, and, if the donor is male, his wife should acknowledge that her husband might legally become the father of a child or children of which she is not the mother.²⁰⁴

If research is conducted apart from or in connection with IVF practice, the following special considerations are suggested for a consent form:

(1) The research subject should consent to appropriate genetic screening and the obtainment of background information to control the possible transmission of infectious or genetic diseases.²⁰⁵

(2) Appropriate alternative procedures to IVF, if any, should be disclosed to the research subject.²⁰⁶

(3) The research subject should be informed of any procedures that are experimental.²⁰⁷

(4) A description of any reasonably foreseeable risks (or unforeseeable risks to the embryo or fetus, as the case may be) should be provided to the research subject.²⁰⁸

(5) It should be stipulated that embryo transfer will only be attempted with gametes obtained from lawfully married couples, and the recipient-woman will be the woman whose ova was used

202. See 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:87 (1971).

203. *Id.* at § 202:87.

204. See 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:88 (1971).

205. See *AMA Statement*, *supra* note 170, at 1979 RPTR H.R.L. at II-B-12, II-B-13.

206. See 45 C.F.R. § 46.116(a)(4) (1982).

207. See 45 C.F.R. § 46.116(a)(1) (1982).

208. See 45 C.F.R. §§ 46.116(a)(2); 46.116(b)(1) (1982).

in IVF.²⁰⁹

(6) It should be stipulated that no unimplanted blastocysts will be sustained beyond 14 days after fertilization.²¹⁰

(7) An explanation should be given to the research subject as to whether any medical treatments and compensation for such treatments are available if injury occurs during research involving more than minimal risk.²¹¹

(8) Express consent should be obtained by one or both parents if research is conducted on a dead fetus, stillborn infant, or unimplanted blastocyst of the parents.²¹²

(9) There should be no exculpatory language or release in favor of an IVF researcher that would absolve him of any liability for negligence.²¹³

Finally, the question arises whether further protection may be provided to the IVF practitioner by the execution in his favor of a contractual provision or release that purports to exempt him from liability in the exercise of the practice. As a general rule, the fundamental right to freedom of contract allows a party to stipulate against liability for his negligence provided that such a stipulation is not violative of law or public policy.²¹⁴ However, such contracts are not favored by the law and are strictly construed against exemption from liability.²¹⁵ Thus, it is said that a party may not exempt himself from liability in the performance of a duty owed the public or involving the public interest, or where the public interest requires the performance of a private duty, or where the parties do not have equality of bargaining power so that one party must accept the exemption from liability by the other party in order to obtain something of importance, which for all practical purposes is not obtainable elsewhere.²¹⁶

These principles are generally followed by other jurisdictions.²¹⁷ However, there have been no instructive decisions found in North Carolina, and only a few elsewhere, that have ruled on the propriety of releases or exculpatory contractual provisions for medical malpractice. Of the few cases that have squarely addressed

209. See *EAB Report*, *supra* note 1.

210. *Id.*

211. See 45 C.F.R. § 46.116(a)(6) (1982).

212. See N.C. Gen. Stat. § 90-220.1 through 90-220.9 (1981).

213. See 45 C.F.R. § 46.116 (1982).

214. See *Hall v. Sinclair Refining Co.*, 242 N.C. 707, 89 S.E.2d 396 (1955).

215. *Id.*

216. *Id.*; 3 N.C. INDEX 3D, *Contracts* § 10 (Strong's, 1976).

217. See 57 AM. JUR. 2D, *Negligence* § 20-31 (1971).

the matter, none have upheld such provisions.²¹⁸ Thus, it seems clear that a North Carolina physician could not effectively contract away the statutory²¹⁹ and common law duties of due care that he owes his patient.

