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SAFETY AND ACCESS: IS THE UK REGULATORY MODEL RIGHT FOR AMERICA?

Jocelyn Sweet*

I. Introduction

The development and advancement of assisted reproductive technologies (ARTs) has created both hope and controversy. Infertile couples and individuals now have many choices when it comes to reproduction. At the same time these new technologies have created a huge industry that is in need of regulation. Ethical and financial issues are at stake. On the one hand, couples should have autonomy in deciding how to address fertility issues and start a family. On the other, it is important to ensure that fertility doctors and clinics are acting in the best interest of both the mother and the fetus and are following guidelines to ensure that procedures are being done in a safe and ethical manner. The question becomes: what is the best regulatory model given the ethical and safety issues at stake?

As with many health care issues, regulation of ART is driven by various ethical principles. The United States and Great Britain have approached the regulation of ART in starkly different ways. While the US has allowed fertility clinics and doctors to operate largely unregulated by law, the UK has passed laws to regulate almost all aspects of reproductive technologies.¹ These different policy choices have led to criticism on both sides and sparked varying opinions on whether the US should consider a more heavily regulated system. This paper will focus specifically on the regulation of fertility doctors, clinics, and research in each country. The first section addresses the history of regulating ART in the US and the UK and the current status of the law. The second section examines some of the more controversial regulatory issues, the approaches to regulation taken in each country, and how guidelines protect the health and safety of patients and fetuses. The third section addresses whether different regulatory practices lead to different outcomes in terms of access and fairness. Lastly, this paper discusses whether the US would benefit from more federal and state regulation of ART.

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II. Regulation in the United States

A. Federal Law

Regulation of fertility clinics and doctors in the US comes largely from independent professional societies, supplemented with some federal and state law. The Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA) requires fertility clinics to report pregnancy success rates,² and also requires states to develop and administer certification programs for embryo laboratories.³ As part of the certification program the law required, within two years of its enactment, that the Centers for Disease Control (CDC) "develop a model program for the certification of embryo laboratories to be carried out by the States."⁴ Embryo laboratories are defined as facilities in which human oocytes (eggs) or embryos are "subject to assisted reproductive technology treatment or procedures based on manipulation."⁵ Essentially, the laboratories, not the fertility doctors or clinics themselves, are certified under this program. The law also specifically states that in developing or adopting the certification program, neither the Secretary of the Department of Health and Human Services (HHS) nor the State could, "establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technologies."⁶

The CDC published its final notice of the "Model Program for the Certification of Embryo Laboratories" in the Federal Register in 1999.⁷ In deciding on a model, the CDC consulted with several groups, including the American Society for Reproductive Medicine (ASRM), the Society for Assisted Reproductive Technology (SART), and the College of American Pathologists (CAP).⁸ During the notice and comment period, there was some concern over whether to allow unannounced inspections due to the delicate nature of the work and concerns over patient confidentiality.⁹ The CDC believed that states adopting the model program should have the option of unannounced inspections, "so that investigations of complaints of truly egregious behavior could be conducted immediately and unannounced."¹⁰ There was also some disagreement over whether there should be mandatory minimums for training and performance of certain procedures. Some commentators argued that the laboratory director should decide "the adequacy of

each employee's training/experience."¹¹ The CDC disagreed, stating that its minimums were developed to be consistent with ASRM guidelines.¹²

The Model Certification Program provides requirements for State administration of the program, including minimum standards for agreements with laboratories and standards for the laboratories themselves.¹³ These standards include provisions on personnel qualifications and responsibilities, facilities safety, and quality management.¹⁴ Although the guidelines do provide a framework for States, the certification program is voluntary for both States and the laboratories themselves. The preamble states that, "[w]hile Congress anticipated that the cost of Federal and State monitoring and oversight of embryo laboratories would be covered by the fees paid by participating laboratories, participation . . . is voluntary and laboratories not willing to pay these fees would not be limited in their ability to operate."¹⁵ According to the Institute on Biotechnology & the Human Future, some states have based accreditation requirements on the Model Program, but no state has officially adopted it.¹⁶ The result is that there is no federal law mandating the licensing, accreditation, or inspection of fertility clinics or embryo laboratories in the US.¹⁷

B. State Law and Practice Guidelines

States have also attempted to regulate ARTs. Most state laws focus on insurance coverage of infertility treatment, a topic which will be discussed in detail in the third section of this paper. Some of these states have chosen to follow the federal approach of requiring disclosure of success rates. The focus is on consumer protection and ensuring that clinics are upfront about the chances that their services will result in a live birth. The main concern seems to be on cost-effectiveness for the consumer; i.e., what are the chances the investment will result in a baby? For example, in Virginia, physicians are required to disclose success rates for different age groups at the particular clinic or hospital for the ART procedure being performed.¹⁸ Laws like these contribute little to the federal regulations already in place.

