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The Frustaci Septuplets: Miracle or Malpractice

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NOTE

THE FRUSTACI SEPTUPLETS: MIRACLE OR MALPRACTICE?*

I. Introduction

On May 21, 1985, Patti Frustaci, a thirty year old high school English teacher, was wheeled into the delivery room at St. Joseph's Hospital in Orange, California. A thirty-eight member medical team[1] had been assembled to assist her in what was to become the largest multiple birth in American medical history. While the births marked the culmination of months of careful preparation on the part of the medical team, the caesarean section itself took only three minutes.[2]

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[1]For a more detailed description of the medical team assembled to assist with the birth of the Frustaci septuplets, see Summers, *The Frustaci Septuplets: Behind the Headlines*, 85 AM. J. NURSING 1323 (1985).

[2]Cummings, *Six Babies Born to Californian; 7th is Stillborn*, N.Y. Times, May 22, 1985, at A1, col. 1.

The seven infants, one of whom was stillborn, were twelve weeks premature.[3] Their weights ranged from 1 pound, 1 ounce to 1 pound, 13 ounces. Shortly after delivery, the infants were transferred to a special neonatal unit and placed on respirators and antibiotics to compensate for the immaturity of their lungs and immune systems.[4]

Within several weeks three of the septuplets had succumbed to the effects of the hyaline membrane disease[5] which had plagued each of the infants from birth.[6] By the end of October the three surviving septuplets, one girl and two boys, stabilized and were discharged from the hospital. The cost of their medical care has been estimated at $750,000.[7]

The events preceding the birth of the septuplets were as traumatic for the Frustacis as were the births themselves. From August to November of 1984, Mrs. Frustaci underwent treatment with the fertility drug Pergonal.[8] Ultrasound examinations[9] performed the following January revealed the presence of seven fetuses.[10] Mrs. Frustaci was confined to the hospital from March 25,

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[3]The average duration of a pregnancy is 280 days (40 weeks), calculated from the first day of the last menstrual period. Most babies — 85 to 95% — are born between the 266th and the 294th days. Common deviations thus range up to 14 days in either direction. L. NILSSON, A CHILD IS BORN 75 (1977).

In the Frustaci case, the medical team determined that the babies would have a much better chance of surviving if they completed 28 weeks of gestation before their birth. Surgery was scheduled after Mrs. Frustaci's condition declined from good to fair as a result of hypertension. (The hypertension threatened to deprive the fetuses of nutrition.) Cummings, *supra* note 2, at B4. *See infra* note 51 and accompanying text.

[4]Cummings, *supra* note 2, at B4.

[5]Hyaline membrane disease is a disorder of the alveoli and respiratory passages that results in inadequate expansion of the lungs. B. MILLER & C. KEANE, ENCYCLOPEDIA AND DICTIONARY OF MEDICINE AND NURSING 444-45 (1972). This condition is the major cause of death in the newborn period. It is estimated that 50% of all neonatal deaths result from hyaline membrane disease or its complications, and that it accounts for 10,000 to 25,000 deaths each year. The incidence of the disease is inversely proportional to the gestational age and weight. It occurs in about 60% of infants less than 28 weeks of gestational age, in 15 to 20% of those between 32 and 36 weeks, in about 5% beyond 37 weeks, and rarely at term. Behrman, *The Fetus and the Neonatal Infant*, in NELSON TEXTBOOK OF PEDIATRICS 428-29 (W. Nelson ed. 1979).

[6]Cummings, *Mother of 7 Visits Surviving Infants*, N.Y. Times, May 27, 1985, at A8, col. 1.

[7]Cummings, *supra* note 2, at B4.

[8]*Septuplets' Parents Charge Fertility Drug Malpractice*, Akron Beacon Journal, Oct. 9, 1985, at A1, col. 4.

[9]Ultrasonography is the process of representing deep structures of the body by measuring and recording the reflection of pulsed or continuous high frequency sound waves. It is valuable in many medical situations, including the diagnosis of fetal abnormalities and gestational age, and in other medical conditions, such as gallstones, heart defects, and tumors. Also called sonography. MOSBY'S MEDICAL AND NURSING DICTIONARY 1112 (1983).

[10]Cummings, *supra* note 2, at B4.

1985, until well after the delivery. In addition to the septuplets, Mrs. Frustaci and her husband Samuel have another child who had also been conceived during previous treatment with the drug.[11]

Although the Frustacis initially referred to the births as a "blessing"[12] on their family, the grief of losing four children, as well as the reality of caring for three premature infants, have resulted in their filing a multimillion dollar lawsuit against the doctor and clinic which prescribed the fertility drugs. The suit alleges medical malpractice, four wrongful deaths, loss of earnings and of earning capacity as a result of the overprescription of these drugs.[13] The Frustacis are seeking $1 million for current and future medical expenses, and $1.25 million for non-economic losses ($250,000 for each parent and for each of the three surviving infants).[14]

The possibility of imposing such liability has tremendous implications not only for the physician and clinic directly involved, but also for other health care practitioners, health care consumers, and the legal profession, as well. This Note will focus on those implications and proposes a solution to the issues raised by this type of litigation.

II. Infertility

Experts define infertility as "the inability to conceive a pregnancy after one year of sexual relations without contraception or the inability to carry a pregnancy to live birth."[15] Infertility in couples with no previous history of pregnancy is referred to as primary infertility. Secondary infertility implies that there has been at least one pregnancy before the present difficulty. Absolute infertility or true sterility describes an individual or couple in which conception is impossible and the causative factor is irreversible. Relative infertility is produced when various correctable factors hinder or delay conception.[16]

While the incidence of infertility has not been systematically documented in this country, it is estimated that fifteen percent of the population of child-

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[11]*Id.* The Frustaci's son was fourteen months old at the time the septuplets were born. Cummings, *Six Surviving Septuplets Weaken, But Doctor Says They're 'Fighters'*, N.Y. Times, May 23, 1985, at A1, col. 3.

[12]Cummings, *supra* note 2, at B4.

[13]Akron Beacon Journal, *supra* note 8, at A1.

[14]*Id.* at A10.

[15]A. BURGESS & A. LAZARE, COMMUNITY MENTAL HEALTH: TARGET POPULATIONS 105 (1976) [hereinafter A. BURGESS].

[16]J. WILLSON, E. CARRINGTON, & W. LEDGER, OBSTETRICS AND GYNECOLOGY 160 (1983) [hereinafter J. WILLSON].

bearing age is involuntarily infertile.[17] "This represents as many as one of every six couples of childbearing age, or approximately ten million Americans."[18] Of equal concern is the fact that the infertility rate seems to be increasing. Precise reasons for the increase are unknown. In recent years, however, many couples have opted to delay marriage and childbearing until after they have reached the age of thirty. This delay, along with the prolonged use of birth control, may be partially responsible for the increase.[19]

Although many consider infertility to be a female disorder, statistics indicate that this is far from true. "The three basic causes of infertility break down almost equally: male factor 35%, female factor 35%, and combined factor 30%."[20] In approximately 10% of all infertility cases no reason is ever found to account for the inability to conceive.[21]

III. Alternatives and Resources for the Infertile Couple

Adoption remains the standard alternative for those infertile couples who wish to become parents, yet are unable or unwilling to pursue medical treatment. Adoptive couples may choose from four general types of adoption — non-agency independent adoption (also called private adoption), agency adoption, adoption of children with special needs, and international adoption.[22]

Adoptive parenthood often proves to be a rewarding experience. The adoptive process is another matter entirely. The widespread distribution of contraceptives and the availability of legalized abortion have significantly reduced the number of children available for adoption. The social stigma associated with unwed motherhood has waned in recent years as well. Over 70% of single mothers now keep their babies. As a result, a couple may wait five years or more for a healthy white infant.[23] In addition, adoptive couples

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[17]A. BURGESS, *supra* note 15, at 105.

