Octomom and Multi-Fetal Pregnancies: Why Federal Legislation Should Require Insurers to Cover In Vitro Fertilization

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ABSTRACT

On January 26, 2009, Nadya Suleman, dubbed Octomom by the media, delivered octuplets after using in vitro fertilization. The same day, Congressman Anthony Weiner of New York introduced the Family Building Act of 2009 in the United States House of Representatives—a federal mandate requiring insurers to provide coverage for in vitro fertilization. The octuplets are no longer headline news, but issues associated with in vitro fertilization are still newsworthy. In this paper I propose that Congress should take a serious look at the Family Building Act of 2009. After addressing some additional issues, Congress should pass legislation mandating that insurers provide coverage for in vitro fertilization. Such legislation will have the effect of reducing the number of multi-fetal pregnancies and preterm births, as well as the costs and risks associated with such pregnancies and births.

Although in vitro fertilization is used to treat infertility, it has replaced one problem (the inability to procreate) with a more serious problem (multi-fetal pregnancies). This problem exists largely because the fertility industry is not regulated. While the American Society of Reproductive Medicine (ASRM) and the Society for Reproductive Technology (SART) have issued permissive industry guidelines, there is no serious consequence to the physician or clinic that ignores those guidelines. As in vitro fertilization is expensive and largely funded with out-of-pocket monies, patients and their physicians are inclined to transfer more than one embryo for implantation during

* Assistant Professor, Charlotte School of Law. BBA magna cum laude Millsaps College, J.D. Georgetown University Law Center. The author thanks Joan Krause, Professor of Law University of North Carolina at Chapel Hill, and Judith Daar, Professor of Law Whittier University, for encouraging her to join the discussion about reproductive technology; Ruqaijah Yearby, Associate Professor University at Buffalo School of Law, and the Northeast People of Color Scholarship Conference participants for comments on drafts of this paper; and Elizabeth A. Grymes, Charlotte School of Law class of 2010, Stratford N. Kiger, Charlotte School of Law class of 2010, and her colleagues at the Charlotte School of Law.

1. H.R. 697, 111th Cong. (1st Sess. 2009). The Act requires coverage for assisted reproductive technologies. In vitro fertilization is the most common assisted reproductive technology.
each cycle of in vitro fertilization. They do so in order to increase the chances of a “successful” pregnancy and maximize a patient’s use of funds. As a result, women who undergo in vitro fertilization often have more than one baby at a time.

Moreover, the only federal law that regulates the industry—the Fertility Clinic Success Rate and Certification Act—also encourages multiple embryo transfers by requiring physicians and clinics to report their pregnancy success rates each year. A successful pregnancy is one that results in a live birth—regardless of how many children. This encourages physicians to transfer multiple embryos to increase their chances of a successful pregnancy so that they can attract additional consumers. Because the human uterus is designed to carry only one baby at a time, multi-fetal pregnancies are risky and usually result in preterm babies. The children often have long-term health and other needs. This is a public health concern.

The Family Building Act would help regulate the largely unregulated fertility industry. If passed, women and their physicians would be inclined to transfer fewer embryos for implantation during a cycle of in vitro fertilization because an unsuccessful pregnancy would not mean the loss of out-of-pocket dollars. A patient would be more willing to try again if insurance covered the procedure. Furthermore, physician reimbursement rates could be tied to the industry guidelines. A federal mandate requiring insurers to cover in vitro fertilization would strengthen the industry guidelines without a need for an additional regulatory industry. An insurance mandate will reduce the incidence of multi-fetal pregnancies, the largest problem associated with in vitro fertilization, and ultimately increase the incidence of healthy single-baby pregnancies.

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INTRODUCTION

In January of 2009, Nadya Suleman delivered eight babies at the Kaiser Permanente Medical Center in Bellflower, California. The media excitedly awaited details as to who delivered the latest octuplets. Soon, the excitement turned to anger and judgment as the following information came to light:

3. Id. at C8.
• The mother was identified as a thirty-three-year-old single mother who already had six children under the age of seven.4
• The mother received some public assistance for at least two of her older children.5
• The mother was unemployed with no visible means of income.6
• The mother lived with her parents, who were also in financial trouble.7
• The mother used in vitro fertilization in each of her pregnancies.8
• The mother’s physician transferred six cryopreserved embryos for implantation, and they resulted in eight babies.9

The media dubbed Ms. Suleman “Octomom,” and several pundits offered solutions to the Octomom problem. Such solutions included the following:

• Remove the babies from Ms. Suleman. She cannot nurture them and care for them because she has no husband and no money.10
• Bring charges against the physician for transferring six embryos for implantation.11

4. Id. at C1.
7. Id.
8. Octuplets’ Mom On Welfare, supra note 5.
• Create a regulatory agency to put limits on the number of embryos that a physician may transfer, and regulate cryopreserved embryos.¹²
• Mandate insurance coverage for in vitro fertilization.¹³

Octomom and her babies are no longer headline news. The issues raised as a result of the saga, however, are still newsworthy. Before the single unemployed Octomom gave birth to her eight babies, the media celebrated other multi-fetal pregnancies and rewarded the parents and children of these “miracle births” with endorsements and television shows.¹⁴ Octomom’s saga, however, has helped the general population understand the serious side effects of multi-fetal pregnancies.¹⁵ The largest risk factor of multi-fetal pregnancies is pre-term delivery and the long-term health needs and developmental delays associated with such preterm babies. The March of Dimes has recognized not only that preterm labor and delivery is a serious public health issue that must be addressed, but also that the rate of such births has increased thirty-six percent over the last twenty-five years.¹⁶

The impact of such multi-fetal pregnancies does not just affect the mother and her children; it affects all of society. In the case of extreme multi-fetal pregnancies like Octomom’s pregnancy, hospitals are generally not able to recoup the costs associated with the pregnancy and delivery of the resulting babies.¹⁷ Even in the case of

¹⁵ The reasons why Octomom was vilified are subjects for another paper. Unlike famous moms of multiples, Octomom was a single, non-Christian, woman of color.
¹⁷ Robert Stillman, How to Promote Single Embryo Transfers, N.Y. TIMES ROOM FOR DEBATE BLOG (Oct. 11, 2009, 3:00 PM), http://roomfordebate.blogs.nytimes.com/200910/11/the-trouble-with-twin-births/. As a “reproductive endocrinologist and medical director of Shady Grove Fertility Center in Rockville, Md.” and a past board member of the American Society for Reproductive Medicine, Stillman stated that:

Between 1996 and 2007, following professional guidelines and improved clinical outcomes, we saw an 87 percent decrease in triplet and quadruplet pregnancies as the average number of embryos transferred steadily dropped and while the number of I.V.F. cycles and live births increased.

Id.
twins and triplets, multi-fetal pregnancies tend to result in premature births. Such pregnancies and deliveries are costly and risky—requiring additional medical professionals and neonatal intensive care units that are not required of healthy single pregnancies. In addition, as a result of being born underweight and underdeveloped, many of the babies have long-term physical or mental disabilities.\(^{18}\) Treatment for such disabilities is often covered through insurance or social programs such as Medicaid. Thus, all of society bears the costs for multi-fetal pregnancies through either increased insurance premiums or taxpayer funded programs.

Though preterm birth is known to be one of the largest neonatal health issues in the United States, the focus on curing the issue has primarily been directed at prenatal care for lower income women.\(^{19}\) For example, the recently passed Patient Protection and Affordable Care Act provides grants for states and other entities “to develop and implement evidence-based maternal, infant and early childhood visitation models.”\(^{20}\) These visitation programs target at-risk “communities with concentrations of premature birth, low-birth weight infants, and infant mortality, including infant death due to neglect, or other indicators of at-risk prenatal, maternal, newborn, or child health.”\(^{21}\) In actuality, more than one-third of preterm births are a result of fertility treatments.\(^{22}\) Thus, it is not simply an issue for at-risk communities. Because multiple embryo transfers result in multiple babies, the rate of multi-fetal pregnancies is significantly higher for women who undergo fertility treatment than those who conceive naturally.\(^{23}\) While the incidence of multi-fetal pregnancies “is one pair per 90 live births” with natural conception, such rate for women who successfully undergo fertility treatments is about one in three.\(^{24}\)

Thanks to the Octomom saga, it is now widely known that the three billion dollar fertility industry is largely unregulated.\(^{25}\)


\(^{21}\) Id. § 2951(b)(1)(A)(i).

\(^{22}\) Stobbe, *supra* note 19.


\(^{24}\) Id.

\(^{25}\) See Cate Vojdik, *Octuplets: The Cost of Making Babies*, AC360 BLOG (Feb. 2,
Octomom and her physician have suffered criticism for the large number of embryos transferred for implantation during a cycle of in vitro fertilization and failure to follow industry guidelines, statistics suggest that most fertility clinics do not follow such industry guidelines. Furthermore, there are no real penalties for physicians who do not follow such guidelines.

On the same day that Octomom delivered her babies, Congressman Anthony Weiner introduced the Family Building Act of 2009 in the House of Representatives. Senator Kirsten Gillibrand introduced similar legislation in the Senate later that year. The companion bills require insurers to provide coverage for in vitro fertilization and other assisted reproductive technologies. I suggest that Congress should take a serious look at the legislation. This bill should not languish in committee without the benefit of hearings and a markup.

A federal mandate requiring insurers to cover in vitro fertilization will reduce multi-fetal pregnancies and lower the rate of preterm births. Society will benefit from healthy single-birth pregnancies, and there will probably not be increased costs for insurers. Here is why: in vitro fertilization is a costly out-of-pocket procedure. With a success rate of approximately twenty-seven percent, women and their physicians may maximize their chances for a successful pregnancy by transferring multiple embryos for implantation. Sadly, such multiple embryos often result in multi-fetal pregnancies. The federal mandate requiring insurers to provide coverage for the procedure would remove the primary incentive for patients to request or physicians to offer to transfer multiple embryos for implantation—money, or lack of money.
A standard maternity benefits package includes coverage for labor and delivery, regardless of the number of children. Those costs are significantly higher for multi-fetal pregnancies than they are for single-birth pregnancies. Additionally, insurers already cover the hidden costs associated with in vitro fertilization when they cover the medically necessary treatments for twins, triplets, quadruplets or more. As an insurance mandate will translate to fewer preterm babies, the long-term health costs of preterm babies will diminish. Therefore, the insurance mandate will not cost the insurance industry any more money than it already spends for labor and delivery, as well as for the long-term health needs of babies born in a multi-fetal pregnancy and their mothers. Coverage for in vitro fertilization would be a shift in costs and possibly lower long-term outlays for health insurance.

Part I of this paper identifies the problems associated with multi-fetal pregnancies. There are long-term societal costs associated with multi-fetal pregnancies and the resulting preterm births. Part II looks at the current fertility industry guidelines and federal law. The Association for Reproductive Medicine and the Society for Reproductive Technology have industry guidelines that are to be used when clinics do not have internal data. The guidelines are permissive and a majority of clinics do not follow the guidelines. Currently, the Fertility Clinic Success Rate and Certification Act is the only federal law that regulates the fertility industry. The law was passed to assist consumers as they identified successful clinics but encourages clinics and physicians to transfer multiple embryos in order to be seen as successful.

Part III addresses why federal legislation is necessary. Although the medical community has defined infertility as a disease and the Supreme Court has said that reproduction is a major life activity, the Supreme Court has stopped short of requiring insurers to provide coverage for in vitro fertilization under the Americans with Disabilities Act or the Pregnancy Discrimination Act. Furthermore, state regulation is inadequate. Only a few states have addressed the issue and there is no uniformity. In addition, ERISA has a loophole that exempts self-funded insurance plans from state mandates on

33. Id.
insurance providers. In Part IV, I recommend that Congress should hold committee hearings and markups to strengthen the Family Building Act and eventually pass federal legislation. It is my belief that such legislation is needed and support for the legislation may be garnered in the same way that support was garnered for the Drive Through Maternity Benefits legislation that passed in the mid 1990s. In the last Part, I conclude by acknowledging that a federal insurance mandate will not answer all policy issues associated with in vitro fertilization. In vitro fertilization is, however, the simplest and most effective way to curb multi-fetal pregnancies and promote healthy single-baby pregnancies.

I. UNDERSTANDING THE PROBLEM—THE HISTORY OF INFERTILITY AND IN VITRO FERTILIZATION; WHY IS THERE A DARK SIDE TO THIS MIRACLE PROCEDURE?