Louisiana has some of the strictest and most comprehensive laws governing ART procedures and embryo disposition.

The laws specifically prohibit the sale of any embryo or ovum and the creation of a fertilized ovum solely for research purposes.¹⁹ The law also gives an in vitro fertilized human ovum status as a juridical person prior to implantation.²⁰ Patients are given ownership over embryos, but physicians are responsible for safekeeping.²¹ The law requires that facilities meet standards of both the American Fertility Society and the American College of Obstetricians and Gynecologists, and are directed by a licensed physician with specialized training in the field.²² The law also allows for adoptive implantation when the donor parents renounce parental rights, but no compensation can be paid or received.²³

Other state laws seem to be reactive rather than proactive, addressing specific situations as opposed to the broader picture. For example, in California, lawmakers sprang into action after a scandal at the University of California, Irvine's Center for Reproductive Health.²⁴ In that case, the clinic was accused of stealing eggs from nine women who believed they were

undergoing routine procedures, while instead the clinic was implanting the eggs in other women.²⁵ The clinic was also accused of unauthorized use of an unapproved drug and research misconduct.²⁶ After the incident the California Legislature found that, "[t]he continued risk of these unethical transfers and implantations without informed consent warrants stronger legislative protections for California families undergoing in vitro and other assisted production procedures."²⁷ The resulting law made it unlawful for providers to "implant sperm, ova, or embryos . . . without the signed written consent of the . . . provider and recipient."²⁸ The law imposed penalties of imprisonment for three to five years, a fine of up to \$50,000, or both the fine and imprisonment.²⁹ Although the California Legislature responded quickly to the UC-Irvine scandal, the law was narrowly tailored to address consent issues and did not veer into murkier issues such as embryo disposition or the implantation of multiple embryos. Moreover, the situation involving the Irvine clinic was fairly straightforward in terms of illegality. In contrast, many of the other regulatory issues surrounding ART are not so clear cut.

In the wake of the 'octomom' controversy, in early 2009, both Georgia and Missouri proposed laws that would limit the number of embryos allowed to be implanted during a single fertility treatment.³⁰ As first introduced in the State Senate, the proposed Georgia bill would have limited the number of embryos that could be transferred into a woman under forty to two and to a woman over forty to three.³¹ That provision did not make it into the version that eventually passed in the Senate. The bill was not enacted in the 2009 session and is currently in the House. The version of the bill that passed the Georgia Senate made it unlawful to create an in vitro embryo by means other than fertilization or ICSI and prohibited the creation of an

in vitro embryo for any purpose other than initiating a pregnancy for the treatment of infertility.³² In other words, the bill bans stem cell research. In Missouri, the bill would have mandated the current ASRM guidelines limiting embryo transfer be followed.³³ Both of these bills were opposed by industry and consumer groups.³⁴

Other states have taken a more proactive approach. In New York, for example, the Task Force on Life and the Law (the Task Force) released a report entitled "Assisted Reproductive Technologies: Analysis and

Recommendations for Public Policy"³⁵ Although the report addressed a wide variety of issues regarding ART and set forth some guidelines, the Task Force was reluctant to put the power of law behind its recommendations. The report found that:

[P]hysicians offering assisted reproduction are under no legal or ethical obligation to treat every individual or couple who requests their services . . . physicians are entitled to consider the welfare of any child who might be born as a result of an assisted reproduction procedure. Physicians should also develop written policies setting forth their standards and procedures for the screening of patients and their partners. Regarding multiple gestations . . . ART practitioners have a professional obligation to minimize the likelihood of multiple gestations resulting from the use of ARTs. Specific limits . . . should not be adopted as a matter of state law.³⁶



Fertility clinics and doctors are not required to be members of SART and ASRM, nor is there strict monitoring as to whether guidelines are actually being followed. It is estimated that about ten percent of US clinics are not members, that as many as eighty percent do not follow guidelines on the number of embryos that should be implanted during IVF, and that some clinics violate guidelines by advertising and providing nonmedical sex selection.

The Task Force essentially relied on professional societies and individual physicians to set practice guidelines when it comes to issues like reduction of multiple gestations and the number of times a woman can donate eggs.³⁷ In a few circumstances the Task Force did recommend state regulation. For example, the report recommended that the state enact legislation to establish minimum standards for obtaining informed consent for ART procedures.³⁸ The Taskforce also concluded that, “[t]o provide maximum oversight of the laboratory procedures involved in assisted reproduction, New York should participate in the certification program for embryo laboratories currently under development by the CDC.”³⁹ The Task Force noted that, although the program would not be required under Federal Law, the state should mandate participation for all of its assisted reproduction laboratories and that the Department of Health itself should provide oversight, as opposed to delegating to private accreditation organizations.⁴⁰ As of yet these recommendations have not been fully adopted.

