Ethics and Uncertainty: *In Vitro* Fertilization and Risks to Women's Health

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Introduction

From the 1940's to the early 1970's, doctors gave diethylstilbertrol (DES) to millions of pregnant women in order to prevent spontaneous abortions. However, physicians did not have adequate information about the potential consequences of this hormone's use. Years later, researchers have found that two to four million daughters of women who took DES suffer cancer of the vagina and cervix at a rate higher than that of daughters of women who did not take DES. These women also have experienced increased rates of infertility, spontaneous abortions, and ectopic (outside the uterus) pregnancies. Moreover, more than 30 years after they used the drug, women who took DES suffer from 40-50% higher rates of breast cancer than women of similar age.[1] The Dalkon Shield case also exemplifies problems in dealing with medical technologies.The Dalkon Shield, an intrauterine contraceptive device, was marketed for several years. Between 1970 and 1974, doctors inserted the Dalkon Shield into more than two million U.S. women and a total of four million worldwide. After women used it extensively, researchers compiled evidence indicating that severe hemorrhaging, infected miscarriages, ectopic pregnancies, infertility, mutilated reproductive organs, and death could result from its use.

Advances in the biomedical sciences are helping to cure diseases, give children to the infertile, improve the quality of life, and increase

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1 *See, e.g.,* Cynthia Orenberg, **DES: The Complete Story** (1981); Renate Klein & Robyn Rowland, *Women As Test Sites for Fertility Drugs: Clomiphene Citrate and Hormonal Cocktails,* **Reproductive and Genetic Engineering. Journal of International Feminist Analysis**, 1:3 (1988); Harriet Simand, *1938-1988: Fifty Years of DES-Fifty Years Too Many,* **The Future of Human Reproduction** (Christine Overall ed., 1989); Robyn Rowland, **Living Laboratories** (1992); S. M. Fisher & R. J. Apfel, *Diethylstilbestrol and Infertility: The Past, the Present, and the Relevance for the Future,* **Technology and Infertility** (MacHelle M. Seibel et al. eds., 1993).

longevity. But some of these biomedical developments are causing death and injury, and creating public alarm. These developments confront society with new ethical dilemmas about reproductive rights, parenthood, medicalization of reproduction, exploitation, consent, and equity in the distribution of scarce medical resources.

Overview

This paper argues that because of inadequate technology assessments, policymakers have made decisions, in relation to *in vitro* fertilization (IVF), that may not be in the public's best interests. I defend the thesis that assessments of IVF are inadequate because, in neglecting epistemological and ethical problems such as choosing criteria for decisions under uncertainty, assessors of IVF may encourage public policies that overlook the possibility of jeopardizing women's health. A brief description of the IVF procedures and a summary of the four reports under analysis will help to contextualize the discussion. Next, I offer an account of the empirical data on IVF risks. I also show that assessors have neglected or underestimated the evidence on IVF hazards. Section six argues that evaluators also have undervalued the insufficiency of investigations on IVF risks. In section seven, I argue that evaluators have erred in their analysis because, faced with a situation of uncertainty, they have recommended minimizing false positives over false negatives. As a consequence, many women may be exposed to needless risks. Finally, section eight tries to answer some possible objections against my arguments. One of those objections is that because evaluators have recommended obtaining written informed consent from women as a way to overcome problems with risks, their recommendations undercut concerns about medical threats to women. A second criticism refers to the fact that interfering with women's ability to choose a risky technology, such as IVF, might be paternalistic.

IVF: The Medical Technique

According to the National Center of Health Statistics and the World Health Organization (WHO) between 8-10% of couples in the industrialized countries have reproductive problems.[2] They

[2] *See* U.S. Congress, Office of Technology Assessment (OTA), **Infertility: Medical and Social Choices** (1988); William D. Mosher & William F. Pratt, **Fecundity and Infertility in the United States**, (1990); World Health Organization,

experience difficulties in conceiving children. The factors that most often contribute to fertility disorders among women are problems in ovulation, blocked or scarred fallopian tubes, and endometriosis (the presence in the lower abdomen of tissue from the uterine lining). In about half of the couples with reproductive problems, there is a contributing male factor. Among men, most cases of infertility are a consequence of abnormal or too few sperm. About 1.6% of couples seeking infertility treatment in industrialized nations participates in IVF.[3] To understand fully the epistemological, social, legal, and ethical issues that arise with evaluating this technology, I shall first offer a description of the procedure.

In its most basic case (i.e., the woman undergoing IVF provides her own eggs, and her husband or partner supplies the sperm) the technique of IVF consists of several stages. First, doctors stimulate the woman's ovaries with different hormones to produce multiple oocytes. Next, they remove the eggs from her ovaries through procedures such as laparoscopy or ultrasound-guided oocyte retrieval. After preparation of semen, specialists fertilize the mature eggs in a laboratory dish with the sperm. If one or more normal looking embryos result, specialists place them (normally between three and five) in the woman's womb to enable implantation and possible pregnancy.[4]

Recent Advances in Medically Assisted Conception (1992); and 23 **Vital and Health Statistics** 19 (1997).

3 Subcommittee on Health and The Environment, **Fertility Clinic Services** (1992).

4 *See* M. C. Macnamee & Peter. R. Brinsden, *Superovulation Strategies in Assisted Conception,* **A Textbook of *in Vitro* Fertilization and Assisted Reproductive Technology** (Peter R. Brinsden & Paul A. Rainsbury eds., 1992); I. Calderon & D. Healy, *Endocrinology of IVF*, **Handbook of *In Vitro* Fertilization** (Alan Trounson & David K. Gardner eds., 1993); M. P. Steinkampf & Richard E. Blackwell, *Ovulation Induction,* **Textbook of Reproductive Medicine** (Bruce R. Carr & Richard E. Blackwell eds., 1993); Edward E. Wallach, *Induction of Ovulation: General Concepts,* **Reproductive Medicine and Surgery**, (Edward E. Wallach & Howard A. Zacur eds., 1994); E. Y. Adashi, *Clomiphene Citrate-Initiated Ovulation: The State of the Art,* **Reproductive Medicine and Surgery**, (Edward E. Wallach & Howard A. Zacur eds., 1994); B. Lunenfeld & V. Insler, *Human Gonadotropins*, **Reproductive Medicine and Surgery**, (Edward E. Wallach & Howard A. Zacur eds., 1994); and Howard A. Zacur & Y. R. Smith, *Gonadotropin-Releasing Hormone and Analogues in Ovulation Induction,* **Reproductive Medicine and Surgery**, (Edward E. Wallach & Howard A. Zacur eds., 1994).

The Four Assessments

The new assisted-conception technologies have raised many challenging ethical and policy issues in recent decades. Decisionmakers, medical practitioners, scientists, courts, and the public in general are facing new quandaries that involve controversies among profoundly held values. When faced with ethical conflicts or complicated technical issues, policymakers often turn to or create commissions for advice.[5] This has been the case with the new assisted-conception technologies.