In vitro fertilization has helped many individuals realize their dream of parenthood. But, there are often costs associated with such parenthood. Also, while parents may think that a multi-fetal pregnancy, one that results in two, three or more children, is a successful pregnancy, many serious health issues are associated with such pregnancies. Such issues include “low birth weight, cerebral palsy, blindness, hearing impairment, and cognitive delays.” These “complications associated with [in vitro fertilization] are often distanced from the more glowing accounts about reproductive conception.”

A. “Be [F]ruitful, and [M]ultiply,” but What if I Can’t?

In the Garden of Eden, God commanded Adam and Eve and all of the animals to “[b]e fruitful, and multiply.” Unfortunately, all human beings do not have the natural ability to do so. Such individuals are deemed to be infertile. Infertility is the inability to multiply after continued unprotected intercourse. It occurs when pregnancy and live birth cannot be achieved because either the male or female reproductive system is not working properly. Various entities define the requisite period of time in different ways. For example, “[t]he World Health Organization defines this period of time as two years, while

39. Id. at 26-27.
41. Id.
42. The Staff of RESOLVE with Diane Aronson, Resolving Infertility 5 (Diane N. Clapp & Margaret R. Hollister eds., 1999).
43. Id. at 63.
the standard medical definition is twelve months, or at least three consecutive miscarriages or stillbirths.”44 The American Society for Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART) define this period as twelve months for women thirty-five and younger, and six months for women over the age of thirty-five.45

Even though most people often think of infertility as a “woman problem,” the condition affects men and women at almost equal rates.46 Female infertility is often caused by blocked fallopian tubes resulting from endometriosis or other such conditions. Other causes include ovulation disorders or disorders of the uterus or cervix.47 Low sperm production, no sperm production, and blocked passage of sperm are some of the causes of male infertility.48 Additionally, fertility declines with age in both men and women.49 Although infertility has been attributed to environmental toxins and poor nutrition,50 conception to birth is a complicated process, and sometimes the causes of infertility are unexplainable.

Generally speaking, the treatment for infertility is as follows: When infertility has been diagnosed, eighty-five to ninety percent of cases are treated using an infertility drug.51 Individuals can also turn to surgery, such as laparoscopy, which may be used to treat female structural problems.52 Intrauterine or artificial insemination, a nonsurgical procedure, is also an option, especially if there is a male infertility issue.53 If these methods are ineffective, which is true for


46. ARONSON, supra note 42, at 7 (“Infertility is a female problem in 40 percent of cases, a male problem in 40 percent of cases, and a combined problem of the couple or unexplained in 20 percent of cases.”).

47. Frequently Asked Questions, supra note 34.


49. ARONSON, supra note 42, at 14.


51. Pendo, supra note 48, at 299 (noting that “clomiphene and gonadotropins [are used] to regulate ovulation and to return female or male hormones to normal levels”).

52. Id. (citing Bonny Gilbert, Infertility and the ADA: Health Insurance Coverage for Infertility Treatment, 63 DEF. COUNS. J. 42, 43 (1996)).

53. Bonny Gilbert, Infertility and the ADA: Health Insurance Coverage for Infertility
a small percentage of individuals, advanced reproductive technologies (ARTs) are necessary. The Centers for Disease Control and Prevention defines ART “as all treatments or procedures that involve the handling of human eggs and sperm for the purpose of helping a woman become pregnant.” In vitro fertilization is the most common ART. Approximately one in eighty babies is a result of in vitro fertilization.

B. The Evolution of In Vitro Fertilization

In vitro fertilization is a surgical procedure that helps women with blocked or non-existent fallopian tubes achieve and sustain a pregnancy. In the most basic form, in vitro fertilization is a procedure in which a woman’s eggs are fertilized with a man’s sperm and then transferred “into the woman’s uterus for possible implantation.” The procedure involves the need to stimulate a woman’s ovaries to produce eggs, and the egg retrieval process requires intravenous sedation. Once retrieved, the eggs are graded and incubated before sperm is added. The number of embryos transferred usually “depends on [the] embryo quality and the woman’s age.” Women can elect to cryopreserve (freeze) the embryos that are not transferred. One reason for cryopreservation is to have embryos already available if the cycle is not successful.

The “first test tube baby,” Louise Brown, was born in the United Kingdom on July 25, 1978. Although much of the world celebrated the new technology, there were critics who considered the procedure to be an unethical and immoral medical experiment. Some even

54. Aronson, supra note 42, at 175 (internal quotation marks omitted).
55. See id. (providing examples such as “gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), embryo cryopreservation, egg or embryo donation, and gestational carriers”).
56. Sanghavi, supra note 31.
57. Aronson, supra note 42, at 176.
58. Id. (noting that doctors today use a plastic dish rather than a glass dish; however, in vitro literally means “in glass”).
59. Id.
60. Id. at 177 (asserting that there is a need “to increase the number of mature eggs that can be retrieved”).
61. Id. at 179.
62. Id. at 180.
63. Aronson, supra note 42, at 181.
64. Id. at 182.
67. Liu, supra note 44, at 315.
likened the procedure to the atomic bomb.\textsuperscript{68} Even so, the procedure allowed Louise’s infertile mother to experience pregnancy and childbirth. Australia and the United States soon followed with their very own test tube babies. Two in vitro pregnancies were documented live in Australia in 1980.\textsuperscript{69} In December of 1981, Elizabeth Jordan Carr was born in Virginia as a result of the new medical technology.\textsuperscript{70}

More than thirty years have passed since the first live birth using in vitro fertilization. The current state of in vitro fertilization has produced issues that are far more complex than those associated with the birth of Louise Brown and Elizabeth Carr.\textsuperscript{71} Although many individuals can testify that in vitro fertilization has helped them realize their dream of becoming parents, the unregulated fertility industry has an unhealthy dark side. In vitro fertilization is an expensive procedure that most individuals fund with out-of-pocket dollars. Only a few states have mandated insurance coverage for the procedure, and all of those mandates have limitations.\textsuperscript{72} As a result of the expense, physicians and patients are motivated to maximize a patient’s investment dollars and transfer multiple embryos for implantation. Such transfers result in a higher incidence of twins, triplets, and even higher order births.\textsuperscript{73} The unhealthy dark side of in vitro fertilization occurs when a woman carries more than one child at a time. Such pregnancies result in significant medical risks to the children and mothers. Deaths, disabilities, and other long-term problems are often overlooked as we celebrate the happy occasion of new babies.\textsuperscript{74}

C. What is Wrong with Multi-Fetal Pregnancies?

Octomom’s babies were born nine weeks early and weighed between one and a half pounds and a little more than three pounds.\textsuperscript{75}

\begin{itemize}
  \item \textsuperscript{68} Id. ("During the early 1970s when scientists were pursuing the possibility of IVF, a British magazine wrote a cover story analogizing IVF to the atomic bomb.").
  \item \textsuperscript{71} Issues such as cloning are beyond the scope of this paper.
  \item \textsuperscript{72} \textit{See State Mandated Insurance for Fertility Treatment}, FERTILITY LIFELINES, http://www.fertilitylifelines.com/payingfortreatment/state-mandatedinsurancelist.jsp (last visited Nov. 22, 2010) ("Currently only 15 states have laws requiring insurance coverage for infertility treatment.” These states are Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Texas, and West Virginia.).
  \item \textsuperscript{73} Mark I. Evans, \textit{The Truth About Multiple Births}, NEWSWEEK, Mar. 2, 2009, at 14.
  \item \textsuperscript{74} Id.
  \item \textsuperscript{75} Vojdik, supra note 25.
\end{itemize}
Four dozen medical professionals helped ensure their safe arrival. In vitro fertilization is considered a treatment for infertility. The procedure has, however, replaced one problem (inability to have children) with a more severe problem (multi-fetal pregnancies). The largest problem of multi-fetal pregnancies is that they result in the preterm births of multiple babies. Although super multi-fetal pregnancies like Octomom’s are rare occurrences, twins, triplets, and quadruplets are not rare occurrences. The March of Dimes has stated that fertility treatments have contributed to the significant increase of preterm babies.

Preterm labor and delivery is costly and dangerous to both a mother and her children. Approximately 51% of twins and 91% of triplets are born preterm, compared to 9.4% in single-birth pregnancies. Approximately 14% of twins and 41% of triplets are born very preterm, compared to 1.7% in single-birth pregnancies. The average gestational age for twins is 34 to 36 weeks, for triplets is 32 to 34 weeks, and for quadruplets is 28 to 30 weeks. Physicians often do not do the greatest job of explaining the risks associated with delivering more than one baby, including twins.

Babies who are born prematurely have low birth weights, which means that they have a greater risk of complications and even death. A mother may require more medical care during her pregnancy and her children may require additional medical care during the pregnancy.

76. Sanghavi, supra note 31.
77. See Vojdik, supra note 25 (noting that the babies were “underweight and underdeveloped”).
78. Pamela Prindle Fierro, Twin and Multiple Birth Rate Statistics, ABOUT.COM, http://multiples.about.com/od/funfacts/a/twinbirthrate.htm (last visited Nov. 22, 2010). According to data collected in 2006, rates of quadruplets, quintuplets and other higher-order births are on the decline, whereas the rate of live births in twin deliveries has more than doubled since 1980.
79. Stephanie Saul, The Gift of Life, and Its Price, N.Y. TIMES, Oct. 11, 2009, at A1 (stating that “an increasing number of the newborns are twins, and they carry special risks often overlooked”).
81. Id.
82. Christopher J. De Jonge & Don P. Wolf, Embryo Number for Transfer Should Be Regulated, 68 FERTILITY & STERILITY 784, 785 (1997).
83. See Christina Vienna, Comment to The Trouble with Twin Births, N.Y. TIMES ROOM FOR DEBATE BLOG (Oct. 12, 2009, 6:27 PM), http://community.nytimes.com/comments/roomfordebate.blogs.nytimes.com/2009/10/11/the-trouble-with-twin-births/(commenting that “[n]o one sat down and told us the risk of prematurity, and all the other worries that came along with that”).
84. De Jonge & Wolf, supra note 82, at 785.
and at birth.85 Such babies may have long-term health needs and developmental delays, which can also affect parents.86

According to a 2006 report of the Institute of Medicine, preterm births cost the United States an average of approximately $51,000 per infant or $26 billion.87 Most of the expense is associated with medical care.88 In 2007, the average cost of an uncomplicated childbirth was approximately $8,802.89 “In one study, the average hospital charge for mother and infant was $9,845 for singletons, $37,947 for twins ($18,974 per baby), and $109,765 for triplets ($36,588 per baby).”90

In addition to the costs for delivery, preterm babies born as a result of a multi-fetal pregnancy generally require more medical attention throughout their first year of life and are less healthy than babies born as a result of a single birth. There is a greater risk of death associated with low birth weight babies.91 Additionally, such babies have a substantial need for care and often suffer long-term damage, in spite of advances in medical care.92 The low birth weight often means that the babies will have disabilities that require long-term—and costly—medical treatment.93

The average cost of medical care for a premature or low birth-weight baby for its first year of life is about $49,000, according to a new report from the March of Dimes Foundation. By contrast, a newborn without complications costs $4,551 for care in its first year of life, the report said. Newborns with other kinds of com-

85. Saul, supra note 79, at 1.
86. Id.
87. Vojdik, supra note 25.
88. Id.
90. Carson Strong, Too Many Twins, Triplets, Quadruplets, and So On: A Call For New Priorities, 31 J.L. MED. & ETHICS 272, 274 (2003). “These higher costs are due to a number of factors, including an increase in cesarean sections, more ICU (intensive care unit) admissions for the infants, and longer hospitalizations for the infants and mothers.” Id. (citing T.L. Callahan et al., The Economic Impact of Multiple-Gestation Pregnancies and the Contribution of Assisted-Reproduction Techniques to Their Incidence, 331 NEW. ENG. J. MED. 244, 244-49 (1994)).
93. Id.
plications, such as congenital defects, have medical expenses of $10,273 on average in the first year.94

One example of a long-term treatment cost for preterm babies is the Synagis vaccine.95 Most preterm babies are at risk for RSV, a severe respiratory virus. As a result of such diagnosis, the babies require the Synagis vaccine. Each dose of the vaccine costs approximately $2,000, so the full treatment cost is approximately $8,000 to $10,000.96 There are also greater frequencies of cardiovascular, urogenital, and musculoskeletal defects in children born with the assistance of in vitro fertilization than those born through natural conception.97 There are significant long-term costs associated with treating these defects.

