January 1997

The Role of the Federal Government in Assisted Reproductive Technologies

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I. INTRODUCTION

"New technologies challenge societal values, and values influence the direction of technological development." Biotechnology promises to yield an infinite number of medical choices, improvements, and developments especially with respect to reproduction. Technological intervention in this area is not limited just to the creation or prevention of offspring, but also applies to the manipulation of traits to control resulting characteristics.

In the newly emerging field of reproductive technologies, where medical prowess is pushed to its limits, dynamic issues and concerns are quick to rise to the forefront. This paper will argue for the increasing need for federal government intervention in providing a framework to guide the involved parties in the process of reproductive technologies. Participants include the child, medical clinicians and technicians, researchers, geneticists, donors of sperm and ova, surrogate mothers, family members, embryologists, attorneys, and the courts. Lack of a national policy has resulted in the existence of exploitation and commercialization of one of the most valued and personal aspects of our society.

Many of the third parties involved in this emerging enterprise seek to gain profits from the commercialization of procreation. A national policy is required because such commercialization presents a risk that women and children will be treated as commodities due to specialization in the reproductive process. Such commercialization also dictates that each aspect of the cycle from conception to birth would be controlled by a different agent.

Since its development, in vitro fertilization (IVF) has undergone several variations due to scientific evolution. These include gamete intra fallopian transfer, zygote intra fallopian transfer, superovula-

2. The Congressional Office of Technology Assessment has defined biotechnology as "any technique that uses living organisms to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." OTA-F-285, OFFICE OF TECHNOLOGY ASSESSMENT, TECHNOLOGY, PUBLIC POLICY AND THE CHANGING STRUCTURE OF AMERICAN AGRICULTURE, 31 (1986).
3. BLANK & MERRICK, supra note 1, at 16.
4. Id. at 17.
5. Id. at 87. Gamete intra fallopian transfer (GIFT) is a process in which the eggs are retrieved transvaginally under ultrasound guidance, similar to IVF. However, immediately following this a laparoscopy is performed and 3-4 eggs from the woman and the husband’s sperm is transferred into the fallopian tube.
tion, transvaginal ultrasound-directed oocyte recovery. However, to thoroughly examine the controversial and complex issues raised by technological and social innovations in human reproduction, this paper will focus specifically on IVF and similar reproductive technologies.

Although each of the above procedures is subject to technological differences, there are nonetheless common characteristics among the group which would allow them to come under the same regulatory scrutiny. In the absence of federal legislation, the courts are the sole policy making institutions available to resolve related disputes. Given the variations in policies amongst the states, the result has been contradictory and confusing public policy.

A noted author states that "a society can safely leave important and potentially dangerous interventions without legal regulations only if there is a sufficient degree of moral consensus so that individuals can be expected to act morally without regulation." He further adds that "legal regulation may be necessary in areas of human conduct where liberty is often abused and important moral values are in jeopardy."

Given the conflicting interests and motives of the various people involved, a moral consensus would be difficult, if not impossible, to obtain. Rights to privacy provide the key to the problem of developing a moral consensus with regard to the use of human reproductive technology. The resulting quasi-bureaucratic nature of the business and the legal, social, and ethical issues provoked by these technologies need appropriate legislation to impose quality control standards and to ascertain accurate record keeping and clarification of liability.
questions.

Part II of this paper will provide background information on IVF. Part III will analyze the abuses prevalent in the field of IVF, including their implications and consequences. Part IV will set forth a summary of the current status of public policy and governmental considerations of IVF. Part V will discuss the constitutional basis for federal regulation. Part VI will present this author’s recommended regulatory proposal.

II. BACKGROUND INFORMATION ON IVF

IVF was developed in Great Britain where the technology-assisted birth of Louise Brown on July 25, 1978 was deemed a success by Drs. Robert Edwards and Patrick Steptoe. In the United States, more than three million couples sought help for infertility in 1995. Of those, approximately 40,000 tried technology-assisted reproduction. Today, assisted reproductive technology is a billion dollar industry and a leading combative tool against infertility, but it is not a cure for infertility. The more well-known of the techniques is IVF.

A. Procedures and Terminology

IVF is literally defined as fertilization in glass. The procedure begins with the surgical removal of eggs from female ovaries for fertilization outside the body. One of two procedures is used to extract the eggs from female ovaries: laparoscopy or oocyte recovery. In laparoscopic egg retrieval, the woman undergoes three abdominal incisions under general anesthesia. A laparoscope, a fiberoptic viewing tube, is inserted into the abdomen to provide the practitioners with a visual advantage as the woman’s ovaries are held open with forceps. A teflon-coated needle is inserted into each of the stimulated follicles and the woman’s eggs are extracted with a vac-

15. Id. at 38.
17. Id. at 79.
18. ALPERN, supra note 8, at 25; see also Steinberg, supra note 16, at 81.
19. ALPERN, supra note 8, at 25.
uum pressure device. A more recent technological development offers a nonsurgical alternative to laparoscopy. Ultrasound directed oocyte recovery enables practitioners to direct a needle, guided by ultrasound, through the vagina to extract the eggs. Oocyte recovery is a difficult procedure because the physician must guide the needle to the ovary without puncturing other vital organs.

After their successful removal, the eggs are transferred to culture medium containing some of the mother’s blood serum. Here the eggs are maintained at constant temperature (98°F), pH, and osmolarity, and depending on how ripe the eggs appear, sperm may be added to the eggs immediately or as much as a day later. The sperm must also be obtained and prepared for IVF. Sperm are prepared for insemination by replacing the fluid part of the semen with artificial medium and holding them at room temperature for a few hours, which increases their fertility. In the case of subfertile men, additional steps may be taken to concentrate and stimulate the motile sperm, as well as to remove the dead cells and debris. Then, several thousand sperm are placed in droplets of culture medium, and eggs are transferred into the droplets. The eggs are examined after about 24 hours to determine the rate at which fertilization occurred, which under normal conditions will exceed 75%.

