IVF and the Law: How Legal and Regulatory Neglect Compromised a Medical Breakthrough

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IN VITRO FERTILIZATION AND THE LAW: How Legal and Regulatory Neglect Compromised a Medical Breakthrough

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Abstract: The rise of assisted reproductive technology like in vitro fertilization (IVF) as a method of human reproduction represents a remarkable medical achievement. It has allowed millions of infertile and same-sex couples to have children who were previously only the subject of their unrequited dreams. Live births and success rates have increased dramatically in the past decade, so much so that many fertility clinics “guarantee” a baby to clients who sign up. But with success comes inevitable downsides. Everyone knows that the price tag is steep, but given the demand, that obstacle seems to deter relatively few determined individuals. More insidious are the increased birth defect risks associated with reproductive technologies. For some time it was assumed that these risks were due to the fact that individuals attempting IVF were older and possessed greater risk factors themselves. Now, however, recent research is showing that it may be IVF itself, and in particular the dramatic rise of a new technique called ICSI, that is responsible for negative outcomes. IVF providers face little incentive to impress these risks on their customers, and operate in a largely unregulated environment in which cash is king and informed consent is optional. The incentive to report high live birth rates dictated by the profit motive pushes clinics to implant more embryos than necessary, and recommend technologies that may increase births despite the fact that they increase defect rates.

Sadly, law and regulation lag far behind the incredible technology in this arena. While some industry groups have promulgated responsible guidelines for appropriate use of reproductive technology, they come with no viable enforcement or disciplinary mechanisms. Law’s absence has contributed to a “wild west” mentality in some fertility clinics, where anything goes if it will make money. It is past time that the law and

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medical regulators become involved in assessing the rapidly growing reproductive technologies available today in order to preserve their benefits while mitigating the risks that are largely unknown or ignored by most patients.

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INTRODUCTION

A remarkable transformation in human reproduction is underway in our society. For all of human history, there was but one tried and true method available to individuals who wished to be parents. Today, however, assisted reproduction made possible by extraordinary pharmaceutical and technological innovation is fundamentally changing the way Americans have children. The technology is expanding by leaps and bounds every year now, while law and governmental regulation lag far behind. From fertility drugs to intra uterine insemination to the advent of in vitro fertilization and now intracytoplasmic sperm injection, modern medicine has paved the way for millions of Americans to have children that they only could have dreamed of previously.

Obviously, these transformational reproductive breakthroughs have provided immeasurable joy for new parents. Today, ten million children are alive that would not have been born just one generation ago.

However, these new innovations and technologies carry their own unique risks, from multiple births to low birth weight to severe birth defects. The inherent dangers are often glossed over though by a fertility industry now making billions of dollars per year. The perverse financial incentives and pressures for reproductive clinics to post better outcomes (i.e., live births) have led some to engage in practices that are questionable, and sometimes even quite dangerous for their patients.

Why are these risks and dangers becoming exponentially worse today? Quite candidly, it is the stunning absence of law and regulation in the medical reproductive arena. Technological advances have greatly outpaced the introduction of responsible laws and regulation. Politicians are wary of touching the controversial subject with a ten foot pole, and federal funding of embryo research is explicitly banned. Not surprisingly, government regulators have therefore been largely uninvolved and ineffective in the field. Further, the reproductive professionals themselves resist all forms of outside interference, fearing that their skyrocketing profits might be in danger. They cry, “we can regulate ourselves – keep law out!”, but we all know what happens when the fox guards the hen house.

Part I of this Article details the historical background of fertility treatments, ranging from pharmaceutical breakthroughs to
intrauterine insemination to in vitro fertilization (IVF) and now intracytoplasmic sperm injection (ICSI). Part II explores the downside of what appeared like unparalleled success, examining in particular the hidden dangers of fertility drugs, the risk of multiple births, birth defects, and the unique challenges posed by IVF and ICSI. The “wild west” mentality of the industry has even prompted the inventor of the latter technique to publicly criticize its dramatic overuse. Part III lays out the current legal and regulatory oversight scheme in America, paying attention to the enormous gaps in coverage, the lack of enforcement mechanisms, and the consequences for patients. Part IV offers normative recommendations for legal and public policy reform, including mandated disclosure of risks, mandatory certification of fertility clinics, and the explicit federal regulation of IVF and ICSI. Adopting these legal and regulatory approaches provides the ability to maintain the benefits of these amazing new reproductive innovations while preventing their abuse in the future.

In sum, it is past time for legislatures and regulators to address the unique benefits and challenges created by the rise of modern reproductive technologies. If we fail to muster the political will to do so today, thousands of future lives will suffer as a result.

I. THE REMARKABLE HISTORY OF ASSISTED REPRODUCTION

For many people, starting a family is the most fulfilling and important task they will ever undertake; an intimate act central to realizing one’s life’s goals. However, biology has not always been kind. For all of human history, countless millions of people have been unable to have children. Today, however, assisted reproductive technology has opened the doors of parenthood to millions for whom those doors were once firmly shut.

A. EARLY DISCOVERIES

Modern assisted reproductive technology (ART) is the culmination of over one hundred years of research and experimentation. As early as 1878, researchers began attempts to fertilize mammalian eggs in vitro. These early attempts were
largely unsuccessful, and although the possibility that fertilization occurred in some cases cannot be ruled out, most early claims of success were inadequately substantiated or based on misinterpreted results.\(^2\) However, a major breakthrough in IVF experimentation came with the discovery of sperm capacitation by Colin Russell Austin and Min Chueh Chang in 1951.\(^3\) Capacitation refers to changes that sperm undergo prior to fertilization while residing in a female’s reproductive tract.\(^4\) Within a few years of their discovery, researchers successfully fertilized rabbit eggs \textit{in vitro} for the first time.\(^5\) During the “golden age” of IVF research that followed, numerous experiments were conducted on a wide range of mammal species,\(^6\) culminating in 1969 with the first convincing fertilization of human eggs \textit{in vitro}.\(^7\) The achievement was made possible by research done on hamster IVF that allowed for the proper modification of culture medium protocols.\(^8\) However, despite researchers’ success in fertilizing eggs in vitro, it would be nearly another decade before it yielded fruit in the human population.\(^9\)

\(^2\) Id. at 182-83.
\(^3\) Id. at 183 (“Both Austin and Chang postulated that the spermatozoa of some mammalian species need to reside for some time with the female reproductive tract before acquiring the capacity to penetrate eggs, and Austin (1951) coined the term ‘capacitation’ to refer to the change spermatozoa undergo during this time.”); see also C.R. Austin, \textit{Observations on the Penetration of Sperm into the Mammalian Egg}, 4 AUSTL. J. OF SCI. RESEARCH SERIES B 581 (1951); M.C. Chang, \textit{Fertilizing Capacity of Spermatozoa Deposited into the Fallopian Tubes}, 168 NATURE 697 (1951).
\(^4\) Id.
\(^5\) Id. at 183.
\(^6\) Id. at 183-84 (IVF research was performed with hamsters, mice, rats, sheep, pigs, and cats).
\(^7\) Id. at 184 (citing B.D. Bavister, R.G. Edwards, and P.C. Steptoe, \textit{Identification of the Midpiece and Tail of the Spermatozoon During Fertilisation of Human Eggs In Vitro}, 20 J. REPRODUCTION AND FERTILITY 159 (1969)) (Fertilization of human eggs \textit{in vitro} was first “convincingly achieved in 1969, as evidenced by sperm penetration, polar body emission and formation of pronuclei.”)
\(^8\) Id. (citing R. Yanzgimzchi and M.C. Chang, \textit{Fertilisation of Hamster Eggs In Vitro}, 200 NATURE 281 (1963); R. Yanzgimzchi and M.C. Chang, \textit{In Vitro Fertilisation of Golden Hamster Ova}, 156 J. EXPERIMENTAL ZOOLOGY 361 (1964)) (“[I]t may be claimed that hamster IVF paved the way for human IVF.”).
\(^9\) Id. (the first human birth from an IVF embryo occurred in 1978).
In July 1978, Louise Brown became the first person to be born as a result of IVF.\textsuperscript{10} Her mother, Lesley Brown, had enlisted the aid of Patrick Steptoe and Robert Edwards at Oldham General Hospital in England in an attempt to overcome her persistent infertility.\textsuperscript{11} The successful procedure involved laparoscopic surgery to retrieve one of her eggs, which was then fertilized in the laboratory, and later transferred back into the uterus.\textsuperscript{12} This original procedure did not utilize any fertility drugs.\textsuperscript{13} Steptoe and Edwards would not only successfully repeat this result in future experiments, but would substantially improve their technique over the next several years.\textsuperscript{14}

\textbf{B. DRAMATIC EXPLOSION IN ART TECHNOLOGY DURING 1980s}

The 1980s witnessed dramatic growth and advancement in assisted reproductive technologies. Between 1980 and 1983, the widespread use of fertility drugs such as clomiphene\textsuperscript{15} and leuprorelin\textsuperscript{16} in the IVF process drastically improved the


\textsuperscript{11} Id.

\textsuperscript{12} Id. (citing Steptoe and Edwards, \textit{Birth after Reimplantation of a Human Embryo}, 1 LANCET 880 (1978)).

\textsuperscript{13} Id. (noting that no medications were used to “stimulate the ovaries” of Lesley Brown prior to laparoscopic egg retrieval).

\textsuperscript{14} Id.

\textsuperscript{15} Commonly marketed as Clomid, clomiphene has been around since the 1960s and has long been used to treat ovulatory dysfunction in women desiring a pregnancy. In a clinical study of over 7000 patients suffering from impediments to ovulation, administration of Clomid resulted in a roughly 30 percent pregnancy rate. Of those pregnancies, about 8 percent were multiple. See \textit{Clomid FDA Label}, U.S. FOOD & DRUG ADMIN. (Nov. 22, 2012), http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/016131s026lbl.pdf.

\textsuperscript{16} Commonly marketed as Lupron, leuprorelin is indicated to treat female fertility conditions such as Endometriosis and Uterine Leiomyomata. See \textit{Lupron FDA Label}, U.S. Food & Drug Admin. (Nov. 30, 2013), http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory. However, it should be
pregnancy rate from 6% to 30% per cycle.\textsuperscript{17} By the mid-1980s, several alternative methods of assisted reproduction came to fruition including gamete intrafallopian transfer (GIFT) and zygote intrafallopian transfer (ZIFT).\textsuperscript{18} These procedures differed from IVF in a number of ways. GIFT involves fertilization \textit{in vivo} – in other words, within the woman’s reproductive tract rather than in a laboratory.\textsuperscript{19} ZIFT was similar to traditional IVF but also involved a second laparoscopy to transfer the fertilized egg into the fallopian tube.\textsuperscript{20} Both procedures offered advantages over the original IVF method developed by Steptoe and Edwards.