[18]Woods, *Infertility*, in HEALTH CARE OF WOMEN: A NURSING PERSPECTIVE 257-58 (1981).

[19]The woman's age is an important determinant of her fertility. At very young ages fertility is low, but it peaks at about 24 years of age and then declines, with a rapid fall ensuing after age 30. *Id.* at 259.

[20]A. BURGESS, *supra* note 15, at 105.

[21]Infertile couples for whom no medical diagnosis can be made are labeled normal infertile by most specialists. *Id.* at 113.

[22]Mitchell, *Adoption Counseling*, in CURRENT THERAPY OF INFERTILITY 1984-1985 272, 274-75 (1984) [hereinafter INFERTILITY].

[23]*Id.* at 272. For the couple willing to accept either a minority child or one with a special need, the outlook for adoption is much brighter. (Children with special needs include those with physicial, mental, or emotional handicaps, older children, and sibling groups.) *See* Wilson & Hitchings, *Adoption Is Not Impossible*, BUS. WEEK, July 8, 1985, at 112; *To Adopt A Child, Get Ready To Wait*, CHANGING TIMES, Nov. 1984, at 45.

are frequently subjected to the close scrutiny of a social service agency and risk elimination once the home study is underway.[24] Adoption can be expensive, especially if private adoption is contemplated.

While adoption may no longer be readily available, the outlook for those undergoing medical treatment for their infertility appears much brighter. Recent improvements in research and technology have led to tremendous advances in this specialized field of medicine. "It is now estimated that at least half of all problems of infertility can be diagnosed and treated by either medical or surgical means."[25] As a general rule, active treatment of infertility is directed toward the factors responsible for the failure to conceive.[26]

When infertility rests solely with the male partner, the couple can be offered only two choices — adoption or therapeutic insemination.[27] "Therapeutic or artificial insemination refers to the artificial injection of semen into the cervical canal."[28] It is termed homologous insemination (artificial insemination husband or AIH) if the husband's semen is used and heterologous insemination (artificial insemination donor or AID) if the semen is from a man other than the husband.[29] In order for either method to be effective, it must be timed so as to coincide with the ovulatory phase of the woman's menstrual cycle.

The selection of the method to be employed is dependent on the needs and desires of both partners. Homologous insemination "may be indicated when the sperm count is adequate, but the volume of ejaculate is low; when the sperm count is low normal, but the volume of semen is inadequate, or

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[24]This process may find "unfit" any couple who have passed a certain age (*i.e.*, over 40 and desiring an infant), who have certain medical problems (*i.e.*, diabetes, heart disease, even obesity), who earn less than a certain income, or who cannot convince the adoption worker that they are well-motivated or secure in their marriage. A. BURGESS, *supra* note 15, at 119.

[25]Menning, *The Psychosocial Impact of Infertility*, 17 NURSING CLINICS OF NORTH AMERICA 155 (1982).

[26]Normal fertility is dependent on many factors in both the man and the woman. The male must produce a sufficient number of normal, motile spermatozoa that can enter the urethra through patent pathways and be ejaculated. The spermatozoa must be deposited in the vagina, penetrate the cervical mucus, and ascend through the uterus to the fallopian tube to meet the ovum. The female must produce a normal, fertilizable ovum that enters a fallopian tube and becomes fertilized within a period of a few hours. The conceptus must be transported through the tubal lumen to the uterine cavity. There it must implant itself in endometrium that has been prepared to receive it. The embryo then must grow and develop normally. If any one of these essential processes is defective or impeded, infertility may result. J. WILLSON, *supra* note 16, at 160.

[27]This statement is based on the assumption that the male's infertile state cannot be altered by either surgical or medical intervention. For a complete discussion of male infertility, see INFERTILITY, *supra* note 22, at 136-251.

[28]J. WILLSON, *supra* note 16, at 172.

[29]Woods, *supra* note 18, at 277.

when normal coitus is not possible (e.g., paralysis)."[30] If the fertility workup reveals an absence of spermatozoa in the husband's semen, the couple may request that heterologous insemination be performed. AID may also be indicated when the male is a known carrier of a serious hereditary disease or for couples with Rh immunologic incompatibility.[31]

Insemination with the husband's semen presents few, if any legal problems. Heterologous insemination, on the other hand, continues to be the center of many ethical, legal, and religious controversies.[32] The Roman Catholic Church, for example, prohibits donor insemination.[33] Some clergy regard it as adultery. Orthodox Judaism also takes a firm stand against donor insemination.[34] Despite the controversy, it is estimated that 10,000 to 20,000 babies are conceived by this technique annually in the United States.[35]

Surrogate gestation "is sometimes described as the female version or 'flip side' of artificial insemination donor."[36] The term surrogate mother is frequently used because it is the biological mother's role that the surrogate performs. In exchange for a fee or expenses, the surrogate mother agrees to become pregnant through artificial insemination with the sperm of the biological father. Immediately after birth, the child is surrendered to the biological father and his wife, who must then take the steps necessary to become the child's legal mother and father. For the most part, this involves complying with the adoption laws and procedures of the state in which they reside.

Surrogate parenting has also been the source of intense ethical, legal, and religious debate.[37] These concerns may prevent a couple from pursuing this alternative even when available.

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[30] *Id.*

[31] *Id.*

[32] *See* Andrews, *The Stork Market: The Law of the New Reproduction Technologies*, A.B.A. J., Aug. 1984, at 50; Beck, *A Critical Look at the Legal, Ethical, and Technical Aspects of Artificial Insemination*, 27 FERTILITY & STERILITY 1 (1976); Boone, Book Review, HASTINGS CENTER REP., Aug. 1984, at 48 (reviewing M. BAYLES, REPRODUCTIVE ETHICS (1984)); Boone, Book Review, HASTINGS CENTER REP., Aug. 1984, at 47 (reviewing R. BLANK, REDEFINING HUMAN LIFE: REPRODUCTIVE TECHNOLOGIES AND SOCIAL POLICY (1984)); Boone, Book Review, HASTINGS CENTER REP., Aug. 1984, at 46 (reviewing R. SNOWDEN, G. MITCHELL, & E. SNOWDEN, ARTIFICIAL REPRODUCTION: A SOCIAL INVESTIGATION (1983)).

[33] Woods, *supra* note 18, at 263.

[34] Rosner, *Jewish Religious Considerations in Artificial Insemination, In Vitro Fertilization, and Surrogate Motherhood*, INFERTILITY, *supra* note 22, at 209.

[35] Menning, *supra* note 25, at 161.

[36] Jorgensen, *Surrogate Parenting*, INFERTILITY, *supra* note 22, at 302.

[37] *Id.* at 299. *See* Rosner, *supra* note 34, at 208.