The development of the embryo outside the uterus is critically important to IVF. Once the embryos have divided two to four times, forming four to eight cells, two to four embryos are inserted through a catheter into the cervix of the woman’s uterus. This is referred to as embryo transfer. Prior to the embryo transfer, the woman is injected with progesterone to prepare the uterus for im-

20. Id. at 26.
22. Id. at 26.
24. Id.
25. Id.
26. Id.
27. Id.
28. Id.
29. Id.
plantation.\textsuperscript{32} If the embryo is introduced into the uterus too soon or too late, implantation will not occur.\textsuperscript{33} Pregnancy is achieved if implantation occurs. Although implantation is technically simple, it is a critical process. It is at this stage that most IVF cycles are unsuccessful.\textsuperscript{34} A low success rate of 21.2\%\textsuperscript{35} could perhaps be due to endometrial inadequacy in the uterus.\textsuperscript{36}

Studies indicate that the likelihood of getting pregnant with IVF diminishes with each consecutive attempt.\textsuperscript{37} The success rate drops with each procedure, from 13\% on the first IVF to 4.3\% by the fourth try.\textsuperscript{38} Despite these discouraging statistics, many women return for two, five, and some for more than ten cycles.\textsuperscript{39}

\textbf{B. Variations of IVF}

Modern reproductive technologies have provided society with options and hope for those who otherwise will not be able to conceive. In 1993, the United States had over 267 IVF institutions\textsuperscript{40} with a large number of these operating for profit.\textsuperscript{41} An estimated 31,900 IVF treatment cycles occur within these clinics annually.\textsuperscript{42} Unfortunately, less than 15 percent of these treatment cycles lead to a live birth.\textsuperscript{43} Consequently, the need for research to perfect these procedures and minimize risks to women is great.

After the introduction of IVF in 1978, medical expertise has led

\begin{itemize}
\item \textsuperscript{32} Id.
\item \textsuperscript{33} Id.
\item \textsuperscript{34} Id.
\item \textsuperscript{35} Begley, supra note 14, at 40.
\item \textsuperscript{36} The endometrium is the uterine lining. Normal preparation of the endometrium is essential for embryo implantation and early pregnancy maintenance. Because of the high estrogen levels resulting from the hormonal ovulation induction, endometrial inadequacy can be seen in a number of women. McShane, supra note 31, at 37.
\item \textsuperscript{37} Geoffrey Cowley, The Future of Birth, Newsweek, Sept. 4, 1995, at 42, 45.
\item \textsuperscript{38} Id.
\item \textsuperscript{39} Raymond, supra note 7, at 8.
\item \textsuperscript{40} American Society for Reproductive Medicine, Assisted Reproductive Technology in the United States and Canada: 1993 results generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry, 64 Fertility and Sterility No. 1, 13 (July, 1995) [hereinafter 64 Fertility and Sterility No. 1]. This study found that out of 31,900 IVF cycles/procedures, only 6,321 resulted in pregnancies with only 5,103 deliveries. Out of 4,992 GIFT cycles/procedures, there were 1,472 pregnancies with 1,182 deliveries. Finally, with 1,792 ZIFT cycles/procedures, there were only 466 pregnancies with 380 deliveries.
\item \textsuperscript{41} Raymond, supra note 7, at 8.
\item \textsuperscript{42} 64 Fertility and Sterility No. 1, supra note 40, at 15.
\item \textsuperscript{43} John A. Robertson, Children of Choice: Freedom and the New Reproductive Technologies 9 (1994).
\end{itemize}
to the development of several variations of IVF such as GIFT, ZIFT, and superovulation with fertility drugs. Metrodin and Pergonal are hormone drugs used to superovulate women on IVF programs so that they produce multiple eggs. These drugs can result in increased ovulation with multiple gestations and premature delivery or pregnancy loss. The dangers of superovulation are the resulting overstimulation and enlargement of a woman’s ovaries with potential rupture, cysts, and cancer.

Pregnancy rates with GIFT are reported to be 5 to 10% higher than with IVF. There is a noted advantage of GIFT for women aged forty and over whose eggs are more sensitive to external conditions that may influence the egg’s likelihood of achieving a pregnancy. Although this procedure allows for a more natural process of fertilization, since it occurs in the woman’s body rather than a glass dish, the disadvantage is the necessity of a laparoscopy and the increased risk of having multiple pregnancies that can lead to a wide array of medical and psychological complications.

ZIFT, a hybrid of IVF and GIFT, involves vaginal egg retrieval and fertilization in the laboratory after which time the embryo is replaced directly into the fallopian tube rather than the uterus through laparoscopy.

This increase in scientific knowledge and technological abilities is accompanied by equally significant problems and controversies. The following sections will discuss the intense debates focused on the consequences of these technological developments and the ethical, social, and legal implications of IVF.

44. BLANK & MERRICK, supra note 1, at 87.
45. Id.
47. Id.
48. RAYMOND, supra note 7, at 13.
49. Begley, supra note 14, at 41.
51. Atlanta Reproductive Health Centre, Laparoscopy (visited Mar. 6, 1997) <http://www.ivf.com/lararcsopy.html> (Laparoscopy is a surgical procedure where an incision is made in the area of the umbilicus (navel), and a telescope-like instrument (laparoscope) is inserted and used to view the ovaries. The ovarian follicles, which contain the mature eggs, are located and using a special needle, the fluid inside each follicle is suctioned out).
52. BLANK & MERRICK, supra note 1, at 91.
53. Id.
III. Abuses and Concerns

A. The Fates of Surplus Embryos

Given the market demands for IVF utilization by infertile couples for whom the procedure is their final means of having a biological child together and the absence of procedural controls over IVF clinics, severe abuses of IVF have occurred. One of the most controversial issues deals with the treatment of surplus embryos.