However, IVF soon returned to the forefront of reproductive technology due to major breakthroughs in ultrasound technology in the late 1980s. These improvements transformed the process of oocyte retrieval into the modern outpatient IVF procedure we know today. In 1987 the development of ultrasound-guided transvaginal follicle aspiration created numerous advances over its predecessor techniques, and quickly became the “procedure of choice.”\textsuperscript{21} The innovation did away with the necessity of laparoscopy, decreasing the time, expense, and risk involved in the

\textsuperscript{17} Id.; see also R.G. Edwards and P.C. Steptoe, \textit{Current Status of In-Vitro Fertilisation and Implantation of Human Embryos}, 2 LANCET 1265 (1983).

\textsuperscript{18} Wang and Sauer, supra note 10, at 357.

\textsuperscript{19} STEVE PARKER, \textit{IN VITRO FERTILIZATION} 32 (2007) (“In this technique, eggs and sperm . . . are collected and checked as in a standard IVF procedure. But instead of placing the eggs and sperm into a culture medium, they are put back into the woman’s fallopian tube using a laparoscope. Fertilization then takes place in the fallopian tube, as happens in natural conceptions.”).

\textsuperscript{20} Id.; see also Wang & Sauer, supra note 10, at 357 (explaining that ZIFT allowed for the confirmation of fertilization while maintaining some of the theoretical benefits of GIFT but that the procedure required two laparoscopies to complete).

\textsuperscript{21} Wang & Sauer, supra note 10, at 358 (citing Matts Wikland et al. \textit{Use of a Vaginal Transducer for Oocyte Retrieval in an IVF/ET Program}, 15 J. CLINICAL ULTRASOUND 245 (1987)) (“First reported in 1987, this oocyte retrieval technique quickly became the procedure of choice due to better visualization, finer control, and less patient discomfort compared to other methods.”).
The improvement was so substantial that IVF procedures transitioned from 1-2 hours of hospital-based operating room time to a mere 10-15 minute process that could be performed in an office setting.\textsuperscript{23} The dramatic improvement in ultrasound technology marginalized GIFT and ZIFT as those procedures continued to necessitate invasive surgery.\textsuperscript{24} In contrast, IVF could now be performed without laparoscopy, instead utilizing less expensive and minimally invasive ultrasound-guided aspirations.\textsuperscript{25} Thus, despite a lower pregnancy rate per procedure, by the early to mid-1990s IVF had become firmly ensconced as the preferred method of assisted reproduction and has remained so ever since.\textsuperscript{26}

C. ADDRESSING MALE INFERTILITY: ICSI AND IVF

While traditional IVF was often successful in treating female infertility, the overall effectiveness of the procedure was limited by its inability adequately address male infertility.\textsuperscript{27} However, the male end of the fertility equation was soon addressed. In 1992 researchers introduced a new procedure, known as intracytoplasmic sperm injection (ICSI), designed to address many of the challenges posed by male infertility.\textsuperscript{28} ICSI differs from traditional IVF in that instead of letting the sperm and eggs mingle freely in order to achieve conception, a single sperm is isolated and injected directly into the cytoplasm of the egg with a micro

\begin{footnotesize}
\textsuperscript{22} Wang & Sauer, \textit{supra} note 10, at 358
\textsuperscript{23} \textit{Id.}
\textsuperscript{24} \textit{Id.}
\textsuperscript{25} \textit{Id.}
\textsuperscript{26} \textit{Id.} ("By 1995, Society for Assisted Reproductive Technology (SART) data noted that IVF, GIFT, and ZIFT consisted of 70%, 6%, and 2% of ART cycles respectively, despite pregnancy rates of 22.3%, 28.7%, and 30.3% for each procedure. . . .In 2003, GIFT and ZIFT were used in only 0.1% and 0.4% of ART cycles, while IVF represented the remaining 99.5% of cases."); see also \textit{Ctrs. for Disease Control and Prevention, Assisted Reproductive Technology Report: National ART Success Rates} (2003), http://nccd.cdc.gov/DRH_ART/Apps/NationalSummaryReport.aspx (select “2003” from the drop down menu at the top of the page).
\textsuperscript{27} Wang & Sauer, \textit{supra} note 10, at 359.
\textsuperscript{28} \textit{Id.} (citing Gianpiero Palermo et al., \textit{Pregnancies After Intracytoplasmic Injection of Single Spermatozoon into an Oocyte}, 340 \textit{Lancet} 17 (1992)).
\end{footnotesize}
needle. Because the procedure requires only a single healthy sperm, it is especially useful to treat infertility in a man who suffers from a low sperm count or the presence of abnormal sperm (e.g., those that cannot “swim” on their own). The development of testicular sperm extraction (TESE) has allowed fertilization rates up to 70% despite using only a few poor-quality sperm.

After its introduction, ICSI quickly gained popularity, rapidly transitioning into clinical practice and accounting for 11% of all IVF cycles by 1995. Moreover, the popularity of ICSI has continued expand rapidly; in 2011 the procedure accounted for a shocking 67% of all IVF cycles. However, Jeff Wang and Mark Sauer note that significant debate continues on the propriety of so drastically “altering the process of natural selection,” since ICSI allows potentially poor quality sperm to fertilize eggs that never would have had a chance before its invention.

D. REMARKABLE OUTCOMES (AND EXPENSES)

Today IVF is practiced in a majority of the world’s countries, and since its inception is estimated to be responsible for the birth of around 10 million babies. In the United States, roughly 10 percent of Americans suffer from some kind of fertility problem leading approximately one million people to seek fertility

29 See STEVE PARKER, IN VITRO FERTILIZATION 32 (2007).
30 Id.
31 Wang & Sauer, supra note 10, at 359.
32 Id. (citing CTRS. FOR DISEASE CONTROL & PREVENTION, ASSISTED REPRODUCTIVE TECHNOLOGY REPORT: NATIONAL SUMMARY AND FERTILITY CLINICS SUCCESS RATES (1995) [hereinafter “1995 ART REPORT”]).
34 Wang & Sauer, supra note 10 at 359 (discussing inheritable causes of male infertility, their transmission via ICSI, and the potential for increased health problems in children conceived via ICSI). See also infra, Part II on “The Downsides of Success.”
35 KAY ELDER & BRIAN DALE, IN-VITRO FERTILIZATION viii (3d. ed. 2011).
36 Id.
treatment annually. The revenue generated by this market activity is immense. IVF is a costly procedure, with a single cycle of treatment costing between $10,000 and $20,000. What’s more, because IVF is not always successful in producing a pregnancy, many patients have to undergo multiple procedures, significantly raising the overall cost (and risk) of treatment. The fertility industry has grown to accommodate this demand. With nearly 500 clinics in existence nationwide, fertility drugs alone make up a $3 billion per year industry. In light of the incredible cost for what is essentially an elective procedure, it should not come as a surprise that insurance coverage for IVF is limited or nonexistent in most states.

As the industry has grown, the use of artificial reproductive technology (ART), including both IVF and pharmaceutical interventions, has steadily increased. In 1996 there were nearly 65,000 ART cycles resulting in 14,507 live-birth deliveries for a total of 20,840 live born infants. By 2011 the number of ART cycles had more than doubled to over 150,000, resulting in 47,818 live births for a total of 61,610 live born infants. Moreover, as the usage of IVF has increased so has the prevalence of ICSI – which in 2011 accounted for 67% of all ART cycles. This represents a dramatic increase in the use of a procedure that

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39 KINDREGAN & McBRIEN, supra note 38, at 95.
40 Id.
41 Id. (citing Judith F. Darr, Accessing Reproductive Technologies: Invisible Barriers, Indelible Harms, 23 BERKELEY J. GENDER L. & JUST. 18, 36 n.64 (2008)).
42 See CAHN, supra note 37.
44 CTRS. FOR DISEASE CONTROL & PREVENTION, 2011 ART REPORT, supra note 33.
45 Id.
sixteen years ago accounted for only 11% of all IVF procedures.\footnote{Wang & Sauer, supra note 10, at 359 (citing NAT’L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, 2003 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS (2005)).} In fact, the percentage of IVF cycles utilizing ICSI has increased every single year from 1997 to 2011.\footnote{See CTRS. FOR DISEASE CONTROL & PREVENTION, ASSISTED REPRODUCTIVE TECHNOLOGY REPORT: NATIONAL SUMMARY AND FERTILITY CLINICS SUCCESS RATES (1997) [hereinafter “1997 ART REPORT”].}

The explosion in the popularity of ICSI also tracks a dramatic uptick in the success rate of IVF. According to the Centers for Disease Control and Prevention’s National Summaries of ART success rates, in 1997 30.7% of IVF cycles resulted in live births for mothers under the age of 35.\footnote{Id.} In that year, ICSI was used in only 35% of all IVF cycles.\footnote{Id.} In contrast, by 2010 41.5% of all IVF cycles resulted in live births for mothers under the age of 35 – with ICSI being used in 66% of all IVF cycles.\footnote{Id.}\footnote{Id.} The trend holds true for all the age groups surveyed: as the percentage of IVF cycles utilizing ICSI has increased, so has the percentage of cycles resulting in live births.\footnote{Id.} This trend is particularly pronounced among older women. In 1997 only 7.6% of IVF cycles resulted in live births for women aged 41-42.\footnote{Id.} By 2010, the live birth rate among this age group had risen to 12.4%, a 63% increase.\footnote{Id.}

The data shows several unmistakable trends over the last 15 years: (1) the percentage of IVF cycles utilizing ICSI increased dramatically; (2) the percentage of IVF cycles that led to live births increased almost every single year; and (3) the percentage of

\footnote{Wang & Sauer, supra note 10, at 359 (citing NAT’L CTR. FOR CHRONIC DISEASE PREVENTION & HEALTH PROMOTION, 2003 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS (2005)).}
\footnote{See CTRS. FOR DISEASE CONTROL & PREVENTION, 1997 ART REPORT, supra note 47.}
\footnote{Id.}
\footnote{Id.}
\footnote{Id.}
successful outcomes for older mothers increased substantially.\textsuperscript{54} Between traditional IVF and ICSI, many of the genetic factors that prohibited spontaneous reproduction in both sexes have now been overcome.\textsuperscript{55} The inevitable tick of the biological clock is no longer the same barrier it once was to older women.\textsuperscript{56} In the words of one commentator, “[c]reating a family, regardless of whether you are an infertile husband-and-wife couple, a same-sex couple, or a single person, now involves a deliberate choice.”\textsuperscript{57}

However, it should be noted that all of the successes detailed above offer no glimpse into patient outcomes after a live birth has occurred. As with every pioneering technology, there are inevitably downsides, some of which may not be immediately apparent.