The options available for the infertile female are more numerous and refined than are those for the male. Partial or complete occlusion of the fallopian tubes is an etiologic factor in about 30% of all infertile women.[38] For many of these women, tubal patency and functioning can be restored only by undergoing a surgical procedure known as tuboplasty. The cause of the occlusion, the extent of the damage, and the ability and experience of the surgeon determine the outcome of the surgery.[39] Microsurgical techniques have resulted in pregnancy rates as high as 50% or more.[40]

If damage to the fallopian tubes proves to be irreparable, a couple may wish to consider *in vitro* fertilization (IVF or test- tube gestation). The procedure consists of three steps: recovery of an ovum from a woman by laparoscopy, which is a minor surgical procedure; fertilization of the ovum *in vitro* and subsequent culture of the embryo; and replacement of the embryo in the uterus of the patient from whom the ovum was obtained.[41] Pregnancy is anticipated in about 20% of all laparoscopic attempts.[42]

The first birth following fertilization outside of the mother's womb occurred in 1978. Since that time, the American Fertility Society estimates that 800 to 1,000 IVF births have taken place, 300 of them in the United States alone.[43]

Menstrual disorders associated with ovulatory failure are another common cause of female infertility.[44] Induction of ovulation is currently managed

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[38]J. WILLSON, *supra* note 16, at 163.

[39]*Id.* at 173.

[40]*Id.*

[41]Rosner, *supra* note 34, at 208, 210.

[42]Jones, *In Vitro Fertilization*, INFERTILITY, *supra* note 22, at 124.

[43]As the numbers of births from IVF steadily increase, so too do questions regarding the legal status of children conceived through such high-tech means. *See* Annas & Elias, *In Vitro Fertilization and Embryo Transfer: Medicolegal Aspects of a New Technique to Create a Family*, 17 FAM. L.Q. 199 (1983); Barnett, *In Vitro Fertilization: Third Party Motherhood and the Changing Definition of Legal Parent*, 17 PAC. L.J. 231 (1985); Eccles, *The Use of In Vitro Fertilization: Is There a Right to Bear or Beget a Child by any Available Means?*, 12 PEPPERDINE L. REV. 1033 (1985).

[44]Menstruation is an important phase of the reproductive cycle. It is caused and controlled by the activity of four hormones (two from the pituitary gland and two from the ovaries). Each new menstrual cycle is initiated by the pituitary gland. The pituitary gland secretes its follicle-stimulating hormone (FSH) which in turn stimulates the follicles in the ovaries. Follicles are minute sacs containing unripe eggs. The follicle stimulating hormone zeros in on one particular follicle. In response, this target follicle begins to mature and the egg sac begins to secrete the hormone estrogen. The estrogen causes the lining of the uterus to thicken in preparation for a fertilized egg. With the rise in the level of estrogen production, the pituitary begins to secrete luteinizing hormone (LH). LH zeros in on the same ovarian follicle, stimulating it to release the mature egg. The process by which the egg is released is referred to as ovulation. As the level of LH increases, the now empty follicle changes to an orange-yellow color (corpus luteum). In its new form it produces not only estrogen but another hormone known as progesterone. Progesterone causes an additional thickening of the uterine lining. If conception does not occur, the pituitary ceases its production of LH, and the corpus luteum begins to wither. As it shrinks, its production of progesterone and estrogen declines. It is the withdrawal from the bloodstream of estrogen and progesterone that triggers menstruation. S. KAUFMAN, YOU CAN HAVE A BABY 176-80 (1978).

with drug therapy. Clomiphene citrate (clomid) and human menopausal gonadotropin (HMG, Pergonal) are two of the drugs commonly used for this purpose.

Clomid, the mainstay of ovulation induction therapy, is administered when ovulation is absent or infrequent. Clomid does not directly stimulate ovulation, but rather, "initiates a sequence of events that are features of a normal cycle by causing an appropriate FSH discharge."[45] A dose of 50 milligrams (mg.) daily for five days is recommended for the first course of treatment. If necessary, the treatment can be repeated at monthly intervals. The dose of the drug may be increased as well. "Ovulation is achieved in most patients whose pituitary and ovaries are capable of stimulated function, and pregnancy occurs in 40 to 50% of such women."[46]

The potential side effects include abnormal ovarian enlargement, multiple ovulations, and spontaneous abortion. Birth defects have also been linked with clomiphene administration. "Side effects tend to be dose-related, occurring more frequently with higher doses and prolonged therapy."[47]

Pergonal, which is the drug that Mrs. Frustaci received, has been described by some physicians as the "big gun" of fertility drugs.[48] It is recommended for use only after all other methods to overcome infertility have been tried and proven unsuccessful. Of the 200,000 women who undergo treatment with fertility drugs in this country each year, only 9,000 receive Pergonal.[49]

The drug consists of a purified preparation of gonadotropins extracted from the urine of post-menopausal women. It is administered by intramuscular injection for nine to twelve consecutive days. The dose necessary to produce maturation of the follicle must be individualized for each patient.

When clinical assessment of the patient indicates that sufficient follicular maturation has occurred, ovulation is stimulated by administration of a single dose of human chorionic gonadotropin (HCG).

The woman is encouraged to have intercourse beginning the day of the HCG injection and for the next two days. "More than 90% of women with competent ovaries will ovulate in response to HMG-HCG, and a pregnancy rate of between 50% to 70% is likely to occur. Two to five therapeutic cycles are usually required to achieve pregnancy."[50]

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[45]Woods, *supra* note 18, at 273.

[46]GOODMAN AND GILMAN'S THE PHARMACOLOGICAL BASIS OF THERAPEUTICS 1433 (A. Goodman Gilman, L. Goodman & A. Gilman 6th ed. 1980) [hereinafter GOODMAN & GILMAN].

[47]FACTS AND COMPARISONS 115a (E. Kastrup & J. Boyd, eds. 1979).

[48]Lyons, *Drug-Caused Multiple Births Decline*, N.Y. Times, May 27, 1985, at A8, col. 3.

[49]*Id.*

[50]Woods, *supra* note 18, at 274.

Ovarian hyperstimulation is the most serious health risk associated with ovulation induction therapy. If not detected immediately, this condition can be life-threatening or even fatal.

Multifetal pregnancies pose an additional risk.[51] Of the pregnancies following therapy with gonadotropins, 80% have resulted in single births and 20% in multiple births (15% of the total pregnancies have resulted in twins, and 5% in three or more conceptuses).[52] Patti Frustaci is the first American woman known to have given birth to septuplets following treatment with Pergonal.

Because of the possibility of serious side effects, it is essential that the treatment be monitored very closely. The more traditional method of monitoring a patient's progress involves physical examination of ovarian size, observation of cervical mucus, and determination of daily serum estrogen. An increase in the serum estrogen level indicates that the ovaries are active. HCG is administered when the serum estradiol level reaches 1000 to 1500 micrograms per milliliter (mg/ml) and changes in cervical mucus indicate a normal midcycle pattern.[53]

In recent years, serial ultrasonography has also been employed to observe ovarian responses to HMG stimulation. Ultrasonographic monitoring provides a more direct way to evaluate follicle development during treatment. It also aids in the timing of HCG administration by showing the numbers and sizes of the follicles.[54]

The necessity of routine ultrasound monitoring in patients undergoing HMG-HCG therapy has yet to be clearly established.[55] Proponents of the

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[51]Multiple pregnancy remains a very high risk situation, with published perinatal mortality rates in developed countries ranging between 65 and 120 per 1,000 births for twins and between 250 and 310 per 1,000 births for triplets. The high rates of prematurity and intrauterine growth retardation in multiple gestation pregnancies are also associated with a significant incidence of neonatal morbidity. Both maternal mortality and morbidity rates are increased in multiple pregnancy as well. Maternal complications include pregnancy-induced hypertension, anemia, and hemorrhage. Cord prolapse, cord entanglement, incoordinate uterine function, and fetal distress are all more common during labor in multiple gestation than in single gestation. These risks increase enormously with triplets, quadruplets, etc. R. CREASY & R. RESNICK, MATERNAL FETAL MEDICINE 527-38 (1984).

