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A SURVEY OF THE LEGAL, ETHICAL, AND PUBLIC POLICY CONSIDERATIONS OF IN VITRO FERTILIZATION

M. KAREN MCCARTAN*

Modern technology enables physicians to fertilize human ova *in vitro* and to transfer human embryos to the wombs of mothers. The practice of *in vitro* fertilization (IVF) provides a striking and dramatic example of a region where scientific, ethical and legal issues intersect and where the need for the guidance of the law is particularly urgent. A rapidly advancing technological civilization challenges a legal system which historically has responded to existing problems and seldom has anticipated them. While the law has demonstrated its capacity to meet new problems, the nature of the new reproductive technology demands an active rather than a reactive policy approach, for the failure of the law to keep pace with scientific development and to challenge some of the basic assumptions of a technological society could affect the future of humans as a species.

The role of the law in guiding scientific development has not been clearly established, and in fact regulation of scientific advancement has not been welcomed by those active in progressive areas of medical research. Still, according to Chief Justice Warren E. Burger, the law does govern the advancements of medical science. Upon reviewing an article which characterized law and medicine as two restless horses drawing the chariot of medical science but often pulling in conflicting directions, Burger claimed that "[t]he thrust of this analogy is sound, but I challenge the cast of characters. I would frame the analogy with one horse as the practicing physician, the other horse as the medical investigator while the chariot carries the human race. And whether one likes it or not, the law is the driver."¹ Burger would refuse to allow law to "steer" medical research but it has the duty to keep it within the "speed limits" of society.

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1. Burger, *Reflections on Law and Experimental Medicine*, 15 UCLA L. REV. 436, 440 (1968). Burger wrote this article while serving as Judge of the U.S. Court of Appeals of the D.C. Circuit.

I. THE STATE OF THE IVF ART

A. *Human Reproduction and the IVF Procedure*

For some in our society, fertility is not a condition taken for granted and the human reproductive system, in these unfortunate cases, is completely "inefficient." IVF offers help to the infertile, but the medical procedure is only partially efficient.² Still, many seeking the treatment are encouraged by the fact that since the birth of Louise Brown on July 25, 1978, more than 700 pregnancies have resulted from IVF and the subsequent transfer of the embryo to the womb of the mother.³

In order to fertilize human ova in the laboratory, the medical doctor must first harvest ova from the female. Since human females normally produce only one mature ovum per menstrual cycle, doctors often employ the technique of superovulation, that is, the administration of a hormone which induces the production of a larger than usual number of ova. The ova are secured from the female by means of a surgical procedure called laparoscopy in which a needle is inserted into the patient's abdomen under general anesthesia. The laparoscope allows visual sighting of follicles containing mature ova, and the ova are removed from the follicles by means of the needle. The timing of the operation is crucial because an egg will not develop properly if it is collected too early. If attempts at collection are too late, the ovary may al-

2. Dr. R.G. Edwards and Dr. P.C. Steptoe report that at Bourn Hall, Cambridge, embryos fertilized *in vitro* were replaced in the uteri of 1200 women. The "clinical" pregnancy rate rose from 16.5% from October, 1980, to almost 30% in 1983. See Edwards & Steptoe, *Current Status of In-Vitro Fertilisation and Implantation of Human Embryos*, 2 LANCET, 1265 (1983).

While the IVF procedure is not "totally efficient," neither is the process of natural human reproduction. That is, not every meeting of sperm and ovum results in the production of a viable embryo. One study estimates that in 16% of cases where human ova are exposed to sperm, fertilization fails to occur. When fertilization does occur, the rate of embryonic loss during the first week is estimated to be 18% and in the second week an additional 32%. According to this study, only 37% of human zygotes survive to be delivered subsequently as live infants. See ETHICS ADVISORY BOARD, DEP'T OF HEALTH, EDUCATION AND WELFARE, REPORT AND CONCLUSIONS: HEW SUPPORT OF RESEARCH INVOLVING HUMAN IN VITRO FERTILIZATION AND EMBRYO TRANSFER, 1 (1979) [hereinafter cited as Ethics Advisory Board Report].

3. Hogden, Statement Before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U.S. House of Representatives, August 9, 1984.

ready have released the egg, and the egg is then lost.

Following the successful harvesting of ova, technicians unite the ova with the sperm of a male in a laboratory medium and incubator to allow fertilization. The egg is studied at intervals to ensure that cell division is in progress. If the embryo has developed satisfactorily, the doctor will transfer it to the uterus of the female (usually on the second day following laparoscopy) via the cervical canal.⁴ The leading IVF research team in Australia and other research groups have shown that replacement of two or three embryos, rather than a single embryo, will substantially increase the chance of pregnancy. However the replacement of three or more embryos may lead to triplets or even higher order multiple pregnancies.⁵

When embryos are placed in the uterus, they are between the 2-cell stage and blastocyst (4 or 8-cell stage).⁶ At this early stage of development, all of the cells of the embryo are more or less equivalent. Once more than 16 cells are present, however, some distinctions between different types of cells begin to appear. These distinctions become more pronounced as division and growth continue and form the foundation for later differentiation of cells and organs.⁷ Approximately one week after fertilization, the blastocyst attaches to the uterine wall to continue further development. This stage is known as "implantation," and is the process during which the blastocyst sends fingers into the wall of the uterus as anchors. These fingers are composed of embryonic cells which manufacture hormones to support pregnancy; they also form the network of supporting tissues that will eventually become the placenta, nourishing the developing embryo and later the fetus. Two weeks after fertilization, the implantation process is complete.⁸

Clearly, the major benefit to be derived from IVF and embryo transfer is that it may enable otherwise infertile women to conceive and to bear children, but the procedure is not one without risks. The conditions under which the early embryo is cultured are not of primary concern because the

4. Ethics Advisory Board Report, *supra* note 2, at 2-3.

5. Tronson, Wood & Leeton, *Embryo Research*, AGE May 10, 1983, at 11.

6. Edwards & Steptoe, *supra* note 2 at 1266.

7. OFFICE OF TECHNOLOGY ASSESSMENT, FERTILIZATION, IMPLANTATION AND DEVELOPMENT 53 (1984) [hereinafter cited as OTA BACKGROUND PAPER.]

8. *Id.*

early mammalian embryo is highly resistant to damage from environmental insults. However, damage to the early embryo could result from aberrant development of ova, selection of sperm, the fertilization process or the freezing of gametes or embryos.⁹ Specifically, potential sources of damage are the following:

1. Superovulation may be correlated with an increase in chromosomal abnormality.¹⁰
2. The quality of sperm reaching and fertilizing the ovum *in vitro* may differ from the quality of sperm fertilizing the ovum in the course of natural reproduction, since the female reproductive tract selects against some types of abnormal sperm.¹¹
3. The quantity of sperm reaching the ovum simultaneously *in vitro* may break down the usual block to fertilization by multiple sperm; a polyploid embryo may result.¹²
4. The use of freezing techniques to preserve gametes or embryos may produce mutations.¹³

We cannot estimate with certainty the extent to which each of these sources of risk is likely to occur in clinical applications of IVF. As in the course of natural reproduction, natural selection against most embryos with serious chromosomal abnormalities seems to occur during pregnancy, particularly during the first eight weeks following fertilization.¹⁴ Still, one researcher notes that there is an estimated three percent additional risk of abnormality in offspring suggested by animal studies, and suggests that such an added risk would be acceptable, particularly in light of the fact that some couples who receive genetic counseling are not deterred from efforts to conceive children despite twenty-five percent risks of genetically abnormal offspring.¹⁵ A recognition of the risks involved in the IVF procedure has prompted some regulation of the novel treatment.

9. Ethics Advisory Board Report, *supra* note 2 at 45.

10. *Id.*

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.* at 2.

15. *Id.* at 46.

B. Regulation Concerning IVF

The only existing Federal control of human *in vitro* fertilization is a regulation of the Department of Health and Human Services concerning the protection of human subjects.

No application or proposal involving human *in vitro* fertilization may be funded by the Department or any component thereof until the application or proposal has been reviewed by the Ethical Advisory Board and the Board has rendered advice as to its acceptability from an ethical standpoint.¹⁶

Two additional general requirements of HHS regulations presumably apply to research involving human *in vitro* fertilization as well. All such research conducted or supported by the Department must be reviewed by a local Institutional Review Board (IRB);¹⁷ also, studies involving human IVF should not be conducted or supported by HHS unless "appropriate studies on animals and nonpregnant individuals have been completed."¹⁸ While other provisions of the HHS regulations limit "activities directed toward fetuses"¹⁹ as research subjects, "fetus" is clearly defined as that which exists from the time of implantation.²⁰ Therefore, the product of *in vitro* fertilization is not protected by these provisions prior to transfer and implantation in the uterus of a host.