Commissions in several countries around the world have issued reports on IVF and related procedures.[6] The four analyzed in this essay have special significance for several reasons. The Victorian report resulted in the first piece of legislation in the world to regulate assisted-conception techniques such as IVF. The British assessment has been the single most influential institutional inquiry on reproductive technologies and is the one that set the agenda for action in other countries. The Spanish report has been the basis for Law No. 35/1988. This legislation is one of the most detailed undertaken on the subject of assisted-conception procedures. It covers artificial insemination, IVF, and gamete intrafallopian transfer (GIFT).[7] Finally, the U.S. assessment is the most complete of the four studies analyzed here. It covers the scientific, legal, economic, and ethical issues surrounding reproductive problems. Specifically, it evaluates medically assisted conception (including IVF and GIFT), surgically assisted reproduction, artificial insemination, basic research supporting reproductive technologies, and surrogate motherhood.[8]

New reports and new legislation are been passed in these and other countries.[9] The analysis of the four reports evaluated here is still

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5 *See, e.g.,* Susan S. Connor & Hernan L. Fuenzalida-Puelma, **Bioethics: Issues and Perspectives** (1990); Robert Blank, **Regulating Reproduction** (1990); U.S. Congress, Office of Technology Assessment, **Biomedical Ethics in U.S. Public Policy** (1993); and **Society's Choices. Social and Ethical Dimensions Making in Biomedicine** (Ruth Ellen Bulger et al. eds., 1995).

6 *See, e.g.,* OTA, **Infertility**, *supra* note 2; Blanck, *supra* note 5; **Embryo Experimentation** (Peter Singer et al. eds., 1990); and Jennifer Gunning & Veronica English, **Human *In Vitro* Fertilization** (1993).

7 *See* **Comisión Especial de Estudio de la Fecundación "*In Vitro*" y la Inseminación Artificial Humanas** [Special Commission for the Study of Human *in Vitro* Fertilization and Artificial Insemination], Informe [Report] (1987).

8 *See* OTA, **Biomedical Ethics in U.S. Public Policy,** *supra* note 5, at 3.

important because they are, at least in part, responsible for the current development and use of IVF and related procedures.

The first of the assessments was published in the State of Victoria, Australia, in 1982. The Committee, under the direction of Louis Waller, produced three reports over two years, the first of which dealt specifically with IVF treatment. The Victorian Committee presented its Interim Report in September 1982, the Report on Donor Gametes *in Vitro* Fertilization in August 1983, and the Report on the Disposition of Embryos Produced by *In Vitro* Fertilization in August 1984. Following the recommendations of these reports, the Victorian Government enacted the Infertility (Medical Procedures) Act in 1984.[10] This bill sets out the provisions to regulate IVF and associated technologies. It allows the fertilization of ova outside a woman's body only for implantation and only for married couples. Counseling is mandatory. It limits the practice of IVF to approved hospitals and provides for record keeping and confidentiality.

In July 1982, two months after the appointment of the Victorian Committee, the British parliament established the Warnock Committee that produced the Report of the Committee of Inquiry into Human Fertilization and Embryology. Although both the Victorian and the British commissions reported their findings in 1984, the former led to immediate legislation, the latter to an extended period of consultation. Nevertheless, in 1990 the British parliament brought about the eventual recommendations of the Warnock proposals in the Human Fertilization and Embryology Act.[11] The Act establishes the statutory licensing of IVF, the donation and storage of eggs and sperm, and embryo research. It allows licensed research, but it does not permit the storage or use of embryos beyond fourteen days of fertilization. The Act also prohibits cloning and the placing of a human embryo in any other animal.[12]

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9 *See, e.g.,* Singer, *supra* note 6; Gunning, *supra* note 6.

10 *See, e.g.,* Singer, *supra* note 6; Gunning, *supra* note 6.

11 *See* Mary Warnock, **A Question of Life. The Warnock Report on Human Fertilization and Embryology** (1985); *See also,* Blanck, *supra* note 5, at 143; Gunning, *supra* note 6.

12 *See* Warnock, *supra* note 11; *see also*, Blanck, *supra* note 5, at 143; Gunning, *supra* note 5.

In 1986, the third assessment on new reproductive techniques under analysis appeared in Spain. The Spanish parliament set up a Special Commission to study human IVF and artificial insemination.[13] Following this report, the parliament passed a law know as Health: Assisted Reproduction Techniques. The law lays down general principles for the application of these technologies that emphasize informed consent, patient data collection and confidentiality, fertilization of ova for the sole purpose of procreation, and the minimization of spare embryos.

Finally, in 1988 the U.S. Office of Technology Assessment (OTA) issued its report entitled, Infertility: Medical and Social Choices. This assessment seems to have triggered the proposal of a federal law relating to IVF. After several hearings in 1988 and 1989,[14] the U.S. Congress enacted the Fertility Clinic Success Rate and Certification Act of 1992.[15] This Act requires all infertility clinics that perform IVF services to communicate annually their pregnancy success rates to the Secretary of Health and Human Services. It also requires the identity of each embryo-laboratory working in association with the clinic. The Act also directs the Secretary to develop a model program for state certification of embryo laboratory accreditation programs. In addition, it demands that the Secretary publish and disseminate data concerning pregnancy success rates and other related information. The Centers for Disease Control and Prevention is in charge of the development of the actual mechanisms for the implementation of the Act.[16]

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13 *See* Spanish Commission, *supra* note 7.

14 *See* Subcommittee on Regulation and Business Opportunities, **Consumer Protection Issues Involving *In Vitro* Fertilization Clinics** (1988) (hereinafter SRE, **Consumer**); Subcommittee on Regulation, Business Opportunities and Energy **Consumer Protection Issues Involving *In Vitro* Fertilization Clinics** (1989) (hereinafter SRBE, **Clinics**).

15 *See* Subcommittee on Health and The Environment, *supra* note 3; **Fertility Clinic Success Rate and Certification Act of 1992** H.R. Rep. No. 102-624 (1992); and U.S. Senate, **Fertility Clinic Success Rate and Certification Act of 1992** S. Rep. No. 102-452 (1992).

16 *See* Society for Assisted Reproductive Technology, 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** 1 (1995); and Centers for Disease Control and Prevention, **Assisted Reproductive Technology Success Rate in the United States: 1995 National Summary and Fertility Clinic Report** (1997).

The main goal of these four committees was to provide direction for public policy in relation to IVF and other associated technologies. Unlike the Victorian, the British, and the Spanish studies, the U.S. report does not offer recommendations. Its main purpose is, however, similar to that of the other studies: to help legislative policymakers by providing information about the new reproductive technologies.

The main conclusions of these IVF assessments are analogous, although there are areas of disagreement. For married or stable couples, all of the reports conclude that artificial insemination and IVF are legitimate medical responses to infertility but that informed consent is a precondition for treatment. They argue that some forms of embryo research, such as cloning, clearly are unacceptable. However, others forms of embryo research are permissible within the first fourteen days of development *in vitro,* provided that ethics committees regulate and approve them. Commissioners also agree that governments should allow the donation of embryos. Similarly, the reports concur that governments should regularize the legal status of children conceived through the new reproductive technologies. They also emphasize the need to establish some form of national accreditation or licensing for assisted-conception clinics.

Underestimating IVF Risks

The issue of whether women undergoing IVF may be exposed to serious risks is important not only for scientific reasons, but also basic ethical, political, and social ones. Assessment of the existing scientific evidence on IVF safety and efficiency is therefore crucial in order to provide input to policymakers. In this section, I offer a brief account of the data on IVF risks. Next, I argue that evaluators on the four commissions seem to have underestimated the importance of IVF hazards.

IVF Risks

According to empirical evidence, risks to women undergoing IVF treatment vary from simple nausea to death. For example, the hormones that doctors use to stimulate the ovaries are associated with numerous side effects. Some studies assert that ovulation induction may be a risk factor for certain types of hormone dependent cancers.