[52]FACTS AND COMPARISONS, *supra* note 47, at 115b. As more has been learned about the drug and its use, the incidence of multiple births attributable to Pergonal has declined. Some experts estimate that multiple gestations occur in only 10% of HMG-induced cycles. Interview with Dr. Leon Speroff, M.D., Department Director and General Manager of the Obstetrics-Gynecology Management Center, University Hospitals of Cleveland, in Cleveland, Ohio (Jan. 28, 1986).

[53]Woods, *supra* note 18, at 274.

[54]If there is an adequate estrogen value but no large follicle exists, HCG can be withheld. If too many stimulated follicles are present HCG can be withheld and hyperstimulation avoided, and in some cases when follicular size is normal but the estrogen level is low, further treatment with HMG can be avoided. Dornbluth, Potter, Shepard, Balmacedo & Siler-Khodr, *Assessment of Follicular Development by Ultrasonography and Total Serum Estrogen in Human Menopausal Gonadotropin-stimulated Cycles*, 2 J. ULTRASOUND MED. 407, 411 (1983) [hereinafter Dornbluth].

[55]Ultrasound is widely used in University-associated fertility centers but is not available to many private practitioners. One machine costs $30,000 to $40,000. Blakeslee, *Septuplets Evoke Questions on Drug*, N.Y. Times, June 13, 1985, at A23, col. 1.

procedure point to its usefulness in directly evaluating follicle development. This is especially significant if one considers that a "dose of Pergonal can stimulate the production of one egg one month and the next month generate 10 eggs. Another month, on the same dose, no eggs may be formed."[56] When multiple follicles are present a patient can be advised to bypass the cycle and refrain from sexual intercourse. This eliminates the risk of both multiple pregnancy and ovarian hyperstimulation. Some experts also suggest that the complementary use of ultrasonography and estrogen monitoring permits a more efficient use of the drug.[57] An efficient use of the drug can represent a significant savings for the patient and more than compensate for the cost of ultrasound examinations.[58] Finally, it is important to note that the procedure itself is noninvasive and involves only mininal patient discomfort.

Many physicians who do not require routine ultrasound monitoring believe that the cost of the procedure outweighs the potential benefits. Each course of treatment with Pergonal costs between $500-$1,000.[59] Serial untrasonography would increase the cost by hundreds of dollars per month. The patient's financial resources are an important factor to be considered when developing a treatment protocol.

Of equal or greater importance is the fact that multiple follicles develop in most HMG-stimulated cycles.[60] It becomes clear, therefore, that not all multiple ovulations result in a multiple pregnancy. In addition, ultrasonography does not eliminate the need for serum estrogen monitoring. Even if normal follicle growth patterns can be demonstrated by ultrasound, conception will not occur if the patient has a low serum estrogen level.[61] Nor has ultrasound been shown to significantly increase the conception rate.[62]

The biological safety of diagnostic ultrasound has also come under scrutiny. Although the data is far from conclusive, there is a concern among some health care practitioners that preovulatory follicular scanning may be harmful.[63]

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[56]*Id.*

[57]Dornbluth, *supra* note 54, at 412.

[58]*Id.*

[59]Blakeslee, *supra* note 55, at A23.

[60]Speroff, *supra* note 52.

[61]Dornbluth, *supra* note 54, at 409.

[62]*Id.* at 412.

[63]Speroff, *supra* note 52. Ultrasonic energy does interact with tissue in several ways that are not yet completely understood. At the molecular level, ultrasonic energy has been shown to cause chemical degradation of DNA, the substance of which genetic material is composed. However, there have been no confirmed reports of fetal injuries caused by ultrasonic radiation at diagnostic energy levels. This does not mean that ultrasound is harmless, but it does mean that any harmful effects are either genetic, and so may remain concealed for several generations, or somatic, but subtle or with a long latency period. OBSTETRICS AND GYNECOLOGY 557-58 (D. Danforth 4th ed. 1982).

IV. Frustaci v. J. Marik, M.D. and the Tyler Medical Clinic

Most cases in malpractice sound in negligence.[64] In order to succeed the plaintiff must demonstrate that he sustained damages or actual loss during the course of the medical treatment; that the treatment violated the standard of due care; and that the injury was causally related to the negligent treatment.[65] The burden falls squarely on the plaintiff to establish through expert testimony both the standard of care and the fact that the defendant's conduct did not measure up to that standard.[66]

"Professional persons in general, and those who undertake any work calling for special skills, are required not only to exercise reasonable care in what they do, but also to possess a standard minimum of special knowledge and ability."[67] Where a physician holds himself out as a specialist, the standard is modified accordingly.[68] The standard of care for a specialist, as set forth by the Supreme Court of Michigan, in *Naccarato v. Grob*, "should be that of a reasonable specialist practicing medicine in light of present day scientific knowledge. ... [G]eographical conditions or circumstances control neither the standard of a specialist's care nor the competence of an expert's testimony."[69]

It is also important to note that even if a treatment or procedure is skillfully performed, a physician may nevertheless be liable for an adverse consequence about which the patient was not sufficiently informed.[70] The doctrine of informed consent, which is based on the belief that every person has the right to determine what shall be done to his body, imposes a duty upon a physician to disclose information regarding the nature of the ailment or condition involved, the risks of the proposed treatment and the risks of any alternative method of treatment, including the risks of failing to undergo any treatment at all.[71] Recovery is premised on the plaintiff's ability to establish a causal link between the physician's failure to provide sufficient information and the harm which in fact resulted.

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[64]In addition to negligence, liability for malpractice may be based on either contract theory (express or implied) or an assertion of intentional misconduct. *See* Curran, *Problems of Establishing A Standard of Care*, in MEDICAL MALPRACTICE 15 (1966).

[65]PROSSER & KEETON ON THE LAW OF TORTS, § 30, at 164-65 (W. Page Keeton 5th ed. 1984) [hereinafter PROSSER & KEETON].

[66]*See* Pisel v. Stamford Hospital, 180 Conn. 314, 334, 430 A.2d 1, 12 (1980).

[67]PROSSER & KEETON, *supra* note 65, § 32, at 185.

[68]The Tyler Medical Clinic specializes in the treatment of infertility. Many of the medical services available to treat infertility were pioneered by Dr. Edward Tyler, founder of the clinic. Since 1950, the clinic has treated over 12,000 couples. Blakeslee, *supra* note 55, at A23.

[69]384 Mich. 248, 254, 180 N.W.2d 788, 791 (1970).

[70]PROSSER & KEETON, *supra* note 65, § 32, at 190.