\textsuperscript{54} See supra note 47 (data is currently available from 1997-2011 allowing for the identification of trends within that range).
\textsuperscript{55} See Wang & Sauer, supra note 10, at 362. Moreover, emerging technologies such as preimplantation genetic diagnosis (PGD) have allowed couples suffering from some sex-linked diseases and other genetic disorders to have children free of those conditions. See CAHN, supra note 37, at 62. PGD is generally available to screen for several kinds of diseases: (1) testing to determine the sex of the embryo for sex-linked diseases like Duchenne muscular dystrophy; (2) diseases that result from a single gene defect such as cystic fibrosis; and (3) chromosomal disorders. Frances A. Flinter, \textit{Preimplantation Genetic Diagnosis Needs to be Tightly Regulated}, 322 BRIT. MED. J. 1008 (2001). PGD can also be used to screen for aneuploidy (Down’s Syndrome for example), though this is not allowed in some countries (the United Kingdom, for instance). \textit{Id.} However, for its many promising benefits, PGD also has risks. One study found the procedure may lower the live birth rate for older women. See Sebastian Mastenbroek et al., \textit{Preimplantation Genetic Screening: a Systematic Review and Meta-analysis of RCTs}, 17 HUMAN REPRODUCTION 454 (2011). Another suggested PGD might be responsible for increasing the perinatal death rate in multiple pregnancies. Inge Liebaers et al., \textit{Report on a Consecutive Series of 581 Children Born After Blastomere Biopsy for Preimplantation Genetic Diagnosis}, 65 OBSTETRICAL & GYNECOLOGICAL SURVEY 240 (2010).
\textsuperscript{56} See Wang & Sauer, supra note 10, at 1 (noting that by the age of 40, 33% of couples are infertile and that 18% of women using ART technology were over the age of 40 in 2004).
\textsuperscript{57} Id. at 3.
II. The Downside of Success

While assisted reproductive technology has provided millions of couples the incredible opportunity to become parents, emerging research suggests that it comes with significant risks for the children produced. The profit motive leads some fertility clinics to prescribe drugs that may unnecessarily cause multiple births and associated negative health outcomes for both mothers and children. When IVF is the reproductive route of choice, some clinics have been known to harvest more eggs and implant more embryos than responsible medical providers should. Worse, the emerging new IVF technique of choice, ICSI, presents risks that many soon-to-be parents are wholly unaware of.

A. The Dangers of Assisted Reproduction: Fertility Drugs and the Risk of Multiples

Assisted reproduction spans a wide range of procedures, each with its own benefits and risks. The most widely used “first option” in the assisted reproduction field is not IVF or ICSI but the fertility drugs (e.g., Clomid, Lupron, Repronex) that form the foundation of most modern infertility treatments. These drugs are generally used to stimulate ovulation and allow for the harvesting of multiple oocytes. The rise of ovulation stimulation drugs has contributed to a rapid increase in the number of high-order pregnancies involving three or more fetuses. ART-related use of the drugs typically involves the removal of multiple eggs after stimulation and then fertilization via either IVF or ICSI. In contrast, when used without ART the ovulation drugs are typically

58 See Laura A. Schieve et al., Estimation of the Contribution of Non-assisted Reproductive Technology Ovulation Stimulation Fertility Treatments to US Singleton and Multiple Births, 170 AM. J. EPIDEMIOLOGY 1396 (2010) (concluding that roughly 4.6% of infants born in the U.S. in 2005 resulted from non-ART ovulation treatments and noting that this is four times greater than the contribution of ART).
60 See Norbert Gleicher et al., Reducing the Risk of High-Order Multiple Pregnancy After Ovarian Stimulation with Gonadotropins, 343 NEW ENG. J. MED. 2 (2000); Schieve et al., supra note 58, at 1397.
61 See Schieve, et al., supra note 58, at 1396.
used in conjunction with timed sexual intercourse or some other form of assisted insemination (like intrauterine insemination – IUI). Both uses are associated with extremely high incidence of multiple gestation and multiple births. In fact, roughly 44% of all ART procedures result in twins, and about 5% result in triplets or higher order multiples.

While some infertile parents are not overly deterred by the thought of having twins or triplets, they are often far less aware that multiple order pregnancies are associated with a dramatically increased risk of substantial health problems. Compared to singletons, multiples experience markedly higher risks of pregnancy complications, preterm delivery, infant death, and neurological impairments in the babies that survive. Preterm delivery is especially common, as the length of pregnancy decreases significantly with each additional fetus. In fact, about 60% of twins, and more than 90% of higher order multiples, are born premature. Low birth weight is also common and often results from preterm delivery. According to data gathered by the CDC, in 2005 97% of all triplets or higher order multiples conceived through ART were born premature. While advances in preterm care have brightened outlooks for these babies somewhat, the costs are extraordinary and the children are still at increased risk.

62 Id. Despite the success of IVF, intrauterine insemination (IUI) remains relatively common, often making up the first step before couples resort to the more invasive (and expensive) IVF. IUI involves the placement of washed and concentrated sperm directly into a woman’s uterus around the time she releases one or more eggs. Tests and Procedures: Intrauterine Insemination: Definition, MAYO CLINIC (June 29, 2013), http://www.mayoclinic.org/tests-procedures/intrauterine-insemination/basics/definition/prc-20018920. The procedure is often undertaken with sperm from an anonymous donor or from a known male, often the husband.

63 Schieve, et al., supra note 58, at 1396..


65 See Schieve et al., supra note 58; see also Wright et al., supra note 64, at 1.

66 Schieve, et al., supra note 58, at 1396. (“More than half of twins and almost all higher-order multiples are born with low birthweight (less than 5½ pounds or 2,500 grams). LBW can result from premature birth and/or poor fetal growth. Both are common in multiple pregnancies.”).

67 See Wright et al., supra note 64, at 1.
risk for early health problems and lasting disabilities like cerebral palsy, hearing loss, and intellectual disability.\textsuperscript{68} Moreover, at least one study has found that opposite-sex twins born from non-IVF-controlled ovarian stimulation had a significantly higher incidence of very low birth weight and severe prematurity compared to naturally conceived opposite-sex twins.\textsuperscript{69}

Singletons and mothers are not entirely immune from the dangers posed by ovulation treatments either. Some studies have suggested that singletons conceived with the aid of non-ART ovulation treatments may be at increased risk of pregnancy complications, low birth weight, preterm delivery, and other poor outcomes.\textsuperscript{70} Mothers too face a risk of health problems associated with carrying twins, triplets, or higher order multiples to term. Especially common is pre-eclampsia, a complication characterized by high blood pressure, swelling, and protein in the urine.\textsuperscript{71} The condition can be dangerous, in some cases leading to seizures, kidney or liver damage, and potentially puts both the mother and child’s life at risk.\textsuperscript{72} Especially concerning, this complication may occur in as much as 40% of all triplet pregnancies.\textsuperscript{73} Finally, for many high order pregnancies, obstetricians strongly suggest “multifetal reduction” – i.e., aborting some fetuses to increase the

\textsuperscript{68} Id. (discussing the health and disability challenges facing low birth weight babies).


\textsuperscript{70} Id. (citing Marco Gaudoin et al., Ovulation Induction/Intrauterine Insemination in Infertile Couples is Associated With Low-Birth-Weight Infants, 188 AM. J. OBSTETRICS & GYNECOLOGY 611 (2003); Bengt Källén et al., Neonatal Outcome in Pregnancies from Ovarian Stimulation, 100 OBSTETRICS & GYNECOLOGY 414 (2002); Willem Ombelet et al., supra note 69).


\textsuperscript{73} See Shepelavy, supra note 72.
chance of good outcomes for the rest.\textsuperscript{74} While the procedure generally poses little risk to the mother, the difficult decision it involves can cause severe emotional and family turmoil.\textsuperscript{75} The decision may be most distressing for women carrying triplets, as triplets face an increased risk of poor outcomes, but not of the same obvious magnitude as higher order pregnancies.\textsuperscript{76}

Hand in hand with the health problems linked to multiple births are the radically increased medical costs associated with caring for twins, triplets, or higher order pregnancies. According to a recent study published in the American Journal of Obstetrics and Gynecology, pregnancies resulting in delivery of twins are about \textit{five times more expensive} than a singleton pregnancy.\textsuperscript{77} However, even more alarming is that higher order pregnancies resulting in the delivery of triplets or more are twenty times more expensive than a singleton pregnancy.\textsuperscript{78} By the numbers, a typical singleton pregnancy costs about $21,000, a pregnancy resulting in twins costs $105,000, and a pregnancy resulting in triplets or more costs a staggering $400,000.\textsuperscript{79} While expenses for singletons are largely maternal-related, costs for multiples skew heavily toward infant-related care.\textsuperscript{80} Given the cost distribution, it comes as little surprise

\textsuperscript{74} See \textit{id.} (“A fairly simple procedure, reduction poses few risks to the mother and is usually recommended by high-risk obstetricians to avoid the dangers of multiples: potentially deadly blood pressure swings and a higher chance of gestational diabetes, anemia and kidney infections for the mom; prematurity, cerebral palsy or death shortly after birth for the babies.”).

\textsuperscript{75} See \textit{id.} (discussing the difficult decisions women pregnant with high order multiples must make regarding multifetal reduction. On one side of the decision, a better chance at normal lives for the remaining fetuses, on the other, deciding to undergo an abortion procedure, often in violation of closely held family or religious beliefs.).

\textsuperscript{76} See \textit{id.} (discussing the difficulty of counseling women carrying triplets on reduction. Many women know families with healthy triplets, introducing anecdotal evidence that may make weighing the risks more difficult.).


