

1999

Addressing In Vitro Fertilization and the Problem of Multiple Gestations

Mary Ann Davis Moriarty
davisma@slu.edu

Follow this and additional works at: <https://scholarship.law.slu.edu/plr>



Part of the [Law Commons](#)

Recommended Citation

Davis Moriarty, Mary Ann (1999) "Addressing In Vitro Fertilization and the Problem of Multiple Gestations," *Saint Louis University Public Law Review*. Vol. 18 : No. 2 , Article 9.
Available at: <https://scholarship.law.slu.edu/plr/vol18/iss2/9>

This Notes and Comments is brought to you for free and open access by Scholarship Commons. It has been accepted for inclusion in Saint Louis University Public Law Review by an authorized editor of Scholarship Commons. For more information, please contact [Susie Lee](#).

ADDRESSING IN VITRO FERTILIZATION AND THE PROBLEM OF MULTIPLE GESTATIONS

I. INTRODUCTION

Assisted reproduction technology (“ART”) is one of the greatest developments of modern-day medicine as it provides individuals who face difficulty in producing offspring potential hope. It has been stated that “ART facilitates the creation of families by persons who really want to become parents.”¹ This is not only positive for the children that are created, it is also good for society as a whole. In 1995, a survey estimated 6.1 million women who desired to have children had experienced some kind of impaired fertility which made them unable to conceive.² In that same year, 1.2 million women reported that they had used an infertility service to assist them in conceiving a child.³ Advances in ART and high success rates have encouraged many couples to seek guidance and help from infertility clinics specializing in assisted reproduction. While ART consists of a variety of options this article will only focus on the oldest method of this technology, in vitro fertilization (“IVF”).⁴

Patients as consumers often seek out clinics that can accommodate their need for a pregnancy in the shortest time frame. This creates strong

1. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, ASSISTED REPRODUCTIVE TECHNOLOGIES 43 (1998).

2. *Id.* Estimates of how many people are affected by infertility vary widely depending on the way infertility is defined. This survey conducted by the National Survey of Family Growth classified a women as being infertile if: 1) it was impossible to have a baby for some reason other than a sterilization operation; 2) it was physically difficult for them to conceive or deliver a baby; 3) they were continuously married, did not use contraception, and did not become pregnant for three years or longer. *Id.* at 13.

3. *Id.* at 14.

4. Other options couples may wish to explore include gamete intrafallopian transfer (GIFT), involving retrieving eggs and placing them directly into the fallopian tubes with a large number of sperm; zygote intrafallopian transfer (ZIFT), a zygote, (a fertilized egg that has not yet divided) is placed in the fallopian tube approximately one day after insemination; and cryopresevation, the freezing of extra fertilized embryos in order to use them for subsequent cycles if a transfer fails. SUSAN LEWIS COOPER & ELLEN SARASOHN GLAZER, CHOOSING ASSISTED REPRODUCTION 40 (1998). IVF has had a slightly lower success rate than GIFT and ZIFT, but many women are not suitable for GIFT and ZIFT procedures. *1996 Assisted Reproductive Technology Success Rates*, NAT’L SUMMARY & FERTILITY CLINIC REP. (Ctr. for Disease Control and Prevention, Atlanta, GA), Dec. 1998, at 6.

competition between clinics to satisfy consumers' demands. To raise success rates and build a good reputation within the IVF market many clinics transfer multiple embryos during a single IVF treatment to optimize the potential for pregnancy. This practice often results in multiple gestations, and adds to pregnancies that already contain potential risks,⁵ even more substantial medical, economical, and emotional consequences.⁶

In order to protect IVF consumers and prevent the high frequency of multiple gestations, thus reducing fetal and maternal complications and health risk, state regulations must be formed that will require particular information to be given to potential IVF patients and limit the number of embryos transferred during IVF.

Part II of this article explores IVF treatment and its procedure and the increasing demand in the United States for IVF to help individuals meet their reproductive needs. Part III will address multiple gestations and the multitude of problems that result when multiple embryos are transferred into a woman's body causing more than a singleton pregnancy. Part IV of this article will identify and analyze current regulations of IVF and examine possible limitations on such regulations. The article will then offer possible guidelines in forming regulations suggesting that the state government might be a more appropriate forum to regulate the number of embryos transferred and mandate that specific information is released to IVF couples.

II. IN VITRO FERTILIZATION TREATMENT

A. *History of In Vitro Fertilization*

In IVF a woman's eggs are extracted from her ovaries and fertilized outside her body.⁷ A variety of drugs can be used preceding the IVF procedure to stimulate the ovaries, resulting in an abnormal number of eggs produced for retrieval.⁸ After removal, the eggs are usually placed in a petri dish and

5. It is argued that higher rates of preterm delivery, low birth weight, maternal and fetal complications, and cesarean sections are associated with pregnancies after ART has been used as compared to those conceived by natural methods. Benjamin E. Reubinoff, et al., *Is the Obstetric Outcome of In Vitro Fertilized Singleton Gestations Different From Natural Ones? A Controlled Study*, 67 FERTILITY & STERILITY 1077, 1081-1082 (1997).