[71]*Id.*

In the instant case, the Frustacis are claiming that serial ultrasound monitoring of patients undergoing treatment with Pergonal is standard medical practice, and that failure on the part of her physician to conform to that standard resulted in the birth of septuplets. More specifically, the Frustacis are claiming that had ultrasound examinations been performed as part of the treatment protocol, it would have been known that the drug had stimulated the production of multiple follicles. Consequently, they would have bypassed the cycle, refrained from intercourse, and thereby prevented conception from occurring.

As suggested in the previous section, it will be difficult to win or lose this case on the ultrasound issue alone. An analysis of Mrs. Frustaci's serum estrogen values by an expert witness will significantly influence the outcome of the litigation as will the factual determination of whether or not the Frustacis had been sufficiently informed of the risk of multiple births prior to the onset of treatment. In addition, the court must decide whether multiple births following active infertility treatment can be the basis for damages.

Unlike negligence, there is no action for wrongful death at common law. Therefore, all actions of this kind require a statutory base. The Frustaci's action was brought under the California Civil Procedure Code, which provides:

> When the death of a person not being a minor, or when the death of a minor person who leaves surviving him either a husband or wife or child or children or father or mother, is caused by the wrongful act or neglect of another, his heirs, and his dependent parents, if any, who are not heirs, or personal representatives on their behalf may maintain an action for damages against the person causing the death, or in case of the death of such wrongdoer, against the personal representative of such wrongdoer, whether the wrongdoer dies before or after the death of a person injured. . . . In every action under this section, such damages may be given as under all the circumstances of the case, may be just, but shall not include damages recoverable under Section 573 of the Probate Code. The respective rights of the heirs and dependent parents in any award shall be determined by the court. . . .[72]

Success in this type of action depends on the plaintiff's ability to establish a reasonable connection between the act or omission of the defendant and the damage which the plaintiff allegedly suffered.[73] What will make causation particularly difficult to establish in the Frustaci case is the fact that neither Dr. Marik nor the clinic provided Mrs. Frustaci with prenatal care after January of 1985, nor were they involved in the delivery and care of the infants.

The Frustacis must overcome an additional obstacle. As noted in the introduction, one of the septuplets was stillborn. California is one of a minority of jurisdictions which holds that a stillborn fetus is not a person within the

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[72]CAL. CIV. PROC. CODE § 377 (West 1973).

[73]*Id.* at 165.

meaning of the wrongful death statute.[74] This is due in part to the wording of the statute. Minority is calculated for the first minute of the day on which persons are born to the same minute of the corresponding day completing the period of minority, thereby excluding unborn fetuses from the class of minor persons.[75]

The purpose of the wrongful death statute "is to enable the heirs and certain specified dependents of a person wrongfully killed to recover compensation for the economic loss and deprivation of consortium they suffer as a result of the death."[76] While neither a fetus nor a neonate is a wage earner, its death can result in an appreciable economic loss to the survivors.[77] In the instant case, for example, the Frustacis have incurred medical and burial expenses in excess of one million dollars.

In determining damages, the court must also consider the parents' loss of consortium claim.[78] Although pleading in the alternative is permissible, there is a certain inconsistency in seeking damages for the loss of consortium which resulted from the deaths of the infants they did not wish to conceive in the first place.

V. Implications for Health Care Practitioners

In terms of dollar amount, health care is the second largest industry in the United States.[79] "According to the latest figures, the United States spent 10.5% of its gross national product (GNP) on health care in 1982, or $322.4 billion, inflating at a rate of 12.5% per annum."[80] Malpractice insurance costs are a major factor in continually rising medical costs.[81] Increases in both the number of suits and the size of awards have produced what is currently

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[74]*See* Justus v. Atchison, 19 Cal. 3d 564, 565 P.2d 122, 139 Cal. Rptr. 97 (1977) (stillborn fetus not a "person" within the meaning of the wrongful death statute).

[75]*Id.* at 576, 565 P.2d at 130, 139 Cal. Rptr. at 105.

[76]*Id.* at 581, 565 P.2d at 133, 139 Cal. Rptr. at 108.

[77]The parents of a stillborn fetus can recover out-of-pocket expenses such as medical and burial costs as incidents of the mother's cause of action for personal injuries. *Id.* at 581, 565 P.2d at 133 n.15, 139 Cal. Rptr. at 108.

[78]Loss of consortium, in this context, means loss of society, affection, and assistance. BLACK'S LAW DICTIONARY 280 (5th ed. 1979).

[79]DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE, REPORT OF THE SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE, at 12 (1973) [hereinafter REPORT].

[80]Neubauer & Henke, *Medical Malpractice Legislation*, TRIAL, Jan. 1985, at 64, 67 [hereinafter Neubauer].

[81]REPORT, *supra* note 79, at 12. *Contra* Neubauer, *supra* note 80, at 64, 66 (the real villains are the medical and insurance industries).

being described as a crisis in malpractice litigation. When faced with skyrocketing malpractice premiums, a physician must either raise his fees, increase his patient load, or abandon his practice entirely.

In most instances it is the consumer or his health insurance carrier who compensates for the cost of a physician's malpractice premiums. The economic impact of this becomes more clear when one considers that "premiums for dentists rose 115% between 1960 and 1970; those for hospitals, 262.7%; those for physicians other than surgeons, 540.8%; and those for surgeons, 949.2%."[82]

Furthermore, the threat of malpractice induces physicians to practice defensive medicine.[83] Defensive medicine can take one of three forms. Positive defensive medicine occurs when a physician performs a diagnostic or therapeutic procedure primarily to prevent or defend against the threat of malpractice.[84] If liability is established in the Frustaci case, it is likely that those physicians treating patients with Pergonal will insist on ultrasound monitoring, regardless of whether they believe the benefits outweigh the cost. Under these circumstances, the end result may be an increase in the overall cost of the treatment without a corresponding increase in its quality and effectiveness.

Failure on the part of a physician to perform a potentially beneficial procedure because of the fear of a later malpractice suit constitutes negative defensive medicine.[85] Finally, the threat of malpractice may discourage a physician from publishing a detailed and informative case study in a medical journal for fear that the article will be used as evidence against him in a lawsuit.[86]

For various reasons, the risks of being sued for malpractice are not shared equally among health care providers.[87] Obstetricians and gynecologists, for example, are subject to claims more frequently than are general practitioners. This is due to the nature and diversity of the services provided by obstetricians/gynecologists, the intense emotions and values associated with issues of reproductive health, and the delicate relationship that exists between the physician and his patient.[88]

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[82]REPORT, *supra* note 79, at 13.

[83]Defensive medicine is the alteration of modes of medical practice, induced by the threat of liability, for the principal purposes of forestalling the possibility of lawsuits by patients, as well as providing a good legal defense in the event such lawsuits are instituted. *Id.* at 14.

[84]*Id.*

[85]*Id.*

[86]*Id.*

[87]*Id.*

[88]*See* Olender, *Obstetric Negligence: An Introduction to a High Risk Specialty*, TRIAL, May 1984, at 52. *See also* K. FINEBERG, J. PETERS, J. WILLSON, & D. KROLL, OBSTETRICS/GYNECOLOGY AND THE LAW (1984).