\textsuperscript{78} Id.

\textsuperscript{79} Id.

\textsuperscript{80} Id. at 586.e4 (“For singleton pregnancy, maternal expenses accounted for approximately 60% of overall cost, whereas, for twins or higher
that multiples were considerably more likely than singletons to require admission to the neonatal intensive care unit (NICU) after delivery.\textsuperscript{81} Overall, the increased costs resulted from a wide variety of factors including increased use of the NICU, heavy use of caesarean section for delivery, and longer overall hospital stays for both the mother and infants.\textsuperscript{82}

The data presented above has made it increasingly clear that fertility treatment of any kind increases the chance of a multiple, and especially high order multiple, pregnancy. Currently, however, it is not possible to accurately determine what percentage of multiple births are the result of ovulation induction or ART because ovulation stimulation is not recorded nationally.\textsuperscript{83} Nonetheless, there is general medical consensus that only about 20\% of triplet or higher order pregnancies result from natural conception.\textsuperscript{84} Triplets are conceived naturally in only about 1 in 10,000 pregnancies.\textsuperscript{85} Higher order pregnancies are extremely rare in natural conception.\textsuperscript{86} Thus, the unique and significant risks posed by carrying three, four, or even more babies to term can be almost exclusively attributed to the rise of assisted reproduction technologies.\textsuperscript{87} While a responsible fertility clinic can mitigate

\begin{itemize}
\item order multiple births, expenses for infant care accounted for approximately 70\% and 85\% of total expenses, respectively.
\end{itemize}

\textsuperscript{81} \textit{Id.} at 586.e3 (“Infants of twins or triplets or more were more likely to be admitted to NICU and had a higher mortality rate compared with infants of singletons (47.7\% [triplets or more] vs 24.2\% [twins] and 2.9\% [singletons]; 2.0\% [triplets or more] vs 0.5\% [twins] and 0.06\% [singletons]; all P < .0001.”).

\textsuperscript{82} \textit{Id.} at 586.e4.

\textsuperscript{83} \textit{Id.} at 586.e2.

\textsuperscript{84} \textit{Id.} (citing Practice Committee of American Society for Reproductive Medicine, \textit{Multiple Gestation Associated with Infertility Therapy: an American Society for Reproductive Medicine Practice Committee Opinion}, 97 J. FERTILITY & STERILITY 825 (2012)).

\textsuperscript{85} \textbf{AM. SOC’Y FOR REPRODUCTIVE MED., MULTIPLE PREGNANCY AND BIRTH: TWINS, TRIPLETS, AND HIGH-ORDER MULTIPLES: A GUIDE FOR PATIENTS} (2012), \url{http://www.reproductivefacts.org/uploadedFiles/ASRM_Content/Resources/Patient_Resources/Fact_Sheets_and_Info_Booklets/multiples.pdf}.

\textsuperscript{86} \textit{Id.}

\textsuperscript{87} See Schieve et al., supra note 58, at 1396 (“The striking increase in multiple births in the United States in recent decades is attributed primarily to infertility treatments that include ovulation stimulation medications.”).
some of the risk of a multiple pregnancy by transferring fewer embryos during IVF, the risk of a high order pregnancy is not so easily mitigated for patients using fertility drugs alone. Moreover, not every clinic is responsible. Many choose to implant far more embryos than is recommended by the American Society for Reproductive Medicine, raising the likelihood of a resulting high order multiple pregnancy.

B. THE DANGERS OF IVF AND ICSI: BIRTH DEFECTS AND GENETIC CONSIDERATIONS

IVF, and its subcategory ICSI, have come under increased scrutiny as recent studies show links between the procedures and higher risks of birth defects and other health problems in children. Unfortunately, it can now be fairly concluded that children conceived in the laboratory are more likely to suffer from congenital birth defects and other health problems than those conceived naturally. The defects can be severe. Canadian researchers concluded that children “conceived with use of IVF/ICSI have three times as high a risk of a congenital heart

88 See Shepelavy, supra note 72 (discussing the American Society for Reproductive Medicine’s guidelines that recommend implantation of one embryo for women under 30 and two for women 30-35).
89 See id. (discussing the difficulty in accurately determining the number of eggs released and fertilized after using ovulation stimulation drugs).
90 Naomi R. Cahn & Jennifer M. Collins, Eight is Enough, 103 NW. U. L. REV. 501 (2009) (discussing the case of the now famous “Octomom,” Nadya Suleman. Suleman was a 33-year old unemployed woman, who at the time of undergoing fertility treatment was already caring for six children. Nonetheless, “[t]he fertility clinic that treated Suleman agreed to implant her with at least six embryos during an in vitro fertilization (IVF) procedure.” Suleman later gave birth to octuplets in early 2009 and has been a media sensation ever since.)
92 See Juan Wen et al., Birth Defects in Children Conceived by In-Vitro Fertilization and Intracytoplasmic Sperm Injection: A Meta-Analysis, 97 FERTILITY AND STERILITY No. 6, 1331, (2012) (evaluating 56 previous studies and concluding that children conceived by IVF and ICSI are at “significantly increased risk for birth defects.”).
defect as naturally conceived infants." 93 A recent study published in 2012 provides an illustrative example of the scale of the risks, and remaining uncertainty, surrounding assisted reproductive technology. The study, a meta-analysis published by Juan Wen and colleagues in the Journal of Fertility and Sterility, 94 specifically examined epidemiological data assessing the risk of birth defects after ART and compared the risk difference of birth defects after ICSI and IVF. 95 The results of the study suggest that “there is a significantly increased risk of birth defects in infants conceived by ART, but ICSI did not increase the risk compared with [traditional] IVF.” 96 However, the study concerned only birth defects, and did not evaluate the genetic concerns, particularly the transmission of genetic mutations that cause male infertility, that are unique to ICSI. 97 Moreover, as a meta-study, it is not entirely clear to what extent the authors were able to adjust for risk factors such as maternal age. Regardless, the authors concluded that IVF and ICSI significantly increased the risk of birth defects in children when compared to a spontaneous conception. 98

93 Shi Wu Wen, et al., A Comprehensive Assessment of Outcomes in Pregnancies Conceived by In Vitro Fertilization/Intracytoplasmic Sperm Injection, 150 EUR. J. OBSTETRICS & GYNECOLOGY & REPRODUCTIVE BIOLOGY 160, 161-62 (2010) (noting that heart defects were not minor and were not likely to be associated with prematurity).
94 See Juan Wen et al., supra note 92.
95 Id. at 1333.
96 Id.
98 Juan Wen et al., supra note 92, at 1331. See also Michele Hansen et al., The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization, 346 NEW ENG. J. MED. 725 (2002) (“Infants conceived with use of intracytoplasmic sperm injection or in vitro fertilization have twice as high a risk for a major birth defect as naturally conceived infants.”); Maryse Bonduelle et al., A Multi-Centre Cohort Study of the Physical Health of Five-Year-Old Children Conceived After Intracytoplasmic Sperm Injection, In Vitro Fertilization and Natural Conception, 20 HUMAN REPRODUCTION 413 (2004) (concluding that children conceived via ICSI, and to a lesser extent IVF, experienced more birth congenital malformations than naturally conceived children and were more likely to need healthcare resources).
Increasingly though, studies show that the phenomenal explosion in ICSI may be primarily responsible for causing birth defects though there remains some uncertainty as to what extent parental factors are to blame. Since ICSI involves the direct injection of sperm into an egg even though that sperm would have likely been too weak to fertilize the egg without medical intervention, some researchers understandably became concerned about the health risks of the procedure shortly after it was invented. Despite these common sense fears, there was no experimental phase of testing for the ICSI procedure before it was introduced for human use. This was due, at least in part, to the immediate clinical success of the procedure in producing live births. Additionally, some early studies generally did not show a significantly increased risk of birth defects with either IVF or ICSI. Perhaps unsurprisingly, much of this early research was plagued by methodological problems including small sample sizes and inconsistent definitions for major birth defects. As Kurinczuk and Bower found, such deficiencies may have led to an underestimation of the relative prevalence of birth defects among infants conceived with assisted reproductive technology.

102 Drapkin Lyerly, supra note 101.
103 See Hansen et al., supra note 98, at 725.
104 Id.
105 Id. (citing Jennifer J. Kurinczuk & Carol Bower, Birth Defects in Infants Conceived by Intracytoplasmic Sperm Injection: An Alternative Approach, 315 BMJ 1260 (1997)).
A 2012 study by Michael Davies, published in the New England Journal of Medicine, found that only ICSI, and not traditional IVF, was associated with a statically significant increase in birth defects.¹⁰⁶ The study analyzed data from birth registries and clinics in southern Australia and utilized advanced statistical techniques to isolate the procedural risks associated with different forms of ART.¹⁰⁷ In contrast to the meta-analysis offered by Juan Wen, the New England Journal of Medicine study concluded that “the increased risk of birth defects associated with [traditional] IVF was not . . . significant after adjustment for parental factors.”¹⁰⁸ So while the study suggested that both IVF and ICSI were associated with a higher risk of birth defects when compared to spontaneous conception, once the data was adjusted for maternal age and other parental risk factors, only the ICSI correlation remained.¹⁰⁹ The results suggest that increased risk of birth defects is plausibly linked to the ICSI procedure itself,¹¹⁰ but that “differences in male infertility factors that lead to the use of ICSI may also underlie the association.”¹¹¹ Nonetheless, the magnitude of the risk appears to be substantial. The New England Journal of Medicine study results show that before adjusting for factors such as maternal age, IVF was associated with a 26% increase in birth defects compared with spontaneous conception while ICSI was associated with a staggering 77% increase.¹¹² After adjustment, the increased risk for traditional IVF largely

¹⁰⁷ Id.
¹⁰⁸ Id. (quoting the article’s abstract).
¹⁰⁹ Id. at 1809 (“After multivariate adjustment, the association between IVF and the risk of any birth defect was no longer significant, whereas the increased risk of any birth defect associated with ICSI remained significant.”).
¹¹⁰ Id. (citing Maryse Bonduelle et al., supra note 98; Jennifer J. Kurinczuk, Safety Issues in Assisted Reproduction Technology: From Theory to Reality – Just What Are the Data Telling Us About ICSI Offspring Health and Future Fertility and Should We Be Concerned?, 18 HUMAN REPRODUCTION 925 (2003)).
¹¹¹ Davies, et al., supra note 106 at 1809.
¹¹² Id. at 1803 (“The corresponding odds ratios [before and after adjustment for risk factors such as maternal age] with in vitro fertilization (IVF) (165 birth defects, 7.2%) were 1.26 (95% CI, 1.07 to 1.48) and 1.07 (95% CI, 0.90 to 1.26), and the odds ratios with intracytoplasmic sperm injection (ICSI) (139 defects, 9.9%) were 1.77 (95% CI, 1.47 to 2.12) and 1.57 (95% CI, 1.30 to 1.90.”).
disappeared but ICSI was still associated with a roughly 57% increase in birth defects. These numbers suggest the chance of a birth defect occurring is much higher than may previously been understood. For example, an earlier German study found that before adjustment, ICSI was associated with only a roughly 44% increase in birth defects as compared to spontaneously conceived children.