During a woman’s initial IVF cycle, three to four of the embryos created are transferred to the uterus.\textsuperscript{54} Implantation of multiple embryos increases the possibility of multiple pregnancies.\textsuperscript{55} One study noted that “at the time of the procedure 88 women had triplets, 89 had quadruplets, 16 had quintuplets, and 7 had from 6 to 9 fetuses. These pregnancies were reduced to 189 sets of twins, 5 sets of triplets, and 6 singletons . . . .”\textsuperscript{56} The result of these multiple pregnancies is that fetal reduction is used to terminate a certain number of fetuses.\textsuperscript{57} Since fetal reduction terminates the pregnancy, legal issues similar to those regarding abortion are implicated.

Other legal issues arise with regards to the cryopreservation\textsuperscript{58} of remaining embryos for thawing and transfer at a later date.\textsuperscript{59} The rationale provided by doctors in favor of freezing embryos is that it is in the best interests of the patient to maintain a reserve.\textsuperscript{60} However, accessibility to the reserves presents the problem of unauthorized use of the embryos for research, donation, and discard.\textsuperscript{61} While some IVF programs permit the couples to decide the destiny of their extra embryos, other programs apply strict policies conforming either to

\begin{itemize}
\item \textsuperscript{54} McShane, \textit{supra} note 31, at 37.
\item \textsuperscript{55} \textit{Blank} \& \textit{Merrick}, \textit{supra} note 1, at 92.
\item \textsuperscript{56} \textit{Id.}
\item \textsuperscript{57} \textit{Raymond}, \textit{supra} note 7, at 14. Fetal reduction is where the pregnancy is terminated, similar to an abortion.
\item \textsuperscript{58} \textit{Robert H. Blank}, \textit{Regulating Reproduction} 67 (1990). Cryopreservation involves freezing of the embryos upon reaching the two-eight cell stage of division. They are then gradually cooled to minus 196 degrees Celsius and stored in liquid nitrogen until time for implantation when they are thawed and placed in the uterus.
\item \textsuperscript{60} \textit{See generally} Andrea Bonnicksen, \textit{Ethical Issues in the Clinical Application of Embryo Freezing}, in \textit{Issues in Reproductive Technology I: An Anthology} 217 (Helen B. Holmes ed., 1992).
\end{itemize}
Despite these formal policies, the practice of using preserved eggs in other women who are unable to produce their own eggs has been widely exploited by clinics and physicians. Until October 1996, embryo theft was not a criminal offense in California. Recent allegations of physicians stealing eggs from anesthetized women for subsequent implantation in other infertile women has led to closer scrutiny. In June 1995, the once famous Center for Reproductive Health at U.C. Irvine, California, was forced to close its doors after charges of improper egg and embryo handling. Rapid growth of IVF services increases the possibility that clinics will be improperly staffed or will not maintain rigorous quality control, resulting in such exploitation.

In response to the U.C. Irvine situation, Senator Tom Hayden authored a bill making it a felony to transplant eggs without donor consent. The California legislature passed the bill in 1996, thus criminalizing such unethical and abusive practice. This bill makes it a felony punishable by up to five years in prison and/or a fine of up to $50,000 to knowingly use sperm, ova, or embryos in assisted reproduction without written consent of the donor and recipient, except in the case of sperm donations to licensed tissue banks.

Furthermore, California State Assemblywoman Jacqueline Speier authored a bill related to the consent issue in reproductive technologies which was also passed by the legislature in 1996. This bill requires a physician who removes sperm or ova from a patient, to obtain the patient’s written consent prior to using the sperm or ova for purposes other than reimplantation in the same patient or implantation in the patient’s spouse. Violation of the bill’s provisions constitutes unprofessional conduct, not a misdemeanor, and subjects a

64. Nina Martin, Scrambled Eggs, CAL. LAW., Oct. 1995, at 21-22. See also S.J. MERCURY NEWS, Jan. 20, 1997 at B3. Dr. Sergio Stone, one of the doctors involved in the stolen eggs scandal faces only mail fraud charges when his trial begins on Tuesday January 20, 1997. Even though seven to twelve children are believed to have been born from the misappropriated eggs, Stone does not face criminal charges in connection with such reproductive theft because at that time, there was no law against it. Two other doctors involved in the scandal, Dr. Asch and Dr. Balmaceda fled the United States before they could be arrested.
69. Id.
physician who violates the bill to civil penalty payable to the person whose required consent was not obtained. Such penalties range from $1,000 to $5,000 plus court costs for a second violation. While this is encouraging, many other states have not followed suit.

B. Who Controls the Frozen Embryos?

Cryopreservation is further complicated when the parental bond between couples is terminated as a result of divorce, separation, or death. The legal status of embryos receives different treatments in the lower courts nationwide. The emerging technologies raise questions that have yet to be resolved in the courts. The existing statutes and constitutional theories have become less and less adequate to protect reproductive choice. Thus, the need for regulation on these issues is urgent to avoid results similar to those described below.

In *Davis v. Davis*, the genetic father fought with the genetic mother after their divorce regarding the disposition of seven frozen embryos that remained after their earlier attempted use of IVF. Mrs. Davis argued that she had the authority over the disposition of the frozen embryos. She asserted that she could have them transferred to her in order to become pregnant or she could give permission to have them transferred to another woman. Mr. Davis, who did not want to have children, argued that he had a say over the disposition of the pre-embryos and thus could veto his ex-wife’s decision.

The trial court awarded custody of the pre-embryos to Mrs. Davis, finding that frozen pre-embryos were human beings and should be handled in a custody dispute as children. Reversing the trial court decision, the Tennessee Court of Appeals stated that awarding custody to Mrs. Davis violated Mr. Davis’s constitutional right not to beget children. The Court of Appeals awarded joint custody over disposition of the pre-embryo.