6. Peter M. Martin & H. Gilbert Welch, *Probabilities For Singleton and Multiple Pregnancies After In Vitro Fertilization*, 70 FERTILITY & STERILITY 478, 481 (1998). Compared with singleton births, twins have a six time increased risk of mortality, and in triplets the rate is increased by twenty times. *Id.* at 478.

7. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 6; ROBERT BLANK & JANET C. MERRICK, HUMAN REPRODUCTION, EMERGING TECHNOLOGIES, AND CONFLICTING RIGHTS 87 (1995).

8. Specifically, ovulation stimulating drugs stop the woman's own hormonal cycle (giving the practitioner greater control over ovarian stimulation) and stimulate the ovaries in the IVF

inseminated by the man's sperm.⁹ Once fertilization occurs, the resulting embryos are kept in a culture medium for approximately two days.¹⁰ When the embryos reach the four-cell stage,¹¹ they may be transferred to the woman's uterus through the cervix.¹² If the procedure is successful the embryos will implant in six to nine days, resulting in pregnancy.¹³

The first baby conceived through IVF, Louise Brown, was born in England in 1978.¹⁴ After obtaining state government approval in 1980, Norfolk General Hospital in Virginia, made the technique available in the United States.¹⁵ One year later, Elizabeth Carr, was the first baby born in the United States who was conceived through IVF.¹⁶ The IVF procedure quickly became popular and continues to be widely practiced today.

Approximately three thousand procedures were performed in the United States during 1985.¹⁷ By 1990, more than two hundred clinics in the United States offered IVF procedures.¹⁸ In 1996, the National Report of ART Success Rates, released by the Center for Disease Control and Prevention, stated a total of 20,659 babies had been born that year as a result of 64,036 assisted reproduction cycles, most of which used IVF procedures.¹⁹

The cost of IVF varies depending on the clinic that performs the procedure and the couple's type of infertility. In 1987, it was estimated that American couples spent one billion dollars on infertility treatment.²⁰ A more recent estimate indicated that couples may pay anywhere from \$7,000 to \$11,000 for the actual IVF treatment cycle.²¹ This estimate does not include additional

cycle. IVF can be performed without using stimulating drugs, but there is a lower success rate if this is done. See THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 43, 53-54.

9. An embryologist carefully examines sperm so only the healthiest are used. LEWIS, *supra* note 4, at 40.

10. BLANK & MERRICK, *supra* note 7, at 87.

11. Deciding when an embryo should be transferred varies among IVF practitioners. 1996 *Assisted Reproductive Technology Success Rates*, *supra* note 4, at 6. For example some practitioners believe the embryo should reach the eight-cell stage before it is transferred. *Id.*

12. LEWIS & GLAZER, *supra* note 4, at 40.

13. BLANK & MERRICK, *supra* note 7, at 87.

14. *Id.* at 89.

15. *Id.*

16. *Id.*

17. Martin & Welch, *supra* note 5, at 478.

18. BLANK & MERRICK, *supra* note 7, at 89.

19. IVF procedures were used in 71% of the cycles, GIFT was used in 5% of the cycles, and ZIFT was used in 2% of the cycles. 1996 *Assisted Reproductive Technology Success Rates*, *supra* note 4, at 6.

20. ANDREA BONNICKSEN, IN VITRO FERTILIZATION 25 (1989). According to this figure it was estimated that 7,000 couples were paying an average of \$10,000 each for IVF treatment. *Id.*

21. James M. Goldfarb, et al., *Cost Effectiveness of In Vitro Fertilization*. *Obstetrics & Gynecology*, 18 (Jan 1996); see also THE NEW YORK STATE TASK FORCE ON LIFE AND THE

expenses, such as maternal and neonatal complications and loss wages due to time away from work. When other factors are taken into account, the cost per delivery may lead to an investment of at least \$50,000.²² Regardless of the high cost of IVF treatment, most clinics in the United States have a waiting list of people who are willing to pay any amount for the chance to become pregnant.

B. Choosing to Use in Vitro Fertilization Treatment

There are several reasons why many couples have turned to this expensive treatment. First, current data shows a higher rate of infertility among couples than in the past.²³ Generally, infertility is defined as the inability to conceive after one year of unprotected intercourse.²⁴ Couples may experience infertility due to either the female or the male or both combined.

A primary cause of female infertility is blockage or damage to the fallopian tubes, making it difficult for the egg to be fertilized or for an embryo to travel to the uterus.²⁵ Increased sterility in women is also due to scarring from pelvic inflammatory disease or sexually transmitted diseases such as gonorrhea, herpes simplex II, and chlamydia.²⁶ Male infertility is generally attributed to the damaging of testes or cells that can cause an insufficient number of sperm to be produced. Also, males may experience problems with sperm mobility or sexual functioning due to inadequate hormones that make it difficult for fertilization to occur under normal conditions.²⁷

Second, medical services for infertile couples offering various options for treatment have become widely available and are well publicized.²⁸ As the

LAW, *supra* note 1, at 119. At one program in the United States, women with various types of infertility and one open fallopian tube, were treated for anywhere from \$7,800 to \$10,300 per delivery. At the same clinic another women received IVF at the cost of \$37,000.