The New England Journal of Medicine study also provides revealing additional insight into the world of assisted reproduction technology and the women who undertake it. The authors note that women who used reproductive technology were more likely to be older, white, affluent, and nulliparous than women who conceive spontaneously. Moreover, their children were more likely to be stillborn, delivered by cesarean section, and had a lower mean birth weight than naturally conceived children. These observations are consistent with previous studies which also found that pregnancies achieved after ICSI resulted in “a higher number of preterm and low birth weight children.”

On a slightly unrelated note, one of the most interesting aspects of the study involved a comparison of outcomes between frozen embryos and fresh embryos in traditional IVF and ICSI. Surprisingly, for both IVF and ICSI the researchers “found a significant increase in the risk of birth defects associated with fresh-embryo cycles but not with frozen-embryo cycles.” While admittedly a small sample size, the study’s results suggest that using frozen embryos may be safer than using fresh ones, in both IVF and ICSI. The authors explore possible explanations that

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113 Id. (“The increased risk of birth defects associated with IVF was no longer significant after adjustment for parental factors.”).
115 See Davies et al., supra note 106, at 1805.
116 Id.
117 Katalinic et al., supra note 114, at 1604 (quoting the article’s abstract).
118 See id.
119 See Davies et al., supra note 106, at 1810.
120 Id. (noting however that the risk of birth defects with fresh cycles of IVF was “significantly lower” than the risk with fresh cycles of ICSI).
include “a reduced likelihood that developmentally compromised embryos will survive the thawing process and the temporal separation of the developing embryo from exposure to hormonal stimulation drugs.”\textsuperscript{121}

More importantly, the risk of ICSI is distinguished from that of traditional IVF by unique genetic considerations associated with the removal of natural selection from the fertilization process. Some of these genetic risks, especially those relating to passing down infertility, may not manifest themselves until later in life – and thus escape analysis in most studies of IVF outcomes.\textsuperscript{122} A recent study of boys conceived through ICSI suggested they may have shorter fingers than their peers, a metric that is associated with fertility problems.\textsuperscript{123} These revelations are particularly concerning given the rapid increase in the number of couples undergoing IVF\textsuperscript{124} and the proliferation of ICSI as the most popular method of IVF.\textsuperscript{125} Recently, ICSI inventor Andre Van Steirteghem quite shockingly came out publicly urging against ICSI’s widespread use, citing concerns that defective sperm may allow genetic disorders to be passed on to the next generation.\textsuperscript{126} Specifically, Professor Van Steirteghem warned that problems like

\textsuperscript{121} Id. at 1811.
\textsuperscript{122} See David Derbyshire, \textit{Infertility Time Bomb: IVF Children Have Higher Risk of Infertility, Obesity, and Diabetes}, THE DAILY MAIL, Feb. 22, 2010, http://www.dailymail.co.uk/health/article-1252901/Infertility-time-bomb-IVF-children-higher-risk-infertility-obesity-diabetes.html (noting that the increased number of multiples resulting from IVF pregnancies puts them at risk for problems later in life); \textit{Zorlu}, supra note 97 (noting that the boys in the study were still too young to test for infertility directly).
\textsuperscript{123} Id.
\textsuperscript{124} See \textit{CNTS. FOR DISEASE CONTROL & PREVENTION}, 2011 ART REPORT, \textit{supra} note 33 (indicating that there were over 150,000 ART cycles performed in the United States during 2011).
\textsuperscript{125} See \textit{id}. (ICSI made up 67\% of all IVF procedures performed in the United States in 2011).
\textsuperscript{126} Maren Urner, \textit{IVF Technique is Overused, Says its Inventor}, BIONEWS.ORG, Mar. 1, 2010, http://www.bionews.org.uk/page_55180.asp (speaking at this year’s conference for the Advancing Science Serving Society (ASSS), Professor van Steirteghem highlighted “the possibility that the direct injection of sperm into the egg, a technique known as ICSI . . . might enable fertilisation with genetically-defective sperm, raising the prospect that problems like diabetes, heart disease and obesity could be passed on to future generations.”).
diabetes, heart disease, and obesity could be passed on to future generations through defective sperm.\textsuperscript{127} In his view, the ICSI procedure should be reserved for only those situations where more traditional methods of IVF have failed.\textsuperscript{128}

However, responsible voices opposed to the proliferation of ICSI are at odds with powerful market forces behind its growth into the new mainstay procedure of a multi-billion dollar industry. Early studies suggested that ICSI was capable of higher fertilization rates than traditional IVF and that was all that mattered.\textsuperscript{129} While there may be some truth in those results,\textsuperscript{130} the modern consensus is that ICSI does not improve outcomes in cases of unexplained infertility or advanced maternal age, and its routine use should be confined to treating male factor infertility.\textsuperscript{131}

In the United States, the government tracks fertilization and live birth rates for each individual clinic.\textsuperscript{132} These statistics are public and permit direct comparison and competition between clinics, allowing patients to shop around for the clinic with the highest “success” rates. Given that in the United States IVF is only available to those who can pay for it privately,\textsuperscript{133} clinics

\textsuperscript{127} Id. (referring to comments made by Professor Andre Van Steirteghem at the 2010 conference for Advancing Science Serving Society).

\textsuperscript{128} Id.

\textsuperscript{129} See. e.g., Gloria Calderón et al., \textit{Intracytoplasmic Sperm Injection Versus Conventional in-vitro Fertilization: First Results}, 10 \textit{HUMAN REPRODUCTION} 2835 (1995); Dianna Payne et al., \textit{Successful Treatment of Severe Male Factor Infertility in 100 Consecutive Cycles Using Intracytoplasmic Sperm Injection}, 9 \textit{HUMAN REPRODUCTION} 2051 (1994).

\textsuperscript{130} The Practice Comm. of the Am. Soc’y for Reproductive Med. & Soc’y for Assisted Reproductive Tech, \textit{Intracytoplasmic Sperm Injection (ICSI) for Non-male Factor Infertility: a Committee Opinion}, 98 \textit{FERTILITY & STERILITY} 1395, 1397 (2012) (conceding that “ICSI can increase fertilization rates when lower than expected or failed fertilization has previously occurred with conventional insemination.”).

\textsuperscript{131} See id. (summarizing the conclusions of the committee).


\textsuperscript{133} See PARKER, supra note 19, at 50.
necessarily compete for a limited pool of patients. In this environment, posting a higher success rate than one’s competitors can have a significant impact on a clinic’s bottom line.\textsuperscript{134} Perhaps most troubling is that in light of these perverse incentives, ICSI’s rapid rise could reflect overuse of the procedure and inadequate disclosure of the procedure’s risks to patients. But once the initial studies reported higher live birth rates associated with ICSI, those other concerns were quickly swept aside by the fertility industry.

III. CURRENT LEGAL AND REGULATORY OVERSIGHT OF ASSISTED REPRODUCTIVE TECHNOLOGY

A. REGULATIONS BARELY EXIST AND GUIDELINES DO NOT WORK

Modern assisted reproduction is a multibillion dollar industry that affects hundreds of thousands of people every year in the United States. However, despite its size and rapid growth, the fertility industry is subject only to very limited state and federal regulation.\textsuperscript{135} While some industry groups have promulgated responsible guidelines for the use of assisted reproductive technologies, the absence of viable enforcement mechanisms leaves many clinics subject only to self-regulation or, in some cases, the enforcement of more general laws by the courts. Moreover, a comparison of the American Society for Reproductive Medicine’s U.S. guidelines to those issued by the organization’s counterpart in the U.K. suggests that the U.S. guidelines are somewhat less stringent. Assisted reproductive technology’s

\textsuperscript{134} Patients seeking fertility treatments that often cost in excess of $10,000 per attempt have strong incentives, both financial and emotional, to choose a clinic with a rate of successful births per cycle of treatment. Because the CDC makes these success rates public, they serve as a de facto ranking system for fertility clinics. Much like colleges and professional schools are ranked by \textit{U.S. News \& World Report}, so are clinics ranked by their success rates. Every clinic fights to post better numbers than its competitors leading to shady reporting practices and a singular focus on inflating success rates. Without sufficient regulatory oversight, the profit motive takes over.