The Task Force addressed access to ARTs and discrimination in two distinct ways. In terms of marital status, the report states that, “[t]he law should neither prohibit nor require the provision of assisted reproductive services to unmarried individuals, including lesbians.”⁴¹ When it comes to sexual orientation, the Task Force leaves access decisions in the hands of individual providers. In contrast, the report reinforces that with ART, “[a]s with other medical treatments, physicians may not refuse . . . services on the basis on race, color, creed, religion, or national origin.”⁴² It is troubling that the Task Force leaves gender and sexual orientation off of this list.

C. Professional Societies

Beyond the limited state and federal laws currently on the books, the fertility industry in the US is largely self-regulated. Two organizations, the American Society for Reproductive Medicine (ASRM) and the Society for Assisted Reproductive Technology (SART), have taken the lead. The organizations work together to issue guidelines and best practices. ASRM is a non-profit organization, “dedicated to the advancement of the art, science, and practice of reproductive medicine . . . through the pursuit of excellence in education and research and through advocacy on behalf of patients, physicians, and affiliated health care providers.”⁴³ ASRM is a multi-disciplinary organization that, among other things, issues practice guidelines, works on legislative issues, and publishes the well-known journal *Fertility and Sterility*.⁴⁴ SART is a professional society of member clinics. It represents ninety-five percent of ART clinics in the US with a mission of

“set[ting] and help[ing] maintain the standards for ART in an effort to better serve our members and our patients.”⁴⁵ SART is involved in data collection, setting practice guidelines and standards, government interaction, quality assurance, and ART research.⁴⁶ In order to be a SART member, a clinic is required to:

- Have an accredited laboratory. The lab accreditation program run by ASRM with the College of American Pathologists (CAP) has explicit standards on the identification and documentation of all tissues involved.
- Adhere to all standards and recommendations of the ASRM Practice Committee.
- Adhere to all standards and recommendations of the ASRM Ethics Committee.⁴⁷

Both ASRM and SART publish a series of practice guidelines and standards on their websites.

Fertility clinics and doctors are not required to be members of SART and ASRM, nor is there strict monitoring as to whether guidelines are actually being followed. It is estimated that about ten percent of US clinics are not members, that as many as eighty percent do not follow guidelines on the number of embryos that should be implanted during IVF, and that some clinics violate guidelines by advertising and providing nonmedical sex selection.⁴⁸ Moreover SART can only punish its member clinics by revoking their membership status.⁴⁹

The American Medical Association (AMA) has also issued a series of guidelines in order to, “ensure ethical practices in assisted reproductive technology.”⁵⁰ These guidelines encourage disclosure of clinic specific success rates, self-regulation, clinic participation in credible professional accreditation programs, reporting unethical practices, full patient consent, and a payment scheme not based on outcomes.⁵¹ The American Academy of Fertility Care Professionals (AAFPCP) requires its members to pledge adherence to a code of ethics and report the unethical behavior of any member.⁵²

III. Regulation in Great Britain

In contrast to a largely self-regulated American industry, fertility clinics in the UK are heavily regulated by the government. The Committee of Inquiry into Human Fertilisation and Embryology was created to address, among other issues, whether the National Health Service (NHS) should provide treatment for infertility and then to address who should be eligible for such treatment.⁵³ The committee, established in 1982, was created in response to the birth of Louise Brown⁵⁴ and

rapid technological developments in the fields of IVF and embryology.⁵⁵ In 1984 the committee released the “Report of the Committee of Inquiry into Human Fertilisation and Embryology” (known as the “Warnock Report”).⁵⁶ The report lays the groundwork for a robust regulatory framework for ART, stating that:

We believe that all the techniques require active regulation and monitoring, even though, as we realize, such restrictions may be regarded by some as infringing clinical or academic freedom . . . The interests of those directly concerned, as well as those of society in general, demand that certain legal and ethical safeguards should be applied.⁵⁷

In order to achieve that goal, the report recommended the creation of a, “new statutory licensing authority to regulate both research and those infertility services which we have recommended should be subject to control”⁵⁸ The Warnock report envisioned that this new regulatory agency would have both advisory and executive functions.⁵⁹ In its advisory role, the agency would issue practice guidelines and advise the government on the changing landscape.⁶⁰ The executive role would include granting licenses to doctors and clinics, both in the public and private sector, and to grant licenses to researchers in the field.⁶¹ The recommendations and framework set forth in the Warnock report are reflected in the current legislation and regulatory authority.