Congress imposed a temporary moratorium on federally sponsored human *in vitro* fertilization research in 1973, after the National Institutes of Health received its first request for a grant for fetal research. The thirteen month moratorium was technically lifted in 1975, when the Ethics Advisory Board of the Department of Health and Human Services (then the Department of Health, Education & Welfare) proposed and published guidelines sanctioning carefully constrained research. The findings of the Ethics Advisory Board

16. 45 C.F.R. § 46.204(a) (1985).

17. 46 C.F.R. § 46.205 (1985). It is possible to claim, however that an IVF program is not research and that no IRB review and approval are necessary. One can argue that IVF is a *treatment* that uses a series of techniques, each of which has moved beyond the experimental stage, at least as far as risks to subjects is concerned. Still, institutions are advised to request IRB reviews since a procedure with so few successful outcomes is ordinarily deemed an experiment. See Edgar, *The Legal Implications: Are Restraints Likely?*, 20 CONTEMP. OB/GYN 233, 235 (1982).

18. 45 C.F.R. § 46.206(a)(1) (1985).

19. 45 C.F.R. § 46.208-46.209 (1985).

20. 45 C.F.R. § 46.203 (1985).

(EAB) have never been accepted by the Secretary of HHS (or HEW), the EAB has been disbanded, and no Federal grants have been approved for research on *in vitro* fertilization.²¹

There then has been a de facto moratorium on federally sponsored research on human *in vitro* fertilization in the United States since 1975. Nevertheless, there are at least 60 centers and 200 programs which offer the procedure in this country. Practitioners here have adopted the technology developed in the United Kingdom and in Australia and have treated patients who pay considerable fees from private resources.²²

In contrast to the federal law concerning IVF, restrictive state laws on fetal research have created barriers to private practice of *in vitro* fertilization. Following the U.S. Supreme Court's 1973 decision regarding abortion, *Roe v. Wade*,²³ numerous state legislatures passed laws restricting or banning research on fetuses. Many of the state laws explicitly define the term "fetus" to include an embryo or any product of conception. To the extent that *in vitro* fertilization, embryo freezing and other related practices are experiments and fail to provide clear and immediate therapeutic benefit to the embryo, the fetal research laws may hinder the use of some infertility treatments.²⁴

Fourteen of the twenty-five states with fetal research laws cover research done either in anticipation of or subsequent to abortion. Others cover only research directed toward a fetus that exhibits a heartbeat, spontaneous respiratory activity, spontaneous voluntary muscle movement or pulsation of the umbilical cord. These laws would not cover *in vitro* fertilization because the procedure does not involve an abortion and, by the time the fetus exhibits the capabilities mentioned, it is no longer a subject of *ex utero* research but rather is developing *in utero* in the course of a normal pregnancy.²⁵

Laws more generally banning research on fetuses, however, might preclude the practice of *in vitro* fertilization. The Michigan statute, for example, prohibits research on a live human embryo if its life or health may be jeopardized. In Minnesota, the law forbids experimentation on a living

21. Abramowitz, *A Stalemate on Test-Tube Baby Research*, HASTINGS CENTER REP., Feb. 1984, at 5-9.

22. OTA BACKGROUND PAPER, *supra* note 7 at 43.

23. 410 U.S. 113 (1973).

24. Andrews, *The Stork Market: The Law of the New Reproduction Technologies*, 70 A.B.A. J., Aug. 1984, at 51.

25. *Id.*

human conceptus, including one conceived outside the body, unless scientific evidence has proven that sort of experimentation to be harmless. Statutes in three other states use similar language.²⁶

It is evident that regulation applicable to IVF is by no means uniform, and according to some, quite inadequate. Ethicist Paul Ramsey, who testified before the Ethics Advisory Board of the Department of Health, Education and Welfare, maintains "that the Ethics Advisory Board, the National Institutes of Health—and, in absence of action from these Federal sources, the medical profession itself has any remaining power to enforce standards on the legislatures of the several States—should take appropriate action to the extent of their jurisdictions to stop embryo manipulation as a form of human genesis."²⁷ At this point, what appears to be a political or regulatory debate becomes a fierce ethical controversy in which noted ethicists and theologians have taken polarized positions.

II. THE ETHICAL DEBATE

While respected ethicists have taken positions similar to Paul Ramsey's and like him have maintained that "*in vitro* fertilization and embryo transfer should not be allowed by medical policy or public policy in the United States—not now, not ever,"²⁸ others have joined the ranks of Joseph Fletcher who alleges that "[m]an is a master and a selector and a designer, and the more rationally contrived and deliberate anything is, the more human it is."²⁹ According to Fletcher, "[l]aboratory reproduction is radically human com-

26. *Id.* Andrews notes that the laws restricting fetal research present an even greater barrier to a practice known as embryo transfer, potentially prohibiting the process in at least 16 states. Embryo transfer (ET) flushes an embryo from the uterus of the woman who conceived and places it in the uterus of another woman. A greater number of statutes would extend regulation to this procedure rather than to *in vitro* fertilization because many of these laws prohibit fetal research in connection with an abortion. Under most of these laws, the definition of abortion would seem to encompass the flushing technique used in embryo transfer. Hence, where *in vitro* fertilization is untouched by statutes that limit their scope to research on the fetus aborted or intended to be aborted, embryo transfer after *in vivo* (in the body) fertilization would appear to fall within the prohibitions.

27. P. Ramsey, On in Vitro Fertilization, 1 (Americans United for Life Studies in Law and Medicine, No. 3).

28. *Id.* at 1.

29. Fletcher, *Ethical Aspects of Genetic Controls*, 285 NEW ENG. J. MED. 776, 781 (1971).

pared to conception by ordinary sexual intercourse. It is willed, chosen, purposed and controlled, and surely these are among the traits that distinguish *Homo sapiens* from others in the animal genus, from the primates down." Fletcher concludes that "[c]oital reproduction is, therefore, less human than laboratory reproduction."³⁰ My purpose in this section is not to advocate any one ethicist's analysis of the ethics of *in vitro* fertilization but rather to present and to evaluate various approaches to the issue.

The ethical debate concerning IVF has focused on four major issues: first, whether an ovum fertilized *in vitro* becomes a human person at the time of fertilization; second, whether this procedure threatens marriage, the family and the nature of human parenthood; third, whether IVF "treatment" is too experimental and may produce a damaged human being; finally what are the long-term consequences of IVF and of related spin-off practices such as surrogate motherhood, the long-term freezing of embryos, alterations in genetic and chromosomal structures performed upon blastocysts *in vitro* and nuclear transplantation or cloning.³¹ The remainder of this section will address these four issues sequentially.

A. *The Beginning of Human Life*

In a society polarized by the issue of abortion, it is likely that many who oppose abortion will morally object to the practice of *in vitro* fertilization because of the numerous "discards" the procedure requires.³² At present, more than one ovum is fertilized in the course of the procedure, and those not used for implantation will perish. Others regard the unimplanted embryo as mere human tissue and have no objection to the creation and loss of multiple embryos. Yet another group would assess the zygote as between these alternatives—not yet a human person but nonetheless entitled to respect and protection.

Paul Ramsey believes that fully protectible human life begins at conception and that discard of human zygotes is the equivalent of both an early abortion and of murder; Richard

30. *Id.*

31. See Ethics Advisory Board Report, *supra* note 2 at 30.

32. Discards are not essential to the IVF procedure. IVF could be performed either by freezing ova in advance or, during successive menstrual cycles, by doing successive laparoscopies. See R. McCORMICK, *HOW BRAVE A NEW WORLD* 329 n.41 (1981).

McCormick also argues for protection of human zygotes, however he maintains that discard of the zygote is not immoral. McCormick claims that when the goal of *in vitro* fertilization is to study and to experiment upon the product of conception, we do arguably fail to respect and to protect early human life; but where the goal of the procedure is to achieve a pregnancy, the goal is laudable and the means are appropriate.³³ He balances the moral good of procreation against the moral evil of failing to promote early human life, and he chooses the procreative good.

McCormick's balancing tests are subject to criticism. Some critics, such as John Finnis, classify him as a "proportionalist theologist." A proportionalist, according to Finnis, "threatens ethics by asserting a criterion of moral judgment which makes moral choice ultimately insignificant."³⁴ Still, the proportionalist does not *avoid* moral judgment, rather, he takes grave responsibility upon himself in choosing his actions. He views himself as not only responsible for the choices themselves but for everything that he could affect in making those choices. The goal of the proportionalist is to choose so as "to maximize overall net good, on the whole and in the long run."³⁵

Finnis claims that the logically necessary implication of the proportionalist method is to cease to consider the rights of the weak and innocent whose very existence impedes the overall net good. The proportionalist rationalizes compromising between the overall pursuit of the net good and achievement of the cultural and moral standards that he chooses to admire and retain. "Thus he preserves himself from the otherwise inevitable psychological effect of shouldering responsibility for everything: Collapse of any principled moral concern for anything."³⁶

McCormick recognizes the value in our culture's moral interest in protecting human life, but he also recognizes the value that we place on procreation and on all that fosters that good, even if artificially as in the case of IVF. How does McCormick rationalize or compromise between these two recognized goods so as to benefit the overall net good? First, he looks to factors that will allow him to attach a value to the zygote which is inevitably discarded in the course of an IVF

33. *Id.* at 329.