\textsuperscript{135} See Anne Drapkin Lyerly, \textit{supra} note 101, at 698 (2010) (“[R]esearch and clinical treatment of infertility has been virtually unregulated.”); NAOMI R. CAHN, \textit{supra} note 37, at 44 (discussing the limited state and federal oversight of participants in the fertility industry).
meteoric rise strongly suggests that it will play an increasingly important role in reproduction for future generations. Nonetheless, law has lagged far behind this groundbreaking technology in the United States. Today, for example, the IVF industry mostly operates as a free market and there is little that restricts or controls choices made by physicians, patients, or donors.\textsuperscript{136}

Assisted reproduction technology exists largely outside the current reach of federal regulatory powers. Professor Anne Drapkin Lyerly concludes that this may partly be the result of the dissociation of innovation in reproductive medicine from experimentation.\textsuperscript{137} Generally, federally funded medical researchers are subject to significant regulation and oversight by the Department of Health and Human Services (DHHS).\textsuperscript{138} However, the reluctance of the United States government to fund research on embryos and reproductive medicine has seriously eroded any oversight or regulatory ability that DHHS may have had over ART.\textsuperscript{139} In 1994 President Clinton declared that federal funding should not be made available for research involving the creation of destruction of embryos.\textsuperscript{140} Shortly thereafter in 1996, Congress began attaching a rider to DHHS appropriations bills which effectuated the presidential declaration.\textsuperscript{141} Thus, Lyerly argues that the absence of federal funding in the field of assisted reproduction helps explain ICSI’s “curious” evolution:

Because scientifically rigorous development and refinement of ICSI would have involved the creation, destruction, and discarding of embryos,

\textsuperscript{136} See K\textsc{indregan} & M\textsc{cBrien}, \textit{supra} note 38, at 96.
\textsuperscript{137} See Lyerly, \textit{supra} note 101, at 698.
\textsuperscript{138} See, \textit{e.g.}, 45 \textsc{C.F.R.} \textsection 46.101 (2013).
\textsuperscript{139} See Lyerly, \textit{supra} note 101, at 698.
\textsuperscript{140} \textit{Id.} (citing Jennifer C. Fletcher, \textsl{Ethics and Society: U.S. Public Policy on Embryo Research: Two Steps Forward, One Large Step Back}, 10 \textsc{Human Reproduction} 1875 (1995)).
\textsuperscript{141} Lyerly, \textit{supra} note 101, at 700-01 (citing \textsc{1 Nat'l Bioethics Advisory Comm'N, Ethical Issues in Human Stem Cell Research} 35 (1999)) (“1) the creation of a human embryo or embryos for research purposes; or 2) research in which a human embryo or embryos are destroyed, discarded or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 \textsc{C.F.R.} 46.208(a)(2) and section 498(b) of the Public Health Service Act (42 \textsc{U.S.C} 289g(b)).”).
research involving this technique would not have been eligible for federal funding. As such, the technology advanced rapidly with neither federal funding, nor the scientific scrutiny or human subjects’ protections that accompany it.\textsuperscript{142}

As the comment suggests, Congress’s fear of political controversy created a vacuum of federal oversight, and in turn played a major role in ICSI’s quick transition from experimental procedure to mainstay of the of the IVF industry.

Other federal agencies only possess limited regulatory oversight of the assisted reproduction industry. The Food and Drug Administration (FDA) has largely steered clear of directly regulating assisted reproduction, and has only recently engaged in limited regulation surrounding cloning\textsuperscript{143} and the classification of medical devices used in the assisted reproduction.\textsuperscript{144} By contrast, the federal Centers for Disease Control and Prevention has been at least somewhat involved in regulating assisted reproduction technology and the fertility industry. The CDC has statutory authority to regulate pursuant to the Fertility Clinic Success Rate and Certification Act.\textsuperscript{145} However, CDC regulation concerns only the certification of laboratories and the reporting of pregnancy success rates achieved by fertility clinics utilizing ART.\textsuperscript{146} While the Fertility Clinic Success Rate and Certification Act provides some basic (but voluntary) reporting of clinics’ advertising claims, the federal government has thus far not attempted to effectuate mandatory regulation of the fertility industry’s use of ART in the United States.\textsuperscript{147}

State regulation of ART is similarly undeveloped, providing little substance to fill the void left by the absence federal

\textsuperscript{142} Id. at 701.
\textsuperscript{143} See KINDREGAN & McBRIEN, supra note 38 at 220; see also Richard Merrill, Human Tissues and Reproductive Cloning: New Technologies Challenge the FDA, 3 HOUS. J. HEALTH L. & POL’Y 1 (2002).
\textsuperscript{144} See FDA Obstetrical & Gynecological Devices, 21 CFR § pt. 884 (2013).
\textsuperscript{145} 42 U.S.C. § 263a (2012).
\textsuperscript{146} See id. (laying out the requirements for certification as a “laboratory”); 42 U.S.C. § 263a-1 (providing the standards for reporting pregnancy success rates to the CDC).
\textsuperscript{147} See KINDREGAN & McBRIEN, supra note 38, at 97, 221.
legislation. Most states have not attempted to regulate the fertility industry’s use of ART or its advertisement. However, a few states have taken a more aggressive approach, enacting statutes that govern issues such as insurance coverage and disclosure requirements. Virginia, for example, requires fertility clinics to disclose a variety of success metrics to patients before performing fertility treatments. However, noticeably absent from the statute is any specific, mandatory disclosure of the health risks associated with fertility drugs, IVF, or ICSI.

Presumably, the general tort law doctrine of informed consent would operate to require disclosures regarding risks, but it is far from obvious whether proper disclosures and truly informed consent are occurring under the current lax regulatory regime. In 1996, a joint council of the American Medical Association (AMA) issued a report that identified several serious ethical violations within the practice of assisted reproduction. The report characterized these violations as “subtle deception” and noted that “deceptive advertising and insufficient informed consent are probably the most common manifestations of this type of ethical violation.” The report recommended stricter adherence to ethical guidelines and increased self-regulation but stopped short of calling for a legislative solution to the unethical practices plaguing the industry. Nonetheless, despite the absence of legislation, some patients have been able to maintain causes of action against clinics employing deceptive marketing under more general consumer protection laws.

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148 Id. at 217.
149 Id. at 98 (discussing a varied patchwork of state regulation regarding insurance, written parenthood agreements, and counseling requirements).
150 VA. CODE ANN. § 54.1-2971.1 (2014) (requiring disclosure of live birth success rates, pregnancies per completed cycle, total number of live births, and testing protocols for gamete providers).
152 Id.
153 See Karlin v. IVF America Inc., 93 N.Y.2d 282, 712 N.E.2d 662 (1999). The advertising also plays on infertile parents’ fear of “not doing everything they can” to have a baby of their dreams. For example, Seattle Reproductive Medicine regularly runs radio ads featuring a woman who is “partly” worried about bills and expenses, but “all” of whom desperately desires a baby. The spot concludes with an ominous
In sum, legislation addressing the concerns raised by assisted reproductive technology has not been forthcoming, and today the United States is unquestionably a “guideline” country. The majority of existing assisted reproduction regulation takes the form of professional guidelines published by the American Society for Reproductive Medicine (ASRM). While the ASRM guidelines cover a variety of important issues relating to both sound clinical and ethical practice, they have nonetheless faced criticism from commentators. Perhaps the most poignant criticism is that the guidelines have no teeth. They do not provide any approved protocols that must be followed; in fact, adherence to the guidelines is voluntary, subject to the discretion of the individual physician. As such, the usefulness of ASRM guidelines to mitigate the negative effects of the profit motive is suspect at best.

The only real avenue of enforcement for ASRM guidelines is through a process of clinical certification. The United States Society for Assisted Reproduction (SART), a subsidiary of ASRM, operates a certificate program for clinics that adhere to ASRM minimum guidelines, maintain high ethical standards, and report annual data to SART. However, there is no requirement that a clinic be SART-certified to operate in the United States. As a result, while SART can revoke its certification from rogue clinic, that clinic may continue to operate and many customers would never notice the difference. Roughly 10% of all fertility clinics in the United States are not SART-certified. Thus, consider

sounding male voice implicitly warning infertile individuals that despite their other valid concerns, they will live to regret a decision not to pursue assisted reproductive technology.

154 See Lyerly, supra note 101, at 702.  
155 See AM. SOC’Y FOR REPRODUCTIVE MED., PRACTICE COMMITTEE DOCUMENTS, http://www.asrm.org/Guidelines/ (last visited Dec. 18, 2013) (“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.”).  
157 Id.
that while the ASRM recommends that no more than two embryos be implanted in a woman younger than 35, there is no explicit mechanism to compel adherence to this guideline and it is frequently violated. This is hardly the robust “written commitment to ethical principles” envisioned by the 1996 AMA joint committee as the optimal self-regulatory solution to ethical lapses in the practice of assisted reproduction. Moreover, it highlights the shortcomings of guidelines as an effective regulatory mechanism to protect patients. Finally, as one commentator pointed out, even if the guidelines were enforceable, they are directed toward the fertility profession and do not enjoy any input from the public or disciplines outside of law and medicine.

B. FOREIGN APPROACHES

Many other countries have taken a much more aggressive approach to the regulation of assisted reproductive technology (ART). A 2010 survey conducted by the International Federation of Fertility Societies examined ART regulation in 107 countries and found that 42% employed legislative regulation of assisted reproductive technologies. This proportion had previously been larger, but the first time inclusion of many developing countries in the 2010 survey likely resulted in the change. Over forty countries, including most of Europe, had enacted specific legislation regulating the use of ART. Twenty-five countries, including the United States, have only voluntary guidelines in place. Two-thirds of the countries that have enacted legislation have some version of licensing requirement, and many are quite stringent. For example, in Australia, the penalty for operating a non-accredited facility is up to ten years in prison, a far cry from the voluntary certification requirements imposed by SART in the United States.

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159 AM. MED. ASS’N COUNCIL ON ETHICAL & JUDICIAL AFFAIRS & COUNCIL ON SCI. AFFAIRS, supra note 151.
160 See Lyerly, supra note 101, at 702.
161 See Jones, et al., supra note 156, at 12.
162 Id. (discussing the inclusion in the survey of developing countries, many of which had little or no regulation on the use of ART).
The United Kingdom has perhaps the most well developed system of ART regulation and should be used as a model for what is necessary in America. The Human Fertilisation and Embryological Authority (HFEA) has several key responsibilities, including issuing licenses to IVF clinics and establishments carrying out embryo research. It also regulates the storage of gametes and embryos, and implements the directives of the European Union relating to ART. The HFEA requires that before a license will be issued, all clinics must demonstrate that they can comply with a Code of Practice. The Code is frequently updated and covers “all details of the clinical and embryological practice associated with assisted reproductive technology.” While at first glance this might seem similar to the American system of guidelines, consider that in the U.K. licensure is mandatory and that clinics cannot operate “outside” the code. In addition to the independent HFEA, the National Institute for Health and Clinical Excellence, part of the National Health Service, publishes guidelines for providers to compliment the regulations promulgated by the HFEA.