Researchers have associated excessive estrogen secretion with ovarian and breast carcinoma, and gonadotropin secretion with ovarian cancer.[17] A substantial body of experimental, clinical, and epidemiological evidence indicates that hormones play a major role in the development of several human cancers.[18] The ability of hormones to stimulate cell division in certain organs, such as the breast, endometrium, and the ovary, may lead (following repeated cell divisions) to the accumulation of random genetic errors that ultimately produce cancer. Hormone-related cancers account for more than 30% of all newly diagnosed female cancer in the U.S.[19] Hence, techniques such as IVF, that rely on massive doses of hormones, may be quite dangerous.

The ovarian hyperstimulation syndrome (OHSS) is another possible iatrogenic (caused by medical treatment) consequence of ovulation induction. Women with the severe form of OHSS may suffer renal impairment, liver dysfunction, thromboembolic phenomena, shock, and even death. The incidence of moderate and severe OHSS in IVF treatment ranges from 3-4%. An incidence of 3-4% is high, considering IVF is a selective procedure that treats a non-life-threatening condition. Moreover, this syndrome is extremely rare following natural conception.[20]

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[17] *See, e.g.,* John Jarrel et al., *Adverse Health Effects of Drugs Used for Ovulation Induction,* **New Reproductive Technologies and the Health Care System. The Case for Evidence-Based Medicine,** Royal Commission on New Reproductive Technologies (1993); Patricia Stephenson, *Ovulation Induction During Treatment of Infertility: An Assessment of the Risks*, **Tough Choices**, (Patricia Stephenson & Marsden G. Wagner eds., 1993); A. Brzezinski, et al, *Ovarian Stimulation and Breast Cancer: Is There a Link?* 52 **Gynecol. Oncol.** 3 (1994); and R. E. Bristow & B. Y. Karlan, *The Risk of Ovarian Cancer after Treatment for Infertility*, 8 **Curr. Opin. Obstet. Gynecol.** 1 (1996).

[18] *See, e.g.,* S. Fishel & P. Jackson, *Follicle Stimulation for High-Tech Pregnancies: Are We Playing It Safe?* 299 **British Med J.** 309 (1989); Stephenson, *supra* note 17, at 105.

[19] *See, e.g.,* H. P. Schneider & M. Birkhauser, *Does Hormone Replacement Therapy Modify Risks of Gynecological Cancers?* 40 **Int. J. Fertil. Menopausal Studies** suppl. 1 (1995); T. J. Key, *Hormones and Cancer in Humans,* 333 **Mutat. Res** 1 (1995); F. Berrino et al., *Serum Sex Hormone Levels after Menopause and Subsequent Breast Cancer,* 88 **J. Natl. Cancer Inst.** 5 (1996).

[20] *See, e.g.,* B. Rizk, *Ovarian Hyperstimulation Syndrome,* **A Textbook of *in Vitro* Fertilization and Assisted Reproductive Technology,** (Peter R. Brinsden & Paul A. Rainsbury eds., 1992); I. Calderon & D. Healy, *Endocrinology of IVF*, **Handbook of *In Vitro* Fertilization,** (A. Trounson & D. K. Gardner eds.,1993); M.

Procedures doctors normally use to obtain women's eggs, i.e., laparoscopy and ultrasound-guide oocyte retrieval also pose risks to them. Although there is no accurate statistical data about hazards associated with these two procedures, risks related to these technologies include postoperative infections, punctures of an internal organ, hemorrhages, ovarian trauma, and intrapelvic adhesions.[21] Furthermore, intrapelvic adhesions can exacerbate preexisting infertility or cause it in healthy women who undergo IVF treatments when their male partners have reproductive difficulties.[22] Thus IVF could increase or produce the very problem for which women use it as treatment.

Implantation of embryos or gametes into women's bodies also may be hazardous for them. Some of the possible risks are perforation of organs and ectopic pregnancies. Studies show that 5-7% of all IVF pregnancies implant outside the uterus.[23] That hazard in the general population, however, is approximately 1%.[24] Ectopic gestations may be life-threatening for the woman and can aggravate infertility.[25]

P. Steinkampf & Richard E. Blackwell, *Ovulation Induction*, **Textbook of Reproductive Medicine** (Bruce R. Carr & Richard E. Blackwell eds., 1993); Stephenson, supra note 17; J. G. Schenker & Y. Ezra, *Complication of Assisted Reproductive Techniques,* 16 **Fertility and Sterility** 3 (1994); and J. G. Schenker, *Ovarian Hyperstimulation Syndrome,* **Reproductive Medicine and Surgery** (Edward E. Wallach & Howard A. Zacur eds., 1994).

21 *See, e.g.,* Rowland, *supra* note 1, at 325-30; Lene Koch, *Physiological and Psychosocial Risks of the New Reproductive Technologies*, **Tough Choices** (Patricia Stephenson & Marsden G. Wagner eds., 1993); and P. J. Taylor & J. V. Kredentser, *Diagnostic and Therapeutic Laparoscopy and Hysteroscopy and Their Relationship to in Vitro Fertilization,* **A Textbook of *in Vitro* Fertilization and Assisted Reproductive Technology** (Peter R. Brinsden & Paul A. Rainsbury eds., 1992).

22 *See* Peter R. Brinsden, *Oocyte Recovery and Embryo Transfer Techniques for in Vitro Fertilization,* **A Textbook of *in Vitro* Fertilization and Assisted Reproductive Technology** (Peter R. Brinsden & Paul A. Rainsbury eds., 1992); Rowland, *supra* note 1, at 25; Koch, *supra* note 21.

23 Medical Research Institute, Society of Assisted Reproductive Technology, The American Fertility Society, *In Vitro Fertilization/ Embryo Transfer in the United States: 1988 Results from the National IVF-ET Registry,* **Fertility and Sterility** (1990)

24 *See* O. K. Davis & Z. Rosenwaks, *Assisted Reproductive Technology,* **Textbook of Reproductive Medicine** (Bruce R. Carr & Richard E. Blackwell eds., 1993); *See also,* S. F. Marcus & Peter R. Brinsden, *Analysis of the Incidence and Risk Factors Associated with Ectopic Pregnancy Following In Vitro Fertilization and Embryo Transfer,* **Human Reproduction** (1994).

25 *See* Brinsden, *supra* note 22; Rowland, *supra* note 1, at 30-32; Koch, *supra* note 21.

Likewise, multiple gestation occurs in about 25% of IVF pregnancies,[26] while it has an incidence of only 2% in the general population.[27] Multiple-birth pregnancies increase the danger of miscarriages, cesarean sections, early labor, and placental dysfunction.

The Assessments' Treatment of Evidence on IVF Risks

In spite of the significance of data on IVF risks, particularly those related to cancer, evaluators on the four commissions seem to have undervalued this information. In the Victorian and the British reports discussion about the known and suspected dangers of IVF is insignificant. They describe the steps of the procedure without referring to possible associated hazards. For instance, when addressing ovulation induction (a step in IVF), the Victorian report argues that using fertility drugs to stimulate the ovaries during IVF treatments seems "reasonable since pregnancy often followed the use of fertility drugs in women who were not ovulating."[28] According to this report, having ovarian stimulation therapy is almost routine for treating women who undergo IVF.[29] Despite the cancer risks, there is no mention, however, of any possible hazards associated with such a therapy. Similarly, the British report presents the use of ovarian stimulation as "very desirable" because it allows the transfer of more than one embryo to the woman's uterus and thus increases the chances of obtaining a pregnancy.[30] Like the Victorian assessment, here there is no discussion whatsoever about cancer risks associated with ovulation-induction drugs.