34. J. FINNIS, *FUNDAMENTALS OF ETHICS* 136 (1983).

35. *Id.*

36. *Id.*

procedure.

McCormick refuses to refer to discarded zygotes as abortions. A very high percentage of naturally fertilized ova never implant in the uterus of the host and are lost. "This means that there is a tacit acceptance on the part of the couple that their normal sexual relations will lead to this as the price of having a child If it is by no means clear that couples engaging in normal sexual relations are 'causing abortions' because foreseeably many fertilized ova do not implant, it is not clear that the discards from artificial procedures must be called 'abortions,' especially if the ratio of occurrence is roughly similar."³⁷

A response to this explanation is that man may not artificially reproduce all that occurs in nature. "Thus, though people inevitably die, we do not kill them. Though there are life-taking earthquakes in nature, we ought not manufacture life-taking earthquakes."³⁸ McCormick, however, distinguishes the replication of nature's disasters from the replication of nature's achievements which are accompanied by unavoidable undesirable consequences (the loss of some zygotes) both in natural and artificial settings.³⁹ For those who recognize the zygote as a "person," a reasonable number of "discards" ought to be sanctioned. If spontaneous loss of a zygote in the course of normal sexual relations does not violate the zygote's right to life, then loss occurring in artificial attempts to achieve pregnancy should be similarly acceptable.

Following his analysis of the protectability of human life at the zygote stage in light of the status of zygotes in the course of natural reproduction, McCormick has reasoned to his choice of the procreative good over the good of protecting human life. But Finnis' criticism of proportionalist choices pierces this choice in particular: in compromising the

37. R. MCCORMICK, *supra* note 32, at 330.

38. *Id.*

39. Debate concerning the powers of man to play God is quite complex but revolves in part, upon the validity of various "models" of man. The "power-plasticity" model of man holds that nature is alien, independent of man, possessing no inherent value. It is capable of being used, dominated and shaped by man. Man sees himself as possessing an unrestricted right to manipulate nature in the service of his goals. Events like death are to be outwitted and overcome.

The "sacral-symbiotic" model of man views nature as God's creation, to be respected and heeded. Man is not the master; rather he is the steward, and nature is a trust. In secular forms, man is seen as a part of nature. If man is to be respected, so is nature, and man should live in harmony and balance with it. *Id.* at 7.

rights of embryonic life, McCormick has failed to consider the rights of the weak and the innocent. He has aided the "net good," has chosen according to the wishes of those who have voices and who demand the right to procreate by whatever means, but he has ignored the voiceless unborn. The conception of the "net good" is in question. Do the "heard" voices determine what we perceive and choose to be the net good, to the extent that the voiceless are virtually irrelevant?

B. *Marriage, The Family and the Nature of Human Parenthood*

"To put radically asunder what God joined together in making love procreative, to procreate without love or to attempt to establish a relation of sexual love beyond the sphere of marriage means a refusal of the image of God's creation in our own."⁴⁰ Paul Ramsey's perspective on the inseparability of the procreative and unitive aspects of sexual love is characteristic of many traditional theologians. Ramsey uses a scriptural base to discover the nature of marriage and of human parenthood and argues that human procreation mirrors the original mystery by which God created the world.

God created nothing apart from his love; and without divine love was not anything made that was made. Neither should there be among man and woman, whose man-womanhood is the image of God, any love set out of the context of responsibility for procreation or any begetting—apart from or beyond the sphere of their love. There is a reflection of God's love binding himself to the world and the world to himself to be found in the claim he placed upon man and woman in their creation when he bound the nurturing of marital love and procreation together in the nature of human sexuality.⁴¹

While Paul Ramsey's view is traditional and would preclude the use of IVF which he views as divorcing the procreative and unitive aspects of sexual love from one another and from the sexual act, the issue can be approached differently. When the unitive and procreative purposes are not achieved in a single sexual act, nonetheless, the *spheres* of marital love

40. P. Ramsey, *One Flesh: A Christian View of Sex Within, Outside and Before Marriage* 15 (Grove Booklet on Ethics No. 8). (1975).

41. *Id.* at 14.

and procreation are not radically put asunder when artificial means are used to achieve pregnancy.⁴² If the child is brought into being in the context of marriage and owes its life to the genetic contributions of a man and woman united in marriage, this child is the fruit of marital love. Like any other child, this child is desired by its parents and is joyfully anticipated within an intimate, marital relationship.

Even moderate theologians agree with those more traditional in nature in that moving procreation into the laboratory undermines the support which sexual parenthood provides to the monogamous marriage and is both depersonalizing and dehumanizing. As McCormick has stated, "by removing the origin of the child from the sphere of specifically marital (bodily, sexual) love, that love itself is subtly redefined in a way that deflates the sexual and bodily and its pertinence to human love, and therefore to the human itself."⁴³ Parents breach traditional thought and values when they limit the notion of love and of parenthood to desiring and caring for a child, never having coitally engendered that child. Nonetheless, the benefits and positive support that children provide to marital love and to the family structure might justify atypical, artificial parenthood and the engendering of children in laboratory situations.⁴⁴

A discussion of the ethical debate concerning the effects of IVF on the nature of human parenthood is incomplete without consideration of theologians who see neither the need for debate nor problematic assaults on human parenthood. Charles Stinson speaks of Paul Ramsey and of other ethicists similarly distressed by artificial parenthood as adhering to a faulty theory of creation "which assumes that God intended certain aspects of natural structures and forces to remain always beyond the control of man's intelligence."⁴⁵ Stinson follows the Rahnerian view that man's limitless power to experiment on himself is a sign of the creative freedom given to him by God.⁴⁶ Harshly critical of Paul Ramsey, for maintaining on theological grounds that man's growing

42. See R. MCCORMICK, *supra* note 32, at 303.

43. *Id.*

44. While this might appear to be a utilitarian, consequentialist treatment of the problem, it is not truly such. Rather it is an example of "proportionate reasoning" where various risks and benefits are balanced, weighed and treated accordingly in policy implementation.

45. Stinson, *Theology and the Baron Frankenstein: Cloning and Beyond*, 89 CHRISTIAN CENTURY, (Jan. 19, 1972), 60, 61.

46. See R. MCCORMICK, *supra* note 32, at 296.

power over procreation and other processes of life usurps the power of the Divine, Stinson claims that Ramsey's ethics are rooted in fear—fear about the scientific destruction of our belief in life's ultimate significance.

If mental and spiritual life grows out of brain structures, if it is not a "separate entity" beyond genetic manipulation, then such life is somehow not as "true" or "valid" as we had thought; it is a mere "epiphenomenon." . . . And if such [Divine] limits are transgressed by man, then either the Divine Being is "powerless" to stop it—God has been "dethroned"; or perhaps the Divine is a fiction, an illusion finally exposed.⁴⁷

Stinson's, Ramsey's and McCormick's positions represent the extremes and the middle ground respectively which have characterized the ethical debate on the threat posed by IVF to the nature of human parenthood. McCormick, the mediating theologian, is certainly more sympathetic to Ramsey's view than to Stinson's and believes that while human genesis need not be sexual to be moral, artificial procreation nevertheless must occur within the covenanted relationship of marriage.⁴⁸ The logical basis for McCormick's, for Ramsey's, or for Stinson's position in this area is admittedly weak.

While various warrants, some biblical, some teleological can be gathered to support that assertion, it remains true that it cannot be proved by rational arguments or analytical reasoning in a totally satisfactory way. This will be viewed as a fatal weakness only if one fails to realize that in all moral judgments concerned with basic human values there is a prethematic and instinctive component that cannot be totally recovered in analytic discourse; for our knowledge of those values or goods is not first of all discursive.⁴⁹

McCormick further explains the "instinctive component" of moral reasoning as a "natural sense of the fitness of things" or as a "spontaneous sense of the rightness or wrong-

47. Stinson, *supra* note 45, at 61.

48. McCormick maintains that IVF is acceptable if (1) the gametes are those of husband and wife; (2) embryo wastage is not significantly higher in the artificial process than it is *in vivo* (3) the likelihood of fetal abnormality is no greater than it is in normal procreation; (4) there is no intention to abort if abnormality does occur. R. MCCORMICK, *supra* note 32 at 332.