22. BLANK & MERRICK, *supra* note 7, at 89. This cost analysis indicated that the cost per delivery ranged from \$50,000 for the first cycle in a woman with a tubal disease to \$800,000 over delivery for the more extreme case of the sixth cycle in an older woman in whom there was also a male infertility factor present.

23. *Id.* at 13.

24. Institute for Assisted Reproduction, *The In Vitro Fertilization Program available at* (visited Nov. 8, 1999).

25. 1996 *Assisted Reproductive Technology Success Rates*, *supra* note 4, at 10 (reporting this as responsible for 29% of infertility problems).

26. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 18.

27. 1996 *Assisted Reproductive Technology Success Rates*, *supra* note 4, at 10 (reporting this as responsible for 25% of infertility problems).

28. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 15.

methods used in IVF treatment improve and technology expands, the number of couples whom are treatable increases.²⁹

Third, there are more women of reproductive age than in the past.³⁰ It is estimated that women who are part of the baby boom generation will not reach the end of their reproductive years until 2010.³¹ Postponing parenting until the mid-to-late thirties has also become a social pattern among this generation.³² Thus, as data has indicated that infertility increases with a woman's age, a higher proportion of these women are experiencing problems when they decide to become pregnant.

Last, the alternative option of adoption for couples that face reproductive problems has become a slow and complicated process.³³ The availability of healthy newborns for adoption is low because of more effective birth control, increased use of abortion, and a trend of single mothers desiring to keep their children.³⁴ Also, the absence of complex adoption procedures in IVF treatment makes the medical intervention of IVF more favorable to most couples.

III. DISCUSSION OF MULTIPLE GESTATION AS A RISK OF IN VITRO FERTILIZATION

The ultimate goal of ART is the birth of a healthy child. In order to maximize the probability of this goal being achieved ART clinics will transfer multiple embryos within in a single IVF procedure. Health institutes and researchers, such as the American Society for Reproductive Medicine, discourage the transfer of multiple embryos. While the greater number of embryos transferred increases the chance that at least one embryo will implant, it also increases the likelihood of multiple gestation. A multiple gestation pregnancy creates new risks and complications for the couple and their unborn children.³⁵ Ultimately, the couple must make the difficult decision of either carrying the pregnancy to full term with its associated risks, selectively aborting some of the fetuses, or terminating the pregnancy.

29. Micromanipulation of sperm is an example of such improvements. This makes IVF treatment possible to couples in which the male produces a low amount of sperm. *Id.* at 43, 53-54.

30. *Id.* at 15.

31. *Id.* at 43, 53-54.

32. BLANK & MERRICK, *supra* note 7, at 13. Between 1976 and 1986, the number of women who had their first child at forty years of age or older doubled. *Id.*

33. It is estimated that in a given year there are 3.3 couples seeking adoption for everyone who succeeds. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 16.

34. BLANK & MERRICK, *supra* note 7, at 13.

35. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 58.

A. *Embryo Transfer*

There are four distinct phases of IVF that are critical to its success: 1) ovarian stimulation and monitoring; 2) egg collection; 3) fertilization and embryo culture; and 4) embryo transfer.³⁶ In the last stage, the question of how many embryos should be transferred arises. In order to select which and how many embryos should be transferred, most IVF programs grade the embryos on shape and appearance, believing the better-graded embryos will yield more pregnancies.³⁷ The number of embryos transferred varies widely among ART clinics. The average number of embryos transferred ranges from 1.0 to 5.9 for women younger than thirty-five years of age.³⁸ The highest number of embryos is usually transferred if the majority of the embryos are of marginal quality, if the IVF program has a poor record of pregnancies per transfer, or if IVF is being performed on an older woman.³⁹ Additionally, newly developed techniques in IVF and increased use of ovulation-inducing drugs have led to the transferring of a larger number of embryos.

The practice of transferring more embryos has led to an increase in high-order multiple gestation⁴⁰ by at least 200% since the early 1970's.⁴¹ Specifically, between 1973 and 1990, in the United States, triplet and high-order multiple pregnancies increased by seven times the amount of singleton births.⁴² In 1996, 38% of assisted reproductive births resulted in multiple births.⁴³ Today, one third of twins, three fourths of triplets, and nearly all of quadruplets and high order multiple pregnancies are the result of infertility treatments.⁴⁴

B. *Problems Associated with Multiple Gestations*

Multiple gestations resulting from IVF treatment are associated with a wide range of complications and adverse effects. First, the overall miscarriage rate for pregnancies conceived through IVF is about 17%. The highest of these

36. *Id.* at 53-59.

37. *Id.* at 57-58.