Comparison of ASRM guidelines for the U.S. and NICE guidelines for the U.K. reveals that the ASRM guidelines allow for the transfer of greater numbers of embryos to women undergoing IVF than their NICE counterparts. For a woman’s first cycle, the ASRM recommends the transfer of one to two high quality cleavage stage embryos for women under 35, two for women 35-37, three for women 38-40, and five for women 41 and older. If the patient has already gone through one unsuccessful cycle, the ASRM then recommends two embryos for women under 35, three for women 35-37, four for women 38-40, and five for women over 41. This is in stark contrast to the much more conservative

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163 See Who We Are and What We Do, Our Role as Regulator, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY (HFEA), http://www.hfea.gov.uk/135.html (last updated Dec. 5, 2013).
164 See Jones et al., supra note 156, at 10.
167 Id.
approach favored by NICE. NICE recommends that in the first cycle of treatment, clinics transfer only one embryo for women under 37.\footnote{See NICE, supra note 163, at 10-11.} Even after an unsuccessful cycle (or two), the NICE guidelines strongly suggest transferring only a single high quality embryo, and never more than two. For older women, the NICE guidelines are similarly conservative, and in no case suggests that more than two embryos be transferred. This far more conservative approach to IVF is an explicit attempt by the British Government to decrease the incidence of costly multiple births.\footnote{See Bazian, New NICE Guidelines for NHS Fertility Treatment, NATIONAL HEALTH SERVICE (Feb. 20, 2013), http://www.nhs.uk/news/2013/02February/Pages/New-NICE-guidelines-for-NHS-fertility-treatment.aspx (“The NICE guidelines also include new recommendations on the number of fresh or frozen embryos that should be transferred to a woman’s womb, these are designed to reduce the risk of multiple births following IVF.”).} As multiple births are significantly more costly than singletons,\footnote{See supra Part II, The Downside of Success.} this is an issue of obvious importance in a socialized healthcare system and is also especially relevant given that, on average, Europeans use ART services at twice the rate of Americans.\footnote{See Norbert Gleicher et al., A Formal Comparison of the Practice of Assisted Reproductive Technologies Between Europe and the USA, 21 HUMAN REPRODUCTION 1945 (2006).} Some European countries, for instance Germany, set explicit legal maximums on the number of embryos that may be transferred in an IVF procedure and consider breach of the law a felony violation.\footnote{Id. at 1946 (citing Embryonenschutzgesetz [ESchG] [Act on the Protection of Embryos], Dec. 13, 1990, Bundesgesetzblatt I [BGBL] at 2746 (Ger.)).}

Given the differences in legal and regulatory environment, it is not surprising that researchers have compared ART outcomes between Europe and the United States. In particular, a recent study published in the Journal of Human Reproduction explored why IVF patients in the United States have significantly higher rates of clinical pregnancy and delivery than European patients.\footnote{Gleicher et al., supra note 171, at 1947 (finding that clinical pregnancy rates in the U.S. were 32.8% per cycle start in the U.S. and only 24.3% per cycle start in Europe).} The study confirms that clinics in the United States transfer a greater number of embryos per ART cycle than their European counterparts.\footnote{See supra note 171.
counterparts. Specifically, Europeans were far more likely to receive a single or double embryo transfer than patients in the U.S. Americans, by contrast, were nearly twice as likely as Europeans to receive three or four embryos. Perhaps unsurprisingly, the study’s data also shows that multiple pregnancies were also far more common in the U.S. However, the study’s authors note that the increased number of embryos transferred does not alone explain the differences in clinical pregnancy rates between the two continents. Nonetheless, the authors conclude there are substantial differences in the practice of ART between the continents, and “[t]hese differences appear primarily driven by greatly diverging regulatory environments on both sides of the Atlantic and, at least based on pregnancy rates, do not appear to benefit the European population.” However, some commentators have been critical of this conclusion, noting specifically Europe’s reduced rate of multiple pregnancies evidences the substantial benefits of increased regulation of ART.

While the United States may never elect to regulate reproductive technology to the same extent as witnessed in Europe, the current regulatory void and lack of meaningful oversight has contributed to a “wild west” mentality at some IVF clinics. In this environment the profit motive reigns supreme, breeding conflicts of interest between clinics and patients, institutionalizing practices of subtle deception, and contributing to the health crisis of multiple births. A well-functioning free market for ART services depends upon consumers having the best possible information to make informed treatment decisions and avoid negative outcomes. To the contrary, the current regulatory system in the United States has failed to ensure the integrity of the

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174 Id. (“The study confirms that the US transfers more embryos than Europe (Table IV). Indeed, only 33.5% of U.S., and 63.7% of European, cycles received one or two embryos. In contrast, almost twice the number of patients had three or four embryos transferred (66.4%) in the US than in Europe (36.3%).”).
175 Id. (“[M]ultiple pregnancies were significantly more frequent in the US (38.6%) than in Europe (25.5%).”).
176 Id.
177 Id.
informed consent process and has not adequately addressed the growing burden of multiple births. The existing patchwork of voluntary guidelines, state law, and limited federal oversight is not sufficient to ensure the fertility market remains free, fair, and safe for the 21st century.

IV. RECOMMENDATIONS FOR LAW AND POLICY REFORM

It has become clear that the meteoric rise of assisted reproductive technology has vastly outpaced the development of a cohesive legal framework. The increasing use of IVF, ICSI, and other ART procedures raises important and often emotional issues that deserve considered legal and policy solutions. ART is here to stay, and it seems likely that the technology will play an increasingly important role in human reproduction in the future. As this groundbreaking technology continues to advance, the law must keep pace. The current state of lax self-regulation and patchwork state law is ineffectual at mitigating the conflicts of interest created by profit motive. Conceiving a child is an emotional rollercoaster for infertile couples; as they look for hope in an otherwise bleak situation, they may be especially vulnerable to the methods “subtle deception” that sparked the concern of the AMA back in 1996. But what can law accomplish, and, perhaps more importantly, what should new regulation of ART look like?

There are several distinct areas of ART that might benefit from increased oversight and regulation, but two issues deserve special attention because existing regulation in both has been insufficient to mitigate conflicts of interest in the profit driven fertility industry.

A. DEALING WITH COMPLICATIONS RAISED BY MULTIPLES

First, we must address the oft-written about problem of multifetal pregnancies as a result of ART. This topic has received much attention over the years from commentators and is an area where many European countries have pursued expanded

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Some commentators have called for increased regulation of ovulation-inducing fertility drugs and have even gone so far as to suggest their complete prohibition. Another outside-the-box idea might be the implementation of a tradable “permit system” for multiple pregnancies, something akin to the cap and trade system used for pollutants but where the number of multifetal pregnancies would be capped and clinics could purchase permits that would allow it to provide treatments likely to result in multiple pregnancies. This system, Richard Hawkins suggests, would force interested parties to internalize the costs of their reproductive choices and, as a consequence, reduce the incidence of multiple births and their externalities to the health care system. Still others have suggested a federal law that would codify embryo transfer limits in the provision of infertility care. Such a law would likely resemble the mandatory embryo transfer limits present in some foreign countries. However, the true goal of any new regulation in this area must be to mitigate or displace the incentive structure that pushes for-profit clinics to produce pregnancies regardless of the risks of a multiple pregnancy.

B. Influencing the Choice of ART Method

The second major area deserving regulatory attention is the choice of reproductive technology to be utilized by a patient. This issue is of special importance given the meteoric rise of ICSI and the abundance of research that suggests the procedure may carry

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180 See Part III.B, supra (discussing the more stringent regulatory environment in Europe and the continent’s propensity to employ measures to combat the increasing incidence of multiple pregnancies).

181 See Lars Noah, Assisted Reproductive Technology and the Pitfalls of Unregulated Biomedical Innovation, 55 FLA. L. REV. 603, 664 (2003) (“[A]n effort to further restrict or entirely prohibit the continued marketing of fertility drugs may offer a simpler and more effective (though no less controversial) approach to the problem of multifetal pregnancies.”).


183 Id. at 753.

greater risks to future children than more traditional methods of IVF. However, the issues deserving of attention here are even broader. At least one commentator, Anne Drapkin Lyerly, has suggested a need for a significant revaluation of how research is performed in the ART field. Specifically, Lyerly notes that the challenges of regulating ART innovation are separate and distinct from those of regulating the practice of ART. She proposes that the requirements for informed consent be both clarified and standardized, including explicit disclosure and separate requirements for participating in research versus standard clinical procedures. A clear and standardized system for obtaining informed consent would be of significant benefit to clinical practice and would go a long way to ameliorate the practices of subtle deception that undoubtedly still plague the profit-driven fertility industry. Any law effecting a standardization of disclosures to ART patients should also mandate full disclosure of (1) the for-profit nature of the fertility clinic, and (2) the potential conflict of interest between the clinic (in its desire to post high pregnancy and birth rates) and the patient who desires a healthy, and likely, singleton baby.

C. Is Regulation a Panacea?

Finally, it should be noted that not all commentators agree that increased regulation of ART is desirable. In fact, Professor Kerry Lynn Macintosh has expressed significant reservations about restricting access to ART, warning that advocates of increased public oversight “have failed to recognize the eugenic implications of acting to “protect” children from their own existence.” She worries that regulation of “conventional” technologies like IVF

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185 See supra Part II, The Downside of Success.
186 See Lyerly, supra note 101, at 708 (“The challenges of regulating innovation in ARTs are distinct from those of regulating the practice of ART and need their own solutions.”).
187 Id. (“[R]equirements for informed consent should be both clarified and standardized. They should include guidance about the distinct differential requirements for consent to participating in research versus consent to participating in clinical practice that necessarily includes inadequately tested though standard procedures.”).
and ICSI could have serious eugenic implications, relegating an entire class of people to perpetual childlessness. 189

D. MANDATED DISCLOSURE AND THE REGULATION OF ICSI

ICSI has transformed assisted reproduction by allowing infertile men the chance to reproduce. However, with a great advance in technology comes the risk of its misuse. ICSI’s success at producing live births comes with downsides and as ICSI becomes the mainstay of fertility clinics across the nation, it is imperative that clinics adequately counsel patients on the risks of the procedure lest patients misconceive ICSI’s popularity for its safety.