The Supreme Court of Tennessee rejected both the notion that a pre-embryo is a legal person and that it is a form of property to be disposed of as is other property in a divorce case. Instead, the court

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70. Id.
72. Id. at 592.
73. Id.
74. Id.
77. Id.
held that pre-embryos "occupy an interim category that entitled them to special respect because of their potential for human life."\textsuperscript{79} Both the husband and the wife, as gamete providers, were held to have "decision making authority concerning the disposition of the pre-embryos, within the scope of the policy set by the law."\textsuperscript{80} The court stated that a prior agreement between the couple for disposition of the frozen embryos in the case of divorce would need to be enforced.\textsuperscript{81} Since there was no prior agreement between the husband and wife, the court had to decide which of the two gamete providers would prevail in this dispute. The husband's desire to avoid "genetic parenthood" was given preference in \textit{Davis} due to the fact that he should not be compelled to become a father against his will. The court opined that "the technological fact that someone unknown to these parties could gestate these pre-embryos does not alter the fact that these parties, the gamete providers, would become parents in that event . . . . Ordinarily, the party wishing to avoid procreation should prevail, assuming that the other party has a reasonable possibility of achieving parenthood by means other than use of pre-embryos in question."\textsuperscript{82}

In justifying its decision, the Tennessee Supreme Court pointed to alternatives available to the woman such as adoption and IVF cycles with a new partner.\textsuperscript{83} The Court further stated that if the party seeking control of the pre-embryos intends merely to donate them to another couple, the objecting party obviously has the greater interest and should prevail.\textsuperscript{84} The \textit{Davis} case illustrates that a woman's rights may be considerably diminished by these new technologies because a woman who chooses to freeze her eggs may not be able use them later if the biological father does not want to be a parent.

In contrast, a Virginia court in \textit{York v. Jones}\textsuperscript{85} ruled on an injunction regarding the disposition of a pre-zygote and concluded that the pre-zygote was defined as property and therefore lacked a moral status.\textsuperscript{86} Declining to give the embryo any moral status, the court denied the embryo the benefit of any rights. In \textit{Jones}, the couple had moved from Virginia to California and had informed their IVF pro-

\textsuperscript{79} Id.
\textsuperscript{80} Id.
\textsuperscript{81} Id.
\textsuperscript{82} 842 S.W.2d at 603-04.
\textsuperscript{83} Id. at 604.
\textsuperscript{84} Id.
\textsuperscript{86} Id. at 425-26.
gram in Virginia that they wished to transport their frozen embryos to California to be thawed and placed in the wife by their Californian physician.\textsuperscript{87} Upon refusal by the Virginia program to follow the couple's instructions, the couple sued the clinic.\textsuperscript{88} The court ruled on the assumption that the embryos are the property of the gamete providers and found that any transfer of their ownership rights must be explicitly documented.\textsuperscript{89} Relying on the terms of the agreement between the Yorks and the clinic, the court found that the Yorks had limited their choices regarding the disposition of their embryos.\textsuperscript{90} Nonetheless, the \textit{York} court, finding that a bailment relationship existed between the Yorks and the clinic, agreed that the clinic must agree to the transfer because the frozen embryos were the property of the Yorks.\textsuperscript{91}

These two cases illustrate that courts are not consistent in their treatments of frozen embryos. Some federal regulation is necessary to clarify the legal status of the frozen embryos to avoid further confusion and inconsistency in the law.

\textbf{C. Ethical Concerns}

In addition to raising legal issues, the freezing of embryos raises additional conflicts between the ethical dimensions and technological capabilities of IVF. In 1990, 23,865 embryos were frozen as a result of the IVF process, an approximate 62\% increase from 1988.\textsuperscript{92} Cryopreservation permits the combination of germ cell materials from persons of different generations.\textsuperscript{93} Consequently, identical twins may be created years or even generations apart, thus challenging the structure of family relationships.\textsuperscript{94} As well, the ethical concerns are related to the length of storage and the consequent harm to the embryo cells. Frozen-thawed embryos divide and result in preg-

\begin{itemize}
\item \textsuperscript{87} \textit{Id.} at 424.
\item \textsuperscript{88} \textit{Id.}
\item \textsuperscript{89} \textit{Id.} at 427.
\item \textsuperscript{90} \textit{Id.} at 425.
\item \textsuperscript{91} \textit{York}, 717 F.Supp. at 425.
\item \textsuperscript{92} \textit{Robertson}, \textit{supra} note 43, at 109. Not only can the embryos be frozen but so can the unfertilized eggs. The issue arises due to the fact that embryos can survive for many years through cryopreservation, however, unfertilized eggs are extremely fragile and more than half of those frozen disintegrate upon thawing. Those that survive can be fertilized, but the resulting embryos rarely develop properly or implant in the womb. They are more likely to be aborted as they gestate. \textit{Cowley}, \textit{supra} note 37, at 42.
\item \textsuperscript{93} \textit{Blank & Merrick}, \textit{supra} note 1, at 88.
\item \textsuperscript{94} \textit{Id.}
\end{itemize}
nancies at a lesser rate than do fresh embryos.95

D. Administrative Concerns

Not only do IVF procedures raise legal and ethical issues, the monitoring and reporting of successful IVF procedures also implicate administrative concerns. Methods of reporting significantly influence the derivation of the actual success rate. A national success rate has been difficult to determine because most IVF clinics have differing definitions of IVF successes and, therefore, differing reporting methods. In figuring the total pool from which to derive the success rate, some clinics consider all applicants including women who dropped out of the program, regardless of the reasons for withdrawal, while others base their success rates on clinical pregnancy per attempted egg recovery trial rather than on live births.96 The variance in success rates lures hopeful women to the IVF institutions and encourages extensive financial and emotional investments in programs with questionable credibility.