The Spanish report, on the other hand, does allude to some of the dangers associated with IVF. Nevertheless, it refers to them as "scarce but existent."[31] After this characterization, there is a succinct reference to some of the risks related to IVF. Assessors say that there are some

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26 *See, e.g.,* World Health Organization (WHO), *Recommendations on the Management of Services for in Vitro Fertilization from the WHO 1990,* **British Medical Journal** (July 25, 1992); and Stephenson, *supra* note 17, at 100.

27 *See, e.g.,* Stephenson, *supra* note 17, at 100; and S. Brownlee, *The Baby Chase: Millions of Couples Have Infertility Problems, and Many Try High-Tech Remedies. But Who Minds the Price Clinics They Turn to?,* **News and World Report** (Dec. 5, 1994).

28 Committee to Consider the Social, Ethical, and Legal Issues Arising from *In Vitro* Fertilization, Interim Report (1982).

29 *Id.* at 9.

30 Warnock, *supra* note 11, at 30-31.

31 Spanish Commission, *supra* note 7, at 107.

hazards "derived from overstimulation of the ovaries."[32] They fail to mention, however, what those risks are. Next, they say that there are some dangers "derived from general anesthesia, and generated from the surgical procedures used to obtain the eggs, including infections."[33] There is no reference to what kinds of risks are associated with the techniques employed for the retrieval of oocytes or the type of infections these procedures may cause. Evaluators also refer to the risks "derived from multiple-births pregnancies."[34] They say that these kinds of gestations may "produce triplets, quadruplets, etc., with the related obstetric problems (for the woman and children), pediatrics (for the children), and psychological (for the couple)."[35] Again, evaluators fail to mention specific obstetric or pediatric risks, such as use of caesarian sections, early labor, and low-birthweight children that are associated with multiple births.

The U.S. study offers more information about IVF risks than the other reports. It describes some of the potential hazards associated with IVF and related techniques. The U.S. assessment mentions risks produced by the use of fertility drugs such as hyperstimulation, hazards derived from the utilization of techniques to retrieve oocytes such as blood in urine, and dangers attributable to the embryo-transfer procedure such as trauma to the endometrium.[36] It also refers to the fact that "transferred embryos may implant in the fallopian tube"[37] Furthermore, the report says that "the miscarriage rate for infertility patients is generally higher than that for the normal population."[38] And that "preterm delivery is more common in pregnancies after IVF than in spontaneous pregnancies."[39] The U.S. study fails to mention, however, any data about cancer risks. When summarizing the main points of the chapter, the report neglects to mention any information at all about hazards.[40]

32 *Id.*
33 *Id.*
34 *Id.*
35 *Id.*
36 OTA, **Infertility**, *supra* note 2, at 131.
37 *Id.*
38 *Id.*
39 *Id.*

Overlooking the Insufficiency of Data on IVF Risks

Apart from overlooking or underestimating the known risks associated with IVF and related procedures, the commissions also have undervalued the importance of the deficiencies in the existing research and the significance of the scarcity of good investigations on IVF hazards. Assessors seem to have failed to take into account what experts do not know about IVF and related techniques. For instance, evaluators neglect the fact that there is insufficient evidence concerning the long-term effects, such as ovarian and breast cancer, of ovulation-induction drugs in women. Although they recognize the need for improvement in IVF and related procedures, neither the Victorian, the British, nor the Spanish reports pay attention to the lack of studies on hazards associated with IVF. Only the U.S. assessment mentions the scarcity of research on maternal health consequences and anomalies in offspring.[41] It does not concede, however, particular significance to this lack of evidence.

Today, more than ten years after the presentation of the first IVF reports (the British and the Victorian), there is a lack of scientifically valid information obtained from clinical trials and other epidemiological investigations on IVF and related techniques. A study conducted in 1993 by the Canadian Royal Commission on New Reproductive Technologies shows that comprehensive evaluations of costs, benefits, risks, and efficiency are still necessary. Systematic data collection is lacking because no organization or agency gathers information on IVF outcomes. For the same reason, little or no follow-up data exist on what happens to children and women after the pregnancies. Record-keeping practices vary markedly among clinics and practitioners, with some clinics not recording data on whether a particular IVF procedure resulted in a live birth.[42] Moreover, because physicians still do not report all adverse health effects of the ovulation-induction drugs that doctors use in IVF treatment, identification of short-term and long-term risks associated with exposure is difficult.

40 *Id.*

41 *Id.*

42 *See* SRB, **Consumer,** *supra* note 14; SRBE, **Clinics,** *supra* note 14; SHE, **Fertility,** *supra* note 3; and Royal Commission on New Reproductive Technologies, **Proceed with Care** (1993).

Insufficient information about the type of reproductive problem, hormones used, dosage, and duration of infertility treatment make it arduous to assess the impacts of these drugs. Likewise, because of the long latency period of cancer, early detection of the disease is difficult.[43] Despite the evidence that shows hormones play an important role in the development of ovarian and breast cancer, the overall picture indicates that researchers have displayed very limited interest in investigating the frequency, mechanisms, or impact of the negative health consequences of ovulation-induction therapy.

Investigators have never properly evaluated hormone and IVF-related drugs prior to their introduction into clinical practice. Their omission is serious. In the past, disastrous consequences have followed from the use of drugs, pesticides, and technologies prior to their assessment. In addition to DES and the Dalkon Shield cases, other instances illustrating the danger of a "use first, evaluate later" practice are the utilization of the pesticide DDT and the implementation of commercial nuclear fission. For example, after years of using DDT, scientists found that this pesticide had the paradoxical consequence of producing a greater pest problem than the one it was supposed to combat. This is because evolution selects for pesticide-resistant insects. The new, stronger insects are more lethal and require more powerful pesticides, which in turn lead to increasing threats to humans and to even more resistant insects.[44] Commercial nuclear fission constitutes another example of implementation of a technology prior to its assessment. Nuclear power has been used for decades in spite of our ignorance of the dangers of low-level nuclear radiation, our knowledge of the probabilities of core melt, and our inability to give a guarantee that disposing of nuclear waste will not harm future generations.[45]

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43 *See* Royal Commission on New Reproductive Technologies, **New Reproductive Technologies and the Health Care System. The Case for Evidence-Based Medicine** (1993) (hereinafter RCNRT, **Evidence-Based Medicine**); *See also*, SRB, **Consumer,** *supra* note 14, at 30-32; SRBE, **Clinics**, *supra* note 14; SHE, **Fertility,** *supra* note 3; Finoa J. Stanley & Sandra M. Webb, *The Effectiveness of in Vitro Fertilization: An Epidemiological Perspective*, **Tough Choices** (Patricia Stephenson & Marsden G. Wagner eds., 1993); and WHO, *Recommendations, supra* note 1, at 251.

44 *See, e.g.,* Rachel Carson, **Silent Spring** (1962); **The Environmental Crisis** (N. Bernard 1991); Kristen Shrader-Frechette, *Pesticide Toxicity: An Ethical Perspective,* **Environmental Ethics** (1991).