38. *1996 Assisted Reproductive Technology Success Rates*, *supra* note 4, at 10. This is the age group that is most likely to become pregnant from IVF treatment. *Id.*

39. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 58.

40. For purposes of this article, this term is meant to refer to gestations that are greater than three.

41. Jeffrey L. Angel, Craig S. Kalter, et al., *Aggressive Perinatal Care For High Order Multiple Gestations: Does Good Perinatal Outcome Justify Aggressive Assisted Reproductive Techniques?* 181 AM. J. OBSTET. GYNECOL 253 (Aug. 1999).

42. Christopher J. De Jonge & Don P. Wolf, *Embryo Number for Transfer Should Be Regulated*, 68 FERTILITY & STERILITY 784 (Nov. 1997).

43. *1996 Assisted Reproductive Technology Success Rates*, *supra* note 5, at 14.

44. De Jonge & Wolf, *supra* note 42, at 784.

rates occurs when procedures result in multiple gestations.⁴⁵ In utero death of one of the fetuses is also more likely to occur in a multiple gestation pregnancy because of the rupturing of the uterus, placental abruption,⁴⁶ or placenta previa.⁴⁷

Second, postnatal difficulties arise for those fetuses that survive prenatal complications. Babies of multiple gestations are often delivered prematurely and have a low birth weight.⁴⁸ The average gestational age for triplets is thirty two to thirty four weeks and for quadruplets is twenty eight to thirty weeks.⁴⁹ These babies typically require extensive neonatal care and have postnatal abnormalities. Some multiple birth babies of IVF also suffer from permanent injuries such as blindness, respiratory complications, cerebral palsy and brain damage.⁵⁰ Multi-fetal births are also associated with high portions of postnatal mortality.⁵¹

Risk also becomes higher for the mother as the number of fetuses she carries increases. These complications include pregnancy-induced hypertension,⁵² hyperemesis gravidica,⁵³ and operative delivery problems.⁵⁴ More medical intervention such as extensive bed rest, longer hospitalization prior to delivery, and the use of medication to stop preterm labor will be required in multi-fetal pregnancies than in singleton pregnancies.⁵⁵ Also during a multi-fetal pregnancy a woman is more likely to develop pregnancy related diseases such as anemia,⁵⁶ gestational diabetes, pre-eclampsia,⁵⁷ and

45. This percentage includes the results of more advanced techniques of GIFT and ZIFT. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 69.

46. The pulling away of the placenta from the uterine wall. DORLANDS MEDICAL DICTIONARY 1164 (24th ed. 1965).

47. A placenta which develops in the lower uterine segment, so that it covers or adjoins the internal organs. *Id.* at 1165.

48. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 128 (1998).

49. De Jonge & Wolf, *supra* note 42, at 784.

50. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 2, at 73.

51. Angel, *supra* note 41, at 257; BLANK & MERRICK, *supra* note 7, at 92. The incidence of infant mortality for triplets and quadruplets is almost ten times that of singletons.

52. Abnormally high tension, especially high blood pressure. DORLANDS, *supra* note 46, at 707.

53. Excessive vomiting. *Id.* at 702.

54. Cesarean delivery is more common in pregnancies involving multiples. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 70; Alejandro Manzur, Jane L. Fredrick, et al., *Outcome of Triplet Pregnancies After Assisted Reproductive Techniques: How Frequent Are The Vanishing Embryos?* 63 FERTILITY & STERILITY 252, 253 (1995).

55. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 128.

56. A reduction below normal in the quantity of hemoglobin, or the volume of packed red blood cells. DORLANDS MEDICAL DICTIONARY, *supra* note 46, at 82.

57. A toxemia of late pregnancy, characterized by hypertension, albuminoidal, and edema. *Id.* at 1212.

high blood pressure.⁵⁸ Further, pre-existing medical conditions will usually intensify more during a multiple gestation than during a singleton pregnancy, and result in a worsening of the condition that is permanent.

Moreover, couples experiencing a multiple gestation also undergo great emotional trauma. This may be caused by loss of work and prolonged separation from loved ones because of increased hospitalization of the woman that is associated with high order multiple gestations.⁵⁹ Also because of the high risk that accompanies these pregnancies, there is often intense monitoring of the woman and great restrictions on her activities.⁶⁰ The complications and burdens associated with multiple gestations often perpetuate the feelings of a woman that she is being “cheated” of a normal reproductive experience.⁶¹

Last, the increased financial cost of multi-fetal pregnancy and multi-fetal births can become an unexpected burden on the couple. The high-risk pregnancy requires extensive prenatal care including doctor visits, tests, and overall monitoring of the fetus development.⁶² Furthermore, neonatal complications often present a demand for sophisticated medical attention including prolonged periods of hospitalization in a neonatal intensive care unit and expensive treatments.⁶³

C. *A New Decision for the In Vitro Fertilization Treated Couple*

When a couple learns they are pregnant with three or more babies conceived through IVF treatment in order to ensure the safety of the unborn fetuses and their mother they will be made aware of three main options. First, the couple can carry all the fetuses to term. As identified above, multifetal pregnancies are a high-risk and can result in great complications.⁶⁴ Ultimately, there is a high probability that the pregnancy will end in a miscarriage or premature death of all the fetuses.⁶⁵ Second, the couple may choose to abort all the fetuses. Often, electively choosing to terminate a much-wanted pregnancy results in the couple suffering longer and more intense devastation.⁶⁶

58. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 70.