Specifically, full and clear disclosure of recent research on ICSI’s risks compared to alternative treatment methods is necessary to provide truly informed consent. While this life-giving advance has helped countless parents over the last twenty years, the increasing evidence of its dangers should counsel prudence for both patients and doctors. Today, researchers agree that the full disclosure of ICSI’s risks, both for birth defects and for less obvious long term genetic problems, should be fully disclosed to potential patients. 190

However, the rapid takeover of the assisted reproduction market by ICSI raises the possibility that consumers may not currently be operating with full information, raising the specter of inadequate

189 Id. ("That public eugenics should reemerge in the twenty-first century, speaking solemnly about the welfare of children, should give us all serious pause. Whatever the dangers of ART may be, they are nothing compared to the power of the state to relegate a class of disabled persons to childlessness based on the prejudgment that the lives of their offspring are not worth living. Such discrimination betrays our core values and must not be tolerated.").
190 See, e.g., Katalinic et al., supra note 114, at 1613 (discussing the need to counsel couples that there is an increased risk of complications in pregnancy course, pregnancy outcome, and a risk of major malformation); The Practice Comm. of the Am. Soc’y for Reproductive Med. & The Practice Comm. of the Soc’y for Assisted Reproductive Tech., supra note 97, at 104 (“Only those fully apprised of the risk for transmitting a genetic defect and its potential effect on their offspring should be offered ICSI.”); Davies et al., supra note106, at 1812 (“[O]ur findings can help provide guidance in counseling patients who are considering treatment for infertility.”).
informed consent. While the most recent 2011 data from CDC shows that in United States 67% of IVF cycles involved ICSI, that number may be much higher in certain states or at individual clinics. For example, in some U.S. states like Arizona, nearly three quarters of fertility clinics utilize ICSI more than 90% of the time. While it is not impossible that ICSI’s extensive use simply reflects consumer preferences, it seems more plausible that many consumers are simply unaware of the most recent research into the unique risks of the ICSI procedure.

Many experts in the field, including ICSI’s inventor Andre Van Steirteghem, argue that in light of the risks, ICSI should be reserved only for when absolutely necessary. In their view, ICSI must not be the first choice for helping infertile couples become parents; instead, it should be a tool used only when absolutely necessary. Thankfully, ICSI’s overuse has not gone entirely unnoticed and recently appears to have attracted the scrutiny of regulators in the U.K. According to the Independent, Lisa Jardine, who chairs the U.K.’s Human Fertilisation and Embryology Authority (HFEA), believes that some IVF clinics are using ICSI simply because it is “easier and has a lower chance of fertilization failure than standard IVF, rather than because it is in the best interests of patients.” In Britain, data collected by the HFEA shows that 30% of ICSI cycles are not related to male infertility – even though male factor infertility was the driving force behind its invention. In addition, Allan Pacey, the chairman

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192 See, e.g., Ctrs for Disease Control & Prevention, supra note 132 (showing that seven out of Arizona’s ten fertility clinics utilize ICSI in more than 90 percent of all IVF cycles).
193 See Urner, supra note 126 (quoting Allan Pacey, IVF specialist the University of Sheffield, as stating that ICSI should be used only when absolutely necessary); Brooke Hodes-Wertz et al., Is Intracytoplasmic Sperm Injection Overused?, 187 J. of Urology 602 (2012) (“Although intracytoplasmic sperm injection is one of the greatest advances in our field, it is overused and should only be done for clinically proven indications.”).
194 See Urner, supra note 126.
196 Id.
of the British Fertility Society, has also sought to confront the procedure’s overuse, suggesting that in light of ICSI’s risks, it should be used only “when it’s needed, and not as some kind of guarantee against fertilization failure, which is how some clinics approach it.” In a similar vein, a group of researchers recently concluded that not only are more stringent criteria desirable to combat ICSI’s overuse, but that reserving the procedure for proven applications may not negatively affect pregnancy outcomes. Regardless, patients undergoing treatment for infertility deserve full disclosure of the risks for the procedures they elect to undertake.

Jennifer Jurinczuk captured this sentiment succinctly in a 2003 piece for the Journal of Human Reproduction:

>Pregnancy is something of a lottery for all couples. However, compared with couples who conceive spontaneously, for those who require IVF or ICSI the lottery is weighed more heavily against a successful outcome at every stage of the process, not just conception. This is the reality alongside the hope that must be conveyed at counselling to all couples contemplating treatment. Indeed this counselling must be sufficiently detailed to ensure that, whilst the ICSI procedure itself is regarded as a routine procedure in most IVF clinics, prospective recipients do not equate routine with being completely safe and completely risk-free for their offspring.

E. MOVING FORWARD INTO THE FUTURE

In sum, there is no silver bullet to combat infertility. IVF technology has come a very long way and provided an entire

197 Id. (quoting Allan Pacey, Chairman of the British Fertility Society)
198 Hodes-Wertz et al., supra note 193 (concluding that more stringent criteria for ICSI do not compromise clinical outcomes and as such ICSI should be reserved for proven applications).
generation of adults the chance to start a family, but it remains a somewhat risky endeavor. Regulations that ensure the full disclosure of the multitude of risks that come with assisted reproduction are a critical starting point in bringing ART regulation into the 21st century and ensuring that patient consent is truly informed.

To start, significant reforms must be made to the current patchwork of laws governing the use of ART in the United States. ART has evolved at such a breakneck pace that it has far outgrown the system of voluntary self-regulation and reporting as it currently exists. Moreover, the patchwork of state law regulating ART is far from sufficient and does not supplant the need for nationwide standards. Remedying the conflicts of interest that have become ensconced in the practice of ART will take a concerted effort by lawmakers and healthcare regulators and cannot be expected to occur without some form of governmental intervention. While the exact form of governmental intervention should take remains a topic for discussion, as ART business booms the need for clear ethical and practice standards grows ever more pressing. But what will regulation of ART in the United States look like?

i. FEDERAL OVERSIGHT

One possibility is that the threat of statutory regulation might be enough to coerce the fertility industry to better self-regulate. At least one commentator has suggested that the threat of federal legislation on embryo transfer limits might prompt the SART and the ASRM to adopt “more stringent restrictions with greater consequences for noncompliance.” 200 In that situation, the option of direct regulation would always remain on the table if the threat alone did not lead to the desired outcome. 201 Such an approach could also be successful in other areas of ART regulation. For instance, the threat of explicit federal regulation of the informed

200 Lyria Bennet Moses, Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization, 6 MINN. J.L. SCI. & TECH. 505, 617-18 (2005) (“To create stronger restrictions on multiple embryo transfer in the United States than exist at present, one could either regulate the practice directly or threaten such regulation, hoping to encourage ASRM and SART to adopt more stringent restrictions with greater consequences for non-compliance.”).

201 Id. at 618 (“Direct regulation will remain as an option if the threat proves to be ineffective.”).
consent process might prompt ASRM and SART to standardize the system of informed consent and better police the disclosure practices of clinics. The threat of legislative action has been effective in other countries; it was this sort of regulatory threat that led to the creation of the Voluntary Licensing Authority in the U.K.\(^{202}\)

Regardless, some form of increased federal oversight of the informed consent process is likely necessary to ensure that patients are able to make their own decisions about innovative procedures with full knowledge of the risks and benefits. Clinics should also be required to disclose to patients both their for-profit nature and the potential conflict of interest between the patient and a clinic seeking higher pregnancy and birth rates. Disclosure is of special importance with regard to novel procedures like ICSI. Despite its widespread use, a growing body of research strongly suggests ICSI carries increased risks for children as compared to traditional IVF; any reform of the informed consent process should mandate full disclosure of these risks to prospective patients. Finally, while the ASRM guidelines are a solid foundation for a strong self-regulatory regime, they need stronger, federal enforcement mechanisms to be successful in mitigating the perverse incentives created by the pursuit of profit.

\section*{ii. Mandatory Clinic Certification}

Eliminating the ability of ART clinics to operate without SART certification would go a long way to ensuring compliance with the ethical and practice guidelines promulgated by the ASRM.\(^{203}\) Such a move would protect a doctor’s discretion for individual patients’ treatment plans, but would also ensure that clinics do not systematically operate outside the accepted ethical norms of the industry.

A strong and enforceable clinic certification system is perhaps the best option for addressing the conflicts of interest and ethical shortcomings that have long haunted the fertility industry. With

\(^{202}\) Id. at 617 (citing Michael Mulkay, THE EMBRYO RESEARCH DEBATE: SCIENCE AND THE POLITICS OF REPRODUCTION 57-58 (1997)).

\(^{203}\) See Jones et al., supra note 156 (describing the SART certification process, enforcement of ASRM guidelines, and the ability of clinics to operate without SART approval).
mandatory certification come clear and enforceable rules that apply the ethical norms of the industry to all clinics. Eliminating the ability of the IVF clinics to ignore ASRM embryo transfer guidelines is a reasonable first step in addressing the rising costs of multiple births in the United States. Similarly, conditioning clinic certification on the implementation of a standardized and robust informed consent process would add additional protection for patients and prevent clinics from sugar coating the risks of ART procedures. Whether the ASRM would be up to the task of significantly strengthening its current SART certification system remains to be seen, but mandatory certification of ART clinics, either through the ASRM or through a federal agency, is a sensible way to start regulating ART in the 21st century.

There are likely dozens of other possible details to work out, but the most important detail of all is that it is well past time for meaningful government intervention in the ART industry.

V. CONCLUSION

The drive to reproduce is at the center of human beings’ survival on this planet. Sadly, not all individuals are born equally capable in this quest. For those that desperately desire children but cannot have them on their own, the remarkable growth of assisted reproductive technologies over the past few decades has been a transformative innovation. Some ten million babies now inhabit the earth because of unbelievable breakthroughs in reproductive technology.

All pioneering advancements eventually create challenges and can lead to potential abuses if left unchecked, however. Today, thousands of would-be parents are spending their life fortunes on ART without being adequately informed of all the benefits and all the risks. The dramatic increase in the use of ICSI during IVF procedures is of particular concern, since modern medicine is now capable of fertilizing eggs with sperm that would have failed nature’s natural selection process on their own. IVF providers face little incentive to impress these risks on their customers, and operate in a largely unregulated environment in which cash is king. The incentive to report high live birth rates dictated by the profit motive pushes clinics to implant more embryos than
necessary, and recommend technologies that may increase births despite the fact that they increase defect rates.

Law and regulation have lagged far behind technological advances in this arena. Their absence has contributed to a “wild west” mentality in some fertility clinics, where anything goes if it will make money. It is now past time we act to change that reality. At a minimum, stricter federal regulation of the fertility industry is necessary to preserve its benefits while mitigating its risks. Truly informed consent can only be achieved when patients know exactly what they are getting themselves into. Legislation or regulation mandating specific information disclosures is necessary, because our current system of voluntary guidelines lacks teeth and viable enforcement mechanisms. Mandatory fertility clinic certification would also ensure that all enterprises are operating on a level playing field, and that patients receive standardized information regarding risks and outcomes.

We are living in a transformative time in the history of human reproduction. With common sense regulation, we can ensure that the miracle of parenthood will be available to millions more would-be parents in generations to come.