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Regulation (or Lack Thereof) of Assisted Reproductive Technologies in the U.S. and Abroad

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Among developed nations, the U.S. assisted reproduction or fertility industry is one of the least regulated. This has led to a reproductive free-for-all. Any technological means, regardless of the medical and ethical consequences, can be utilized in the pursuit of parenthood if the price is right. Arguments that this industry is effectively self-regulated fall flat in the face of evidence which suggests otherwise.¹ While many of the 400-500 clinics offering assisted reproductive technologies (ART) in the U.S. are members of professional organizations such as the Society for Assisted Reproductive Technology (SART) or the American Society for Reproductive Medicine (ASRM) and follow clinical and ethical guidelines produced by these organizations, the majority do not. A Centers for Disease Control and Prevention study found that only 20% of ART programs follow such guidelines.² As the “Octomom” (Nadya Suleman) case publicly demonstrated, there is no legal detriment to clinicians engaging in clinical or ethically dubious practice.³ Not surprisingly, the U.S. has high rates of multiple pregnancies, which are associated with astronomical healthcare costs and more importantly serious risks to the health of both mother and child. Many European countries have recognized these risks and have moved to legally restrict the number of embryos transferred per reproductive cycle. Additionally, many of these countries have moved to limit some practices that are ethically problematic, such as the use of third-party donor gametes and surrogacy. These legal changes have resulted in a significantly different situation than the current state of the ART industry in the U.S. Additional regulation is needed, whether it be at the state or federal level, to provide additional safeguards.

Multiple Gestations

The U.S. has one of the highest rates of multiple births in the world. This rate is directly attributed to the increased use of ART in achieving pregnancy. In 2003, for example, 31% of pregnancies conceived using *in vitro* fertilization (IVF) were twin gestations and 3% were triplets or higher order gestations. Only 1% of spontaneous pregnancies are multiple gestations.⁴ The health risks of multiple pregnancies to both mother and child are well documented. Women carrying multiple embryos are at a higher risk of pregnancy complications including high blood pressure, preeclampsia, anemia, post-partum hemorrhaging, and increased risk of miscarriage. While multiple gestations account for only 3% of all live births in the U.S., they are responsible for 23% of early preterm births (delivered before 32 weeks) and 26% of very low birth weight infants (less than 1500 g or 3 pounds, 4 ounces). Excess hospital costs for multiple births resulting from IVF cycles is estimated to be \$640 million per year in the U.S.⁵ Multiple pregnancies also have a higher mortality rate (including still birth and neonatal deaths) compared to singletons. It has been calculated that the mortality rate for twins is seven times greater than singletons, whereas triplet and higher order multiples is twenty times greater.⁶ Additionally, children from multiple pregnancies are at a higher risk of long-term medical and developmental problems including cerebral palsy and other neurological complications.

The U.S. is lagging behind European efforts to limit the number of multiple pregnancies following ART. Germany, Italy, Spain, and Switzerland have enacted regulations limiting the number of embryos transferred in one reproductive cycle to 3. In Italy, however, limiting the number of embryos transferred to 3 has actually increased rates of multiples due to the prohibition of embryo cryopreservation, encouraging women to transfer multiple embryos as a means of increasing pregnancy (50.4% of ART cycles involved the transfer of 3 embryos in 2005).⁷ The prohibition of embryo cryopreservation has caused the fertility industry in Italy to become a leader in improving methods of egg cryopreservation, an alternative to freezing supernumerary embryos (otherwise referred to as “excess” or “spare” embryos).⁸ The Human Fertilization and Embryo Authority in the United Kingdom limits the number of embryos to a maximum of 2 for women under 40 years and 3 for women over 40. As a means of contrast with actual practice, approximately 43% of ART cycles in the U.S. involved the transfer of 3 or more embryos. In 0.5% of ART cycles, 7 or more embryos were transferred.⁹

More recently, the trend in Europe has been to transfer a single embryo per reproductive cycle (*i.e.*, “single embryo transfer” or SET), particularly in Scandinavian countries. Typically a fresh embryo is transferred in the first cycle and single cryopreserved embryos are transferred in subsequent cycles. The pursuit of SET does not eliminate the ethical issues surrounding the fate of surplus embryos or embryo destruction from the freeze/thaw process of cryopreservation, but is ethically preferred to multiple embryo transfer due to the reduction of maternal and fetal health risks associated with multiple pregnancy. Countries such as Belgium and Sweden that have regulations requiring the transfer of singleton embryos for initial ART cycles have seen a marked decrease in multiple births since SET practices were adopted. Clinical studies following SET programs have demonstrated a drop in multiple pregnancies from approximately 30% to 10%, while still achieving high overall pregnancy rates.¹⁰ Sweden has maintained an unchanged delivery rate while decreasing the multiple pregnancy rate to under 10% since enacting SET in 2003.¹¹ These statistics demonstrate that the transfer of multiple embryos is not necessary to achieve a high pregnancy or delivery rate.