45 *See, e.g.,* Kristen Shrader-Frechette, **Nuclear Power and Public Policy** (1980); N. Lenssen, *Nuclear Waste: The Problem That Won't Go Away*, **State of the World**

Likewise, after 30 years of using ovulation-induction hormones, and despite the strong correlation between hormones and cancer, sound investigations of their adverse consequences still are scarce.[46] In comparison, investigators have extensively reviewed drugs administered for chemotherapy and cardiac arrhythmia for their side effects. According to the Canadian study, however, the potential for adverse health consequences in young women using these ovulation-induction drugs is as great as, or greater than, that associated with the treatment of cancer or heart disease.[47] The differences in the investigations of the health impacts of various medications and techniques force one to wonder whether unfair discrimination against women has played a role in the inadequate attention given to the analysis of ovulation-induction drugs. Discrimination has already occurred in other areas of biomedical science, as research into cardiovascular disease illustrates. Although heart trouble is the leading cause of death of women in the U.S., cardiac research has concentrated almost entirely on men. Similarly, an investigation demonstrating the effectiveness of aspirin in preventing migraine headaches involved only male subjects, although women outnumber male migraine sufferers three to one.[48]

Assessment, of both the available scientific evidence and the insufficiency of data on IVF risks, is essential to provide information to guide public policy. Assessors have undervalued both areas. By underestimating hazards and the insufficiency of information on dangers, evaluators erroneously have presented this technology as safe. They seem to have assumed that because the evidence has not proved IVF to be risky, then the procedure is safe. Assessors have, therefore, overlooked a third possibility: that IVF threats are uncertain.

(Lester R. Brown ed., 1992); and Kristen Shrader-Frechette, **Burying Uncertainty** (1993) (hereinafter Shrader-Frechette, **Burying**).

46 C. D'Arcy et al., *Infertility Treatment--Epidemiology, Efficacy, Outcomes, and Direct Costs: A Feasibility Study, Saskatcheman 1978-1990,* **Evidence-Based Medicine, RCNRT** 765.

47 Jarrel et al, *supra* note 17, at 520.

48 *See, e.g.,* Hilde Lindemann Nelson & James Lindemann Nelson, *Justice in the Allocation of Health Care Resources: A Feminist Account*, **Feminist and Bioethics** (Susan M. Wolf ed., 1996), at 351-370 (hereinafter Lindemann Nelson, *Justice*). *See also, The Special Report On Women's Health Research*, 269 **Science** (Anna C. Mastronianni et al. eds., August 11, 1995); **Women and Health Research: Ethical and Legal Issues of Including Women in Clinical Studies** (hereinafter Mastronianni et al., **Women and Health Research**).

Ethical Alternatives Under Uncertainty

We are forced to make numerous decisions every day. In some cases they are thoughtful, while others are the result only of habit. Because the consequences of our choices affect our lives, we try to make good decisions. However, the conditions under which we have to choose are not always similar. Thus, we may face situations of certainty, risk, and uncertainty. In a situation of certainty we know that a choice will result in a particular outcome. For example, if we use cars that burn gas then we are certain to have the outcome of producing CO2. In conditions of risk, we know, with a specific probability, whether a choice will result in a given outcome. For instance, when rolling a fair die, we know the particular probability of obtaining a "five." Finally, situations of uncertainty occur when we have partial or total ignorance about whether a choice will result in a given outcome with an assigned probability. For example, if using ovulation-induction hormones, we have partial ignorance about whether such a choice will result in the probability that at least 10,000 women undergoing IVF treatment will die because of reproductive cancers in a time period of 30 years following the procedure.[49]

Decisions under conditions of certainty and risk are relatively unproblematic because we can attach specific probabilities to given outcomes. Uncertainty situations, however, present more difficulties for decisions because probabilities of particular outcomes are unknown.

Because of limited data, questionable theories, or problems of theoretical underdetermination by the evidence, much scientific research is uncertain.[50] Given this uncertainty in science, most technology-related decision making takes place in situations of limited knowledge. People rarely have complete, accurate knowledge of all the probabilities associated with various outcomes of taking technological risks (e.g., ovulation-induction drugs, laparoscopy, ultrasound), because very risky technologies are often new.

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49 *See, e.g.,* Kristen Shrader-Frechette, **Risk and Rationality** (1991) (hereinafter Shrader-Frechette, **Risk**).

50 *See, e.g.,* Norwood R. Hanson, **Patterns of Discovery** (1958); M. Polanyi, **Personal Knowledge** (1958) Karl R. Popper, **The Logic of Scientific Discovery** (1959); Karl R. Popper, **Conjectures and Refutations** (1963); Carl Hempel, **Philosophy of Natural Sciences** (1966); Thomas Kuhn, **The Structure of Scientific Revolutions** (1970).

False Positives and False Negatives

Consider the case of evaluators who must assess the uncertain consequences of implementing a new technology, such as IVF, to treat infertility. Because the decision may have serious social, economic, and political consequences, analysts must determine what particular criteria to use to know how to interpret the uncertain results. For instance, if they overemphasize the risks that this new technique may pose to women, the community (e.g., industry and those who are infertile) may bear serious losses because of governments' restricting use and expansion of IVF. If, on the other hand, assessors underemphasize the dangers, many women (those who use IVF) could suffer significant health problems or even death. Thus, because of the uncertainties in scientific information, when analysts reach their conclusions about implementation or regulation of a new technology, they must decide whether minimizing false positives is better or worse than minimizing false negatives, when both are not possible.

In a situation of uncertainty, false positives (type-I errors) occur when one rejects a null hypothesis that is true; false negatives (type-II errors) occur when one fails to reject a null hypothesis that is false. (An example of a null hypothesis might be, "IVF does not pose a statistically-significant increased risk of death to women over a ten-year period after the use of the technique.")[51] In assessing technological impacts under conditions of uncertainty, assessors must then decide whether to run the risks of rejecting a true null hypothesis (not using or expanding IVF when it is really safe and effective), or run the risks of not rejecting a false null hypothesis (using or expanding IVF when it is really unsafe and inefficient). Thus in situations of uncertainty, if evaluators minimize false positives when analyzing IVF, they minimize the possibility of restricting a harmless technology. On the other hand, if they decide to minimize false negatives, they minimize the error of accepting a harmful procedure. Under conditions of uncertainty, decreasing the risks of false positives might result in underregulation of IVF and related techniques and therefore may hurt women's health. To minimize risks of false negatives might, however, produce

[51] *See, e.g.,* Shrader-Frechette, **Risk**, *supra* note 49, at ch. 9; C. F. Cranor, **Regulating Toxic Substances** (1993); Kristen Shrader-Frechette, **Ethics of Scientific Research** (1994).

overregulation. This strategy may impose excessive costs on manufacturers of IVF, and may hurt infertile people who want to use the technology.[52]

Preferences for minimizing false positives in situations of uncertainty may arise for several reasons.[53] Minimizing false positives, for example, appears more consistent with scientific practice. Hypothesis-testing in science functions on the basis of limiting false positives or limiting rejections of a true null hypothesis. The justification for this strategy seems to be that keeping the chances of rejecting a true null hypothesis low, researchers try to ensure an increase in scientific knowledge. Attempting to minimize false positives under conditions of uncertainty is also a common practice in criminal cases. In the criminal law the jury must be sure beyond a reasonable doubt that a defendant is guilty before convicting him. This is the basis for the idea that it is better for ten guilty people to go free rather than for one innocent person to be wrongly convicted.