The need to provide IVF consumers with accurate information was championed by Congressman Ron Wyden who demanded uniform reporting of IVF success rates.97 Congressional hearings by Representative Wyden on the efficacy and competence of IVF programs were initiated.98 As a result of the hearings, the Fertility Clinic Success Rate and Certification Act was enacted in 1992, mandating that live birth rates be reported annually to the Centers for Disease Control.99

Nevertheless, budget constraints have not allowed this program to be implemented. Although the American Society for Reproductive Medicine (ASRM)100 and the Society for Assisted Reproductive Technology (SART) now maintain a database of various IVF clinics that voluntarily submit their information, there is no mandatory re-

95. Id. at 110.
96. RAYMOND, supra note 7, at 11.
97. Id. at 115.
98. Consumer Protection Issues Involving In Vitro Fertilization Clinics: Hearings Before the Subcomm. on Regulation and Business Opportunities of the House Comm. on Small Business, 100th Cong. 33 (1988) (statement of Richard Marrs, Director of the Reproductive Center at Good Samaritan Hospital, concluding that "regulatory control is badly needed because of the proliferation of centers doing IVF.")
99. 42 U.S.C. § 263a-7 (1988 & Supp. IV 1992). The Act defines the live birth rate as the ratio of live births divided by the number of ovarian stimulation procedures tried at each program, and the number of successful egg retrieval procedures performed by each program. Id. § 2(b)(2)(A), (B).
100. Formerly The American Fertility Society.
requirement that all IVF clinics contribute their statistics to this ASRM-SART database. The ASRM, composed of clinicians and researchers involved with these technologies, claims to monitor itself. Although being a SART member requires a clinic to report its statistics to the registry, the problem is that many clinics are inactive or are not SART members. Obtaining an accurate consensus on success rates is further complicated because many physicians who own and operate their own businesses are not compelled to report any data. The SART guidelines for professional IVF clinicians only sets minimum standards and have no authority behind them to ensure compliance. Enforceable federal regulations, including legal sanctions for violations, are necessary to ensure compliance.

E. Economic and Socioeconomic Concerns

The concerns raised by IVF are certainly not limited to the legal, ethical, and administrative realms; on a more personal front, economic and socioeconomic issues must be addressed. A mere 10% of the women who ascribe to the IVF treatments are rewarded with pregnancies and the joys of motherhood. Despite this low "return on investment," women continue to spend as much as $50,000 on IVF programs. At an estimated $8,000 to $12,000 cost per IVF cycle, it is easy to determine that the profitability of private clinics is a function of the number of cycles serviced. Aggressive marketing techniques with exaggerated success rates are an all too common means of luring desperate and vulnerable parent-hopefuls. Although the use of sophisticated reproductive technologies justifies a portion of the medical fees, clinics are not shy about relying on the emotional desperation of childless couples to inflate the asking price. The high cost of reproductive technologies and lack of standard regulations


102. RAYMOND, supra note 7, at 12.

103. 64 FERTILITY AND STERILITY No.1, supra note 40, at 18.

104. 64 FERTILITY AND STERILITY No.3, supra note 101, at 539.

105. BLANK & MERRICK, supra note 1, at 21.


107. BLANK & MERRICK, supra note 1, at 89. See also, Begley, supra note 14, at 40. (Fertility drugs, diagnostic tests, laparascopy costs, surgery fees are examples of the costs involved).

allow the providers of IVF ample opportunities to exploit and profit from the resources.¹⁰⁹

The costs associated with reproductive technologies present additional problems on a socioeconomic level. Social factors are important determinants of acceptance and resistance to technological innovations, of how these innovations emerge and are disseminated, and of whom they affect.¹¹⁰ Reproductive technologies provide choices for affluent middle-class couples who are free to give informed consent for their use; however, the same privilege is denied to the less affluent.¹¹¹ The potential IVF patient selection criteria utilized by many clinics such as age, marital status, and financial ability are additional obstacles to overcome. Furthermore, many states exclude such services as IVF under the Medicaid program.¹¹² Hence, for poor women, who have higher infertility rates than upper-middle class women, access to such technologies is slim.¹¹³

A couple of factors have affected the unavailability of reproductive technologies to the lower class: the lack of insurance coverage for such procedures and the lack of Congressional initiatives to provide the infertile poor with alternative means ofaffording the technologies.¹¹⁴ While insurance companies will not pay expenses for diagnosis of infertility, they may pay for “diseased-sounding diagnosis.” Over $1 billion is spent annually on health care to try to help infertile couples get pregnant.¹¹⁵ Some is paid by insurance companies only because of diagnoses that are used by health providers to disguise the word “infertility.”¹¹⁶

In a 1992 policy statement, The American Fertility Society (AFS) and The American College of Obstetricians and Gynecologists (ACOG) recognized infertility as “disease resulting in the abnormal function of the reproductive system.”¹¹⁷ Despite this recognition of infertility as a disease, the United States Congress has not acted to

¹⁰⁹. Burfoot, supra note 13, at 69.
¹¹⁰. See generally Blank & Merrick, supra note 1.
¹¹¹. Blank & Merrick, supra note 1, at 227.
¹¹⁴. See generally Clayton, supra note 113, at 92.
¹¹⁶. Id.
regulate IVF nor to mandate funding of treatments under health insurance policies. Treating infertility like any other disease would mean that it would have to be covered under insurance as a health risk. A projected cost of adding IVF to a standard health care benefits package in 1995 would be $2.79 per year and the premium would be $3.14. This illustrates that the cost of IVF services would be a small fraction of the annual cost of a typical family benefits program. As costs escalate due to inflation, technological advances and decreases in insurance coverage, increasing numbers of Americans are being priced out of infertility treatments. This creates a disparity in that the rich benefit from IVF whereas the poor are forced, economically, to eliminate IVF as an option.

In response to this crisis, consumer groups have actively pursued legislative insurance reform, arguing that infertility coverage would not significantly increase insurance industry costs. Eight states currently have laws addressing insurance coverage for IVF treatment specifically. The California legislature has made explicit judgment that, although infertility is a medical condition that group insurance should cover, coverage of IVF treatment should not be mandated. Arkansas, Connecticut, Hawaii, Illinois, Maryland, and Texas have adopted statutes that explicitly include IVF treatment in either a mandate to offer or a mandate to provide.