59. Angel, *supra* note 41, at 257.

60. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 130.

61. *Id.*

62. James M Goldfarb, et al. *Cost-effectiveness of In Vitro Fertilization*, 87 AM. J. OBSTET GYNECOL 18 (Jan. 1996).

63. Manzur, *supra* note 54, at 256. Financial burdens can also be greater on the delivering institution of the multiple gestation. One medical center concluded “3 million dollars per year would have been saved by that health care delivery system if all the multiple gestations resulting from ART had been singleton deliveries.” De Jonge, *supra* note 42, at 784.

64. *Id.* at 785.

65. *Id.*

66. THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, *supra* note 1, at 129.

Third, the couple may choose to selectively abort certain fetuses through multifetal pregnancy reduction, also known as selective termination. This is a medical procedure in which some of the fetuses of the multi-fetal pregnancy are aborted while the other fetuses are carried to term.⁶⁷ During the application of the procedure alone there is a risk that all of the fetuses will be lost or it will cause significant abnormalities in the fetuses that survive.⁶⁸ The couple may also experience psychological and emotional effects when they choose fetal reduction.⁶⁹ In one particular study of couples who chose multifetal reduction, more than 65% of the respondents recalled acute feelings of emotional pain, stress, and fear during the procedure and 70% said they mourned for the lost fetuses.⁷⁰ Few couples who go through IVF treatment expect that they will be confronted with the dilemma of choosing to selectively abort one or more fetuses to try and ensure the health and survival of the others.⁷¹

The rates of multi-fetal pregnancies and their associated risk will only become higher unless the number of embryos transferred during IVF is limited. More aggressive perinatal care, fetal reductions, and neonatal intensive care units are not the answer to multiple gestations. A more effective and efficient way to reduce the occurrences of multiple gestations from IVF treatments and the complications they present is by reducing the number of embryos transferred during IVF procedures. Legislative regulations may be one mechanism that can monitor embryo transfer and assure that a limited and appropriate number is transferred during IVF treatments.

IV. ANALYSIS OF IN VITRO FERTILIZATION REGULATIONS

In the area of assisted reproduction, there are limited federal and state regulations directly applicable to its practice. Basically, the government has been content to let the IVF industry operate regulation-free with a few exceptions. One federal regulation exists which provides requirements that should have a positive effect on the IVF industry, however, its future is unstable. On the state level, a minority of states has attempted to regulate the IVF industry.⁷²

67. Richard L. Berkowitz, et. al, *The Current status of multifetal pregnancy reduction*, 174 AM. J. OBSTET GYNECOL 1270 (1996).

68. De Jonge & Wolf, *supra* note 42, at 785.

69. Mary K. McKinney, et al., *Multifetal Pregnancy Reduction: Psychodynamic Implications*, 59 PSYCHIATRY 393 (1996).

70. Berkowitz, et al., *supra* note 67, at 1270; *see also* McKinney, et al., *supra* note 69, at 394.

71. COOPER & GLAZER, *supra* note 4, at 87.

72. Some states have required that IVF is covered under insurance policies. *See i.e.*, Conn. Gen. Stat. Ann § 38a-536 (West 1996) (requiring IVF insurance coverage). In California, a statute makes it a felony to knowingly use sperm, ova, and embryos in any other way that that described in a written informed consent. CAL HEALTH & SAFETY CODE § 1374.55 (West 1997).

Legislation in this area must be separated from similar proposed regulations aimed at controlling abortions and must overcome constitutional issues of privacy. Regulations that merely comfort society's general disapproval of IVF procedures or to hinder the potential inconveniences one might see as being placed on society as a result of IVF will not pass judicial scrutiny. Regulations must serve the state's interest in protecting potential human life. Those that control the associated dangers of IVF treatment to the mother and her unborn children should have a relationship to this interest. Furthermore, regulations that protect the IVF consumer will be beneficial to the IVF industry and work to provide suitable candidates for IVF treatment with a healthy offspring.

A. *Current Regulations of In Vitro Fertilization*

In 1992, Congress enacted the Fertility Clinic Success Rate and Certification Act.⁷³ This legislation requires ART programs to annually report pregnancy success rates achieved by assisted reproductive techniques⁷⁴ and instructs the Center for Disease Control to develop model licensing certification procedures for IVF laboratories that could be adopted by each state.⁷⁵ Lack of congressional funding has caused this legislation to have little impact on the IVF industry.⁷⁶ It was not until 1996, that the Department of Human Health Services decided to allocate approximately \$1 million annually for the purpose of implementing this bill.⁷⁷

It can be assumed that Congress envisioned the Act as providing mandatory standards that would assure consistent and quality performance of ART procedures and adequate record keeping at each certified embryo laboratory. The Act is a positive step toward regulating the multimillion-dollar IVF industry, but unless continuous funding occurs, IVF clinics will be under no obligation to report success rates or comply with any uniform licensing requirements.