Similarly, preferences for minimizing false positives in situations of uncertainty may arise because technical experts almost always use widely accepted Bayesian decision rules based on expected utility and subjective probabilities rather than the maximin principle.[54] As a result, even if everybody agrees that the probability of a high-consequence effect is uncertain but low, utilizing a Bayesian decision rule usually produces a choice in favor of the low-probability, but potentially-catastrophic, technological impact. In the same case, however, employing a maximin decision rule typically produces a conclusion against an uncertain but potentially dangerous consequence. Assessors' sanction of IVF use seems to indicate a preference for

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52 Shrader-Frechette, **Risk,** *supra* note 49, at ch. 9; Cranor, **Regulating,** *supra* note 51; and Shrader-Frechette, **Research**, *supra* note 51, at ch. 6. *See also*, C. W. Churchman, **Theory of Experimental Inference** (1947).

53 *See, e.g.,* Shrader-Frechette, **Risk**, *supra* note 49, at ch. 9; and Cranor, **Regulating**, *supra* note 51, at chs. 2, 4.

54 *See, e.g.,* Shrader-Frechette, **Risk,** *supra* note 49, at ch. 8; and Shrader-Frechette, **Research**, *supra* note 51 at ch. 6; *See also*, John Harsanyi, *Can the Maximin Principle Serve as a Basis for Morality? A Critique of John Rawls's Theory*, 69 **American Political Science Review** 2 (1975); John Harsanyi, *Understanding Rational Behavior,* **Foundational Problems in the Special Sciences** (R. E. Butts & Jaakko Hintikka eds., 1977); John Harsanyi, *Advances in Understanding Rational Behavior*, **Rational Choice** (Jon Elster ed., 1986); and John Rawls, **A Theory of Justice** (1971); *See also,* Michael Resnick, **Choices** (1986).

maximizing expected-utility rather than for using maximin. Thus, although the case of IVF is one of uncertainty with potentially dangerous consequences, evaluators have condoned the extensive use and expansion of the technique.

In the next section, I argue that in a case of uncertainty, such as that regarding the consequences of employing IVF, there are prima facie grounds for minimizing false negatives because underestimating the risks of this procedure may have disastrous consequences for women's health and well being.

Arguments for Minimizing False Negatives when Assessing IVF

There are several reasons for holding that, in situations of scientific uncertainty such as that of implementing IVF, assessors have a prima facie duty to minimize false negatives.[55] First, protecting the public from serious harm usually takes precedence over enhancing its welfare. Second, groups that are especially vulnerable need special protection. I treat these reasons in order.

First, protecting people justifies minimizing false judgments that a potentially damaging technology such as IVF is harmless. Most political theorists would agree that protecting the public from serious harm (e.g., cancer and death) takes precedence over enhancing its welfare (e.g., by permitting wide IVF development).[56] The justification (for preferring to prevent harm rather than to enhance welfare under conditions of uncertainty when both are not possible) is that protecting from harm appears to be a necessary condition for enjoying other freedoms. Thus, most political theorists would agree that individuals are responsible for obtaining their particular enjoyments, whereas the main responsibility of governments should be protecting from harm.[57] Also, health-care professionals often invoke

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55 *See* Shrader-Frechette, **Risk**, *supra* note 49, at ch. 9; Cranor, **Regulating** *supra* note 51; and Shrader-Frechette, **Research,** *supra* note 51, at ch. 6.

56 *See* Jeremy Bentham, *Principles of Civil Code*, **The Works of Jeremy Bentham** (John Bowring ed., 1962) (hereinafter Bentham, *Principles*); William Frankena, **Ethics** (1973); Michael A. Slote, *The Morality of Wealth,* **World Hunger and Moral Obligation,** (William Aiken & Hugh LaFollette eds., 1977); RCNRT, **Care,** *supra* note 42, at ch. 15; Peter Singer, **Practical Ethics** (1993); and Tom L. Beauchamp & James F. Childress, **Principles of Biomedical Ethics** (4th ed. 1994) .

57 *See, e.g.,* Beauchamp, **Principles**, *supra* note 56; and Frankena, **Ethics**, *supra*

the Hippocratic maxim: "Above all do no harm", to exemplify the need to protect patients against harmful actions.

Protecting women against risks to their health posed by IVF is a case of protection from harm rather than an enhancement of welfare, because risks to health are harms. As we have seen, women who undergo the IVF procedure may be exposed to serious hazards such as cancer and death. Obviously, women have rights to bodily security. But assessors of IVF have underestimated the existing scientific evidence and the insufficiency of data on IVF risks. Studies also show that it is likely that infertility doctors underemphasize uncertainty regarding this procedure because, in general, physicians tend to disregard uncertainty in their practices.[58] Thus because womens lack of information may hinder their abilities to give free informed consent, using techniques that might cause cancer and death could jeopardize women's rights to bodily security.

Similarly, IVF induced disease and disability may restrict the range of opportunities individuals have opened to them.[59] Illness also may limit appreciation of other enjoyments. Employing drugs and procedures that may imperil women's health may then disrupt their general well-being. Therefore, in underestimating the risks of a technology that may produce death and illness, assessors have failed to protect against loss of a good, namely women"s health and well being. Thus, they have failed to prevent harm. Someone might argue that restricting IVF is not a case of preventing harm because women want it, and choosers do not select to harm themselves. However, because women lack information on IVF risks and benefits, we cannot say that they really choose to undergo IVF treatment. Therefore, restricting use of IVF is a case of protecting from harm, because women are not adequately informed.

Granted, permitting the implementation of IVF may constitute a case of enhancing welfare for some people (those who might be able to have children through the procedure). However, the success rate of IVF

note 56.

58 *See, e.g.,* Jay Katz, *Why Doctors Don't Disclose Uncertainty*, 14 **The Hastings Center Report** 1 (1984); RCNRT, **Care**, *supra* note 42, at 545-48, and R. L. Logan, *Uncertainty in Clinical Practice: Implications for Quality and Costs of Health Care*, **Lancet**, 347 (1996).

59 *See, e.g.,* Norman Daniels, **Just Health Care** (1998).

is quite low (around 10%), cancer and death may be some of the outcomes, the uncertainties about possible risks are great, and there are other medical and preventive alternatives to IVF. Therefore, protecting women against risks to their health posed by IVF is more a case of protecting from harm than of enhancing welfare. Thus, if protecting from harm (such as illness and death) is more important than providing some good (such as having babies) then, in situations of uncertainty with potentially dangerous consequences, IVF assessors should minimize false negatives.

A second reason for limiting false negatives in situations of uncertainty, is that women historically are a vulnerable group. Even when women decide to undergo IVF treatment, they may be helpless because they lack adequate information on IVF risks and benefits.

Women are vulnerable when facing medical problems and need more protection because they often lack financial resources (they have less access to the job market than men and are often more financially dependent than men). They are vulnerable because frequently they lack information to deal with dangers that may affect them, as cases such as the implementation of DES, the Dalkon Shield, and Thalidomide show.[60] Furthermore, infertility generates a grave problem for women because they often accept the belief that childbearing is necessary for a satisfactory life.[61] As a consequence, they are particularly vulnerable, for they are less likely to be concerned about risks to their lives if they think they will have a chance of becoming mothers.