Multi-fetal pregnancies encumber the parent as well as the child. In addition to risks to the children, multi-fetal pregnancies also adversely affect the mother. For example, mothers often suffer with pregnancy risks such as gestational diabetes and preeclampsia.98 Additionally, parents of multiples often have medical and psychological issues. Many are unprepared for the emotional challenges of raising multiple children. A substantial amount of time is needed to manage a household and care for multiple children. “[F]atigue and stress arising from child care is almost universal for mothers of multiples. Research also shows a higher incidence of depression, alcohol and drug abuse, and divorce among mothers with multiples.”99

II. THE CURRENT STATE OF AFFAIRS—FEDERAL LAWS AND FERTILITY INDUSTRY GUIDELINES

The United States has a higher incidence of preterm births than other developed counties.100 Data from countries that provide insurance coverage for in vitro fertilization shows that such countries

94. Id.
95. Synagis is a medication designed to protect high-risk babies and preemies from RSV (respiratory syncytial virus). See Synagis (Palivizumab), http://www.synagis.com (last visited Nov. 22, 2010).
96. This information was obtained in Author’s conversation with a pediatrician.
98. Lars Noah, Assisted Reproductive Technologies and the Pitfalls of Unregulated Biomedical Innovation, 55 FLA. L. REV. 603, 620 (2003). “ART procedures [also] raise a variety of other safety concerns for the mother, ranging from acute and chronic side effects associated with the use of fertility drugs . . . to complications involved in the harvesting procedure, and higher rates of ectopic pregnancies.” Id. at 620-21.
99. Strong, supra note 90, at 274 (citations omitted).
have lower rates of embryo implantation and lower rates of multi-
fetal pregnancies than the United States, where there is not manda-
tory insurance coverage.101 Because the United States relies on the
guidelines promulgated by ASRM and SART, an insurance mandate
would help strengthen those guidelines by giving physicians an in-
centive to follow them. Current data suggests that most fertility clinics
do not follow the industry guidelines.102 There is no incentive for them
to do so. In fact, the only federal law that regulates the fertility in-
dustry enables physicians to disregard the guidelines. That law, the
Fertility Clinic Success Rate and Certification Act of 1992,103 requires
clinics to report their success rates to the Centers for Disease Control.
Multi-fetal pregnancies count as successful pregnancies. Patients
use this information to assist them as they choose a clinic. As clinics
want to have a high success rate, physicians will often implant mul-
tiple embryos to increase the chances for success. After all, a success-
ful clinic will presumably attract new patients, and those satisfied
patients will refer others. Unfortunately, successful often means two,
three, or more babies.

A. Lack of Insurance Coverage for In Vitro Fertilization Increases
the Rate of Multi-Fetal Pregnancies

When first introduced, in vitro fertilization allowed childless
couples to become parents. Yet no one ever imagined that a huge
and dangerous downside to the procedure lurked—“multiplying” too
much. Within the time-span of three decades, we have gone from the
celebration of Louise and Elizabeth to the shock of Octomom.

The chance of a multi-fetal pregnancy is higher with in vitro
fertilization than with natural conception, and there is no incentive
for a physician to transfer fewer embryos per in vitro fertilization
cycle.104 Money is a motivating factor when it comes to the number of
embryos transferred for implantation during a cycle of in vitro fer-
tilization. Because many families often take out loans or second
mortgages to fund in vitro fertilization, patients request or physi-
cians offer to transfer two, three, or more embryos in order to maxi-
mize chances of a successful pregnancy.105 Multiple embryo transfers

101. In Vitro Fertilization: Doctors Perform More IVF Treatments, But Multiple Births
.msnbc.com/id/29305552/.
103. Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493,
106 Stat. 3146 (codified at 42 U.S.C. § 263a-1 to -7 (2000)).
104. The reasons will be discussed in this paper.
105. See Stephanie Saul, Grievous Choice on Risky Path to Parenthood, N.Y. TIMES,
Oct. 11, 2009, at A1, A14 (stating that multi-fetal pregnancies may also result from the
use of a less effective fertility treatment, such as intrauterine insemination, when in vitro

We were counseled on the likelihood of multiples, issues related to that, and provided a choice of 1-3 embryos being used. Given the cost and the reality that we would likely only ever have one shot at child birth (our history include [sic] 5 years of trying, which is not uncommon), we chose (key word here) to use more than one embryo and had twins as a result.\textit{Id.}} The cost of one cycle of in vitro fertilization is approximately $12,400.\footnote{Frequently Asked Questions, supra note 34. This amount includes lab screenings for both parents, ultrasound and lab work, egg recovery, and embryo transfer. See Cost of In Vitro Fertilization,LOVE ToKNOW, http://pregnancy.lovetoknow.com/wiki/Cost_of_In_Vitro_Fertilization (last visited Nov. 22, 2010).} A successful pregnancy occurs only forty to fifty percent of the time when a single embryo is transferred for implantation.\footnote{Sanghavi, supra note 31.} “[E]ach attempt at [in vitro fertilization] is a financial gamble.”\footnote{Goodwin, supra note 38, at 26 (citation omitted).} Success rates increase as the number of embryos increase. Physicians want to please their patients by producing a successful pregnancy. The happy patients then refer other clients to the physician and the cycle continues.\footnote{See, e.g., Saul, supra note 105, at A14 (stating that Jon and Kate Gosselin used intrauterine insemination (IUI)). Additionally, some patients choose less effective methods for fertility treatments because they are less costly than in vitro fertilization. Those pregnancies too often result in higher order multi-fetal pregnancies.} Sadly, a multi-fetal pregnancy is not necessarily a successful pregnancy.

There are no federal laws that limit the number of embryos that may be transferred for implantation during a cycle of in vitro fertilization.\footnote{See Ronald Chester, Double Trouble: Legal Solutions to the Medical Problems of Unconsented Sperm Harvesting and Drug-Induced Multiple Pregnancies, 44 ST. LOUIS U. L.J. 451, 466 (2000) (noting that an attempt at such a law might lead to an outcry that the government is trying to encroach on “a woman’s right to procreate”).} The only federal law that regulates in vitro fertilization, the Fertility Clinic Success Rate and Certification Act, may actually encourage physicians to transfer multiple embryos for implantation.\footnote{Karey Harwood, Harwood Follows up on Ethical Issues at Stake in the Octuplets Case, UNC PRESS BLOG (Feb. 25, 2009, 6:18 PM), http://uncpressblog.com/2009/02/25/harwood-follows-up/.} Furthermore, the American Society of Reproductive Medicine (ASRM) and Society for Assisted Reproductive Technology (SART) guidelines are not rigid mandates that impose penalties on physicians who transfer more than one embryo.\footnote{Jesse Reynolds, Preventing the Next Fertility Clinic Scandal, BIOETHICS FORUM (Mar. 13, 2009), http://www.thehastingscenter.org/Bioethicsforum/Post.aspx?id=3240&biogid=140.}
After Octomom’s saga, some suggested that a regulatory agency was necessary. While pontificating about the need for a regulatory entity makes for great intellectual discussions, Americans often shun such government intervention, and legislation would undoubtedly be extremely difficult to pass. Federally mandated insurance coverage can, however, have a positive effect on reducing multi-fetal pregnancies.

A federal mandate for insurers to cover in vitro fertilization would provide the needed financial incentive for a physician to transfer fewer embryos because, if the physician did transfer multiple embryos, he or she would not otherwise be reimbursed by the insurance carrier. Additionally, such a mandate would reduce the incentive for a patient to request multiple embryos. Insurance coverage removes the “financial gamble.”  

In states and countries with mandated coverage for in vitro fertilization, there are lower embryo transfer rates and fewer multi-fetal pregnancies. Unfortunately, few states have mandates, and the fertility industry is often described as the “Wild Wild West.” Federally mandated insurance coverage for in vitro fertilization can help curtail the behaviors of patients and physicians in this unregulated market.

B. The Fertility Clinic Success Rate and Certification Act

There is only one federal law that regulates in vitro fertilization, the Fertility Clinic Success Rate and Certification Act of 1992. The purpose of the Act was to help a consumer make informed choices as she selects an appropriate fertility clinic. Unfortunately, the Act is fundamentally flawed. According to the language of the Act, the success of a fertility clinic is determined by the number of live births the clinic “produces” each year; the Act requires fertility clinics to report their success rates annually. The Centers for Disease Control (CDC) compiles the data and publishes the success rates. It also publishes the names of clinics that do not disclose their pregnancy success rates in accordance with the regulations.

118. Id.
119. Id.
120. Lyria Bennett Moses, Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization, 6 Minn. J. L. Sci. & Tech. 505, 568, 593 (2005).
Clinics use various treatment approaches in order to be seen as successful. For example, a clinic with poor success results may be inclined to transfer multiple embryos in order to maximize its chances of a successful live birth.121 In the case of Octomom’s physician, a look at data from the 2004 CDC Report shows that while the live birth rate was the same as the national industry average, the average number of embryos transferred was much higher than the industry average.122 Octomom’s physician needed to transfer greater numbers of embryos in order to keep his success rate at the industry average.

The Fertility Clinic Success Rate and Certification Act created a vicious cycle. A clinic needs customers to be not only successful, but to remain in business. A clinic also needs to show customers that it has a high percentage of live births. The clinic is not motivated to reduce the number of embryos transferred for fear of reducing the number of live births. When “[t]he profitability of a particular practice depends on its success, which in turn is measured by the number of pregnancies and live births,”123 the end result is a large incidence of multi-fetal pregnancies.124 Individuals who are paying for the procedure using out-of-pocket funds have no incentive to reverse the cycle.

Because the industry is unregulated, it is not uncommon for clinics to offer unorthodox methods to attract patients. A search on the internet uncovered money-back guarantees to patients,125 discounts for prepayment of multiple cycles,126 and loan programs.127 “In a perfect market, consumers [would] carefully research their options. They “[would] spend resources to obtain information in proportion to the perceived benefit of that information.”128 When a physician has slick marketing practices, however, patients may not carefully analyze their options.129

121. Terrence Lee, Octuplets Doctor May Have Been Lulled by Past Poor Success, FERTILITY FILE BLOG (Feb. 9, 2009), http://fertilityfile.com/2009/02/09/octuplets-doctor-may-have-been-lulled-by-past-poor-success/.
122. Id. (The physician reported outcomes in 2004 and 2006, but not in 2005. In 2004, for women under 35, his average number of embryos transferred was 3.8 as compared to the national average of 2.5.).
123. Rosato, supra note 97, at 73 (citations omitted).
128. Moses, supra note 120, at 568.
129. Id.
Insurance coverage can counter the vicious cycle that results from the Fertility Clinic Success Rate and Certification Act. Physicians will not be inclined to transfer multiple embryos if their insurance carrier will not reimburse them. When a patient can rely on insurance rather than out-of-pocket funds, she is more inclined to accept the physician’s decision to transfer fewer embryos because she can try again if the cycle is unsuccessful. The additional attempt is not so daunting if the individual patient does not have to finance the procedure with out-of-pocket funds. If insurance covered in vitro fertilization, neither physician nor patient would have an incentive for wayward conduct, and the rate of multi-fetal pregnancies would decline.\(^{130}\)

Clinics need patients to stay in business. More individuals would probably utilize the procedure if it were covered by insurance.\(^{131}\) This would create more business for physicians and reduce the need for money-back guarantees and other such practices.\(^{132}\) In addition, the insurance industry could help ensure that fees are not out of the ordinary. Still another reason for mandating insurance coverage is that many women do not have access to the procedure. Although infertility affects women and men of all races and socioeconomic groups,

Currently, infertility treatments are typically used by better-educated, upper-middle class white professional women. This is a direct result of the high costs and lack of insurance coverage for these procedures. For example, seventy-five percent of low-income women in need of infertility services, a disproportionate number of whom are African-American, do not have access to those services.\(^{133}\)

C. ASRM and SART Guidelines are Limited and Too Flexible

Several of Octomom’s critics suggested that her physician, Dr. Michael Kamrava, should be punished for transferring six embryos for implantation. Some suggested that legal action was warranted because he did not follow industry standards.\(^{134}\) But, Dr. Kamrava

\(^{130}\) Also, insurance coverage would allow younger women, women of color, and less economically-advantaged women to have the same access to the procedure. See Judith F. Daar, Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms, 23 BERKELEY J. GENDER L. & JUST. 18, 36-37 (2008).

\(^{131}\) Dorothy Roberts, Racial Disparity in Reproductive Technologies, CHI. TRIB., Jan. 29, 1998, at 19N (stating that, although infertility affects all races and classes, assisted reproductive technologies “are used primarily by white people, in particular by affluent and highly educated women”).