49. *Id.* at 321.

ness of things.”⁵⁰ While we ideally might expect this “spontaneous sense” to lead to uniform moral judgments among men, this has not been the case in practice. The polarization of the ethical debate concerning IVF demonstrates that one person’s instinct can foster reasoning and conclusions that are quite different from those of another. Whether the diversity of moral opinion concerning the effect of IVF on marriage, the family and the nature of human parenthood should preclude regulation of the area is a complex issue which is best treated in a later section of this article.⁵¹ Still, other ethically problematic issues surround the use of IVF, and some, such as the risk of producing an abnormal child, produce more uniform moral judgments and clearer need for regulatory action.

C. *Human Experimentation*

If the IVF procedure involves the risk of damage to a future child, then IVF is an experiment upon a human and must comply with codes which govern human experimentation. While the procedure may early have been subject to consideration as an experiment upon the mother, her health risks are statistically minimal. However, risks to the future child are still in question.

Books of medical ethics contain a wealth of theoretical and case study discussion concerning the ethics of human experimentation within the doctor-patient relationship. Generally, ethical debate focuses on the circumstances in which the experimenter may imply or construct the consent of an incompetent or minor patient who is to be the subject of an experiment which may or may not be relevant to the minor’s treatment. The issue of consent in the context of *in vitro* fertilization is particularly complex for two reasons. First, it is not clear whether IVF should be characterized as an experiment or as treatment, and if IVF is experimental in nature, the second consideration arises. Who or what is the subject of the IVF experiment and from whom must the researcher obtain or imply consent?

Whether IVF is experimental in nature at this point in time is certainly debatable and probably doubtful. However the procedure was unquestionably experimental in its inception and in its early execution. Those who first attempted

50. *Id.*

51. *See infra* Section III.

IVF could not have known whether they were subjecting a future human being to unacceptable risks of abnormality. In fact, the evidence suggests that these early experimenters proceeded with human IVF before sufficient research on non-human subjects had been completed. Paul Ramsey once expressed the "macabre 'hope' that the first child born by laboratory fertilization would be a bad result—and that it be well advertised so that all might halt the practice."⁵² While IVF may have been unethical in its inception, the question *now* is whether it is ethical in its continuation.

Ramsey has written prolifically on the ethics of experimentation upon fetuses and children and his views are applicable to the IVF situation since the subject of the IVF procedure is either one or both of two entities—the blastocyst and/or the potential future child. If the blastocyst is protectible human life, then Ramsey would argue that experimentation upon that blastocyst which is non-diagnostic or non-therapeutic is morally impermissible. He believes that no adult has the power either to consent by proxy for a child or to imply the consent of a child to non-therapeutic treatment because that is "to treat a child as not a child. It is to treat him as if he were an adult person who has consented to become a joint adventurer in the common cause of medical research. If the grounds for this are alleged to be the presumptive or implied consent of the child, that must simply be characterized as a violent and a false presumption When he is grown, the child may put away childish things and become a true volunteer."⁵³

Whether any form of experimentation upon a blastocyst is therapeutic in nature and thus permissible under Ramsey's scheme is a perplexing question. Clearly, Ramsey would prohibit experiments which might be performed upon a blastocyst that is not intended for transfer to the uterus.⁵⁴ But

52. P. Ramsey, *supra* note 27 at 10.

53. P. RAMSEY, *THE PATIENT AS PERSON* 14 (1970).

54. Many studies in experimental embryology do not include embryo transfer as a component. Several possible goals of laboratory research with human embryos have been identified:

1. Developing or testing more adequate contraceptives;
2. Determining causes of infertility;
3. Investigating the circumstances leading to the development of hydatidiform moles and their potential transformation into malignant tumors;
4. Evaluating the effect of noxious agents or teratogens on the early embryo by means of an *in vitro* screening system;
5. Studying the mechanisms by which chromosomal abnormalities are

whether the IVF procedure which contemplates embryo transfer is "therapeutic" rather than purely experimental to the blastocyst or to the potential resultant child is a vexing issue. To answer "yes" is to claim that life itself is therapeutic to a non-existent entity. It is absurd to imply consent from that which does not exist and to seek consent to life is an equally odd proposition. In any event, Ramsey maintains that we cannot submit a child to procedures that involve risks of harm, and since IVF is not definitively risk-free, submission of the potential child to risk (even before it has become a child) would be unacceptable.

Richard McCormick's views on experimentation differ from Paul Ramsey's. Both McCormick and Ramsey accept proxy consent as legitimate in the therapeutic situation because life and health are goods that a child would choose because he *ought* to choose them. Proxy consent is morally valid insofar as it is a reasonable presumption of the child's wishes, a construction of what the child would wish if he could do so. According to McCormick, however, once we analyze proxy consent in the therapeutic situation in this manner, the following question arises: "Are there other things that a child *ought*, as a human being, to choose precisely because and insofar as they are goods definitive of his well being?"⁵⁵ McCormick's intent to benefit the "net good" surfaces when he suggests that we ought to do some things for others simply because we are members of the human community. "These are not precisely works of charity or supererogation . . . but our personal bearing of our share that all may prosper."⁵⁶ None of these implied choices should involve risk, discomfort or inconvenience. If IVF is a procedure without "notable risk," then McCormick's analysis would permit an IVF researcher to construct the consent of a blastocyst to live, to become a human child because life is a value that it *ought* to choose to benefit its parents and the society of which it has the opportunity to be a part. Again, one must question McCormick's balancing of the interests of society and of the net good against the weak and innocent—children who cannot consent to experimentation.

produced; and

6. Investigating the totipotential cells of very early embryos to increase understanding of normal and abnormal cell growth and differentiation.

See Ethics Advisory Board Report, *supra* note 2 at 22.

55. R. MCCORMICK, *supra* note 32 at 76.

56. *Id.*

D. *Future Applications of IVF*

Ethicists have expressed concern that the potential future application and abuses of IVF procedures undermine any ethical propriety of present IVF practices. Each potential future application of IVF raises its own host of legal and ethical problems which must remain beyond the scope of this article. However, an understanding of the need for regulation of IVF follows from an awareness of the possible long-term implications of laboratory genesis.

In the December 14, 1983 edition of the Australian *Canberra Times*, Professor Carl Wood, head of the Queen Victoria Medical Centre In-Vitro Fertilisation Team, said that his team had rejected requests from overseas to grow human embryos for "spare parts." He claimed, "We've had two overseas approaches—I can't say who—from people who believe the in vitro techniques could be used to grow embryos beyond the five or seven-day stage that we have limited ourselves to. The idea is [that] the organs or tissue of two to three-week-old embryos could be used for spare-part surgery. Although this might be of great benefit to many ill people, it would result in the death of the embryo."⁵⁷

The growth of embryos for spare parts is but one of the futuristic possibilities introduced by the IVF procedure. The alteration of genetic and chromosomal structures which could be performed in the laboratory prior to embryo transfer is not a remote possibility. As human life is increasingly and successfully cultured in laboratories, the means of controlling genetic traits become available to scientists. If human gene therapy is approved for use, it will first be performed on patients who suffer from severe, rapidly fatal diseases caused by defective genes.⁵⁸ While inherited alterations, the most controversial applications of gene therapy, are unlikely to be undertaken in humans in the near future, gene transfer experiments in animals have produced some inherited changes⁵⁹ and application to humans seems scientifically possible. Species barriers have already been broken by transplantation of human genes into certain agricultural animals,⁶⁰ and the formation of human/animal hybrids or chimeras is not in the realm of the impossible. Nuclear transplantation or cloning, the long-term freezing of embryos, and perhaps the sub-

57. *Victoria Lifts In-Vitro Ban*, *Canberra Times*, Dec. 14, 1983.

58. OTA BACKGROUND PAPER, *supra* note 7, at iii.

59. *Id.* at 1.

60. *Id.* at 52 (technical note #3).

stitution of laboratory genesis for human procreation from first to last are remaining future prospects. A final spin-off practice of IVF which is already prevalent in the United States is that of surrogate motherhood. This practice has already raised serious ethical, legal and policy issues.

III. THE POLICY QUESTIONS

While the concern of ethics or morality is the rightness or wrongness of human conduct, the realm of public policy is the common good. When human acts have ascertainable public consequences, they become the proper concerns of society and appropriate subjects for policy regulation. When the rightness or wrongness of the human conduct sought to be regulated is subject to ethical debate, as in the case of IVF, the development of policy for the "common good" is unenviably difficult since any "good" pursued is not perceived by all as "common."