The courts have been struggling with the interpretation of health insurance contracts and the provisions regarding coverage of infertility procedures, usually in regard to reimbursement of assisted reproductive technologies (ART). A few of the decisions have affirmed insurance companies' denials of coverage of ART the other infertility procedures. However, several decisions favored reimbursement of

118. 64 FERTILITY AND STERILITY No.3, supra note 101, at 538.
119. Id.
120. Id.
121. Id.
123. See CAL. HEALTH & SAFETY CODE § 1374.55(a) (West Supp. 1996). The law mentions only group health service plans and thus does not apply to health maintenance organizations (HMOs), individual health insurance plans, or public health insurance.
126. See Thomas v. Truck Drivers & Helpers Local No. 355, 771 F. Supp. 714 (D. Md.)
these claims and obligated the insurer to pay.127

IV. CURRENT IVF POLICIES AND GOVERNMENT INVOLVEMENT

Policy on IVF today combines self-regulation by the private sector, existing laws designed to protect subjects of research, and a few state laws dealing directly with IVF. While some states recognize the need to regulate in this area, many states do not. This is the source of the inconsistent outcomes in legal disputes resulting in continued unethical practices in the business.

A. Assisted Reproductive Technology Act

The phenomenal growth of the industry and its technological advances have been supported primarily by private funding.128 There has been little effort by the states or the federal government to fund assisted reproduction. Existing federal involvement in IVF gives the Secretary of Health and Human Services the power to oversee assisted reproductive technologies.129

On October 24, 1992, the Assisted Reproductive Technology Programs Act (the ACT) was enacted to address such issues as reporting of success rates to the Secretary through the Centers for Disease Control.130 In addition, the ACT required the Secretary to develop a model program for the certification of embryo laboratories to be carried out by the states,131 to distribute a description of the certification program to government officials of each state, and to encourage such officials to assist the state in adopting the program.132

Unfortunately, the ACT does not mandate states to implement a certification program. If a state wishes to adopt the certification program it must first submit an application to the Secretary, who retains the authority to approve or reject the certification request.133 On its face, the ACT appears to be an appropriate measure to regulate IVF

133. 42 U.S.C. § 263a-2(e).
because it provides for guidelines and standards to assure consistent performance of procedures by each embryo laboratory under the certification program, to assure a quality control program, and to provide for a standard for the maintenance of records on laboratory tests and procedures performed. Nonetheless, the ACT fails to protect the interested parties of IVF because the Secretary does not have any power to establish any regulation, standard, or requirement that has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs. Consequently, the IVF practitioners are free to perform procedures for profit without governmental regulation.

Additionally, clinics may continue to operate regardless of whether or not the states apply to the certification program or receive certification approval from the Secretary. Consequently, the establishment of a voluntary certification program by Congress for embryo laboratories fails to fulfill the existing need for clinics’ standardization and internal control. Furthermore, the program, to be monitored by the Centers for Disease Control, has not gone into effect because of budget constraints. Thus, the abuses continue due to lack of any comprehensive regulation of the IVF procedures in the various states.

Unlike the United States, the United Kingdom recognizes the importance of regulation and an active government role in the treatment of infertility. In 1992, an estimated one out of every six couples was infertile in the United Kingdom. The total number of women with impaired fertility was 5.3 million, or 9.1% of all women aged 15-44. The U.S. need for research in infertility is similar to that of the United Kingdom, and it would seem appropriate to spend some of the money used in the assisted reproductive technology business for research to determine the causes of infertility in the

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139. In the United Kingdom, the regulation of IVF is rigorous and all centers must report all treatment cycles on all patients indicating exactly what was done. See Gianelli, supra note 138, at 29. Unlike the United States, the Minister of Health in Victoria, Australia regulates the clinics where IVF procedures are performed pursuant to the Infertility Act of 1986. See Rptr. H.R.L. No. 20, 231-2 (1989).
140. See BLANK, supra note 58, at 143-144.
141. BLANK & MERRICK, supra note 1, at 85.
United States.

IVF is merely a solution to childlessness, not a cure for infertility. The causes of infertility include environmental, heritable, pathological, and sociobehavioral factors. By keeping the federal government involved in the research of infertility and assisted reproductive technologies, rather than just using private funds, debate of the issues surrounding IVF and other reproductive technologies and research findings would be kept in the public domain. This would also benefit potential users of such technologies because they would have accurate and current information which would allow them to better give their informed consent when undergoing such treatments.

The call for federal regulation of IVF programs is justifiable. As "consumers" of IVF technologies, couples are oftentimes too emotionally involved to maintain an objective and cautious stance toward the practices of institutions and individuals providing the service. But the federal government has done nothing except to suggest regulating licensing of IVF clinics by the voluntary certification program. Protecting consumers from fraud, misrepresentation, and incompetent practitioners by implementing a uniform regulatory scheme nationwide is necessary. Unethical conduct by doctors who use women and their gametes and embryos as commodities to make a profit must be addressed by the federal government as a national policy.

B. Research

Federal interest in IVF peaked at approximately 1979, but after the Department of Health, Education and Welfare failed to approve the application for research that formed the basis of the report of the Ethics Advisory Board, federal interest in IVF waned. In 1980, the Ethics Advisory Board dissolved, creating what has been characterized as "an official moratorium on all Federal funding and oversight of IVF research." In 1988, the Department of Health and Human Services reconstituted the Ethics Advisory Board at the same time the Office of Technology Assessment issued its comprehensive re-

142. Id.
143. Id.
146. Id. at 685.
port on infertility. Legislation was passed in 1993 which made it possible to fund IVF research once again. The Embryo Research Panel of the NIH was commissioned subsequent to this legislation to provide recommendations on federal funding for embryo research. However, within hours of receiving the panel’s recommendations, President Clinton ordered the NIH not to spend any federal funds to create embryos for research.