\(^{133}\) Kerr, supra note 50, at 605 (citations omitted).

\(^{134}\) See Octuplets’ Mom On Welfare, supra note 5 (stating that two of the six embryos split, and eight babies were born).
did not violate industry standards. ASRM states the following about its guidelines:

These guidelines have been developed to assist physicians with clinical decisions regarding the care of their patients. They are not intended to be a protocol to be applied in all situations, and cannot substitute for the individual judgment of the treating physicians based on their knowledge of their patients and specific circumstances. The recommendations in these guidelines may not be the most appropriate approach for all patients. Medical science and ethics are constantly changing, and clinicians should not rely solely on these guidelines.135

By its own statement, the ASRM acknowledges that its guidelines are flexible. In fact, they are so flexible that a recent study shows that most clinics do not follow the recommended number of embryos to implant.136 According to data from the Centers for Disease Control, over eighty percent of clinics do not follow the guidelines.137 Although the ASRM and SART usually do not sanction or expel members for failing to follow its guidelines,138 the ASRM expelled Dr. Kamrava from its membership in September of 2009.139 In early 2010, the California Medical Board filed a disciplinary complaint against Dr. Kamrava claiming that his conduct, as it pertained to Octomom, was grossly negligent.140 The industry may be treating Dr. Kamrava unfairly.

In November of 2009, the ASRM and SART guidelines were updated in an effort to curtail multi-fetal pregnancies. The current ASRM and SART guidelines are more structured than prior versions. For example, in 1994, the guidelines did not mention a specific number of embryos that should be implanted. Instead, the recommendation was to transfer a number “so that no quadruplets and no more than 1% to 2% triplet pregnancies were anticipated.”141 This was extremely difficult to enforce. In 1998, the ASRM “suggested that clinics create their own guidelines based on internally generated

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137. Id.
138. Id.
141. Moses, supra note 120, at 592 (citation omitted).
statistics.” The ASRM did make some recommendations in situations where there was not sufficient clinic data. The recommendations in 1999 were that physicians should transfer between three and five good embryos for implantation, “depending on the patient’s profile, taking into account factors such as age and prior treatment history.”

In the late 1990s, the ASRM began to recognize the correlation between the increased number of embryos transferred and the increased chance of multi-fetal pregnancies. So, in 1999, it shifted its recommendation to suggest clinics transfer between two and five embryos, while also “allowing adjustments for individual clinic conditions.” ASRM removed from the guidelines descriptive words like “good quality” to describe the embryos, but continued to emphasize that flexibility was necessary so that there could be adjustments for individual clinics and patients. Consider the following language:

Strict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient’s own unique circumstances. Accordingly, these guidelines may be modified according to individual clinical conditions, including patient age, embryo quality, the opportunity for cryopreservation, and as clinical experience with newer techniques accumulates.

The latest revisions to the guidelines state that only one additional embryo than that recommended in the guidelines should be transferred, regardless of the patient’s prognosis. Additionally, clinics may be audited if clinics have a multi-fetal pregnancy rate that is two standard deviations above the mean rate for all reporting clinics for two consecutive years. But, even with the revisions, the United States is unlike other countries because physicians and clinics do not face penalties if they violate the embryo transfer limit. ASRM and SART continue to err on the side of flexibility. Even with the new revisions, the ASRM guidelines are for use when a clinic does not have internal data to make its own decisions about embryo transfers. The guidelines are merely based on data generated by all clinics

142. Id. (citation omitted).
143. Id. (citation omitted).
144. Id. at 592-93.
146. Id.
147. Id.
148. Id.
that provide assisted reproductive technology services. A look at
the language from the current guidelines shows that the organiza-
tions did not want to limit a physician’s ability to consider each
patient’s situation on an individual basis.

Those who chastise Dr. Kamrava point to language in the guide-
lines that were in effect before November 2009. Those guidelines
stated that when a patient is under the age of thirty-five, “consider-
ation should be given to transferring only a single embryo.” This
language applied, however, only to patients who had a “more favor-
able prognosis.” Even though the language suggested that “[a]ll
others in this age group should have no more than” two embryos
transferred, the language did excuse unique “individual circum-
stances.” The only requirement under the guidelines was that both
the physician and patient should agree on the number of embryos
to be transferred. Perhaps Dr. Kamrava, in his professional judgment,
believed Octomom to be an extraordinary circumstance. Octomom
has defended her physician’s decision.

Before treatment from Dr. Kamrava, Octomom had tried unsuc-
cessfully for seven years to get pregnant; she had used fertility drugs
and artificial insemination. She claims to have had a history of
scarred fallopian tubes and miscarriages. Dr. Kamrava helped her
achieve pregnancy using in vitro fertilization. He transferred six em-

/filenow/2009/02/octuplets.html (stating that Dr. Michael Kamrava of the “West Coast
Infertility Medical Clinic, now named West Coast IVF Clinic,” transferred far more
embryos than the industry norms and recommendations prescribe).

150. Guidelines on Number of Embryos Transferred, supra note 145, at 1518.
151. Id.
152. Id.
153. Id.
154. Id. at 1519.
155. Id. at 1518.
156. See Zarembo & Yoshino, supra note 149 (noting that Suleman stated that the
procedure was “very appropriate” and that Dr. Kamrava “did nothing different” (internal
quotations marks omitted)).
157. Id.
158. Id.
159. See Octuplets’ Mom On Welfare, supra note 5 (stating that the octuplets were a
surprise; Suleman had expected twins at most).
160. See supra note 122 and accompanying text.
Octomom’s eggs had been cryopreserved, which often reduces the success of a pregnancy. Given the past history and clinic data, neither Dr. Kamrava nor his patient had reason to believe that eight babies would result from the embryos. In fact, his professional judgment may have led him to believe that transferring six embryos was necessary to achieve the successful pregnancy.

If Octomom had delivered only one or two babies, there would probably have been no public outcry for legal actions against Dr. Kamrava. In fact, there are known situations (before Octomom and Dr. Kamrava) where physicians in clinics with poor conditions transferred large numbers of embryos to compensate for the poor laboratory conditions. While Dr. Kamrava has been demonized, other physicians who have not followed the industry guidelines have been lauded for creating a miracle birth. One such example is the Kell family of Atlanta. The Kells had tried for several years and spent several thousand dollars in an attempt to have a child. “Sheri Kell’s doctor retrieved eight eggs from her ovaries, five of which were healthy.” Three of those eggs developed into embryos after fertilization and “were transferred into [her] body.” Sheri delivered a son nine months later.

Like Dr. Kamrava, Sheri Kell’s physician adjusted his treatment to meet Sheri’s individual needs. If he had transferred only one embryo, then she may not have had a successful pregnancy. Sheri had spent thousands of out-of-pocket dollars on fertility treatments, and financially, she needed to maximize her chances of having a successful pregnancy. Even with the new 2009 ASRM guidelines, Sheri’s physician might feel justified in transferring two or more embryos.

As ASRM and SART have declined to impose rigid guidelines and penalties, a federal insurance mandate can strengthen the current

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161. See Zarembo & Yoshino, supra note 149 (mentioning that Dr. Kamrava used “breakthrough technology that revolutionized IVF, reducing risks to both the mother and the child” (internal quotation marks omitted)).

162. Id.

163. See Moses, supra note 120, at 588 (citation omitted) (stating that these clinics transfer large numbers of embryos to increase their success rates).


165. Id.

166. See id. (stating that three fertilized embryos led to Ms. Kell giving birth to her son).

167. Id.

168. Id.
ASRM and SART guidelines. Insurers could use the industry information from ASRM and SART to set guidelines for reimbursements and then “mandat[ing] that coverage be provided only for clinics that report according to federal law or adhere strictly to professional guidelines.” Clinic reimbursements could be linked to a requirement that physicians either follow industry guidelines or justify why they did not follow the guidelines. Mandated insurance coverage strengthens the existing industry guidelines. This is a real practical solution to the real problem of in vitro fertilization—multi-fetal pregnancies that pose health risks to both mother and child.

If insurance covered in vitro fertilization, perhaps Sheri Kell’s physician might have encouraged her to transfer one embryo, knowing that if she was unsuccessful, she could try again. The Kells might have agreed with their physician’s recommendation to transfer fewer embryos because they could afford to try again if the pregnancy was unsuccessful. Without such coverage, the incentive for both mother and physician is to transfer multiple viable embryos to the mother during a single implantation procedure.

The insurance industry could also structure coverage so that there is a disincentive to participate in procedures that risk the health of the mother and the children as occurs with multiple embryo transfers:

In practice, bringing insurance companies or other impersonal providers into the equation would force a distinction between cases of infertility, for example, between the twenty-seven-year-old wife with blocked fallopian tubes, who would most likely qualify for several cycles of IVF treatment, and the single fifty-three-year-old recovering cocaine addict and ex-felon, who would not.

Because the low birth weight babies born from multi-fetal pregnancies are a public health risk, why not eliminate the risk by requiring insurers to cover the procedure? Insurance coverage reduces the desire to over-implant, which in turn reduces the number of multi-fetal pregnancies. If insurance coverage were mandated, there

169 Debora Spar & Anna M. Harrington, Building a Better Baby Business, 10 MINN. J. L. SCI. & TECH. 41, 68 (2009) (citations omitted) (adding that “[c]overage could also be structured to disallow or to provide disincentives for risky procedures such as multiple embryo transfer”).
170 Id.
171 Id. (citation omitted).
172 Catherine A. Clements, Note, What About the Children? A Call for Regulation of Assisted Reproductive Technology, 84 IND. L.J. 331, 343 (2009) (noting that some of the problems created include significant increases in healthcare costs, and in the use of educational resources and social services).
would not be a need to approach embryo transfers as “two for one” because there would not be large out-of-pocket investments. Both the patient and her physician would take comfort in knowing that the patient could afford another cycle. This has been true in jurisdictions where insurance coverage is mandated. For example, countries where insurance covers in vitro fertilization have lower rates of embryo implantation and lower rates of multi-fetal pregnancies than the United States, where there is no mandatory insurance coverage. States with mandated insurance coverage for in vitro fertilization also have lower transfer rates and fewer multi-fetal pregnancies, even though there are loopholes in all of the state statutes.

III. THE SUPREME COURT HAS DECLINED TO IMPOSE A REQUIREMENT ON INSURERS AND STATE MANDATES ARE VARIED AND INCOMPLETE

In vitro fertilization coverage is a relatively recent issue. As the use of in vitro fertilization grew in the 1980s, most insurance plans did not explicitly address the issue of coverage. Generally, if an insurance contract does not explicitly exclude coverage for a particular service, then that service is covered under the plan. So, women who underwent the in vitro fertilization procedure would seek reimbursement from their insurers. Unfortunately, even when insurers claimed that they covered the procedure, they denied claims. Insurers reasoned that the denials were because the procedure was deemed to be experimental or not medically necessary. Fertility advocates, such as RESOLVE, began to counsel patients. They encouraged individuals to carefully read their insurance policies. Many women who were denied coverage sought recourse in court; they argued that without the express exclusion in the policy the services were covered. As insurers settled claims, they began to categorically deny coverage for specific fertility treatments such as in vitro fertilization.

173. See DrRChristina, Comment to The Trouble with Twin Births, N.Y. TIMES ROOM FOR DEBATE BLOG (Oct. 12, 2009, 12:49 PM), http://community.nytimes.com/comments/roomfordebate.blogs.nytimes.com/2009/10/11/the-trouble-with-twin-births/(opining that “if IVF was [sic] less expensive . . . I believe more people wouldn’t give in to the idea of ‘2 for 1’ as readily because they [would] feel comfortable knowing they can afford another cycle”).
175. Id.
176. See ARONSON, supra note 42, at 296 (explaining that “most infertility services end up excluded by inference—insurance companies classify them as ‘experimental,’ ‘not standard practice,’ or ‘not medically necessary’”).
177. Id. at xi.
One of the first known lawsuits for denial of a medical benefit was a case against Kaiser Foundation Health Plan of California in 1987. After the Kaiser settlement, approximately 10,000 women qualified for insurance coverage for in vitro fertilization, but the settlement was very specific. It applied only to women “between the ages of 18 and 45 who were enrolled in Kaiser and suffering from infertility between July, 1983, and about July, 1985.” The settlement did not include coverage for all Kaiser enrollees. For enrollees requesting coverage for treatment after 1985, Kaiser denied coverage based on a U.S. Department of Health and Human Services ruling that stated the procedure was “unusual, infrequently provided and unnecessary to the health of the patient.”