Women's vulnerability and their need for protection is also apparent when observing unjust discrimination against women in the provision of health care and in health research. For example, recent studies indicate that when women experience renal failure, they receive fewer kidney transplants than men. Females between the ages of 46 and 60 are only half as likely to receive a transplant as males of the same age.[62]

60 *See* Shrader-Frechette, **Risk,** *supra* note 49, at ch. 9; Beauchamp, **Principles**, *supra* note 56, at chs. 4-5; and Shrader-Frechette, **Research**, *supra* note 51, at ch. 6.

61 *See, e.g.,* Rita Arditti et al., **Test-Tube Women. What Future for Motherhood** (1984); Barbara K. Rothman, **Recreating Motherhood. Ideology and Technology in a Patriarchal Society** (1990); **Motherhood. Meanings, Practices, and Ideologies** (Ann Phoenix et al. eds., 1991); Mardy S. Ireland, **Reconceiving Women** (1993); and Rosie Jackson, **Mothers Who Leave** (1994).

62 *See* Lindemann Nelson, *supra* note 48, at 359.

Similarly, a study completed in 1987 showed that, all things being equal, men were 6.5 times as likely to be referred for cardiac catheterization (a prerequisite for coronary bypass surgery) than women, although men have only three times the likelihood of having coronary heart disease.[63] Medical research practices such as involuntary sterilization, hysterectomy, mastectomy, and high rates for cesarean births also show the necessity to protect women.[64] Women are also particularly vulnerable because of the predominance of males in the biomedical sciences. Medicine has historically excluded women and, still today, women constitute a minority in the hierarchy of this profession. Such exclusion may increase the chances of patronizing, unperceptive, and harmful attitudes toward female patients, including those using IVF.[65]

Because of the vulnerability of women in relation to medical issues in general, and reproductive problems in particular, IVF assessors have a prima facie duty to try to protect them from harms associated with this procedure. Therefore, evaluators have a prima facie duty to limit false negatives, given that doing so would likely protect women.

If assessors have a prima facie duty to minimize false negatives under conditions of uncertainty, then evaluators' decision to minimize false positives (in a situation of uncertainty having potentially dangerous consequences) is questionable. This preference is problematic because evaluators may have encouraged public policies that underestimate the possibilities of jeopardizing women's heath. For example, because decisionmakers might think that IVF does not pose serious risks for women, they might refrain from implementing stricter regulations in its application. They also may neglect the fact that a more adequate assessment of these technologies may be in order. Similarly, because they might assume that IVF is a safe treatment, policymakers might avoid or restrict funding for research about it as an infertility therapy.

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63 *See* J. N. Tobin et al., *Sex Bias in Considering Coronary Bypass Surgery*,107 **Annals of International Medicine** (1987); R. M. Steingart et al., *Sex Differences in the Management of Coronary Artery Disease*, 325 **New England Journal of Medicine** (1991); and Lindemann Nelson, *supra* note 48, at 359.

64 *See, e.g.,* Committee on Labor and Human Resources, **Women's Health: Ensuring Quality and Equity in Biomedical Research** (1992); and Mastronianni et al., **Women and Health Research**, *supra* note 48.

65 *See, e.g.,* Mary A. Warren, *Is IVF Research a Threat to Women's Autonomy?* **Embryo Experimentation** (Peter Singer et al. eds., 1990).

Some Objections and Responses

There are several objections that critics may pose to my analysis of IVF assessments. First, they may argue that evaluators have recommended obtaining written informed consent from women as a way to overcome problems with risks. Second, critics may claim that assessors' sanction of the use and expansion of IVF under conditions of uncertainty is adequate because restricting the use of this procedure would interfere with women's abilities to choose a risky technology, and such interference would be paternalistic. I treat these two objections in order.

Free Informed Consent as a Way to Overcome Problems with Risks

The first criticism of my analysis of IVF assessments (that evaluators have recommended obtaining written informed consent from women as a way to overcome problems with risks) seems particularly compelling because it emphasizes the requirement of informed consent. I argue, however, that this objection is questionable because it ignores the fact that if women lack adequate information about IVF risks and benefits, then they cannot give genuinely informed consent.

Legal, regulatory, medical, psychological, and philosophical literature tend to evaluate informed consent in terms of the following analytical components: (1) disclosure; (2) understanding; (3) voluntariness; and (4) competence.[66] Scholars argue that one gives informed consent to an intervention if and only if one is competent to act, receives a thorough disclosure about the procedure, understands the disclosure, acts voluntarily, and consents to the intervention. Disclosure, the main component of consent (from an institutional point of view), refers to the necessity of professionals' passing on information to decisionmakers and possible risk victims. Understanding, the second element in the process of obtaining free informed consent, requires professionals to help potential risk victims overcome illness,

[66] *See, e.g.,* A. M. & L. H. Roth, *What We Do and Do Not Know About Informed Consent,* 246 **J.A.M.A.** 21 (1981); U.S. President's Commission for the Study of the Ethical Problems in Medicine and Biomedical and Behavioral Research, **Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship** (1982); Ruth Faden & Tom L. Beauchamp, **A History and Theory of Informed Consent** (1986); and Beauchamp, **Principles**, *supra* note 56, at ch. 3.

irrationality, immaturity, distorted information, or other factors that can limit their grasp of the situation to which they have the right to give or withhold consent. Voluntariness, or being free to act in giving consent, requires that the subjects act in a way that is free from manipulation and coercion by other persons. Finally, the criterion of competence demands that potential risk victims give autonomous authorization to some act, such as approving certain fertility treatment.

Given these elements that scholars recognize as necessary for informed consent, to claim that women can give free informed consent to IVF treatment is questionable. If women are ignorant of the fact that IVF is of unproved benefit for many infertility conditions, and if they are not aware that the treatment may have unknown risks, then they cannot give genuinely informed consent. Lack of information may seriously hinder people's abilities to make informed choices. Some of the relevant data necessary for insuring free informed consent of women undergoing IVF include (1) personal chances of having a child as a result of the treatment; (2) alternatives to the procedure; (3) long-term effects; (4) emotional demands that the treatment imposes (timing of sexual relations, frequent visits to the clinic, failing to achieve a pregnancy); and (5) short-term consequences of the treatment. According to some recent studies, the majority of IVF patients surveyed were dissatisfied with information received in these areas.[67]

Critics still may argue that it is the individual's responsibility, and not that of the assessors', to inform themselves about IVF risks and benefits as fully as possible. IVF evaluators' roles are not to educate infertile people on the hazards and effectiveness of this procedure but to analyze the data they consider relevant for policymaking. This objection is questionable. Government IVF commissions are fundamental steps in the adoption and implementation of particular policy decisions. Thus, they are obligated to ensure that inappropriate or unethical use of IVF is prohibited and that the necessary mechanisms to protect informed decision making are in place. Furthermore, given the infertile couples' strong desire to utilize all possible successful treatments, their ability to give genuinely informed consent could be compromised. Because of the committees' influence on the approval of

67 *See* RCNRT, **Care**, *supra* note 42, at 547.

certain public policies, they also have a responsibility to reduce, where possible, vulnerability in relation to infertility treatments and to ensure that those who are in positions of power and authority do not manipulate or control those who are vulnerable. For this reason, accurate information seems particularly important.

Interfering with Women's Rights to Choose Risky Technologies

A second objection to my analysis of IVF assessments is that evaluators' sanctioning the use and expansion of IVF under conditions of uncertainty is adequate.The argument is that by restricting the use of this procedure, it would interfere with women's abilities to choose a risky technology, the benefits of which they desire. According to those who support procreative rights, such interference would be paternalistic.[68] I argue that criticizing my analysis for encouraging interference with the implementation and use of IVF, on grounds of unjustified paternalism, fails. The objection errs because such interference may not be paternalistic at all or may be a case of justified paternalism for several reasons. First, women's consent to IVF is not adequately informed. Second, extensive use of IVF may harm other members of the community such as children, the poor, and minority women. I treat these reasons in order.