This does not mean, however, that it would be absolutely useless for a physician to incorporate an exculpatory clause or release provision in a consent form with the patient. If the physician is not negligent in treating his patient and obtains proper informed consent from his patient for innovative treatment or procedure, it would seem unreasonable for the physician not to effectively contract against liability for adverse consequences. This should be particularly true where the physician expressly does not and cannot warrant the success of the treatments or procedures that he administers, and such treatments or procedures serve as "consideration" for and are consented to by a patient with lost hope. It would seem that IVF patients would fall squarely in this category.

Accordingly, the IVF practitioner might consider including a release or exculpatory clause in a consent form that essentially amplifies the patient's awareness of possible adverse consequences, and his understanding that the physician does not guarantee, warrant, or otherwise contract that the results of IVF procedure will be free of complications and be successful. As a practical matter, such a clause should be styled in a tenor which to the ears of a judge or jury would not appear overreaching on the part of the physician.²²⁰ In this regard, for example, it may be advisable for the physician to expressly acknowledge that his services are governed by the customary standard of due care.

C. Summary

A physician may be subjected to criminal or tort liability, or both, if he fails to obtain the informed consent of his patient to proposed treatment or procedure. Apart from being required to disclose the usual and most frequent risks and hazards inherent in a proposed treatment or procedure, the physician should also disclose any available alternative therapies and their comparative risks such that his patient can make an informed choice. Because

218. See Annot., 6 A.L.R.3d 704 (1966); but see *Nelson v. Harrington*, 72 Wis. 591, 40 N.W. 228 (1888) (suggesting the possibility).

219. N.C. GEN. STAT. §§ 90-21.12, 90-21.13 (1981).

220. See 15 AM. JUR. LEGAL FORMS 2D, *Physicians and Surgeons*, § 202:84 (where exculpatory language is drafted quite broadly).

the legal standard for effective consent hinges on the disclosure practice of other physicians engaged in the same or similar field, a practitioner engaged in innovative procedure such as IVF must be specially on watch for new developments in his field that may necessitate changes in the disclosures he makes. As with ignorance of the law, ignorance of new developments in medical practice provides no excuse for liability.

The use of a detailed consent form is integral to satisfying the requirement of informed consent. There is no such thing as an all-encompassing "boilerplate" consent form that can be used by IVF practitioners as a whole. Specific provisions in consent forms must be carefully tailored to the special nuances in medical procedure employed by the particular IVF practitioner. Where research is conducted or donor sperm or ova is used in IVF, rather special consent form provisions must be included. Finally, while a physician cannot contract away his statutory and common law duties of due care to his patient, it may be advisable to include a release or exculpatory clause in the consent form that essentially emphasizes that the physician is not and cannot be a guarantor against complications or an insurer of success in IVF procedure.

VII. CONCLUSION

The current legal implications of human *in vitro* fertilization amplify the classical maxim: "[i]f the written law be silent, that which is drawn from manners and custom ought to be observed; and, if that is in any manner defective, then that which is next and analogous to it"²²¹ [But] ignorance of law excuses no one.²²²

Given the rapidly growing science and technique of *in vitro* fertilization, medical practitioners and their patients are likely to remain, for the near future, somewhat nonplussed about the legal rights and protections that may be afforded to them in connection with IVF practice. Because of scant statutory and case law, potential claims and liabilities are largely uncertain and uncharted in current jurisprudence. However, the relative silence in the law can be compensated by the doctrine of *stare decisis* which, in its best form, provides a guide to understanding novel legal implications based upon established and analogous legal precedent.

221. 7 Coke 19 ("*Lex scripta si cesset, id custodiri oportet quod moribus et consuetudine inductum est; et si qua in re hoc defecerit, tunc id quod proximum et consequens ei est.*").

222. Bouvier ("*Ignorantia legis neminem excusat.*").

In this context, “ignorance of law” should not be a reason to inhibit IVF practice. The traditional legal principles attending the standard of care in medical practice and the doctrine of informed consent should furnish ample guidance and protection to the IVF practitioner and patient. By understanding and acting within these legal guidelines, IVF practice may continue to develop and serve individuals free from the inexorable constraints of unnecessary litigation.