An obstetrician owes a duty to both the expectant mother and the developing infant. Occasionally, these obligations come into conflict with one another. A treatment which benefits the mother may harm the child, or vice versa. A mistake on the part of the physician can result in the filing of a lawsuit by the mother, the child, or both. Consequently, some obstetricians pay as much as $80,000 per year in malpractice premiums.[89]

The medical profession's concern about malpractice extends beyond financial matters. Being forced to defend one's actions in a court of law can be emotionally devastating, especially when the physician believes that he has been unjustly sued.[90] Finally, there is a concern that a claim of malpractice will not only stigmatize the physician who has been sued, but by implication will also cause the public to discount, in general, the quality of health care provided them.[91]

VI. Implications for Health Care Consumers

The health care consumer who files a malpractice action faces certain emotional and economic risks as well. The public exposure of the case may prove embarrassing, especially if personal details about the individual(s) are revealed. Suits like the one filed by the Frustacis, which have a strong "human interest" component, frequently attract media attention.

Our judicial system itself is responsible for many of the economic burdens which plaintiffs face in the course of litigation. In most cases, a substantial period of time elapses between the date of the alleged injury and the recovery

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[89]Hoff, *Having Babies at Home: Is It Safe? Is It Ethical?*, HASTINGS CENTER REP., Dec. 1985, at 19, 23.

[90]An internist told the Commission of a critically ill patient whose treatment required decisions over which he and a colleague had literally agonized. The medical literature reported only two such instances in which other patients had lived. The doctors pulled their patient through, though he suffered a double leg amputation. The patient sued, and through legal proceedings which the doctor believed to have been most unfair, won a judgment. The event had a considerable effect upon both his professional practice and his outlook on life. Asked what a doctor should do, he replied, "Practice the best medicine possible. ... Retire earlier and seek medical employment which involves less patient contact, which I have done. Practice defensive medicine. And above all, and this to me is the most important thing, despise what could and should be honored jurisprudence." REPORT, *supra* note 79, at 20.

[91]Although products liability is not the focus of this discussion, it should be noted that a drug manufacturer can be held liable for failing to adequately warn of the dangers inherent in the use of an otherwise pure, unadulterated drug. *See* Mann, *Mass Immunization Cases: Drug Manufacturers' Liability for Failure to Warn*, 29 VAND. L. REV. 235 (1976). Ares-Serono, Inc., the company which produces Pergonal, inserts a summary of information about the drug into each package. The insert includes the following: "Warnings: Pergonal is a drug that should only be used by physicians who are thoroughly familiar with infertility problems. It is a potent gonadotropic substance capable of causing mild to severe adverse reactions." Lyons, *Fertility Drug: Single Birth Is Intended*, N.Y. Times, May 23, 1985, at B13, col. 4.

of money damages. During this time, the full impact of the injury is borne by the plaintiff. In addition, it is the plaintiff who is responsible for the court costs[92] involved in the action, even if the case is accepted by an attorney on a contingency basis.[93]

The economic impact of medical malpractice on health care consumers as a whole is of equal importance. As previously noted, the consumer usually must absorb the increased costs in medical care that result from the filing of malpractice claims. In an attempt to avoid liability, a physician may refuse to treat certain categories of patients altogether. As a result, the ability to pay for medical care is no guarantee that such services will be readily available to the high risk patient.

Treatment for infertility can be expensive. Cost increases may very well prevent many couples from seeking such services. Since parenting is regarded as one of the fundamental tasks of adulthood, it would be tragic for many couples if their decision to undergo infertility treatment was governed solely by economic considerations.

One positive aspect of focused media attention is that it tends to increase consumer awareness. An increase in awareness may lead to more informed decision making by health care consumers. Media attention may also effectively apprise those similarly situated of their legal rights. On a broader scale, pressure by the media can serve as an impetus for change and reform.

On the other hand, well-publicized malpractice cases can undermine the public's confidence in the medical profession. Fear and mistrust may discourage an individual from seeking needed medical care.

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[92]These include fees and charges required by law to be paid to the courts or some of their officers, the amount of which is fixed by statute or court rule; e.g., filing and service fees. BLACK'S LAW DICTIONARY 312 (5th ed. 1979).

[93]Under a contingent fee arrangement an attorney agrees to represent a client with compensation to be a percentage of the amount recovered, usually between 33% and 40%. Justifications for the contingent fee include the following: (1) By making the lawyer's gross earnings depend upon the magnitude of the client's recovery, the contingent fee gives the lawyer a direct incentive to work in his client's interest. (2) The contingent fee allows the client to shift some of the risk inherent in his case to the lawyer. If the client does not recover, the lawyer receives no fee. If a client who agrees to pay his lawyer an hourly fee does not recover, he incurs a negative return. (3) The contingent fee allows the client to borrow the lawyer's services in advance of settlement. Because a personal injury claim has economic value, the client should be able to borrow in the capital market against his eventual recovery. Schwartz and Mitchell, *An Economic Analysis of the Contingent Fee in Personal Injury Litigation*, 22 STAN. L. REV. 1125 (1970). The contingent legal fee system has been and continues to be a source of bitter controversy between physicians and lawyers. Many doctors are convinced that the contingent fee system prompts overzealous attorneys to: (1) accept non-meritorious cases, and (2) magnify the nature of the client's injuries in order to win high awards from sympathetic juries. REPORT, *supra* note 79, at 32. *Contra* Brown, *Do Contingency Fees Really Cause Malpractice Suits?*, MED. ECON., Oct. 21, 1985, at 52 (contingency fees have little effect on the number of malpractice suits filed).

VII. Implications for the Legal Profession

If the Frustacis are successful in their suit against Dr. Marik and the Tyler Medical Clinic, it is likely that others will pursue similar litigation. When one considers that approximately 200,000 women undergo treatment with fertility drugs each year, and that multiple births result in 6% to 25% of the cases in which pregnancy is achieved,[94] it becomes clear that the potential for litigation is significant.

For the legal practitioner, the Frustaci case is important because it signals a new trend in tort law. Many of the issues left unresolved by this case will be the source of litigation for years to come. For example, the courts will be asked to decide:

(1) Whether the plaintiff who has given birth to more than one infant, but less than seven, will also be able to recover damages and;

(2) Whether a cause of action will lie if all of the infants survive, if they are healthy, and under what theory the plaintiff can recover.

As a general rule, the new theories of wrongful life,[95] wrongful birth,[96] and wrongful conception[97] have been based on negligent genetic testing or coun-

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[94]The incidence of multiple births with clomiphene is about 6% to 8%, compared with an incidence of 15% to 25% when gonadotropins are used to induce ovulation and fertility. GOODMAN & GILMAN, *supra* note 46, at 1433.

[95]The plaintiff in an action based on wrongful life is the child who suffers from a mental or physical defect or a fatal disease. The child's cause of action rests on the physician's alleged negligence. Such negligence may be due to the physician's failure to diagnose the child's defects as a fetus; or it may be based on failure to inform the parents of the child's defects, or failure to warn the parents of risks. Nicholson, *Damages: Recovery of Damages in Actions for Wrongful Birth, Wrongful Life and Wrongful Conception*, 23 WASHBURN L.J. 309, 322-23 (1984). *See* Gildner v. Thomas Jefferson Univ. Hosp., 451 F. Supp. 692 (E.D. Pa. 1978). Turpin v. Sortini, 31 Cal. 3d 220, 643 P.2d 954, 182 Cal. Rptr. 337 (1982).