In the early 1990s, Jolene Sloter was part of a class action lawsuit against Blue Cross of Western Pennsylvania. The insurance policy did not specifically exclude in vitro fertilization. The company denied her claim, however, when she sought reimbursement for the procedure. Like Kaiser, Blue Cross agreed to pay a settlement, but explicitly began to exclude regular coverage of in vitro fertilization and other advanced reproductive technologies.

In addition to Blue Cross and Kaiser, in April of 1998, Aetna U.S. Health Care declared that it would not cover in vitro fertilization and other advanced reproductive technologies. Aetna reasoned that women chose the plan for its coverage and then left the plan after benefiting from it. Currently, while many private health insurers cover abortion, contraceptives, and sterilization, they do not cover in vitro fertilization.

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179. *See id.* (explaining “that Kaiser now concedes that in-vitro fertilization is not experimental,” and thus, eligible women would be qualified for coverage).
180. *Id.*
181. *Id.* (internal quotation marks omitted).
182. *See Mackenzie Carpenter, Blue Cross Draws Line on In-Vitro Fertilization Procedure*, PITTSBURGH POST-GAZETTE, June 27, 1993, at A1 (noting that in 1991, Blue Cross “estimated in a letter to officials at Magee-Womens Hospital that about 95 percent of all its subscribers were covered for advanced infertility treatments,” including in vitro fertilization).
183. *Id.*
184. *Id.* Jolene Sloter and other women in Western Pennsylvania were reimbursed for expenses that Blue Cross of Western Pennsylvania initially refused to cover because the expenses related to infertility. Although Blue Cross did not specifically exclude coverage, it argued that the procedures were experimental. After the settlement, Blue Cross decided to state the exclusion in its basic group health insurance policy. *Id.*
186. *Id.*
The Patient Protection and Affordable Care Act requires that, by 2014, certain essential benefits must be covered. Maternity and newborn care is one of those essential benefits. In vitro fertilization coverage should be a part of any maternity benefit.

Congress should address the issue because the Supreme Court has opted not to impose such a requirement on insurers. Insurers are not inclined to provide coverage on their own. Insurance coverage will provide strength to the industry guidelines and eliminate the short term need for a regulatory entity. Finally, a federal mandate is necessary because state mandates are inadequate: ERISA prevents state mandates from being comprehensive.

A. The Supreme Court Has Chosen Not to Impose Requirements on Insurers

The issue of coverage for in vitro fertilization is an issue for Congress because the Supreme Court has declined to rule on the issue. Claims have been brought under both the Americans with Disabilities Act and the Pregnancy Discrimination Act; circuits are split. The issue should not be left to patchwork interpretation by conflicting circuits. Rather, Congress should take action.

1. Pregnancy Discrimination Act

Congress passed the Pregnancy Discrimination Act (PDA) in 1978. It amended Title VII of the Civil Rights Act of 1964 to protect pregnant women from workplace discrimination. The Act applies to employers with fifteen or more employees and prohibits discrimination in the workplace on the basis of “pregnancy, childbirth, or related medical conditions.” The Act also provides that “[a]ny health insurance provided by an employer must cover expenses for pregnancy-related conditions on the same basis as costs for other


191. 42 U.S.C. § 2000e(k) (2000). This act is meant “to prohibit sex discrimination on the basis of pregnancy,” and begins by explaining that “the terms 'because of sex' or 'on the basis of sex' include, but are not limited to, because of or on the basis of pregnancy, childbirth, or related medical conditions.” Id.
medical conditions.” While abortion expenses were expressly excluded from the mandate, the Act is silent as to whether infertility is a protected medical condition related to pregnancy.

The Act appears to be clear on its face, but in vitro fertilization was not a common procedure when the Act was passed. Thus, the phrase “related medical condition” is ambiguous as it applies to in vitro fertilization. Although the Supreme Court held in International Union v. Johnson Controls, Inc. that “[w]omen who are either pregnant or potentially pregnant must be treated like others ‘similar in their ability . . . to work,’” the Court stopped short of ruling that the PDA requires insurance coverage of in vitro fertilization. Nor did the Court rule that denial of such coverage is discriminatory.

Most recently, the Seventh Circuit held that Title VII provided a viable claim to a woman who was allegedly terminated from her job for undergoing in vitro fertilization.

The Court reasoned that, although infertility afflicts both sexes equally, the employer conduct under dispute nevertheless was not gender neutral because only women take time off to undergo IVF. Consequently, Nalco’s alleged policy of terminating employees for undergoing IVF treatments was sexually discriminatory because only females would ever be fired on such grounds.

The Seventh Circuit accurately placed in vitro fertilization within the boundaries of the Pregnancy Discrimination Act. This would set the stage to prevent insurers from denying coverage for the procedure. The Second and Eighth Circuits, however, have reached a different result. In both Saks v. Franklin Covey Co. and Krauel v. Iowa Methodist Medical Center, summary judgment was granted to the employer, showing that such circuits held that infertility does not constitute a “related medical condition.” Those courts reasoned that if men and women receive equal treatment under an insurance plan,

198. See Krauel v. Iowa Methodist Med. Ctr., 95 F.3d 674, 681 (8th Cir. 1996) (granting summary judgment to the employer).
then a plan that does not provide coverage for infertility procedures is not discriminatory because the limitations affect both men and women, and, therefore, are not gender specific.\textsuperscript{199}

2. Americans With Disabilities Act

The Americans With Disabilities Act ADA “is an anti-discrimination statute passed with the intention of allowing qualified individuals with disabilities [to] enjoy the same employment opportunities as people without disabilities.”\textsuperscript{200} Scholars have also opined as to whether the ADA extends to treatment for infertility. “When the ADA was passed, many infertile advocates believed that if reproduction was recognized as a major life activity under the ADA, then the ADA would effectively force employers to accommodate employees who wish to undergo infertility treatments and compel health insurers to include infertility insurance in their plans.”\textsuperscript{201} This has not happened.

The Supreme Court held in \textit{Bragdon v. Abbott} that reproduction is a major life activity.\textsuperscript{202} Abbott sued under the ADA and claimed that Bragdon, a dentist, had discriminated against her when he refused to treat her because she was living with HIV.\textsuperscript{203} In order to qualify for protection from discrimination under the ADA, one must have “a physical or mental impairment that substantially limits one or more of the major life activities of such individual.”\textsuperscript{204} “Abbott argued that her HIV status substantially limited the major life activity of reproduction,” and the Supreme Court agreed.\textsuperscript{205} Because her “HIV infection substantially limited her ability to reproduce . . . she was afforded protection from discrimination under the ADA.”\textsuperscript{206} Because the Court ruled that reproduction was a major life activity, scholars began to discuss whether there is a basis to claim discrimination under the ADA if an employer discriminates against an infertile employee.

Unfortunately, \textit{Bragdon} has not had the effect that many hoped for. In \textit{Saks}, the district court held that failure to provide infertility insurance was not a violation of the ADA because the plan “does not

\textsuperscript{199} Saks v. Franklin Covey Co., 316 F.3d 337, 348 (2d Cir. 2003) (citing Johnson Controls, 499 U.S. at 198) (stating that “the exclusion of surgical impregnation techniques limits the coverage available to infertile men and infertile women and, thus does not violate Title VII”).


\textsuperscript{201} Id. (citation omitted).


\textsuperscript{203} Id. at 628-29.


\textsuperscript{205} Roche, \textit{supra} note 200, at 220.

\textsuperscript{206} Id. (citations omitted).
offer infertile people less pregnancy and fertility-related coverage than it offers to fertile people. Therefore, as a matter of law, the Plan does not violate the ADA.”

The ADA treats health insurance terms and conditions more deferentially than actions such as hiring and firing of employees. “The statute specifically provides a safe harbor for certain insurance plans that are based on ‘underwriting risks, classifying risks, or administering risks’ that are based on or not inconsistent with state law.” Furthermore, “health insurance plans do not run afoul of the ADA when they discriminate among types of disabilities so long as all the employees, regardless of disability status, have equal access to the available range of benefits.”

B. State Mandates Are Inconsistent and Can Never Be Comprehensive

Critics of a federal mandate for in vitro fertilization often claim that insurance is a state issue. The McCarran-Ferguson Act allows states to regulate “the business of insurance” without federal government interference. The Act does not prevent Congress from passing laws to regulate the “business of insurance.” We have just witnessed the passage of The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010. These new laws have expanded health care access and coverage. In the same way that Congress passed legislation in the 1990s to require insurers to cover a certain length of hospital stay after childbirth, Congress should now pass legislation to mandate that insurers cover in vitro fertilization.

A typical search for states with statutes that address insurance coverage of fertility treatments usually lists fifteen states.

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209. Id.
211. Id.
is no uniformity among these fifteen states. In fact, several of these jurisdictions receive kudos for what amounts to inadequate coverage. In addition, even the most comprehensive state plan cannot go beyond the Employee Retirement Income Security Act (ERISA) exemption for self-insured plans. Such a provision leaves many individuals confused as to why they live in a jurisdiction that mandates insurance coverage for in vitro fertilization but their insurance plan does not have to adhere to the mandate.

1. Massachusetts Is Good, But Not Good Enough

Massachusetts offers the most comprehensive state insurance mandate.\textsuperscript{215} The state mandate applies to commercial insurers, non-profit insurers such as Blue Cross/Blue Shield, and HMOs.\textsuperscript{216} Massachusetts requires any insurer that provides pregnancy-related benefits to provide coverage for all non-experimental infertility diagnosis and treatment.\textsuperscript{217} In addition to in vitro fertilization, the treatment includes artificial insemination, gamete intra fallopian transfers, sperm, egg or inseminated egg procuring and processing, intracytoplasmic sperm injection, and zygote intra fallopian transfers.\textsuperscript{218} Even if every state followed that model and enacted mandatory insurance coverage, there would not be comprehensive coverage. ERISA would exempt employers who self-fund their insurance. As approximately fifty-five percent of individuals with health insurance are covered under self-insured plans,\textsuperscript{219} there is a serious need for a federal mandate.

Massachusetts is perhaps where critics should look when they suggest that premiums would increase with the mandate and ultimately leave more individuals uninsured. Massachusetts has imposed no limit on treatment cycles and there are no lifetime caps for benefits.\textsuperscript{220} Data suggests that a larger percentage of the population [hereinafter Insurance Coverage in Your State] (last visited Nov. 22, 2010). These states include Arkansas, California, Connecticut, Hawaii, Illinois, Louisiana, Maryland, Massachusetts, Montana, New Jersey, New York, Ohio, Rhode Island, Texas, and West Virginia. \textit{Id.}

\textsuperscript{215} 211 Mass. Code Regs. 37.00 (LexisNexis 2010).


\textsuperscript{217} \textit{Id.} at 37.05.

\textsuperscript{218} \textit{Id.}


\textsuperscript{220} See Carpenter, supra note 182, at A1 (noting that Massachusetts “mandat[es] that all insurers pay for an unlimited number of cycles of in-vitro fertilization as part of a basic
utilizes the services than when the service was not covered by insurance. Even so, the data from Massachusetts shows that this mandate on fertility treatments and drugs has only minimally affected insurance premiums. “[T]he cost of insurance premiums has risen only between 0.2 percent and 0.5 percent annually, or about $1 a month extra for an average policy, because of the coverage of in-vitro fertilization.” 221 As costs are shared among the larger population, no one is unduly burdened.

Massachusetts defines infertility as when an otherwise healthy individual is unable to conceive or produce conception within a year. 222 Although Massachusetts law states that insurers may set reasonable eligibility requirements, such requirements may not be arbitrary. 223 As such, this protects the patient when the insurer attempts to arbitrarily deny a claim. Insurers may look to the ASRM as a guide for implementing standards. 224 Furthermore, an insurer may not impose additional deductibles, co-payments, waiting periods, benefit maximums, or other limitations on coverage for fertility benefits that are not imposed on other services. 225 The mandate applies to the policy holder, as well as to the spouse or other dependents. 226

There are higher utilization rates in Massachusetts and other states with insurance mandates. Data from 2002 showed states with comprehensive coverage had a three-fold utilization rate than those states where there was no mandated coverage. 227 This information suggests that women and couples who are interested in infertility treatments do not pursue the treatment because of the costs associated with the procedure. 228 Given that the demand will increase, any federal legislation should probably have some limits to curtail costs.