73. 42 U.S.C.A. §263a, 1-7, 1999. The main purpose of this act is to assure that consumers of IVF services are not misled by falsely stated success rates.

74. The Act requires the Secretary when defining pregnancy success rates to include the ratio between the number of live birth rates and the number of ovarian stimulations or oocyte retrievals conducted in any one ART center. 42 U.S.C.A § 263a-1(b)(2). The Act also provides that the pregnancy success rate should take into account the effect of age and diagnosis on the live birth rate. *Id.*

75. 42 U.S.C.A. § 201, 263a, 1-7, 1999.

76. Keith Alan Byers, *Infertility and In Vitro Fertilization: A Growing Need For Consumer-Oriented Regulation of the In Vitro Fertilization Industry*, 18 J. LEG. MED. 265, 305 (1997).

77. *Id.*

Traditionally, states have retained the power to regulate areas of familial relations, including marriage, divorce, and adoption.⁷⁸ Pennsylvania was the first state to enact IVF legislation as part of its abortion statute. The statute requires all persons conducting or experimenting in IVF to file quarterly reports that are made available for public inspection.⁷⁹ These reports contain the location and personnel of each clinic, as well as the numbers of IVF eggs fertilized, the number of embryos destroyed or discarded, and the number of women implanted with fertilized eggs at each site.⁸⁰

The statute may make clinics more accountable for the whereabouts of fertilized eggs, but it does little to protect the IVF consumer. The information required by the statute to be made available to the public does not inform the consumer of a particular clinic's success in IVF treatments since it does not mandate the reporting of pregnancy rates or live birth rates. Absent the fear of insufficient success rates being reported this statute probably has little effect in regulating the IVF industry.

In comparison to the Pennsylvania statute, a Virginia statute requires that all ART patients sign a disclosure indicating the rate of success for the patient's particular procedure at the clinic where it may be performed.⁸¹ The Virginia statute is more a consumer oriented and alerts the IVF patient of the likelihood that the treatment will render a positive outcome. The Virginia statute, however, still deprives patients of critical information about the risks and alternatives to the IVF procedure.

A Louisiana statute requires that IVF procedures can only take place in facilities meeting the standards of the American Fertility Society and the American College of Obstetricians and Gynecologist.⁸² It also requires IVF procedures to be directed by a medical doctor who is licensed to practice medicine in Louisiana and possesses specialized training and skill in IVF treatment.⁸³ The guidelines the Louisiana statute mandates may enforce more precautions to be taken in the performance of IVF treatments, but similar to the Virginia statute, it does not make the IVF patient fully aware of alternatives and the potential risk associated with the treatment.

A New Hampshire statute is the most detailed regulation of IVF procedures.⁸⁴ The statute requires all women and their spouses who plan to

78. This is consistent with the notion that "The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the States respectively or to the people." U.S. CONST. amend X.

79. 18 PA. CONS. STAT. ANN. § 3213 (West 1999).

80. *Id.*

81. VA. CODE ANN. § 54.1-2971.1 (Michie 1996).

82. LA. REV. STAT. ANN § 9:128 (West 1999).

83. *Id.*

84. N.H. REV. STAT. ANN. §168-B: 13.

use IVF to be medically evaluated and deemed medically acceptable.⁸⁵ It also requires a non-medical evaluation to be performed on each party by a psychiatrist, psychologist, pastoral counselor or social worker licensed to practice in New Hampshire.⁸⁶ The statute states that the purpose of the non-medical evaluation is to determine the party's suitability to parent by considering the ability of the couple to give a child love, affection, and guidance.⁸⁷ Those that do the evaluation are to keep a record of their findings and conclusion.⁸⁸ Parties must waive their privilege against disclosure of confidential communications and allow a copy of the findings to be filed with the court.⁸⁹ The statute requires that a licensed child placing agency or the department of Health and Human Services also conduct a home study of the IVF candidates.⁹⁰ The purpose of the home study is to assess the ability of the couple to provide a child with food, clothing, shelter, medical care, and other basic necessities.⁹¹

While the evaluations may seem intrusive on couples' lives, the New Hampshire statute presumably is aimed at protecting the potential offspring of the IVF procedure. The statute works to ensure those seeking assisted reproduction are of certain medical and physical health status and have the capacity to provide for children. Even though the New Hampshire statute takes the lead in providing guidelines to protect the children conceived through IVF treatment, it fails to regulate the actual IVF procedure itself that can have the greatest effect on the health and status of these children.