[96]The plaintiff in a wrongful birth action is the parent of an unhealthy child. The child may suffer from a fatal disease or may be mentally or physically deformed. His or her defects are hereditary or were caused by some factor outside the physician's control. However, the parents allege that, had the physician properly informed them of the likelihood of the defect, they would have chosen to abort the child. Nicholson, *supra* note 95, at 317-18. *See* Gilder v. Thomas Jefferson Univ. Hosp., 451 F. Supp. 692 (E.D. Pa. 1978) (child born with Tay-Sachs disease); Schroeder v. Perkel, 87 N.J. 53, 432 A.2d 834 (1981) (child born with cystic fibrosis); Berman v. Allan, 80 N.J. 421, 404 A.2d 8 (1979) (infant born with Down's syndrome).

[97]The plaintiff in a wrongful conception (wrongful pregnancy) action is the parent of a normal, healthy child whose conception was unexpected and usually unwanted. The pregnancy may arise because the prescription for birth control pills has been misprescribed or misfilled. In other cases, the plaintiff is the victim of an unsuccessful sterilization procedure. Nicholson, *supra* note 95, at 311. *See* Troppi v. Scarf, 31 Mich. App. 240, 187 N.W.2d 511 (1971) (pharmacist misfilled prescription for birth control pills); Betancourt v. Gaylor, 136 N.J. Super. 69, 344 A.2d 336 (1975) (healthy child born following tubal ligation); Ball v. Mudge, 64 Wash. 2d 247, 391 P.2d 201 (1964) (child born one year after vasectomy performed on father).

selling, or negligent performance of a sterilization procedure or abortion. A case in which a woman has undergone medical treatment with the intent of becoming pregnant is substantially different.

Perhaps the courts will find it necessary to create a fourth category, wrongful multiple birth. Under this theory, a physician who fails to monitor a patient's infertility treatment properly, or who is aware of the likelihood of multiple births (based on an analysis of the patient's test results) but fails to inform the patient, would be liable for medical malpractice. Liability would be premised on the belief that an uninformed patient is deprived of the opportunity to evaluate and weigh the risks of a multifetal pregnancy, and thereby to choose whether or not to conceive.

Although a thorough discussion of damages is beyond the scope of this note, several key factors must be considered. In order to recover damages in any malpractice action, the plaintiff's evidence must establish that he suffered damage by reason of the defendant's failure to meet the standard degree of care expected by the average practitioner in the class to which the defendant belongs.[98] For this reason, the costs of rearing a normal, healthy child are often denied in wrongful pregnancy cases. Many courts regard the birth of a healthy child, even though unwanted at the time of the birth, as a blessing to the child's parents.[99] Other courts mitigate damages in this type of case by applying the "benefit rule" of torts.[100]

Special damages can be recovered in wrongful birth and wrongful life actions.[101] Medical, educational, and other expenses attributable to the objective condition of the child are included in the award of special damages. As in wrongful pregnancy cases, the emotional benefits attributable to the birth are considered in mitigating damages.

The courts, however, have been reluctant to award general damages in these cases. An award of general damages seeks to put the plaintiff in the position he would have occupied had the injury not occurred. The courts believe that comparing the value of an impaired life to nonexistence is entirely too speculative, and therefore find it impossible to determine damages.[102]

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[98]*See* Harbeson v. Parke-Davis, Inc., 98 Wash. 2d 460, 467-68, 656 P.2d 483, 489 (1983) (court identified the tort principles which govern actions against physicians).

[99]*See* Terrell v. Garcia, 496 S.W.2d 124, 128 (Tex. Civ. App. 1973) (benefits of satisfaction, joy, and companionship enjoyed by the parents outweigh the economic loss in rearing and education of a healthy normal child); Ball v. Mudge, 64 Wash. 2d 247, 250, 391 P.2d 201, 204 (1964) (cost incidental to birth is far outweighed by blessing of a cherished child, even though unwanted at birth).

[100]When the defendant's tortious conduct has caused harm to the plaintiff or to his property and in so doing has conferred a special benefit to the interest of the plaintiff who was harmed, the value of the benefit conferred is considered in mitigation of damages to the extent that this is equitable. RESTATEMENT (SECOND) OF TORTS § 920 (1979).

[101]*See* Turpin v. Sortini, 31 Cal. 3d 220, 643 P.2d 954, 182 Cal. Rptr. 337 (1982); Harbeson v. Parke-Davis, Inc., 98 Wash. 2d 460, 656 P.2d 483 (1983).

[102]*Id.*

VIII. Legislative Intervention as a Possible Solution

Since 1975, almost every state has enacted some form of legislation in an attempt to curb the health care crisis resulting from skyrocketing malpractice premium costs. In California alone, laws have been passed which provide a special statute of limitations for actions against health care providers,[103] establish a requirement of a ninety-day notice of intention to file suit,[104] impose a ceiling of $250,000 on the amount recoverable for non-economic losses,[105] and allow for the periodic payment of awards in excess of $50,000.[106]

The following legislative proposal is unique in that it is designed to avert a crisis in fertility drug malpractice by imposing guidelines for the use of the fertility drug Pergonal. Ideally, the proposal will benefit both the consumer and the health care provider. The consumer will experience an improvement in the quality of the health care services received, while the physician will be relieved of liability should multiple births result from the treatment.

There are several important reasons why this particular drug should receive special legislative attention. First and foremost is the nature of the drug itself. Pergonal is a potent gonadotropic substance. Since its introduction twenty years ago, Pergonal has benefited many individuals, and will continue to do so as its uses are expanded.[107] Unfortunately, the drug can also be unpredictable in its effects and produce serious adverse reactions, even when carefully monitored.

The vulnerability of the patient population being served by the drug must be considered as well. Treatment with Pergonal is often the last hope for an infertile couple. Concern that desperation may overcome or cloud reason justifies such a protective measure.

The disparity in knowledge between the physician and patient is as significant as the disparity in knowledge among physicians regarding this specialized field of medicine. Finally, by acting before the impact of the Frustaci case reaches crisis proportions, a state legislature would be able to conduct a systematic, comprehensive assessment of the problem.

A legislative proposal that addresses the use of Pergonal in medically warranted instances might be stated as follows:

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[103]CAL. CIV. PROC. CODE § 340.5 (West 1982).

[104]CAL. CIV. PROC. CODE § 364 (West 1982).

[105]CAL. CIV. CODE § 3333.2 (West 1986).

[106]CAL. CIV. PROC. CODE § 667.7 (West 1980).

[107]HMG therapy is used to recruit and develop multiple follicles in patients undergoing *in vitro* fertilization. *See* Jones, *supra* note 42, at 119. Pergonal can also be used to treat certain forms of male infertility. *See* Brown, *Idiopathic Infertility*, INFERTILITY, *supra* note 22, at 160.