2. State Mandates Can Never Be Comprehensive Because of ERISA Preemption

Although Congress passed the Employee Retirement Income Security Act of 1974 (ERISA) to address pension programs and ensure that such programs are managed and funded properly, 229 the Act goes

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221. Id.
222. 211 MASS. CODE REGS. 37.03 (LexisNexis 2010).
223. Id. at 37.09.
224. Id.
225. Id. at 37.08.
226. Id. at 37.04.
228. Id.
229. Michael D. Miller, ERISA: The Unbridged Chasm of Health Reform—Challenges for Massachusetts and Federal Action, HEALTH POLICY AND COMMUNICATIONS BLOG
beyond pension programs and governs all employee welfare benefit plans, including disability and health benefit plans. As self-insured health plans are a type of employee welfare plan, they are exempt from state mandates. ERISA contains a broad preemption clause that expressly preempts state laws that conflict with the federal regulation of employee welfare benefit plans. Although there is a savings clause within ERISA that exempts state laws regulating insurance, ERISA deems that an employee welfare benefit plan is not an insurance plan. Ultimately, ERISA leaves employees confused as to why their insurer is not required to cover a service in spite of a state mandate.

Most individuals obtain their insurance through a group plan offered by their employer. This will most likely remain true even after the options provided by the Patient Protection and Affordable Care Act are in effect. While there is no federal or state requirement that employers offer insurance coverage, once an employer chooses to offer insurance, federal and state requirements exist. Employers that do offer insurance coverage have a variety of options. They may purchase the insurance directly from the insurer or insurance company. If they choose this route, they may choose from commercial companies such as Aetna or Cigna or a non-profit company such as the various Blue Cross/Blue Shield plans. Employers may also self-insure and allow an insurance company or other third party administer the plan. Self-insured plans are those where an employer has chosen to pool the risks of its employees and benefit from a healthy work force.

The employer’s goal is to provide quality care at low costs. So, no matter which option an employer chooses to offer its employees, plans under the option may include one or all of the following: Health Maintenance Organizations (HMOs), Point of Service (POS), or Preferred Provider Organizations (PPOs). Generally speaking, an HMO means tighter provider choices from a list of in-network providers, whereas PPOs allow for greater individual choice. The POS is a


230. Id.
233. Id.
234. Id.
235. Medill et al., supra note 208, at 541.
236. Id.
237. Id.
238. Id.
middle ground that offers an in-network option and a higher payment scale if an individual chooses to use an out-of-network provider.  

Employees are often unaware of the type of plan, purchased or self-funded, until a determination must be made with respect to covered services. Many erroneously assume that if they live in a state with mandated coverage for in vitro fertilization, their insurers must provide coverage for the procedure. Because ERISA does not require self-funded insurance plans to adhere to state insurance mandates, when an employer chooses to self-fund insurance benefits, its employees are not protected by any state insurance law mandates. “As of 2003, the majority of covered workers are in a plan that is completely or partially self-insured.” Thus, state mandates will never be comprehensive.

The rationale behind the exemption of self-funded plans was that large companies do businesses in several states. It would be more than cumbersome to require such employers to adhere to state laws in several states. Unfortunately, it is the employee who ends up losing out, and she or he has no real recourse. Even in a state like Massachusetts where there is comprehensive coverage for in vitro fertilization, individuals in the state may find themselves not covered when it comes to in vitro fertilization. Thus, a federal mandate is necessary. Such federal legislation would amend ERISA so that such self-funded plans are not excluded from any insurance mandate to cover in vitro fertilization.

3. State Coverage Is Too Varied and Too Incomplete

The states with statutory mandates for in vitro fertilization coverage vary greatly with respect to requirements for coverage. Such variances include age restrictions for patients who seek the service, number of employees necessary for employers to be covered under the legislation, residence of the insured, number of in vitro cycles covered, number of embryos transferred per cycle or lifetime, whether donor eggs may be used, and lifetime monetary caps. Some states limit insurance coverage to women under a certain age. Others require that the procedure be limited to situations where a woman’s eggs are fertilized with her husband’s sperm. Also, when an individual

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239. Id.
240. Id.
241. T H E K A I S E R F A M I L Y F O U N D. & H E A L T H R E S E A R C H & E D U C. T R U S T, E M P L O Y E R H E A L T H B E N E F I T S: 2 0 0 3 A N N U A L S U R V E Y 1 2 4 (2 0 0 3), a v a i l a b l e a t h t t p : / / w w w . k f f . o r g / i n s u r a n c e / e h b s 2 0 0 3 - 1 - s e t . c f m (f o l l o w “D o w n l o a d P D F: E n t i r e D o c u m e n t” h y p e r l i n k).
242. I n s u r a n c e C o v e r a g e i n Y o u r S t a t e, s u p r a n o t e 2 1 4.
243. S e e i d. M a r y l a n d, A r k a n s a s, T e x a s a n d H a w a i i a l l r e q u i r e u s e o f t h e h u s b a n d’ s
works in one state but the insurance plan is from another state, she is not necessarily covered by the state plan mandating insurance companies to cover the procedure.\textsuperscript{244} Several jurisdictions reference the American Society of Reproductive Medicine (ASRM) or the American College of Obstetricians and Gynecologists (ACOG), requiring that any procedures must be performed in clinics that conform to industry standards.\textsuperscript{245} Some state mandates apply to HMOs, while others specifically exclude HMOs. Some of the legislation is written in a way that allows for broad interpretation, while other legislation is straightforward. Some states define infertility and others do not. All of the variables leave the patient confused and often uncovered in situations where she thought coverage existed. “Recent statistics show that insurance providers cover [in vitro] costs about thirty to forty percent of the time in states that mandate at least some type of coverage. For the thirty to forty percent who are covered, insurance pays an average of fifty percent of the total cost.”\textsuperscript{246}

As previously stated, Massachusetts offers the most comprehensive legislative mandate.\textsuperscript{247} Maryland, Connecticut, Illinois, New Jersey, and Rhode Island offer reasonably comprehensive mandates.\textsuperscript{248} These state laws may also be used as models to draft federal legislation, especially when there is a need to balance the risks and costs

\textsuperscript{244} See MD. CODE ANN., INS. § 15-810 (West 2010) (stating that the section applies to health insurance policies issued or delivered in Maryland); MD. CODE ANN., HEALTH-GEN. § 19-701 (West 2010) (characterizing the health maintenance organizations affected by the statute as those operating in Maryland).

\textsuperscript{245} See Insurance Coverage in Your State, supra note 214. States that require that fertilization procedures follow the ASRM or ACOG industry standards include: Arkansas, Hawaii, Illinois, and Texas. Connecticut requires fertilization procedures to conform to both the ASRM standards and the Society of Reproductive Endocrinology and Infertility guidelines. Id.


\textsuperscript{247} Insurance Coverage in Your State, supra note 214; see also MASS. GEN. LAWS ANN. ch. 175, § 47H (West 2010) (stating that insurance policies that provide pregnancy-related benefits must also provide coverage for medically necessary expenses for the diagnosis and treatment of infertility); MASS. GEN. LAWS ANN. ch. 176A, § 8K (West 2010) (mandating that under health insurance contracts, except those providing supplemental coverage to Medicare or other governmental programs, infertility benefits be provided when coverage is offered for other pregnancy-related procedures); MASS. GEN. LAWS ANN. ch. 176B, § 4J (West 2010) (requiring that subscription certificates under individual or group medical service agreements provide infertility benefits “to the same extent that benefits are provided for other pregnancy-related procedures”); MASS. GEN. LAWS ANN. ch. 176G, § 4 (West 2010) (listing treatment of infertility as a category of required coverage in a health maintenance contract); 211 MASS. CODE REGS. 37.00 (West 2010) (stating that insurers must provide benefits to insured spouses or dependants for required infertility procedures).

\textsuperscript{248} Insurance Coverage in Your State, supra note 214.
associated with in vitro fertilization. Several states give an illusion of coverage, when in practice, there are no real benefits to patients/consumers. Arkansas, Hawaii, Montana, New York, Ohio, West Virginia, and Louisiana have legislation that is less than comprehensive when it comes to coverage for in vitro fertilization.\(^{249}\) New York and California explicitly exclude in vitro fertilization from their mandates for infertility coverage.\(^{250}\) California and Texas only mandate that insurers that cover pregnancy services offer coverage for infertility treatment.\(^{251}\) Even though insurers must let employers know that this coverage is available, insurers are not required to provide the coverage and employers are not required to include it in their health plans.\(^{252}\) Thirty-five states have not addressed the issue at all.

IV. CONGRESS SHOULD PASS THE FAMILY BUILDING ACT—WITH REVISIONS

A. The Family Building Act

In January of 2009, Congressman Anthony Weiner introduced the Family Building Act (H.R. 697).\(^{253}\) To date the legislation has only twenty co-sponsors.\(^{254}\) Although it has been referred to the committees with jurisdiction over the issue, no action has been taken.\(^{255}\) A companion bill (S. 1258) was introduced in the Senate by Kirsten Gillibrand.\(^{256}\) There are no co-sponsors for the Senate bill.\(^{257}\)

The legislation is a good start and a good way to bring the issue of insurance coverage for in vitro fertilization into the public domain. Federal legislation does not need to mandate that insurers cover everything related to in vitro fertilization, and the Family Building Act does have limitations.\(^{258}\) The legislation appropriately weighs the costs and benefits of the procedure against any risks associated with

\(^{249}\) Id.

\(^{250}\) N.Y. INS. LAW § 3221(k)(6)(B)(v)(I) (Consol. 2010); CAL. HEALTH & SAFETY § 1374.55(a) (West 2010).

\(^{251}\) CAL. INS. CODE § 10119.6(a) (West 2005); TEX. INS. CODE ANN. §§ 1366.001-1366.059 (West 2009).

\(^{252}\) Insurance Coverage in Your State, supra note 214.

\(^{253}\) Zhang, supra note 13.


\(^{255}\) Id.


\(^{257}\) Id.

the procedure. The “right to procreate does not necessarily translate into a right to have the cost of reproductive technologies covered by the state. For example, in *Maher v. Roe*, the Supreme Court held that the right to an abortion did not include the right to state funding for it.”

259 The same logic can apply to the “right to insurance coverage.” Even if Congress mandates insurers to cover in vitro fertilization, it does not have to be unlimited and everlasting.

**B. Issues That Congress Should Discuss to Strengthen the Legislation**

The Family Building Act could have more depth. A comparison to some of the state mandates suggests that there are provisions that could make the document stronger. Ultimately, Congress would need to garner support from physicians and insurers in order for the legislation to pass. This task is not necessarily insurmountable.

RESOLVE currently has a list of questions that patients should have answered by their current insurers as they determine whether treatment for infertility is covered under their insurance plan. Many of these questions should be answered as federal legislation is drafted. Such questions include how to define infertility, whether the coverage is limited only to infertile couples, age limits for any coverage, whether less costly methods must first be exhausted before in vitro fertilization is covered, whether coverage benefits apply only to married couples, whether the woman’s eggs must be fertilized with her spouse’s sperm, and whether insurance coverage should apply to donors. Other questions that federal legislation should address include the issue of pre-existing conditions, number of embryo transfers, coverage for cryopreservation, and maximum benefits of coverage.

1. **Offer Versus Cover**

The Family Building Act of 2009 is a mandate for insurers to provide coverage for in vitro fertilization. One of the first issues to address is whether a federal mandate should only require that in-

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261. *Id.*

surers offer an option. Those in favor of a mandate to offer argue that a mandate for coverage requires individuals to pay for a service that they will not use. This is true; however, each of us already pays for services and treatments that do not apply to us. Although California and Texas only require insurers to offer a plan, this is not the approach that federal legislation should take. A mandate to provide coverage means that there is a larger pool over which to spread costs. Thus, the overall cost to everyone is smaller than with only a mandate to offer coverage. Any federal mandate should indeed require all insurers who provide maternity benefits to provide coverage for in vitro fertilization. “[T]he purpose of health insurance is to pool risks in order to provide affordable health care for all members.” 263

2. Group Plans, HMOs, Individual Plans, or What?

What types of plans should be covered under a federal mandate? The Family Building Act of 2009 appropriately mandates coverage for group health plans, health insurance issuers offering group health insurance, and insurance offered through the individual markets and through the Federal Employees Health Benefit Plans, if such plan provides obstetrical services. The Act applies to large or small group markets and, presumably, does not limit the mandate to employers who have only a certain number of employees. In contrast, the Pregnancy Discrimination Act applies to employers with fifteen or more employees, and it includes federal, state, and local governments, employment agencies, and labor organizations. 264

Some state mandates apply only to group health insurers, and others apply only to HMOs. For example, the West Virginia and Ohio mandates apply only to HMOs. 265 California limits its mandate to group health insurers. 266 Some states require a minimum number of employees before the mandate applies to group health insurers. For example, although the Maryland legislature enacted legislation that mandated private insurance companies to cover infertility services, including in vitro fertilization, 267 the law applies only to policies issued in Maryland, and only to employers with more than fifty employees. 268 If a Maryland resident is insured under a policy issued in another


266. Id.

267. Jain & Hornstein, supra note 227, at 27.

state, the Maryland statute is not applicable to such Maryland resident. If her employer has less than fifty employees, such employer is also not covered by the state mandate. New Jersey similarly limits its mandate to provide coverage for in vitro fertilization to employers with fifty or more employees. Illinois law applies to policies that cover more than twenty-five people.