The Federal moratorium on IVF research in the United States did not prevent the development of *in vitro* fertilization technology or its clinical application, although its progress has probably been slowed. There is some concern that the technology has developed with an unusual lack of federal oversight and that independent researchers have skipped desirable preliminary steps before using the IVF procedure on humans.⁶¹ Evidence suggests that while researchers performed experiments on lower mammals, they failed to sufficiently research IVF procedures on non-human primates before commencement of human clinical applications.⁶² Experiments have not been subject to the National Institutes of Health's (NIH) peer review process and "may have circumvented systematic accumulation of knowledge."⁶³ Furthermore, the Federal Government may have lost some opportunity to monitor and control the technology by failing to sponsor research or at least to provide a mechanism for federal oversight.⁶⁴

Although we cannot reverse the mistakes of the past, we can avoid future consequences of inadequately supervised IVF if we implement policy which can guide further efforts in reproductive technology. It may have been possible and perhaps wise to impose a moratorium on human IVF two de-

61. OTA BACKGROUND PAPER, *supra* note 7, at 43.

62. *Id.*

63. *Id.* at 152.

64. *Id.* at 151-53.

acades ago, but it is too late to examine the benefits of an absolutist approach to the regulation of the technology. The availability of IVF, like the availability of many commodities and opportunities in our society, has induced a demand. That demand has become intractable, and in the case of IVF, it asks for recognition as a legal right.⁶⁵ The goals of policy in the IVF arena should emphasize control and containment of present applications and procedures.⁶⁶

If and as policy makers develop regulation pertaining to IVF, they must address three questions which will be treated sequentially in the remainder of this section. First, should and can we govern morality? Second, can we govern science? It is critical, however, that the policy maker recognize that IVF is not exclusively a "moral issue" nor is it strictly a scientific procedure; rather it is a medical-technological advancement that has the capacity to affect not only those who avail themselves of the treatment but also all members of society. Having such potential, IVF appropriately enters the province of public concern and policy control. Once the policy maker has overcome the questions surrounding the government of science and morality, he faces the task of development of acceptable policy. In this capacity, he inevitably encounters the final question to be addressed in this section—that of distributive justice.

A. Governing Morality

The propriety of policy regulation of morally controversial conduct has received much attention in recent years. Just as abortion and abortion funding decisions⁶⁷ have divided our nation, so could decisions concerning the use of *in vitro* fertilization as a cure for infertility. Both situations involve prenascent "life" and the rights to procreative privacy.⁶⁸

In attempting to develop sound policy, policy makers are generally bound by moral pluralism and cultural pragmatism: First, a word on moral pluralism: If policy controlling IVF permits the use of the procedure (within bounds), it will inev-

65. See *infra* Section IV.

66. Regulation of numerous potential "spin-off" practices of IVF, such as surrogate motherhood, commercial traffic in human tissue, cultivation of life in the lab beyond the blastocyst stage and long-term freezing of gametes and embryos, ought to be of paramount importance.

67. See *Roe v. Wade*, 410 U.S. 113 (1973); *City of Akron v. Akron Center for Reproductive Health*, 462 U.S. 416 (1983).

68. See *infra* section IV.

itably enrage those who believe that life begins at the moment of fertilization (and that discarded embryos are unacceptable), that any non-therapeutic experiment on a child is abhorrent or that the link between sex and procreation is indissoluble. On the other hand, if policy makers accommodate the beliefs of these "Ramseyesque" persons, they will infuriate countless infertile individuals who wish to conceive a child and who may believe that life begins not at fertilization but at implantation (and that discarded embryos are acceptable), that the IVF experiment is either "therapeutic" to the future child, or if non-therapeutic, is nonetheless acceptable because the child *ought* to wish to live and the parental proxy consent to life of the child is therefore valid. Walking the line between these diverse moral opinions is the difficult task of the policy maker.

When moral pluralism results in a deadlock, cultural pragmatism might enlighten the developer of new policy. For better or for worse, our culture is one where technology is highly esteemed; where moral judgments tend to collapse into pragmatic cost-benefit calculation; where youth, health, pleasure and comfort are highly valued; where maladaptations, such as senility, retardation or age are treated destructively rather than by adapting the environment to special needs.⁶⁹ "Morality often translates into efficiency,"⁷⁰ and this mentality constricts the shaping of policy. These "cultural" limitations may serve as welcomed guidance to a policy maker who otherwise has boundless freedom in making his policy choices and whose culturally unrestricted choice may be neither feasible nor popular.

It seems that ethicists would have little concern for cultural pragmatism and would urge that public policy incorporate the "right" values regardless of the popularity of the policy thus formed or even of the ultimate feasibility of its use in society. Yet, Richard McCormick agrees that "what actions ought to be controlled by policy is determined not merely by the immorality of the action, but beyond this by a single criterion: feasibility. Feasibility is that quality whereby a proposed course of action is not merely possible but practicable, adaptable, depending on the ways, attitudes, traditions of a people."⁷¹

69. See McCormick, *supra* note 32, at 84.

70. *Id.*

71. *Id.* quoting Micallef, *Abortion and the Principles of Legislation*, 28 LAVAL THÉOLOGIQUE ET PHILOSOPHIQUE 294 (1972).

McCormick's testimony concerning the regulation of biotechnology before the House's Science and Technology Committee on August 9, 1984, maintains, in part, that we must regulate only insofar as society will accept that regulation. He asks:

- 1) Will the law be obeyed?
- 2) Is it enforceable against the disobedient?
- 3) Is it prudent to undertake enforcement in view of the possibility of harmful effects in other areas of social life?⁷²

Most likely, bans of the IVF procedure would neither be obeyed nor be enforceable and the possibility of harmful effects from "backstreet" IVF practices might weigh heavily against encouragement of a ban. It is certainly possible that more limited and feasible restrictions on IVF would be obeyed, enforced and beneficial to society as a whole.

It seems that the feasibility of policy implementation must be recognized as a constraint on policy development. While jurisprudential theory takes issue with the notion that the law is defined by the extent of its acceptance in the governed society, this dispute is beyond the scope of this article. Certainly, the law historically has been man's effort to enforce moral and ethical concepts, but to have any practical impact, the law cannot stand as an idyllic values system which the governed refuse to adopt. When governing morally controversial behavior, the law must react to social needs and demands, compromising—not conforming.

B. Governing Science

In vitro fertilization is not only an ethically debatable procedure—it is a *scientific* procedure, and governing science, like governing morality, is a problematic and controversial prospect. Science is a profession which shares features in common with law and medicine. Among the shared features are rigorous educational requirements for entry, the authority of internal bodies over the conduct of members of the profession and hostility to unwarranted lay involvement in

72. *Human Embryo Transfer: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 98th Cong., 2d Sess. 313 (1984) (statement of Richard McCormick, Professor of Christian Ethics, Kennedy Institute of Ethics) (citing J.C. MURRAY, *WE HOLD THESE TRUTHS* 166-67 (1960)).

the profession.⁷³ Dr. R.G. Edwards, the renowned IVF researcher at Cambridge, has questioned whether anything needs to be done to regulate the application of new scientific advances. He claims that the difficulty with both civil and criminal sanctions on the scientific profession "is that they all contain an implicit direction, 'Ask permission before you do your research.' Scientific research began to make progress only when it no longer had to ask permission of the church and it has come a long way since then."⁷⁴ If regulation is inevitable, Dr. Edwards prefers that it emphasize "individual and private action, inquiry and consultation, not . . . authority, control bureaucracy or 'laws with teeth'."⁷⁵ Even if "laws with teeth" are in place, individual doctors, according to Edwards, have placed the interests of their patients ahead of those decreed by society as demonstrated in the cases of abortions executed in the face of severely repressive laws. Edwards' attitude demonstrates that scientists can be recalcitrant and difficult subjects to regulate.⁷⁶

As scientists have strived for immunity from regulation, the public has not fought forcefully to impose control. The public has failed to scrutinize science perhaps in awe of its seemingly magical powers and perhaps in the belief that science is a rational, objective search for truth that is inherently beneficial. Today, however, a formerly "pure" science is extensively controlled by the needs and demands of technology,

73. See Ben-David, *The Profession of Science and its Powers*, 10 MINERVA 362 (1972).

74. Edwards & Sharpe, *Social Values and Research in Human Embryology*, 231 NATURE 88 (1971).

75. *Id.* at 89.

76. It is unfair to characterize all scientists as hostile to regulation of their profession. Dr. Nightingale claims that

[e]xperiences with the recombinant DNA Advisory Committee . . . where the single-minded desire for unhampered research was often obvious — lead me to the conclusion that some kind of oversight mechanism for future research and its applications in this field is not only desirable but necessary. Applications of genetic engineering to man have wide societal and personal, intimate implications and cannot be left to researchers or practitioners alone no matter how well-meaning The implications of genetic engineering for health care in early life need to be monitored by persons other than those interested in promoting new technologies.