Undoubtedly, research in the private sector will continue regardless of the availability or lack of federal funds. But, the failure of the federal government to fund IVF research has placed the research outside of public control and into private control. Federal funding of IVF research would place the heated debates in the public arena and allow for more control and focused goals in the research.

V. THE CONSTITUTIONAL BASIS FOR IVF REGULATION

IVF technology focuses on the earliest stages of human life. The United States Supreme Court has held that the freedom to decide whether or not to have children and to control the use of one’s reproductive capacity is a valuable right. In Griswold v. Connecticut, the Court found a state law pronouncing the use or distribution of contraceptives to be a crime unconstitutional. In maintaining the right of persons to avoid reproduction through contraception, the Court established a general principle that reproductive choice is a fundamental liberty right of married couples and, as later extended, of unmarried couples.

Under Roe v. Wade, whose central holding was reaffirmed in 1992 in Planned Parenthood v. Casey, women, single or married,
adult or minor, have a right to terminate their pregnancy up to viability. Alas, Casey allows states to discourage abortion through reasonable waiting periods before obtaining an abortion, informed consent, and other regulatory requirements, thus modifying the rigid protection provided for in Roe by establishing a stricter test.157

Procreative liberty is a right against government interference with choices to procreate or to avoid procreation.158 Therefore, it would seem logical that any restriction or regulation of these technologies would interfere with or limit procreative freedom. Hence, the law’s recognition of a right to avoid reproduction provides the legal framework for resolving conflicts presented by the new reproductive technologies such as IVF.

In applying the above cases to IVF, a law banning IVF would undoubtedly be found unconstitutional because it would interfere with the right to procreate. Nevertheless, the objective in this instance is not to ban but to regulate the IVF clinics and its practitioners so that consumers are not exploited by false and misleading statistics and information. The federal government must play a role in ensuring that persons who choose IVF have accurate information about the pros and cons of IVF treatment and are provided with better protection against the risks inherent in the treatment process.

One of the reasons why the federal government should be involved in IVF research is to protect women against the potential harm from IVF procedures. The risk IVF procedures include ovarian hyperstimulation syndrome and heightened incidence of breast, genital, and hormone-dependent cancer linked to superovulation.159 If the federal government funds the research in this field, as it already funds other biomedical fields under the NIH,160 then federal regulation and supervision of IVF would be possible. Federal support of IVF research and practice would facilitate federal regulation of the procedure. Considering that the right to procreate or not to procreate is a fundamental right161 and that various products dealing with reproduc-

157. The Casey majority held that, “Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, childbearing and education . . . [These] matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment.” Id. at 851 (citation omitted).

158. Robertson, supra note 43, at 23.


160. E.g., The Human Genome Project.

161. See generally Roe, 410 U.S. 113; Casey, 505 U.S. 833.
tion are already being marketed, Congress' constitutional commerce power would be a viable means by which to regulate IVF procedures.

In a similar exercise of its Commerce Clause power, Congress enacted the National Organ Transplant Act (Transplant Act) in 1984. Title III of the Transplant Act provides that "it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce." The "human organ" is defined as "the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone or skin." Violation of the Transplant Act means a five year maximum prison term plus a $50,000.00 fine. Since it would probably be too far fetched to interpret "human organ" to include frozen embryos and given the high risk of abuse in this area, Congress needs to enact a separate comprehensive regulation dealing exclusively with assisted reproductive technologies.

VI. PROPOSED REGULATION

I would like to make the following regulatory proposals based on the Warnock Committee Report.

162. Marketing of human reproduction has already begun in the form of sex pre-selecton kits, genetic screening devices, for-profit sperm banks and surrogacy.

163. U.S. v. Lopez, 115 S. Ct. 1624 (1995), illustrates that some limits still exist on Congress's Commerce Clause powers. Congress must include explicit findings in the statute that the activity being regulated substantially affected commerce. It is not enough that the activity being regulated merely "affects" interstate commerce; the activity must "substantially affect" interstate commerce. See also NLRB v. Jones & Laughlin Steel Corp., 301 U.S. 1 (1937) (the Court substantially loosened the nexus required between the intrastate activity being regulated and interstate commerce); Wickard v. Filburn, 317 U.S. 111 (1942) (expanded Commerce Clause power via the cumulative effect theory. That theory provides that Congress may regulate not only acts which taken alone would have a substantial economic effect on interstate commerce, but also an entire class of acts, if the class has a substantial economic effect, even though one act within it might have virtually no interstate impact at all.).


165. Id.

166. Id.

167. Id.

168. BLANK, supra note 58, at 142-7. The Warnock Committee was established by the British Parliament in July 1982. In June 25, 1984, the Committee under the direction of its chairman Dame Mary Warnock made the influential report containing 64 separate recommendations for dealing with these emerging ethical and legal issues in the new reproductive technologies. DEPT. OF HEALTH AND SOC. SEC., 98TH CONG., REPORT OF THE WARNOCK COMMITTEE ON HUMAN FERTILIZATION AND EMBRYOLOGY (1984).
SHORT TITLE
The Assisted Reproductive Technologies Act may also be cited as ART ACT.

DEFINITIONS
The following words and phrases shall have the following meanings in the ART ACT.

“Gamete” means the egg (ovum) and the sperm (spermatozoa).
“Person” means individual, corporation, government, agency, business, partnership, or association or any other legal entity.
“Pre-embryo” means the cell mass that results for research in the causes and cure of infertility.
“In-vitro” means fertilization in a glass, outside of the womb.

A. FUNDING
Sufficient federal funding shall be made available for the collection of adequate statistics on infertility and infertility services.
1. Federal funds shall be used for research in the causes and cure of infertility.