B. Limitations on In Vitro Fertilization Regulations

The reasons for lack of legislative action in the area of assisted reproduction may be embedded in our nation's political and constitutional history. Regulation may be limited pertaining to assisted reproduction because it is an issue that is closely affiliated with the abortion debate. Arguments of proponents of assisted reproduction regulations that society not only has the authority, but the duty to intervene in reproductive decision making to protect the existence of unborn children, closely parallels the rejected arguments against abortion.

In the landmark abortion case, *Roe v. Wade*, the Court established the state's compelling interest in protecting fetal life began at the third trimester when the fetus had the capability of meaningful life outside the mother's

85. *Id.*

86. *Id.* at §168-B: 18.

87. *Id.*

88. *Id.*

89. N.H. REV. STAT. ANN. § 168-B: 18.

90. *Id.*

91. *Id.*

womb.⁹² This decision has affected issues of assisted reproduction because of the specific time periods the Court marked concerning the government's interest of the developing fetus. Even though the ultimate goal of IVF to create and abortion are distinct, the law and policymakers may consider the issues that arise in both areas as intertwined.

Governments may also be hesitant to enact more detailed regulations concerning reproductive technology based on a fear that such regulations would invade on an individuals' fundamental right associated with privacy. Although the Constitution does not enumerate privacy as a fundamental right, the Supreme Court has stated, "one aspect of liberty protected by the Due Process Clause of the Fourteenth Amendment is a right of personal privacy."⁹³ This right of personal privacy includes independence in making certain kinds of important decisions.⁹⁴

Supreme Court decisions clearly indicate that among the decisions that an individual may make without the unjustified government interference are those relating to marriage, contraception, procreation, and family relationships.⁹⁵ In *Skinner v. Oklahoma ex rel. Williamson*, the Supreme Court first enunciated the special importance of reproductive decisions.⁹⁶ It stated, "the right to procreate is a basic right of man, so fundamental to the existence of the human race that the government should not interfere."⁹⁷

In *Griswald v. State of Connecticut*, the Supreme Court further indicated the decision to procreate was included in a couples' protected right of privacy when it struck down a law barring contraceptives to married couples.⁹⁸ In its concurring opinion, members of the Court stated, "the right of privacy extended to decisions by married couples about whether or not to have a child."⁹⁹ Further, in *Eisenstadt v. Baird*, the Court struck down a law that made contraceptives less accessible to unmarried individuals based on the idea that "if the right of privacy means anything, it is the right of an individual, married or single, to be free from unwanted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."¹⁰⁰

92. *Roe v. Wade*, 410 U.S. 113 (1973).

93. *Id.* at 152.

94. *Carey v. Population Services International*, 97 S.Ct. 2010, 2016 (1977).

95. *Id.*

96. *Skinner v. Oklahoma ex rel. Williamson*, 316 U.S. 535 (1942).

97. *Id.* at 541.

98. *Griswald v. State of California*, 381 U.S. 479 (1965).

99. *Id.* at 499-506.

100. *Eisenstadt v. Baird*, 405 U.S. 438 (1972). *See also*, *Stanley v. Illinois*, 405 U.S. 645, 650 (1972) ("The right to conceive and the right to raise children is an essential, basic civil right of man"); *Cleveland Board of Educ. v. LaFleur*, 414 U.S. 632, 639- 640 (emphasizing a freedom in personal choice in matters of marriage and family life).

Although the concept of fundamental rights is thought to be the highest possible legal protection of an individual, it is not absolute. Even a burdensome regulation may be validated by a sufficiently compelling state's interest.¹⁰¹ In *Roe v. Wade*, the Court cautioned that certain state interest such as safeguarding health, maintaining medical standards, and protecting potential life, may become sufficiently compelling to sustain a regulation.¹⁰²

The Supreme Court reinstated this principle in *Carey v. Population Services International*. In the 1970's, a New York regulation banned advertisement of non-medical contraceptives and limited their distribution.¹⁰³ A mail order business in North Carolina advertised contraceptives in college newspapers across the country.¹⁰⁴ This advertisement and allowing orders to be fulfilled without proof of age violated the New York law.¹⁰⁵ When the New York law mandated the company to stop its practice, the company asked the Supreme Court to determine if the New York law was constitutional.

This case challenged the Supreme Court to decide on issues of both procreation and privacy. Even though the Court concluded the New York regulation unconstitutional, it stated "where a decision is as fundamental as whether to bear or beget a child, regulations imposing a burden on it may be justified by compelling state interests, and must be narrowly drawn to express only those interests."¹⁰⁶

C. Suggested Guidelines for In Vitro Fertilization Regulations

Regulations applicable to the IVF industry fall short of controlling the risks associated with IVF procedures and protecting the IVF consumer in their decision to undergo IVF treatment. Since the greatest risks of IVF treatment arises when it results in a multi-fetal pregnancy, the most efficient way to reduce this risk is to establish regulations on the maximum number of embryos that may be transferred during a single IVF procedure. It has been proven that it is the quality of the transferred embryo rather than the number of embryos that correlate with clinical pregnancy success rates in IVF.¹⁰⁷ Thus, no significant drop in pregnancy rates should be observed when transferring two or three good quality embryos, rather than four or more.¹⁰⁸ Increasing the probability of implantation by scrutinizing transfers on the basis of embryo quality, rather than implanting more than three embryos, will significantly reduce the number of multiple gestations.