See *Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science & Technology*, 97th Cong., 2d Sess. 500-01 (1982) (statement of Dr. Elena Nightingale, Senior Scholar-in-Residence, Institute of Medicine, National Academy of Sciences).

and technology is not so benign an enterprise as pure science. An MIT biologist has cited three factors which have encouraged science to serve technological development: The first is the availability of funding, the second is the dominance of influential scientists in the technological establishment, and the third factor is feasibility.⁷⁷ Research will be done if it is feasible to do so regardless of other considerations. For example Edward Teller stated his belief in the possibility of developing the thermonuclear bomb and that his scientific duty demanded exploration of that possibility.⁷⁸ Such attitudes forcefully demonstrate not only the urgent need for the regulation of science but also that regulation may in some cases be impossible.

The profound impact that technology has had on our society justifies stringent regulation of the enterprise but the form which that regulation should take is uncertain. Barry R. Furrow has contended that private rather than public action can deal effectively with scientific risks and that private tort litigation can be a powerful regulatory tool.⁷⁹ Furrow would like to return nuisance law to its historical role as a device for technology control and would couple a "risk-averse" strain of nuisance law⁸⁰ with expanded powers of the judiciary to curb undesirable technological advancement. Supportive of what he calls Joel Yellin's "Elitist, Judicial Oversight Model," Furrow outlines Yellin's proposed "committee of standing masters, a high technology review panel, to assist courts reviewing agency decisions in areas of technological complexity."⁸¹ According to Yellin, Federal courts could refer complex

77. See E. SINGER, *GENE MANIPULATION AND THE ROLE OF SCIENCE* 72 (1972).

78. *Id.* at 75-76.

79. Furrow, *Governing Science: Public Risks and Private Remedies*, 131 U. PA. L. REV. 1403 (1983).

80. Furrow would like to redirect the emphasis of nuisance law so that the severity of the hazard involved rather than the probability of harm substantially affects the nuisance calculus:

If the judicial framework is oriented toward a probability — weighted calculus, ignoring high gravity results if the probabilities seem low enough, the consequences, even if potentially catastrophic, will be experienced as trivial to be ignored by a 'rational' decisionmaker. But if the judicial framework for nuisance law is oriented toward consequences, considering catastrophic impacts as a central concern, then public actions derived from private entitlements will be brought into line with modern legislation and contemporary concerns about potential irreversible catastrophe.

Id. at 1454.

81. *Id.* at 1435.

questions to the standing masters, a committee of scientists, lawyers and engineers. While the regulation of the scientific field is not a simple matter, Fuller demonstrates that creative policy makers can discover appropriate methods—both private and public—to control and contain the technological enterprise.⁸²

C. Questions of Distributive Justice

IVF is no longer an esoteric technique but is one that will be available to the majority of the one million infertile women in this country; however the costs of the procedure are prohibitive to many. Patients usually pay \$3000 to \$4000 for each attempt to conceive and each attempt—at the well-established medical centers—has a 15 to 20 percent chance of success. Thus, a woman might invest \$9000 to \$12,000 for three attempts and for less than a 50 percent chance of becoming pregnant.⁸³ Insurance companies either refuse to pay for the procedure or will pay for only portions of the medical costs, such as the hospitalization fees.⁸⁴ On September 25,

82. To imply that IVF is a "technological enterprise" may seem to overstate the nature of what some view as a simple medical procedure. On the other hand, reproductive interventions can be characterized as technological and even industrial in nature. Fertility and Genetics Research, Inc. is a Chicago based operation which has applied for patents on the embryo transfer procedure as well as the equipment used in the transfer. Some, such as Professor George Annas of the Boston University School of Public Health, have called the potential patenting of the procedure "outrageous." "How can you patent human reproduction?" asked Annas. But, Lawrence Sucusy, Chairman of the Board at Fertility and Genetics Research claims that patenting of medical procedures is not at all unusual — kidney dialysis is one example. See *Embryo Transfer: Patent Pending*, 2 FERTILITY ASSISTANCE 1 (1984).

If the patent is granted, it would enable the sponsoring corporation to limit the application of surrogate embryo transfer to those who obtained a license. Such limitation might increase costs and diminish access to the technology, but might also permit enhanced quality and controlled diffusion of the procedure. See OTA BACKGROUND PAPER, *supra* note 7, at 44.

83. There is no shortage of people waiting to pay for the IVF procedure. At Eastern Virginia Medical School in Norfolk, the first place in this country to offer IVF, patients are scheduled six months ahead of time, and there are 3000 to 4000 patients waiting. Since Eastern Virginia can handle only 270 patients per year, this represents more than a 10-year backlog. See Kolata, *In Vitro Fertilization Goes Commercial*, 221 SCIENCE 1160 (1983).

84. *Id.* Papers distributed to patients in the "MacDonald In Vitro Fertilization Program" at University Hospitals of Cleveland warn that components of the IVF procedure not covered by insurance include fertilization, incubation and embryo transfer. Insurance may cover: 1) induction of ovulation including daily ultrasound scans, hormonal medications, lab fees;

1984, the Director of the Office of Health Maintenance Organizations (OHMO) imposed an additional constraint on the availability of the IVF procedure when he decided to allow federally qualified HMO's the option of excluding *in vitro* fertilization from the basic health services that they are required to provide their members.⁸⁵

As IVF becomes increasingly available to those who can afford it, questions of distributive justice arise. If the right⁸⁶ to bear children is afforded to those who presently pay thousands of dollars for a mere chance to conceive, should not the same opportunities exist for those of lesser means who possess the same interest and right to beget children? In our society, notions of distributive justice are rooted in egalitarian theory which maintains that it is discriminatory "to treat people differently in ways that profoundly affect their lives because of differences for which they have no responsibility."⁸⁷ Typically, we do not classify persons based upon wealth and then proceed to treat them unequally because of this difference. If IVF is a scarce medical procedure which can be provided to a very few, we arguably ought not let pure market forces control its availability and must offer the benefits of the procedure to those of lesser means.

Any policy decision concerning the allocation of the IVF procedure must consider both questions of macro- and micro-allocation.⁸⁸ Macroallocation decisions consider how much of society's resources should be exchanged for a certain good (IVF in this case). In the province of medical research and treatment, policy makers must consider which categories of illness or disease should receive priority in the allocation of medical resources if it is not possible to fund research and therapy in all areas.

There are two distinct positions on the macroallocation

2) laparoscopy with egg retrieval; 3) anesthesia professional fee for laparoscopy; 4) hospital fee (operating room and hospital room, recovery room, technical anesthesia).

85. 49 Fed. Reg. 39,109 (1984). The Director, OHMO, has authorized the exclusion of IVF from basic health services because "this service, at the present time, is unusual, infrequently provided, and not necessary for the protection of individual health."

86. See *infra* Section IV.

87. T. BEAUCHAMP & J. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* 183 (1979).

88. Guido Calabresi and Philip Bobbitt have dubbed these questions as "first-order" and "second-order" determinations, respectively. See G. CALABRESI & P. BOBBITT, *TRAGIC CHOICES* 19 (1978).

issue.⁸⁹ One is that we should not spend federal funds for *in vitro* fertilization and embryo transfer in clinical practice. Reasons given for this position vary from the view that the importance of bearing a child that is genetically "one's own" has been overstated⁹⁰ to the belief that other approaches to infertility will be more cost-effective or to the view that significant moral opposition to IVF ought to prohibit use of taxpayers' money to promote human IVF and embryo transfer.⁹¹

In contrast, the second position maintains that the federal government should support the clinical application of IVF because involuntary infertility is a serious problem. "The rabbis put it this way, some fifteen centuries ago. Four are considered as if they were dead: the poor, the diseased, the blind, and the childless."⁹² Federal support of IVF research

89. See Ethics Advisory Board Report, *supra* note 2 at 52.

90. *Id.* This view maintains that the substantial investment of public funds to develop anti-infertility techniques, particularly in light of other "immense needs of our society," (for example, the provision of an effective clotting factor for hemophiliacs) is inappropriate. As Gorovitz claims:

In the competition for support, the burden of making a convincing case should rest with the proponent of a given line of work. With forty million Americans having no adequate access to decent health care, with thousands of children born annually without prospect of a family to nurture them, with venereal disease — a major cause of infertility on the rise, it is implausible that research into making IVF more readily and reliably available should be a project of high priority concern. It isn't so much the harm or risk it involves as the plainly greater importance of addressing more fundamental and widespread problems of health and the delivery of health care.

Id. at 53.

91. Paul Ramsey, on the distributive justice question has said: [He] who can wish this [IVF] to become a "standard medical practice" must want both our present health care delivery system (which is largely funded) and any future national health plan to be profoundly oppressive to consciences In the future, the "distributive justice" argument will stand alone, no matter what the cost of perfecting and delivering this service, or the cost of having done so in supporting the children so produced. I don't suppose that in years to come we are going to prohibit women on welfare from overcoming oviduct blockage, or refuse to fund this medical service, simply because of the cost in ADC payments. Of course, conscientious objectors to funding abortion or funding petri dish discarding do not think highly of this argument, since for them it is meaningless to speak of fairness in justly distributing an immoral practice.