Philosophers often define "paternalism" as the intentional overriding of one person's preferences or actions by another individual or institution under the justification of benefiting or avoiding harm to the person whose will is overridden.[69] Most moral and political philosophers also agree that paternalistic interventions are sometimes justified.[70] Similarly, they usually distinguish between weak (soft) and strong (hard) paternalism.[71] In weak paternalism, an agent intervenes on grounds of beneficence or nonmaleficence only to protect people against their own substantially nonautonomous actions. These actions

68 *See, e.g.,* John Robertson, **Children of Choice** (1994).

69 *See, e.g.,* Joel Feinberg, *Legal Paternalism*, 1 **Canadian Journal of Philosophy** 105 (1971) (hereinafter Feinberg, *Paternalism*); Gerard Dworkin, *Paternalism*, 56 **The Monist** 64 (1972); Immanuel Kant, **On the Old Saw: That May Be Right in Theory But It Won't Work in Practice** (E. B. Ashton trans., 1974); John S. Mill, 18 **On Liberty. Collected Works of John Stuart Mill** (1977); John Kleinig, **Paternalism** (1983); D. Van DeVeer, **Paternalistic Intervention** (1986); and Beauchamp, **Principles**, *supra* note 56, at 271.

70 *See, e.g.,* Feinberg, *Paternalism*, *supra* note 69, at 105.

71 *Id.*

include cases of consent that are not adequately informed, severe depression that precludes rational deliberation, and critical addiction that precludes free choice and action. Strong paternalism, on the other hand, involves interventions intended to prevent harm to an individual despite the fact that the individual's risky actions are informed, voluntary, and autonomous.[72] The case of IVF constitutes, as we shall see, a case of weak paternalism.

If the previous discussion of informed consent is correct, then we cannot say that women's consent to IVF is adequately informed, because many women appear to lack relevant information on IVF risks and benefits. Therefore, promoting restrictions on the use of IVF would be a case of weak paternalism because women cannot give free informed consent to the procedure. But, that persons deserve to be protected from harm caused to them by conditions beyond their control is hardly questionable.[73] If this is so, then evaluators' support for regulation or restriction of IVF does not constitute a case of strong or unjustified paternalism, because women are not adequately informed about the possible hazards to their health or about the likelihood of becoming pregnant through this procedure.

Second, encouraging interference with women's procreative liberty by restricting use of IVF may not be paternalistic in the strong sense because such use may harm others. Certainly, procreative liberty is extremely important because of the effects that the decision to have or to refrain from having children may present to our sense of dignity, identity, and meaning of life.[74] However, emphasizing the primacy of procreative liberty risks overlooking the fact that reproduction clearly involves the community.[75] Reproduction always occurs with a partner and normally requires the collaboration of doctors and nurses. Moreover, reproduction affects others by creating a new person. In centering the debate on the right to have children, critics may treat as

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72 *See* Feinberg, *Paternalism*, *supra* note 69, at 113, 116; and Beauchamp, **Principles,** *supra* note 56, at 277.

73 *See* Joel Feinberg, *Harm to Self,* **The Moral Limits of the Criminal Law** (vol. III, 1986); and Beauchamp, **Principles,** *supra* note 56, at 277.

74 *See, e.g.,* Robertson, **Choice,** *supra* note 68.

75 *See, e.g.,* Mary A. Glendon, **Rights Talk: The Impoverishment of Political Discourse** (1991); Elizabeth Kingdom, **What's Wrong with Rights: Problems for Feminists Politics of Law** (1991).

irrelevant to moral analysis or public policy the effects of reproductive choices on women, on offspring, on family, and on society.

Furthermore, restricting IVF and related technologies may not be paternalistic in the strong sense because these procedures also can affect other members of the community and the community as a whole by changing profoundly held values. For example, using IVF techniques, a child may have up to three mothers: the woman who provides the egg, the woman who bears the child, and the one who rears her. The impacts of IVF on children's psychological well being and on society in general are unforeseen and may be far-reaching. Also, the use of IVF may harm women as a social group. For example, these medical procedures affect women as a group by promoting commercialization of reproduction. Sperm, eggs, embryos, and babies now have become commodities. This is obvious when the donation of gametes or the use of the uterus (in so-called "surrogate motherhood") involves profits for the donor. Exploitation of low-income women would be a clear reality in a system where gametes, embryos or wombs can be bought and sold. Participants at the UNESCO 1985 International Symposium (on the Effects on Human Rights of Recent Advances in Science and Technology) pointed out the problem of social and racial discrimination in the case of reproductive medicine. The Conference recognized that those most at risk from the assisted-conception procedures are poor, migrant, refugee, or ethnic minority women. Such risk comes, for example, from the possibility of using them as "Guinea pigs" in research on these technologies, as producers of eggs, or as surrogate mothers.[76]

If using IVF may substantially harm other members of the community, or women as a whole, then restrictions on this procedure may not be paternalistic at all or may be justified paternalistic actions. Certainly, the social consequences of the extensive utilization of IVF

[76] *See* UNESCO, **International Symposium on the Effects on Human Rights of Recent Advances in Science and Technology** (1985). S*ee also,* Rowland, **Laboratories,** *supra* note 1, at 211-216; R. Koval, *The Commercialization of Reproductive Technology*, **Baby Machine. Reproductive Technology and the Commercialization of Motherhood** (Jocelynne A. Scutt ed., 1988); and Gena Corea, *Women, Class, and Genetic Engineering. The Effect of New Reproductive Technologies on all Women,* **Baby Machine. Reproductive technology and the Commercialization of Motherhood** (Jocelynne A. Scutt ed., 1988).

and related technologies are far from known. However, when assessing these procedures, evaluators also should analyze the ways in which reproductive decisions may alter and reflect all kinds of social forces. Total freedom to choose a technological option such as IVF may damage the achievements of liberty for many women, for people living in poverty, or for disabled people.

Furthermore, in countries with socialized health care such as Australia, Spain, and the United Kingdom, assessors charged with evaluating medical technologies have a duty to ensure that their evaluations do not encourage inefficient use of scarce resources. Not to do so may harm the public. Because the state's money is always scarce, decisions about resource allocation may have important ethical, economic, and political consequences. Encouraging public policies that use taxpayers money on an inefficient and expensive technology such as IVF might prevent decisionmakers from spending those same resources on more beneficial measures.

Summary and Conclusion

Because the Victorian, British, Spanish, and the U.S. reports influence public policies in relation to infertility treatments, evaluating their deficiencies is extremely important. Without such assessments, governments may make decisions that are not in the public's best interests. This essay has analyzed some of the inadequacies present in the reports mentioned. I have argued here that IVF assessors have underestimated the possibility of jeopardizing women's health because they have neglected epistemological and ethical problems such as choosing criteria for decisions under uncertainty. I have defended the thesis that evaluators have erred in their conclusions because, in a situation of uncertainty with potentially dangerous consequences, they have condoned the use of IVF. They have preferred to minimize false positives over false negatives. As a consequence, decisionmakers might promote policies that underestimate the possibility of endangering women's health.