Several states specifically provide a religious exclusion for employers who have a bona fide religious reason for not providing coverage for in vitro fertilization. Those states are Connecticut, Illinois, Maryland, New Jersey, and Texas. While the Family Building Act does not mention such an exclusion, it probably should. In the alternative, a provision for a religious exclusion should be implemented through any regulations.

3. Deductibles

Given that employers are not required to offer insurance coverage, a federal mandate should not be so onerous as to cause the employer to eliminate health insurance benefits for its employees. The Family Building Act is silent as to any caps on lifetime benefits. It merely states that deductibles, coinsurance, and other cost-sharing or limitations should not exceed those applied to similar services. Comparatively, Maryland and Arkansas have lifetime maximum benefits. In Maryland, that amount is $100,000, far more reasonable than the $15,000 that the Arkansas law permits insurers to impose. This issue should be further addressed during committee hearings.

4. Embryos

Should a federal mandate restrict the number of embryos transferred for implantation? If so, what is the appropriate number of embryos to be transferred? How much deference should be given to a physician’s professional judgment? Should there be a penalty on physicians who transfer more than a certain number of embryos? Would Octomom’s physician, who transferred six embryos for implantation, receive reimbursement for his services?

Multi-fetal pregnancies are significantly more frequent in the United States than in Europe. The main reason is that the number

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270. Insurance Coverage in Your State, supra note 214.
271. Id.
272. Id.
273. Id.
274. Id.
of embryos transferred is significantly different. A physician in the United States is far more likely to transfer multiple embryos than a physician in most European countries. A comparison of situations where a physician transferred four or more embryos shows this group represented 31.9% of women in the United States but only 5.5% of European patients. As the women were similar in age, the distinguishing factor appears to be insurance coverage for the procedure. Coverage deterred the desire of women to request multiple transfers and for physicians to perform multiple transfers.

"Germany, Sweden, Denmark, and Switzerland limit implantations to three pre-embryos, at most, per cycle," and the United Kingdom has a limit of two implantations. In Germany, it is a felony to breach the number of embryos to transfer. But such a limit may not be necessary in the United States. "In most states of Australia and in New Zealand, there is no mandatory limit on the number of embryos that may be transferred. Still, the number of embryos transferred per cycle is on average significantly less than in the United States . . . ." These results tend to suggest that coverage alone is enough of a deterrent for physicians and patients.

The Family Building Act does not, and should not, restrict coverage to a single embryo transfer. In fact, the bill does not state how many embryos should be transferred for implantation. It only requires that the medical facility conform to ASRM standards or any standards set by an appropriate federal agency. This is a sound approach. A single embryo transfer sounds too much like government entering the womb, which is not something the American culture would readily agree to. Rather, it is reasonable to rely on the expertise of

276. Id. at 1947.
277. Rosato, supra note 97, at 86 (citation omitted).
278. See Gesetz zum Schutz von Embryonen [ESchG] [Embryo Protection Act], Dec. 13, 1990, BGBl. I at 2746, § 1, no. 3 (Ger.) (stating that violations of the Act, including "attempts, within one treatment cycle, to transfer more than three embryos into an woman[,]" may result in imprisonment not exceeding three years); see also THE GERMAN PENAL CODE 6 (Stephen Thaman trans. 2002) (defining felonies under German law as "unlawful acts punishable by imprisonment one year or more"); Germany’s Embryo Protection Law is ‘Killing Embryos Rather Than Protecting Them,’ HEALTH & MED. WEEK (July 16, 2007), available at http://www.newsrx.com/newsletters/Health-and-Medicine-Week/2007-07-16/2007162007515W.html (“The German embryo protection law, passed in 1991, stipulates that no more than three embryos can be created per cycle of IVF and all three, regardless of their quality, must be transferred to the patient’s womb at one time, and cannot be frozen or discarded.”).
279. Moses, supra note 120, at 596.
281. Id.
282. Davi Stamford, Comment to The Trouble with Twin Births, N.Y. TIMES ROOM FOR
ASRM and SART to provide guidance as to the range of acceptable number of embryos to transfer. Clinics with lower success rates should have to explain the conditions in which they perform the procedure and explain why their rates are lower than the industry average. Clinics with pregnancy rates too far removed from the industry average will not be reimbursed if they attempt to overcompensate for their deficiencies with larger embryo transfers. This should prevent another Octomom. A requirement that clinics adhere to industry guidelines in order to receive reimbursement from insurers does not limit rights of a physician or patient, but it gives an incentive for each to follow industry standards and explains why they do not follow them.

The Fertility Clinic Success Rate and Certification Act could also be amended such that twins and triplets do not count as “success” when calculating successful pregnancies. This change, as well as coverage for the procedure, may deter transferring larger numbers of poorer quality embryos.

5. Cycle Limitations

How many cycles of in vitro fertilization should an insurer be required to cover? There are at least two scenarios for an insurer to consider: (i) the case where a woman tries to sustain a pregnancy on multiple occasions yet she is unsuccessful, and (ii) the case when a woman who successfully produced a child desires a second or third child. At some point, it is not economically feasible for an insurer to continue to provide coverage when a woman is not successful. Equally important is whether an insurer should fund unlimited pregnancies. After all, each of Octomom’s pregnancies was a result of in vitro fertilization.

The Family Building Act caps the number of egg retrievals at six. It is similar to the language in the Illinois statute, where “[e]ach patient is covered for up to 4 egg retrievals. However, if a live birth occurs two additional egg retrievals will be covered, with a lifetime maximum of six retrievals covered.” In contrast, Maryland allows insurance companies to limit their coverage to three attempts per live birth. Hawaii is extremely limited in that it only covers one cycle per live birth.
of in vitro fertilization.\textsuperscript{287} Connecticut limits coverage where there are two implantations per cycle and only two cycles per lifetime.\textsuperscript{288}

Generally, a woman has approximately a twenty-seven percent chance of a successful pregnancy using in vitro fertilization.\textsuperscript{289} Although this number varies with age and other factors, it would seem to be a good starting point for determining the number of cycles an insurer should be required to cover. If a woman may need at least four cycles to sustain a successful pregnancy, then a minimum of four covered cycles seems reasonable. If she was successful with in vitro fertilization, two additional cycles does not appear to be unreasonable. This issue should be addressed during Congressional hearings.

6. Clinic Standards

The Family Building Act requires any treatment to be performed at a facility that conforms to the standards of the American Society of Reproductive Medicine (ASRM).\textsuperscript{290} Several states also have this requirement, or one that is similar. Maryland requires that the procedure be performed in a clinic that conforms to the standards of the ASRM and (or) the American College of Obstetricians and Gynecologists (ACOG).\textsuperscript{291} Other states with such restrictions include Connecticut, Hawaii, Illinois, New Jersey and Texas.\textsuperscript{292} This is an excellent way to add strength to the industry guidelines. There is no need for the guidelines to impose penalties. The lack of reimbursement should be enough to discourage physicians from straying from the industry guidelines.

7. Definition of Infertility

Congressman Weiner and Senator Gillibrand acknowledge that the primary purpose of in vitro fertilization is to assist infertile couples. They define infertility as the inability to conceive after one year of unprotected intercourse or the inability to carry a pregnancy years or the infertility is associated with one of the following: endometriosis; DES exposure; blocked or surgically removed fallopian tubes; abnormal male factors contributing to the infertility." \textit{Id.}

\textsuperscript{287} \textit{Id.}

\textsuperscript{288} \textit{Id.}


\textsuperscript{290} H.R. 697, 111th Cong. (1st Sess. 2009); S. 1258, 111th Cong. (1st Sess. 2009).

\textsuperscript{291} \textit{Insurance Coverage in Your State}, supra note 214.

\textsuperscript{292} \textit{Id.}
to live birth. This definition does not require a couple to be married, nor does it make length of time distinctions based on the age of the mother. Most states that define infertility have language similar to that used by Weiner and Gillibrand. The definition, however, is not as liberal as the ASRM; nor is it as restrictive as some state legislation. A glance at states that have defined infertility results in a web of confusion. For example, Texas and Hawaii appear to have the most restrictive state definitions of infertility. In each state the patient and her spouse shall have had five continuous years of infertility. Neither state requires the five year history if the infertility is caused by one of the following conditions: endometriosis, DES, blocked or surgically removed fallopian tubes, or oligozoospermia, an abnormal male factor.

Maryland and Arkansas require a history of infertility for two years, but again provide an exception to the two year history if the infertility is associated with endometriosis, DES, blocked or surgically removed fallopian tubes, or abnormal male factors.

New Jersey defines infertility differently based on the age of the female partner, as does the ASRM. New Jersey defines infertility as a two year period of unprotected sex when the female partner is under thirty-five, and one year when she is over thirty-five. It also defines infertility as the inability to carry a baby to term. The ASRM defines infertility as the inability to conceive after one year for women under thirty-five, and six months for women over thirty-five.

Several states restrict mandated coverage to situations where a married couple has been unable to conceive after a certain period of time, or they require that a woman’s egg be fertilized with her husband’s sperm. Montana and West Virginia do not define infertility. The lack of uniformity leaves too much room for confusion and possible litigation when coverage for services is denied.

Insurance coverage should not be limited to only married couples. Courts have already determined that coverage for contraceptives

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295. Id.
296. Id.
297. Id.
298. Id.
299. Definitions of Infertility and Recurrent Pregnancy Loss, supra note 45.
300. See Insurance Coverage in Your State, supra note 214 (referencing the statutes of Arkansas, Hawaii, Maryland, Texas and Rhode Island). Rhode Island and Texas restrict their definitions of infertility to married individuals. Rhode Island defines infertility as married individuals who cannot conceive or produce conception during a two year period. Id.
applies to both single individuals and married couples. The same rationale should apply to coverage for in vitro fertilization:

Some countries such as France, Finland, Australia and South Africa permit single women and lesbian couples access to ART. While Great Britain’s Human Fertilisation and Embryology Act of 1990 does not specifically forbid single and lesbian women from use of ART, its “welfare of the child” provision . . . could allow health care providers to discriminate against them if they deem it to be in the child’s welfare.301

. . . .

The American Medical Association has taken the position generally that providers of health care should not discriminate against persons due to sexual orientation and has encouraged all medical practices and physicians to include “sexual orientation, sex or perceived gender” in any nondiscrimination statements.302

As a result of the non-discriminatory language, coverage for the procedure should apply to single individuals and those with alternative lifestyles.

If insurance coverage applies beyond married couples, then coverage cannot be limited to circumstances where a wife’s eggs are fertilized with her husband’s sperm. In fact, even if it were limited only to married couples, the limitation that the wife’s eggs must be fertilized with the husband’s sperm seems to be too limiting. Several married individuals require the use of donors in order to have a successful pregnancy. These circumstances should also be covered under the federal mandate. It is also important that the mandate require insurers to cover the services at the same deductible rates, coinsurance, and out-of-pocket limitations as any other maternity benefit provisions. Given these minimum requirements, we must address the associated costs and determine how to balance them.

As infertility may be caused by male or female issues, the definition should define the term so that it applies to both men and women. When the cause of infertility is known, a waiting period seems unnecessary. In such instances, the federal legislation should borrow those exceptions from Texas, Hawaii and Maryland. If the cause is unknown, the federal legislation should follow ASRM and distinguish between women over thirty-five and under thirty-five. When a woman under thirty-five has not been able to conceive or produce conception through natural means for a period of at least a year, the


302. Id. at 40.
procedure should be covered. When a woman thirty-five or older has not been able to conceive or produce conception through natural means for a period of at least six months, the procedure should be covered. Additionally, the federal legislation should keep the inability to carry a pregnancy to a live birth language in its definition of infertility. There is no real benefit to forcing an individual to endure multiple miscarriages before labeling her as infertile.