In addition to decreasing the health risks inherent in multiple pregnancies, single embryo transfer may be more successful and cost effective than multiple embryo transfer. The transfer of multiple embryos in a single reproductive cycle gained notoriety as a cost saving measure by increasing pregnancy rates. In the U.S., the average cost of a standard IVF cycle is approximately \$12,500 USD, substantially higher than the majority of international ART programs. In comparison, a standard IVF cycle is \$8,500 in Canada, \$6,534 in the United Kingdom, \$5,645 in Australia, \$5,549 in Scandinavia, and \$3,956 in Japan (all USD 2006).¹² Due to the expense of IVF in the U.S., patients and their physicians strive to achieve pregnancy in the fewest cycles possible. Many patients also prefer to conceive twins as a means of achieving their desired family size as quickly as possible due to time or financial concerns. Some parents simply have a preference for twins over singletons.¹³ These patients may not be aware of the increased health risks and the exponential healthcare costs associated with multiples.

New research has demonstrated that transferring a single embryo at a time may be as effective in achieving pregnancy as transferring multiple embryos at once.¹⁴ While it may take more cycles to achieve pregnancy with the transfer of single embryos than the transfer of multiple embryos, SET drastically reduces the financial burden associated with multiple gestations and it also reduces the maternal and fetal health risks thus increasing the live birth rate. Without some form of subsidization, however, IVF may initially be more expensive for SET patients due to the repeated cycles. These repeated cycles may also pose additional health risks for women associated with controlled ovarian hyperstimulation if eggs or embryos are not cryopreserved. In countries where IVF is partially or completely covered by insurance or governmental health programs (e.g., Australia, Sweden), there is less financial pressure to obtain pregnancy in the fewest cycles possible. This has resulted in both greater utilization of ART and a decrease in the overall rate of multiples.¹⁵ Belgium in particular is unique in the fact that it explicitly links public funding for ART with good clinical practice. In order to receive federal funding, patients and their physicians must subscribe to established limits on the number of embryos transferred in one cycle. From a societal perspective, SET greatly reduces the overall financial burden to the healthcare system due to the reduction of medical complications associated with multiples. Belgium has calculated that the money they have saved by avoiding half of the multiple pregnancies finances all IVF and intracytoplasmic sperm injection (ICSI) in one year.¹⁶

It is imperative that the U.S. follows the lead of European countries and takes measures to reduce what has rightly been called an epidemic of multiple births. In doing so, the serious maternal and fetal risks involved in multiple pregnancies will be significantly diminished. Decreasing multiple births will also have a societal benefit, by reducing the overall financial burden on the healthcare system. The media attention given in the U.S. to high order multiple births following ART can be misleading. Multiple gestations often end in tragedy, not in celebrated successes. Given the advances of assisted reproduction it is no longer necessary to place women and their children at risk of developing serious, lifelong, and in many cases deadly, medical complications through the transfer of multiple embryos.

Encouraging Ethical Practices

In addition to the inherent health risks involved in current U.S. ART practices, the U.S. permits many ART practices considered by many to be ethically problematic, specifically the use of donor gametes and surrogacy. This is in contrast to several of the G12 countries, which more strictly regulate such practices and in many cases restrict their utilization. In the U.S., egg and sperm donors can be commercially compensated for their donation, a practice that lends itself to coercion of donors and makes the term “donation” somewhat of a misnomer. This has led to high-paying advertisements¹⁷ for egg donors in college newspapers and more recently through social networking sites such as Facebook, targeted as a way for young women to earn money by “giving the gift of life.” This trend is especially alarming given the serious medical risks associated with the process of egg donation, including risks of infection and ovarian hyperstimulation syndrome.¹⁸ Sperm donors are traditionally medical students who are given a small compensation (\$30-100 USD) per donation. Many clinics do not place limits on the number of times sperm donors can donate or the number of children that can be conceived from a single donor, even though the American Society for Reproductive Medicine suggests a general limit of 25. It is not uncommon for the sperm from a single donor to be used to conceive dozens of children or more. This has caused concern, particularly in countries with smaller populations and communities that frequent a select number of sperm banks, that half-siblings may grow up as neighbors or in rare cases may unwittingly date or marry each other. Additionally, there are concerns that sperm donors, even though screened, will pass on rare genetic disorders as is the case of a 22 year old donor who passed on a rare genetic heart disease to 9 of his 24 known offspring, 22 of which were the result of sperm donation.¹⁹ The protection of donor anonymity and lack of a central registry tracking donors and their offspring has made contacting potentially affected offspring difficult and in many cases impossible.

Many have suggested that egg and sperm donation is analogous to “half-adoption,” a wonderful means of providing a child to an infertile couple. The experience of children conceived through donation suggests otherwise. A recent study by the Institute of American Values comparing the psychosocial well being of offspring from sperm donation, adopted children, and biological offspring found that in many categories, donor offspring struggle with their origins and identity, are confused by who is a “real” member of their family, and are more likely to have substance abuse and legal problems compared to biological offspring.²⁰ Approximately half of donor offspring agree that they “feel sad” when they “see friends with their biological fathers and mothers” and 65% agree that their “sperm donor is half of who I am,” suggesting that donor offspring experience the loss of not knowing their biological parent and view their donor as contributing more to their identity than a haploid cell.²¹ A significant number (45%) of donor offspring are bothered by the fact that money was exchanged to conceive them. Registries such as Donor Sibling Registry exist to help connect donor offspring with their donor parents and half-siblings, helping donor offspring understand their origins and increasing their sense of family. Donor conceived offspring, however, tend to lose interest as the number of offspring of a particular donor increases.