101. *Carey*, 97 S.Ct. at 686.

102. *Roe*, 410 U.S. at 154.

103. *Carey*, 97 S.Ct. at 431.

104. *Id.*

105. *Id.*

106. *Id.* at 686.

107. *Manzur*, *supra* note 54, at 257.

108. *Id.*

Furthermore, in order to protect IVF consumers, regulations should require ART programs and clinics to give patients considering IVF treatment adequate information about the likelihood of success, the risk of IVF, alternative approaches to infertility, and the likely cost in the couple's case. Such information should be required to establish that complete informed consent was given.¹⁰⁹

Prospective patients of IVF treatment commonly seek treatment with unrealistically high expectations about the likelihood of success. Currently, there is a wide variability in the source and detail of success rates that the ART programs present to potential IVF patients. Patients considering IVF are particularly vulnerable, and should be fully aware of unsuccessful outcomes. Requiring that a program discloses success rates by a set standard, enables the patient to carefully choose a program and determine if they are a proper candidate for IVF or better suited for a different assisted reproduction procedure.

The risks of assisted reproduction do not only apply to the patient undergoing the treatment, they also extend to any offspring that may result. It is important that the patient is fully aware of all risks, especially those associated with multiple gestations and the likelihood that it will happen when multiple embryos are transferred. Identifying emotional and health risk associated with IVF treatment may make couples more cautious when authorizing the number of embryos transferred.

Information about alternatives to infertility may include a description of other assisted reproductive techniques and its best candidates or the ability to refer patients to an agency that will explore adoption options with couples seeking IVF. Even after IVF is unsuccessful, couples that would make superior parents, never explore the possibility of adopting a child. Informing the couple of their alternatives may open their minds to additional options never considered or provide additional avenues to explore in the unfortunate case that the treatment fails.

Considering the states already regulate some familial relations and some states have taken the initiative in forming current IVF legislation, it may be more acceptable if each state forms regulations that would include the above suggestions. Monitoring by the federal court will continue as it renders decisions in response to state legislation that some may challenge as unconstitutional.

109. Obtaining informed consent prior to medical treatment is required by law and is essential to sound medical practice. Under the law in most states, the treating physician must ensure all the elements of informed consent have been met. *See Arato v. Avedon*, 5 Cal. 4th 1172, 1183 (1993); *Petriello v. Kalman*, 215 Conn. 377, 387 (1994); *Wecker v. Amend*, 22 Kan. App. 2d 498 (1996) (physicians must ensure patient understands all alternatives to undergoing medical treatment). The principle of informed consent recognizes that patients typically lack medical knowledge and relies on their physician for information necessary to make decisions.

In formulating IVF regulations, states must comply with two guidelines. First, since it has been argued that IVF regulation may invade the fundamental right of privacy, a compelling state's interest must be identified in such regulations. If the state's interest in preserving and protecting the health of pregnant women and in protecting potential human life can be invoked to justify the statute, it should be sustained. Regulations that reduce the dangers associated with multi-fetal pregnancy should relate to the above state's interest.

Second, each state regulation must be narrow and limited so that the state's interest is served with as little infringement on the right of an individual as possible. Regulating the number of eggs transferred and requiring particular information is given to the IVF patient imposes minimal standards that will help ensure IVF procedures are done with the utmost safety.

IV. CONCLUSION

When one sees a mother pushing a stroller with two babies that look identical or of the same age they will often say, "look at the twins." Today, the chance that such an encounter will take place is greater than in the past and it is more likely that the word "twins" will be replaced with the word "triplets," "quadruplets," or even "septuplets." An increase in multi-fetal pregnancies and births, along with their associated risks, are a side effect of ART advancements and the transferring of multiple embryos during IVF treatments.

It is inevitable that technology will continue to advance, regardless of the negative consequences it may produce. In the United States, limited regulations of the developing industry provide little protection to the IVF patients and their potential offspring. A collective mission of policymakers and IVF practitioners should be to use IVF to optimize singleton birth rates while reducing multiple births in ART patients. This may only be achieved if the number of embryos transferred per IVF procedure is regulated and patients are adequately informed about IVF procedures.

Regulations including these practices will reduce the number of multiple gestations as a result of IVF treatments, thus relieving some IVF patients from the emotional, medical, and financial consequences of multi-fetal pregnancy. Also, regulations that require vital information about the IVF treatment is given to potential patients will minimize unnecessary harm and disappointment to infertile people who have faced a tiring and difficult challenge in trying to conceive a child.

MARY ANN DAVIS MORIARTY*

* The author would like to thank Madison, Mike, and her mother, father, and brother for their unconditional support and love. She would also like to thank Professor Greaney and Watson for their guidance while she was writing this article. This article is dedicated in loving memory of Frances Luchsinger, a virtuous person and special grandmother.