P. Ramsey, *supra* note 27, at 6.

92. Ethics Advisory Board Report, *supra* note 2 at 52.

and practice would facilitate federal regulation of the procedure, a result which must be considered as an advantage. Finally, "[i]t would be a sad commentary on the American ethos if federal funds could be used for the taking of human life, that is, therapeutic abortion, but not the creation of human life, that is therapeutic conception."⁹³

If infertility is recognized as a serious problem or if in the interests of egalitarianism, public policy supports Federal funding of the IVF procedure, issues of microallocation arise. Microallocation decisions or "second-order determinations" decide "who shall get what is made."⁹⁴ Public policy governing microallocation of IVF must determine both who will make the allocation decisions and what criteria will be used for selection of the recipients. First, it is not fair to ask the physician to be a policy maker. "A physician or other provider must do all that is permitted on behalf of his patient without counting society's resources and without taking into account the range of factors, e.g. statistical lives, that policy makers rightfully should consider."⁹⁵

Calabresi and Bobbitt have recognized the tendency of our society to entrust many difficult decisions to decentralized, irresponsible agencies or juries.⁹⁶ Delegation of microallocation decisions concerning IVF to such a body may be the best course as we develop regulation of IVF. A "jury" could sit in all centers which would be granted Federal funds for IVF and would consider and choose among applicants for the procedure.

The use of such a jury would not meet with agreement from all quarters. As Calabresi and Bobbitt have noted, the irresponsible agency makes decisions and gives no reasons for them, "[a]nd giving no reasons, it avoids, or at least mitigates, the conflict between the wish to recognize differences and the desire to affirm egalitarianism in all its forms."⁹⁷ If the decisions of juries follow a discernible pattern, they will be criticized, for the pattern is evidence of bias. On the other hand, "the lack of a pattern is taken as clear evidence that each case is decided merely on the basis of favoritism."⁹⁸

93. *Id.*

94. G. CALABRESI & P. BOBBITT, *supra* note 88, at 19.

95. See T. BEAUCHAMP & J. CHILDRESS, *supra* note 87, at 195. See also, H. Hiatt, *Protecting the Medical Commons: Who is Responsible?*, 293 NEW ENG. J. MED. 235 (1975).

96. See G. CALABRESI & P. BOBBITT, *supra* note 88, at 57.

97. *Id.*

98. *Id.* at 64.

We face, then, three possibilities. Either we abandon altogether the use of aresponsible agencies, or we try to modify them further, or we restructure the . . . allocation into the sort of decision made in the criminal law, that is, we transform the situation from an allocation requiring an assessment of relative worthiness to a decision requiring a determination of absolute worthiness or absolute fault, which can be satisfactorily assigned to a true jury.⁹⁹

One goal of policy in the IVF area should be the development of fair and useful criteria which might aid the determinations of "absolute worthiness" or "absolute fault" as we strive for an equitable distribution of funding for IVF.

IV. THE LEGAL DILEMMAS

Legislators are the policy makers who must address the considerations outlined in the preceding section. Yet initial regulation of IVF may not be the product of legislative action. While our system designed legislatures to address and to implement policy in the first instance, the events of the past thirty years have demonstrated that the courts are leaders in policy implementation. Courts often have ruled where legislatures should have acted to determine cutting-edge policy. School desegregation, equal employment opportunities, voting rights, abortion and capital punishment are issues that the courts have addressed and are areas in which the judiciary has served as the primary source of policy and values.

How might the courts first be called upon to address the IVF issue? It is likely that litigants will raise constitutional questions concerning any attempted regulation of IVF. The recognized constitutional right to privacy is the most obvious constitutional issue involved in any regulation of procreative activity, but the character of the attempted regulation may well foster equal protection claims. Actions in tort are other vehicles by which IVF may come before the courts. If a child born of the IVF process should be genetically abnormal or injured, either the child or parents could foreseeably bring an action in tort, claiming substantial damages. This section will address both the constitutional issues and the tort implications surrounding the use of IVF.

99. *Id.*

A. The Constitutional Issues

1. The Constitutional Right to Privacy

The Constitution of the United States does not refer to privacy, but it has been recognized by the courts as a fundamental right. In *Whalen v. Roe*,¹⁰⁰ Justice Stevens categorized the Court's recognition of a right to privacy as follows: (1) freedom from governmental surveillance and intrusion as protected by the Fourth Amendment; (2) the interest in avoiding public disclosure of private matters; and (3) the interest in making independent personal decisions in matters concerning marriage, procreation, and childrearing.¹⁰¹ The category that is pertinent to the use of IVF is clearly the third, and a line of cases has protected the right to privacy in making independent decisions concerning procreation.

In *Griswold v. Connecticut*, the Court struck down a statute prohibiting the sale of contraceptives as "repulsive to the notions of privacy surrounding the marriage relationship."¹⁰² *Eisenstadt v. Baird*,¹⁰³ took the *Griswold* decision further and refused to allow a State to forbid the distribution of contraceptives to unmarried persons. Such regulation would treat unmarried people differently than married people, whose right to use contraceptives had been established in *Griswold*, and would be arbitrary and in violation of the Equal Protection Clause of the Fourteenth Amendment.

It is true that in *Griswold* the right of privacy in question inhered in the marital relationship. Yet the marital couple is not an independent entity with a mind and heart of its own, but an association of two individuals each with a separate intellectual and emotional makeup. If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child.¹⁰⁴

Whether the courts will view access to IVF as a fundamental right depends upon how closely analogous it is to the sexual privacy rights already recognized by the Supreme Court. It is arguable that once genetic material is outside of the body, the privacy interest of the possessor has been atten-

100. 429 U.S. 589 (1977).

101. *Id.* at 599-600.

102. 381 U.S. 479, 486 (1964).

103. 405 U.S. 438 (1972).

104. *Id.* at 453.

uated. Furthermore, the Court has never encountered a situation in which it has been asked to protect procreative liberty outside of the context of *sexual* reproduction. If, however, the right to beget children by IVF is recognized as a fundamental right, the government would have to demonstrate a compelling state interest to justify interference with the exercise of that right. On the other hand, if the right asserted is less than fundamental, the government could limit the exercise of the right on the showing of a rational basis for the restriction. Rational bases that might justify governance of aspects of IVF include the protection of early human embryos, the government's interest in fostering marriage and the insuperable legal problems that would arise from spin-off practices of the technology, such as the use of surrogate mothers or the development of eugenic engineering. However, it is doubtful that these state interests are "compelling," and IVF will be more easily regulated if courts determine that access to the procedure is less than a fundamental right.¹⁰⁵

2. Equal Protection

If, in the interests of distributive justice or in the pursuit of Federal control over IVF, Federal funds are provided for IVF treatment, then the government could become the target of equal protection litigants who may be excluded, for various reasons, from the availability of the IVF procedure. If, for example, future regulation of IVF limits its availability to married couples,¹⁰⁶ a claim of discrimination based upon marital status would be the foreseeable equal protection suit. In light of the *Eisenstadt* decision, which upheld "the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child," such a claim might well be successful.

B. *Liability in Tort*

Courts will likely encounter claims against physicians and

105. See generally Ethics Advisory Board Report, *supra* note 2, at 63-64.

106. Australian policy, in line with a recommendation by the Standing Attorneys General, will offer *in vitro* services to couples with "established de facto relationships." See *Bills Open In vitro to Unmarried Couples*, AGE, March 22, 1984.

institutions for IVF claims that have gone awry. In the past decade, a body of law has evolved concerning physicians' and laboratories' responsibility for failure of sterilization procedures and for prenatal injuries and it is probable that IVF suits would be resolved in accordance with this law.

If a physician has negligently directed the selection of defective ova or semen or has negligently supervised or performed the implantation of a defective blastocyst which develops to term, he could become the subject of a wrongful life action which is initiated by the parents of the injured or defective child. American courts have hesitated to recognize this cause of action against negligent physicians, but since IVF involves the affirmative acts of a human agent who is not a parent of the offspring, a new judicial approach may evolve. Still, proof of causation in these cases would be difficult if not impossible and would limit recovery to be gained from these suits.

It is not inconceivable that causes of action for wrongful death could be extended to permit recovery for wrongful destruction of an unimplanted blastocyst. Judicial recognition of such a cause of action would undermine *Roe v. Wade*, and would accord respect and protection to very early forms of human life. A third claim, that of wrongful birth, might be initiated by a child born of IVF who claims that he should never have been born and would not have been born but for the negligence of the physician against whom the action is asserted. However, to date, only California and Washington recognize suits for wrongful birth.

Courts will continue to struggle with questions of holding health care professionals accountable for their actions, and it is likely that the focus will be on the proper calculation of damages in these novel tort claims. Since the applicability of traditional tort concepts to research involving IVF is uncertain, one lawyer has proposed the establishment of a federal compensation fund to provide monetary redress in the event of injury associated with such research.¹⁰⁷ In her view, society has a substantial interest in the establishment of a program of human IVF and therefore has an obligation to the human subjects who may be injured by participation in the program.