The ethical issues surrounding egg and sperm donation have led countries such as Germany, Italy, Japan, and Switzerland to prohibit the use of donor eggs and sperm for assisted reproduction. In countries that allow egg and sperm donation, the United Kingdom, Switzerland, Sweden, the Netherlands, Germany, and certain parts of Australia prohibit donor anonymity. The loss of donor anonymity in these countries has resulted in an overall reduction of the number of donors willing to donate egg and sperm to ART programs. In Western Australia for example, it

has been reported that after anonymity was prohibited, only 35 sperm donors were available out of a population of 1.4 million.²² In the United Kingdom, the number of women treated with donor sperm dropped 20% in 2006, a year after donor anonymity was abolished.²³ Both Spain and the United Kingdom have limited the number of children that can be born from a single donor to 6 and 10, respectively. Australia, Belgium, Canada, the Netherlands, and the United Kingdom prohibit the commercial purchase of donor eggs and sperm, which is also believed to have led to a reduction in donors.

Like the use of donor eggs and sperm, surrogacy has serious ethical, legal, and social implications. The introduction of a third party in reproduction can complicate the relationships between all parties involved, including the relationship of the parents utilizing a surrogate, between the parent and child, and between the surrogate and the child they are carrying. This practice also treats the human body as a commodity, especially when some form of payment is exchanged for surrogacy services. Commercial surrogacy in particular, where a surrogate is given payment beyond covering expenses incurred from the pregnancy, can be coercive and exploitative of impoverished women. Even altruistic surrogacy can have a coercive element due to the encouragement of contracting parents to pamper their surrogates with gifts and vacations. It is also important to note that pregnancy can have serious medical complications, especially when multiple pregnancy is involved, which places the surrogate at risk for long-term complications, including infertility.

Additionally, surrogacy is legally problematic in terms of identifying the legal parents of a child born to a surrogate. Surrogacy can be genetic, meaning the surrogate donates the egg and is artificially inseminated by the contracting father, or gestational, meaning an embryo created by the contracting parents through IVF is transferred to the surrogate's uterus. Surrogacy complicates the matter of who should be granted legal parenthood: the intended or contracting parents, genetic parents, or birth mother. In the U.S., surrogacy is regulated at the state level. The majority of states do not have any statutes regulating surrogacy. Some states prohibit commercial surrogacy, whereas others do not recognize surrogacy contracts at all. The most permissive state regarding surrogacy is California, which grants legal parenthood to the intended parents. Due to the ethical and legal concerns surrounding surrogacy, France, Germany, Italy, Sweden, and Switzerland prohibit this practice. Spain does not outright prohibit surrogacy, but does not recognize surrogacy arrangements as valid and considers the birth mother to be the legal mother. Canada, the Netherlands, the United Kingdom, and some states in Australia prohibit commercial surrogacy. The prohibition or legal difficulty of arranging surrogacy agreements in these countries has increased local interest in overseas reproductive tourism in countries where surrogacy is legal, such as India and the U.S.

The goal of many ART clinics and their patients is to achieve a clinical pregnancy utilizing all available means, including the use of donor eggs/sperm and surrogacy. These practices, however, are ethically suspect at best. Egg donation and surrogacy in particular are exploitive of women and unnecessarily place women's health at risk, including their own fertility. The experiences and thoughts of donor offspring are seriously troubling and suggest that "the kids are not alright." Additional regulation is needed in order to limit or at the very least monitor the outcomes of using donor eggs and sperm, including the physical and psychological well-being of the donors, parents, and children involved. It would also be best to prohibit all forms of surrogacy due to the ethical and legal complications involved. Industry self-regulation, however, simply

does not work. The drive to have children and the opportunity for monetary gain makes a deadly combination. Steps must be taken to ensure that the health and safety of women and children are protected and do not take a backseat to the end goal of producing children.

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⁸ For more information see Kirsten Riggan, "Egg Cryopreservation: An Update on an Emerging Reproductive Technology," available at <http://www.cbhd.org/content/egg-cryopreservation-update-emerging-reproductive-technology>.

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¹⁰ Jan M.R. Gerris, "Single Embryo Transfer and IVF/ICSI Outcome: A Balanced Appraisal," *Human Reproduction Update* 11 (2005): 105-121. Pregnancy rates must be distinguished from live birth or delivery rates, which are typically lower than pregnancy rates. In other words, many women become pregnant after multiple embryo transfer, but not all deliver a live infant due to the increased risk of miscarriage and fetal death.

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¹⁴ Zdravka Veleva, et al., "Elective Single Embryo Transfer with Cryopreservation Improves the Outcome and Diminishes the Costs of IVF/ICSI," *Human Reproduction*, 24 (2009): 1632-1639.

¹⁵ Chambers, 2292.

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