8. Age Restrictions

The Family Building Act does not limit any insurance mandate to women of a certain age,303 but should it? It is common knowledge that fertility declines with age. Older women require more cycles of in vitro fertilization in order to obtain a pregnancy. For example, data from the Jones Institute of Reproductive Medicine shows their clinical pregnancy rate per IVF transfer was 46.4 percent.304 These rates were directly influenced by the age of the patient. The rate for women under thirty-five was forty-two percent, women between the ages of thirty-five and thirty-nine was thirty-six percent, and women over forty was eighteen percent. In addition to the decrease in fertility, even healthy older women have a higher chance for a riskier pregnancy. As maternal age increases, complications increase, including hypertension, pre-eclampsia, diabetes, and placenta previa, even in healthy women.305

In order to begin to balance the costs to insurers, as well as promote the health and safety of both mother and child, there should be age restrictions for any mandate. Several states have age limits, and Congress should look at those for guidance. New Jersey, Rhode Island, New York, and Connecticut have put age restrictions on their insurance mandates.306 These states recognized that there must be a balance between comprehensive coverage and the costs associated with high risk pregnancies. New Jersey limits coverage for in vitro fertilization to women forty-five or younger.307 Connecticut limits its coverage to individuals under the age of forty.308 Rhode Island’s coverage is limited to women between twenty-five and forty-two.309 New York

307. Id.
308. Id.
limits its mandate for infertility coverage to women between age twenty-one and forty-four.\footnote{310} Age forty-five seems to be a reasonable age limit. Women are delaying childbirth, but the desire for a child must be balanced against real medical risks to both mother and child. There are genuine medical concerns that would allow any mandate to limit the age for coverage without encouraging age discrimination claims.

9. Coverage for Surrogacy and Donors

The use of surrogates, donated eggs, or donated sperm raise controversial issues. Some states avoid the controversy simply by refusing to mandate coverage unless the woman’s egg is fertilized with her husband’s sperm. Such states include Maryland, Arkansas, Hawaii, and Texas.\footnote{311} As discussed earlier, this may be \textit{de facto} discrimination against single individuals and individuals with alternative lifestyles.\footnote{312} The restriction may also deny medically necessary treatment to both married patients and single patients who may have absent eggs, poor quality eggs, or eggs that might transmit serious diseases. While the limitation removes the need to address complex issues associated with in vitro fertilization, any federal legislation should not have such restrictive language. The claim that delaying childbirth results in a need for donor eggs seems to be a myth. Data from the Jones Institute shows the mean age for donor eggs was twenty-eight.\footnote{313}

There are non-conventional situations that may or may not warrant insurance coverage. Any federal mandate should remain silent on these issues. It would be up to the insurer to determine whether coverage is warranted. Consider the following example: Geraldine Wesolowski was a fifty-three-year-old surrogate who carried and birthed her grandchild. The baby was conceived from her son’s sperm and his infertile wife’s eggs.\footnote{314} Should such embryo transplants be covered under insurance? In this case, there were three attempts before success. Should it matter whether Geraldine was the surrogate for a younger couple, or whether she was pregnant with her own child? Perhaps these gray areas are where we give the insurers

\footnote{310. N.Y. INS. LAW § 4303(s)(3)(A) (McKinney 2010); see also N.Y. INS. LAW § 4303(s)(3)(E) (McKinney 2010) (expressly excluding in vitro fertilization as a covered service).}
\footnote{311. \textit{Insurance Coverage in Your State}, supra note 214.}
\footnote{312. \textit{See supra} text accompanying note 243.}
\footnote{313. \textit{In Vitro Fertilization—IVF—Success Rates}, supra note 304.}
discretion as to whether to cover the service. Such discretion would also apply to questions regarding what are covered benefits for a donor. To attempt to address some complex issues in a statute could create issues that are even more controversial and prevent passage of the legislation.

10. Cryopreservation

Octomom’s octuplets were the product of cryopreserved (frozen) embryos. Rather than destroy or donate her unused embryos, she chose to have her physician transfer them for implantation. Some European countries do not permit the ability to cryopreserve human embryos. Such an approach would prevent an Octomom situation. The subject of cryopreservation brings about a host of moral and ethical issues in this country. Though controversial, there are married couples who benefit from cryopreservation. For example, suppose one spouse has been diagnosed with cancer. Cryopreservation may be the couple’s only chance of conceiving a natural child. In determining whether insurance should cover cryopreservation, some issues to address have to do with whether, medically, the quality of the embryos do not suffer with cryopreservation. Cryopreservation can occur at various levels.

The Family Building Act does not address cryopreservation. There probably will not be bipartisan support for any legislation that addresses the issue.


317. See, e.g., Celine Dion: Her Story, Her Dream, CHEALTH, http://chealth.canoe.ca/channel_health_features_details.asp?channel_id=2048&article_id=1201&health_feature_id=378&relation_id=36843 (last visited Nov. 22, 2010). Celine Dion and her husband Rene Angelil began trying to conceive when she married in 1994. Id. She was in her twenties and healthy, but they were not able to become pregnant. Id. After her husband was diagnosed with cancer in 1999, they feared that Rene’s sperm might be affected by radiation from chemotherapy. Id. In the process of freezing some of his sperm for later use, they discovered that he had a low sperm count, and that was the cause of the couple’s infertility. Id. After a procedure called “intracytoplasmic sperm injection,” Dion and Rene used in vitro fertilization and she gave birth to a son in 2000. Id. At that time, she cryopreserved embryos to use at a later date. Id. In November 2009, Angelil confirmed that, although Dion was pregnant using those cryopreserved embryos, the pregnancy was unsuccessful. Id. Nevertheless, after her sixth round of in vitro fertilization, Dion prematurely gave birth to healthy twin boys on October 23, 2010. See Celine Dion Gives Birth to Twins, CNN.COM, Oct. 23, 2010, http://articles.cnn.com/2010-10-23/entertainment/ceLINE.dion.twins_1_rene-angelil-twins-cesarean-section?s=PM:SHOWBIZ.

318. A future article may compare the United States to other countries where cryopreservation is not allowed.
11. Exhaust Less Costly Methods

The Family Building Act requires that less costly infertility methods be exhausted before an insurer is required to cover in vitro fertilization. Although several states also use this approach, it may be more costly than covering in vitro fertilization, and it may also produce more multi-fetal pregnancies. For example, intrauterine insemination is a less costly alternative to in vitro fertilization. It is a process where sperm is injected into a woman’s uterus after hormone shots. It is a cheaper and less effective alternative to in vitro fertilization. The pregnancy rate is lower than in vitro fertilization, and there is no control over multi-fetal pregnancies. Jon and Kate Gosselin conceived their sextuplets through intrauterine insemination (IUI). The cost of the intrauterine insemination, though lower on the front end, was dwarfed by the cost of delivery and care of sextuplets—costs ultimately paid by the insurer. “[A] recent study led by Dartmouth Medical School suggested that because IUI often requires repeated tries, it would ultimately lower both costs and the risk of large multiple births if many patients avoided the procedure and moved straight to IVF.” Therefore, any mandate for in vitro fertilization coverage should not be limited to circumstances where less costly methods have proven to be unsuccessful.

12. What Not to Do

Federal legislation must provide real benefits to patients. Louisiana, Ohio, Montana and West Virginia provide models for what not to do. Louisiana and Ohio have permissive statutory language that provides no real benefits. Louisiana does not require coverage for fertility drugs or in vitro fertilization. It merely “[p]rohibits the exclusion of coverage for the diagnosis and treatment of a correctable medical condition, solely because the condition results in infertility.” Most insurance plans already cover the tests that diagnose infertility. It is the treatment that is at issue. Ohio permits insurers to cover in vitro fertilization and other ARTs, but the statute does not require coverage. A statute is not necessary to give an insurer permission for what it can do without a statute.

321. Id.
322. Id.
323. Id.
324. Id.
325. Id.
Montana and West Virginia have statutory language that gives insurers the ability to deny claims, in spite of the statutory mandate. For example, West Virginia’s statute does not expressly define infertility services, but requires HMOs to cover “basic health care services, including infertility services, when medically necessary.” The law does not define infertility and does not mention in vitro fertilization. Similarly, Montana’s statute does not define infertility, but it does require HMOs to cover infertility services as part of basic health care services. These statutes are rather generic and leave room for open debate (and litigation) about what is and is not covered. The legislation does not address the current issue of what is the effect of a policy that does not address the coverage issue. The insurer has room to deny the claim for what appears to be purely subjective determinations. The Montana and West Virginia statutes may lead to denial of claims, in spite of the so-called statutory mandate.

C. Garnering Support for the Legislation

Congress does not see the importance of the Family Building Act. Mr. Weiner has introduced the legislation several times. Neither the House nor the Senate has scheduled hearings or mark-ups on the legislation. But two things are different during this Congress. First, the Octomom saga has helped generate media attention about the issue, and the general population is beginning to understand the importance of the issue. Second, our nation is in the midst of health care reform. Usually, the committees of jurisdiction—the Committee on Energy and Commerce, and secondarily the Committees on Education and Labor, and Oversight and Government Reform—are not interested in health-related bills. Now, everyone is discussing health care.

Naysayers will argue that in the midst of such a crisis, rather than concern ourselves with in vitro fertilization, we should be more concerned about access to insurance for the millions of Americans who lack health insurance and do not qualify for Medicaid or Medicare. These concerns should not be taken lightly. Access to basic care is more important than infertility treatment for a few. Furthermore, as there are already significant gaps in coverage, why focus on infertility? It is certainly not the only area of treatment that is excluded from insurance coverage. Is it justifiable to mandate infertility coverage while so many other healthcare needs remain unmet?

327. Insurance Coverage in Your State, supra note 214.
328. Id.
329. The legislation was introduced in both the 109th Congress and the 110th Congress.
330. Strong, supra note 90, at 276.
To focus on a single issue does not negate the importance of other issues. In the mid-nineties, Congress mandated that insurers cover a certain length of hospital stay after childbirth and delivery.331 The reasoning used then can apply to coverage for in vitro fertilization today. There was concern that the quality of maternity care was being sacrificed as a result of managed care. Several states passed statutes to require insurance companies to “augment” their coverage of maternity stays.332 Ultimately, federal legislation was enacted to require a minimum of forty-eight hours of inpatient hospitalization for a routine vaginal delivery, and ninety-six hours following a routine cesarean.333 The legislation passed with bipartisan support. Physicians and physicians groups lobbied and testified before Congress. Medical journals began to discuss the issue. The American Academy of Pediatrics, the American College of Obstetrics and Gynecology, and the American Medical Association all supported the legislation.334 Although the legislation was not without naysayers, it quickly addressed an important issue.

Similarly, such support can be garnered for coverage of in vitro fertilization. The problem of multi-fetal pregnancies is a public health concern. A substantial amount of money is spent on reducing preterm births. If the incidence of preterm births (and associated risks and costs) can be reduced, and the cost to insurance companies is negligible, then Congress should pass the legislation.

CONCLUSION

The United States is an “individualistic, market-driven, and choice-focused” culture.335 Therefore, an additional regulatory agency will not happen in the near future. Additionally, we will probably never mandate a specific number of embryos to be transferred. Multi-fetal pregnancies and the resulting preterm births remain health issues that affect society. An insurance mandate is the most effective way to address the public health issue associated with in vitro fertilization without a new regulatory agency and without mandating that a physician transfer a specific number of embryos.

332. Id.
333. Id.
The goal of in vitro fertilization is to produce a healthy single baby. If an insurance mandate can reduce multi-fetal pregnancies, not increase costs to insurers, and not negatively affect a clinic’s overall success rate, then serious thought should be given to passing such legislation.

As discussed previously, data suggests that in countries and states with insurance coverage, there is less inclination for physicians to transfer more embryos. This in turn decreases the risk of multi-fetal pregnancies. America is one of the only developed countries without such a mandate. If coverage for in vitro fertilization were nationally mandated, it would provide equal access and care to all couples who suffer with infertility.336 While the insurance mandate does not solve all policy issues associated with in vitro fertilization, it does provide some necessary consistency with respect to services covered. Currently, the treatment is tied to a patient’s place of residence or financial status.337 The current scheme of state regulation is not effective. Reproductive choice should not be so limited.