PROPOSED SENATE BILL NO._____

AN ACT concerning civil actions; prohibiting certain tort actions relating to multiple births following treatment with human menopausal gonadotropin (HMG). Be it enacted by the Legislature of the State of

_____:

Section 1. No person shall prescribe, monitor the use of, or in any way utilize the biological substance known as human menopausal gonadotropin (HMG) except that she/he:

(a) Is licensed to practice medicine in the State of _____

pursuant to _____ and

(b) Is certified in Reproductive Endocrinology by the American Board of Obstetrics and Gynecology [108] and

(c) Has available to him/her laboratory facilities in which serum estrogen values can be determined, and serial ultrasonography can be performed, in a timely fashion upon those persons undergoing treatment with said drug.[109]

Section 2. No person shall receive treatment with said drug except that she first sign a written consent form in which the physician who is to administer the treatment has described the:

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[108]Endocrine glands regulate body activity by secreting hormones which are delivered directly into the blood stream. Each of the glands within the endocrine system (pituitary gland, thyroid gland, adrenal glands, gonads) has one or more special functions, but they are all dependent upon the others in the system for maintenance of normal hormonal balance in the body. The pituitary gland, in particular, secretes the gonadotropic hormones (FSH, LH, LTH) which play a role in the development and proper functioning of the gonads. The gonads, or sex glands, consist of the testes in the male and the ovaries in the female. Besides producing sperm and ova, respectively, they manufacture androgens and estrogens, hormones responsible for the special characteristics of the male and female. B. MILLER & C. KEANE, *supra* note 5, at 318-19. An endocrinologist is a specialist in the diseases resulting from a disorder in one or more of the endocrine glands. J. SCHMIDT, ATTORNEY'S DICTIONARY OF MEDICINE AND WORD FINDER E-65 (1984). In order to become certified in reproductive endocrinology a physician must complete two years of training after his residency as well as pass both an oral and written examination. Speroff, *supra* note 52. By requiring certification in endocrinology, the patient will be guaranteed that the physician administering the treatment has had experience in the use of the drug.

[109]The purpose of monitoring the treatment is to allow the physician to adjust the dosage of the drug in accordance with the patient's needs. Consequently, neither method of monitoring the treatment will benefit the patient unless the physician obtains the results of the testing procedure(s) prior to administering an additional dose of the drug. Dornbluth, *supra* note 54.

(a) medical condition or diagnosis of the person contemplating treatment;

(b) alternatives available to said person;

(c) treatment protocol of HMG therapy, including but not limited to:

— dosage
— route of administration
— frequency of administration;

(d) methods of monitoring the treatment, including but not limited to:

— serum estrogen determinations
— serial ultrasonography;

(e) necessity of implementing one or both methods of monitoring the treatment in a timely fashion;

(f) risks associated with said treatment, including but not limited to:

— ovarian hyperstimulation
— multiple births;

(g) warning signs of adverse reactions and the procedure to be followed by said person should such warning signs become apparent;

(h) fees for services to be rendered.

Section 3. Compliance with the provisions of this act shall preclude a cause of action based on a claim that, but for the negligence of the physician, the person would not have conceived, or have been delivered of, multiple infants.

Section 4. The failure or refusal of any physician to comply with the provisions of this act shall be considered as prima facie evidence of negligence in any action based on a claim that, but for the negligence of the physician, the person would not have conceived, or have been delivered of, multiple infants.

Although the tenth amendment to the United States Constitution specifically provides the states with power to regulate matters of health, welfare, and safety, constitutional issues arise whenever there has been governmental action. Laws which infringe upon substantive constitutional rights necessarily will be held invalid, if not through the Due Process and Equal Protection Clauses of the fourteenth amendment,[110] then through the operation of other provisions of the Constitution.

[110]The fourteenth amendment provides that "[n]o State shall ... deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws." U.S. CONST. amend. XIV, § 1.

The right to make certain decisions concerning one's body is protected by the federal constitutional right of privacy.[111] The United States Supreme Court first articulated the right of privacy in *Griswold v. Connecticut*[112] by holding that married persons have a constitutional right to use contraceptives. In the landmark decision of *Roe v. Wade*,[113] the Court extended its recognition of the privacy right to include a woman's decision to abort a pregnancy.

Under *Roe*, regulations limiting the right to procreative privacy may be justified only by showing a "compelling state interest."[114] In addition, the legislative enactment must be narrowly drawn to express only the legitimate state interests at stake.[115]

The legislation proposed in the previous section is consistent with the Supreme Court's holding in *Roe*. The proposed bill in no way limits or unduly burdens an individual's right to seek treatment for infertility or to abort a pregnancy should such treatment prove unsatisfactory. Most importantly, it encourages true freedom of choice by requiring that all relevant facts be disclosed prior to the onset of treatment.

Furthermore, the state has a compelling interest in protecting the health and welfare of the mother and child both prior to and after birth. A woman who gives birth to more children than she can afford may be forced to rely on the resources of the state for support.

Differences in treatment, as between classes of tort victims or members of a profession, invoke questions of equal protection. In applying equal protection to most forms of state action, the Supreme Court has sought only the assurance that the classification at issue bears some fair relationship to a legitimate state purpose.[116] The Court has long recognized that "the States have a compelling interest in the practice of professions within their boundaries, and that as part of their power to protect the public health, safety, and other valid interests they have broad power to establish standards for licensing practitioners and regulating the practice of professions."[117]It must also be noted that certified and non-certified physicians are not so similarly situated in terms of education and experience as to require equal treatment under this proposed law.[118]

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[111]In re Conroy, 98 N.J. 321, 348, 486 A.2d 1209, 1222 (1985).

[112]381 U.S. 479 (1965).

[113]410 U.S. 113 (1973).

[114]*Id.* at 155.

[115]*Id.*

[116]Plyler v. Doe, 457 U.S. 202, 216 (1982).

[117]Goldfarb v. Virginia State Bar, 421 U.S. 773, 792 (1975).

[118]*See* Michael M. v. Superior Court, 450 U.S. 464 (1981) (statutory rape law upheld where gender classification is not invidious, but rather realistically reflects the fact that the sexes are not so similarly situated in certain circumstances).

Statutes which restrict the amount of damages recoverable in a malpractice action have been challenged as unconstitutional with only limited success.[119] For the most part, the courts have deferred to the legislatures in fashioning economic legislation.[120] The proposed legislation does not seek to deprive a class of tort victims of full compensation, but rather to avoid the rendering of negligent health care services in the first place.

IX. Conclusion

The birth of the Frustaci septuplets does not constitute a miracle in that it can be explained by means of the known laws of nature. Whether Mrs. Frustaci would not have become pregnant but for the physician's negligence remains for the court to determine. What this case does tell us is that there are no easy answers to infertility. Parenting is one of the fundamental tasks of adulthood. Infertile couples who are denied the parenting experience face a life crisis of major proportions. On the other hand, a multifetal pregnancy may deprive a woman of her preferred life style and force upon her a radically different and undesired future. Because successful treatment is not guaranteed even when the physician exercises the highest degree of care, the time has come to enact legislation that will balance the responsibilities of the health care provider against the whims of nature.

Susan Ferguson Slabaugh

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[119]*See, e.g.*, Wright v. Central Du Page Hosp. Ass'n, 63 Ill. 2d 313, 347 N.E.2d 736 (1976) (limiting recovery in medical malpractice actions to $500,000 was arbitrary and constituted special law in violation of equal protection provisions of the Illinois Constitution); Carson v. Maurer, 120 N.H. 925, 424 A.2d 825, 828 (1980) (medical malpractice statute which prohibits damages for pain and suffering or other non-economic loss in excess of $250,000 is violative of equal protection); Simon v. St. Elizabeth Medical Center, 3 Ohio Op. 3d 164, 355 N.E.2d 903 (1976) (limitation on amount of general damages of the Medical Malpractice Act violated equal protection guarantees of the State and Federal Constitutions).

[120]Neubauer, *supra* note 80, at 65.