Any injury which is not clearly unrelated to participation in the IVF program would be compensable. The amount of

107. *Id.* at 75.

compensation would be determined by calculating the monetary requirements for making the situation of a damaged child or mother equal to that of a normal person, insofar as such calculation is possible. The compensation fund would be financed through premiums paid by researchers or their institutions, by adding a surcharge to hospital bills, or by allocating general revenues to this purpose. The plan would include financial incentives to encourage the exercise of due care by investigators and institutions.¹⁰⁸

When a physician or institution undertakes any novel medical procedure, as IVF, his legal duties towards his patients are particularly confusing. Whether a new procedure, such as IVF, should be characterized as *treatment* or as an *experiment* will determine, in part, the scope of duties and liabilities. What degree of risk is appropriate in treatment and experimental situations? Is and should permissible risk be the same in both situations? In fact, should IVF be performed at all? Is *any* risk to the resulting child unacceptable? While there is no evidence yet of abnormality in IVF offspring, it will be several years before we can determine if IVF children are different from the general population. It is indeed difficult for physicians to behave according to standards of the profession in novel, unexplored areas of medicine because there are no such standards—all is in a state of evolution. The sooner that minimum standards for programs in IVF are imposed, the easier it will be for doctors to ascertain degrees of permissible risk and duties toward patients. The need for incorporating these minimal standards in legislation concerning IVF is apparent and should be welcomed by members of both the legal and medical professions.

V. A PROPOSAL FOR THE REGULATION OF IVF

Both the United Kingdom and Australia have appointed commissions to recommend standards and regulations for the practice of IVF. The United States ought to follow the model established by these countries and begin inquiry into the practice of IVF in this country. The ironies of the discoveries of a commission might surprise physicians and lay persons alike. For example, "[i]t is ironic that the screening of donor sperm for AI [artificial insemination] is much less stringent than that of bull sperm in the cattle industry."¹⁰⁹

108. *Id.*

109. Andrews, *supra* note 24, at 51.

The recommendations of the United Kingdom's Warnock Committee, published in July of 1984, establish strict guidelines and significant limitations on the practice of IVF.¹¹⁰ Among its many provisions are several which are included in an appendix to this article and which the United States would be wise to adopt as it formulates policy concerning IVF. The Warnock Committee suggests that a statutory licensing authority be established to regulate both research and services concerning in vitro fertilization. It urges caution in the use of frozen embryos until further research has demonstrated the safety of procedures involving these embryos. As to experimentation on embryos not intended for transfer and as to the disposal of spare embryos, the Committee again offers needed guidance. Other important issues addressed by the Warnock Committee include trans-species fertilization, surrogacy, commercial traffic in human tissue and the use of donor gametes. The appendix to this article also suggests provisions not included in the Warnock guidelines but which would be wise to adopt in this country.

IN CONCLUSION

Proponents of regulation of IVF may be accused of too great a futurism in their fears of possible risks and undesirable applications of new technology. Joseph Fletcher has criticized "[p]eople who appeal to Brave New World and 1984 and Fahrenheit 457 [T]he tyranny is set up first and then genetic controls are employed. The problem of misuse is political not biological."¹¹¹ Nonetheless, recent events have demonstrated that the biological threats are very real. In an age when industries are applying to patent reproductive processes, when nations are asking physicians to grow embryos for spare parts, and when women are leasing their wombs, the Brave New World analogy is not entirely inappropriate.

The prescience of the law in the area of IVF will preclude future abuses of this novel technology. Certainly, the law can recognize the interests of the many infertile couples who wish to conceive children and who encounter ten year waiting lists at IVF clinics across the country. Yet, uniform legislation should govern private and public practices of IVF

110. See THE REPORT OF THE WARNOCK COMMITTEE ON HUMAN FERTILIZATION AND EMBRYOLOGY (1984).

111. Fletcher, *supra* note 29, at 780.

so that science does not leap ahead of the law, leaving a wealth of legal and ethical dilemmas behind. If policy makers act now to regulate IVF, they will not confront, as one ethicist fears, "a reproductive biologist in need of funds and reputation . . . in search of an animal species whose gestation is close enough to the human for it to be not impossible to use its females as hosts for human embryos. After all, 'herds' of prime cattle in embryo have been flown across the Atlantic within rabbits thereafter to be transferred to scrub cows to bear them."¹¹² It has become the urgent responsibility of the law to examine and to regulate clinical and experimental uses of *in vitro* fertilization.

112. P. Ramsey, *supra* note 27, at 18.

APPENDIX: *Proposed Guidelines for the Practice of in Vitro Fertilization*

The Licensing Body and its Functions

A new statutory licensing authority should be established to regulate both research and those infertility services which the committee has recommended should be subject to control.

There should be substantial lay representation on the statutory authority to regulate research and infertility services and the chairman must be a lay person.

The technique of embryo donation by lavage should not be used at the present time.

The use of frozen eggs in therapeutic procedures should not be undertaken until research has shown that no unacceptable risk is involved. This will be a matter for review by the licensing body.

The clinical use of frozen embryos may continue to be developed under review by the licensing body.

No live human embryo derived from in-vitro fertilisation, whether frozen or unfrozen, may be kept alive, if not transferred to a woman beyond fourteen days after fertilisation, nor may it be used as a research subject beyond fourteen days after fertilisation. This fourteen-day period does not include any time during which the embryo may have been frozen.

Consent should be obtained as to the method of use or disposal of spare embryos.

As a matter of good practice no research should be carried out on a spare embryo without the informed consent of the couple from whom the embryo was generated, whenever this is possible.

Where trans-species fertilisation is used as part of a recognised programme for alleviating infertility or in the assessment or diagnosis of subfertility, it should be subject to license and a condition of granting such a license should be that the development of any resultant hybrid should be terminated at the two-cell stage.

The licensing body be asked to consider the need for follow-up studies of children born as a result of the new techniques, including consideration of the need for a centrally maintained register of such births.

Legal Limits on Research

The embryo of the human species should be afforded some protection in law.

Any unauthorised use of an in-vitro embryo would in itself constitute a criminal offence.

Any unlicensed use of trans-species fertilisation involving human gametes should be a criminal offence.

The placing of a human embryo in the uterus of another species for gestation should be a criminal offence.

The proposed licensing body should promulgate guidance on what types of research, apart from those precluded by law, would be unlikely to be considered ethically acceptable in any circumstances and therefore would not be licensed.*

The Warnock Commission did not prohibit the freezing of embryos, but suggested that embryos be "stored" for a maximum of ten years. This country is advised to adopt a more stringent provision concerning the freezing of embryos:

Human zygotes and embryos must not be frozen for prolonged periods and only for purposes of synchronizing implantation with the host's ovulatory cycle. If diseases causing infertility will affect the gametes of an individual at some future time, extraction and freezing of presently healthy gametes is permissible for use in later fertilization and implantation.

The Commission was moderate in its regulation of sales and purchases of gametes and embryos, allowing these transfers under license and conditions prescribed by licensing body. The U.S. is advised to prohibit all commercial traffic in human tissue.

The Commission failed to acceptably regulate research on embryos and permits research on any embryo resulting from IVF, whatever its provenance, up to the end of the fourteenth day after fertilization. This country is advised to adopt the following provision:

Human zygotes and embryos must not be wantonly created and destroyed, and the ratio of fertilized to destroyed IVF embryos must not exceed the waste ratio that occurs

* These guidelines are taken, verbatim, from those of the Warnock Committee on the Human Fertilization and Embryology. *See*, The Report of the Warnock Committee on the Human Fertilization and Embryology (1984).

normally in the course of natural human reproduction.

IVF and culture of embryos not intended for transfer is prohibited.

The reasonable number of embryos that are "wasted" in IVF and transfer procedures may be used for research, but research must cease and embryos must be discarded at the age of fourteen days.

The Commission was sympathetic to the use of donor gametes in IVF, but this country would be wise to follow the following provision concerning use of IVF:

IVF is available only to married persons or individuals in a "stable" relationship.

Gametes used in the procedure must be those of the parties to the marriage or relationship.

Healthy embryos that are not used by donors of the gametes and would otherwise be "wasted" may be adopted by an infertile host couple and implanted in the womb of the adoptive host.

The following additional constraints on IVF are suggested for adoption in this country:

Appropriate preliminary research on non-human primates must establish the safety of a given *in vitro* procedure.

The state of the IVF art must be such that it involves no greater risk for the conceptus and mother than in normal pregnancy and childbirth.

The IVF practitioner must obtain the informed consent of all participants.

Appropriate liability and compensation for research-related injury must be provided.