B. LICENSING COMMITTEE
To regulate the research and the infertility services, a licensing committee shall be established.
1. The licensing committee shall include representation by laypersons and members who represent medical administration and personnel and physicians with knowledge or skill in the field of reproductive technologies.
2. The licensing committee shall oversee any treatment or research involving human embryos created in vitro or taken from the womb of the mother.
3. The licensing committee shall be responsible for licensing and collecting data on facilities offering reproductive services.
4. The licensing committee shall maintain a central data bank of all gamete and embryo donations and live births resulting from these donations.
5. The licensing committee shall receive from each licensed clinic monthly records of the type of service offered (IVF, GIFT, ZIFT), the number of cycles attempted, the number of live births, the number of failed attempts, and the ages of the patients.
6. The licensing committee shall review the data as it
evolves and publish a report each year.

7. The annual report shall contain:
   a. the names of the licensed clinics;
   b. the types of services offered;
   c. the number of attempted cycles of IVF and other kinds of services such as ZIFT and GIFT;
   d. the number of failed attempts at IVF, ZIFT, GIFT; and
   e. the ages of the patients.

8. This annual report shall be made available to each clinic and each potential client shall be given a copy of the annual report prior to obtaining any reproductive services.

9. The licensing committee shall conduct follow up studies of children born as a result of the new reproductive technologies.

C. EMBRYOS, SEMEN, EGGS

1. The sale of embryos or gametes shall not be permitted.

2. Written informed consent shall be obtained from the couple regarding the disposition of extra embryos prior to any reproductive treatment.

3. No research shall occur on the extra embryos without the written informed consent of the couple who produced the embryo.
   a. No pre-embryo that has been donated for use in research shall be transferred to a uterine cavity.
   b. The number of embryos required for research must be kept to the minimum.
   c. The donors of gametes or embryos must have given informed consent with regard to the nature and purpose of the specific research being undertaken.
   d. The research must only be conducted by scientifically qualified individuals in an appropriate research setting.

4. All semen and egg deposits shall be reviewed every five years, after which time, the right to use or dispose shall pass to the storage clinic.

5. Gametes and pre-embryos shall not be transferable by will or intestate succession.

6. Storage of embryos not to exceed a maximum of ten
years.
7. All potential clients shall be told about the semen, egg, and embryo policy regarding its disposition after the allotted time.

8. No live human embryo derived from in vitro fertilization, whether frozen or unfrozen, shall be kept alive, if not transferred to a woman beyond 14 days after fertilization, nor may it be used for research beyond the 14 days after fertilization.

D. PRACTITIONERS

1. The clinic and practitioners offering any reproductive services shall be licensed by the licensing committee, including the clinics providing for the storage of semen, sperm, human eggs, and embryos.
2. The qualifications and experience of the clinicians on staff at each clinic shall be reported to the licensing committee.
3. The physician shall obtain written informed consent from the patient prior to using the sperm or ova for purposes other than re-implantation in the same patient or implantation in the patient's spouse.
4. Physician shall provide a copy of the patient's written consent to any hospital in which the procedure to remove the patient's sperm or ova is performed.

E. PATIENTS

1. Counseling shall be provided to all couples and third parties involved in the reproductive process prior to and throughout the treatment.
2. Each potential client shall receive accurate statistics from the licensing committee regarding the success of the procedure they undergo. (Annual report by the licensing committee)
3. Each patient shall sign a written consent to the disposition of any unused donated materials.

F. SANCTIONS

1. Use of any of the reproductive techniques without an appropriate license from the licensing committee is a criminal offense.
2. A person who acts in willful noncompliance with any
part of the ART ACT:

a. shall be guilty of a criminal offense;
b. shall be liable for resulting damages.

3. Participating in the sale of embryos or gametes will result in a $60,000.00 fine and an 8 year maximum prison term.

   a. Utilizing the eggs or embryos from one patient and implanting in another patient without prior written authorization will result in loss of license and 5 year maximum prison term and $50,000.00 fine.

4. Performing reproductive services without a license from the licensing committee may result in $20,000 fine and 3 year maximum prison term.

5. Fraudulent actions and misrepresentations may result in maximum 8 year prison term and $35,000.00 fine.

6. Subsequent violations may result in double penalties.

7. The sanctions provided in this section are in addition to any other sanctions provided under applicable law.

VII. Conclusion

Regulation of reproductive technologies would be a solution to the potential for egregious abuses which currently exist. The advantages of federal involvement include a centralized forum for discussing reproductive techniques which would draw national attention in a way that debates within state legislatures fail to do. Restricting the abuses and legislating the contexts and conditions under which such technologies can be used would allow technological advances to be seen as progress. Such legislation should function as a quality control measure to eliminate those IVF clinics operating below federal standards. Thus, success rates could accurately be determined and the risks to women and children could be managed.

As this fast-growing technology reaches new levels by providing more advanced methods of assisting reproduction, the need to establish policies and control measures becomes urgent. The future could provide the use of such technologies in altering or developing specific characteristics of an offspring. Resolution of the controversies will determine how available these techniques become and their ultimate effects on society.

Some people believe that this technological control over reproduction has rendered the human being "master and owner of Nature."\(^{170}\) That is, by manipulating Nature scientists are playing God, thereby diminishing the mystery of conception and pregnancy.\(^{171}\) Implementation of a national policy would allow Congress to address societal values which would influence the boundaries and future direction of such reproductive technologies. "The technology is underway, but how we as a species choose to use it, where we allow it to be used, and when we draw limits are critical issues for all of us . . . ."\(^{172}\)

Finally, further investigation of infertility is warranted. Federal involvement must continue at a greater level to inform state legislatures and the public of the issues created by these new technologies. The medical profession's attempt to self-regulate the new assisted reproductive technologies must be addressed because patient exploitation and abuses persist. It is the responsibility of the federal government to examine and to regulate in vitro fertilization to protect consumers.

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172. Blank & Merrick, supra note 1, at 225.