Then in 1990, the British government passed the Human Fertilisation and Embryology Act of 1990 (HFEA).⁶² Notably, as recommended by the Warnock Report, HFEA created the Human Fertilisation and Embryology Authority (the Authority) to license and monitor fertility doctors and clinics to ensure compliance with HFEA.⁶³ A glance at the Authority website practice guidelines compared to those of SART or ASRM reveals little difference on the surface. Both have sections for patients and donors. Both will help you find a fertility clinic in your area and report success rates. Both provide operational and ethical guidance for fertility clinics and doctors. The difference is clearly in the force behind the guidelines. Whereas SART and ASRM encourage member clinics to report unethical practices, the Authority has strict compliance standards and penalties.⁶⁴ Failure to comply with HFEA can include both informal warnings and formal sanctions.⁶⁵ For example, the Authority can monitor compliance with unannounced visits or go so far as to recommend that a practices’ license be revoked or suspended.⁶⁶ Formal action is permitted when the individual responsible for the facility is unable to properly manage⁶⁷, when a clinic has not taken remedial action within a specified timeframe, if there is a previous history of non-compliance or failure to take remedial actions, if there is risk to patients, gametes, or embryos, or when there is evidence of criminal behavior.⁶⁸ It is important to note that although there are both public and private fertility clinics in the UK, the Authority regulates and inspects all clinics that provide any type of fertility treatments or storage.⁶⁹

The Authority has been able to address concerns from critics that regulation cannot keep pace with technological development. Although the most sweeping reforms came in 2008, several changes have been made over the years. Amendments in 1991 and 1996 allowed extended storage periods for eggs and embryos in certain situations.⁷⁰ In 2001, the regulations were amended to allow embryonic stem cell research.⁷¹ The 2008 amendments to HFEA reflect both advances in ART and shifts in societal values. For example, the amendments extend parental rights to same-sex couples and

unmarried heterosexual couples.⁷² Other highlights include clarifications on what is allowed in terms of embryo research, specifically in relation to ‘human admixed embryos’⁷³ and a ban on sex-selection for social reasons.⁷⁴ The Authority is implementing the amendments in three stages. As of April 9, 2009, the new definitions of parenthood went into effect.⁷⁵ Then in October 2009 the amendments to the 1990 legislation took effect.⁷⁶ Lastly, as of April 2010, same sex and unmarried couples were able to apply to be the parents of children born using a surrogate.⁷⁷

The 2008 version of HFEA also makes several key changes to the compliance cycle. The new compliance structure includes a “Risk Tool” designed to allow facilities to assess their compliance level before being inspected.⁷⁸ The new tool uses generic performance indicators (GPIs) and a self assessment questionnaire (SAQ).⁷⁹ The SAQs are meant to replace the current pre-inspection questionnaires, a change which the Authority suggests will allow for more focused inspections.⁸⁰

IV. Important Regulatory Issues

A. Number of Embryos Implanted During IVF

One of the most controversial regulatory issues is the number of embryos allowed to be implanted during a procedure. Over forty years after the birth of Louise Brown, Nadya Suleman, more commonly known as ‘octomom’, stirred up the debate when she gave birth to octuplets after a fertility doctor implanted her with six embryos.⁸¹ The case garnered national attention, but the number of multifetal pregnancies has been on the rise for years. In fact, between 1980 and 2000, the rate of infants born in triplet or higher order went from thirty-seven to 181 for every 100,000 births.⁸² Although the entirety of the increase is not attributable to ART, one estimate finds it responsible for forty percent.⁸³ Another estimate suggests that ART accounted for sixteen percent of twin births, forty-five percent of triplet births and thirty percent of quadruplet births in 2003.⁸⁴

There are many dangers associated with high order pregnancies. Generally speaking, the more fetuses carried to term, the greater likelihood of premature births and the lower the birth weight of each fetus.⁸⁵ Multiples are also more likely to suffer from a variety of complications, congenital malformations, and long-term handicaps.⁸⁶ Even twins have a sixty percent greater chance of being born prematurely.⁸⁷ In addition to the danger to the fetuses and infants, there are also more instances of maternal health problems in women carrying multiples.⁸⁸ Despite the dangers associated with multiple gestation, “there is an attitude among infertility physicians that the wishes of the infertile couple must be respected. This reflects a certain prioritization of values, according to which the desire of the couple to have a baby is more important than avoiding risks to the offspring.”⁸⁹ The focus is on patient autonomy rather than best practices.

Another motivation to implant more embryos is linked to doctor success rate. In the ‘octomom’ case, the octuplets were not Nadya’s first foray into IVF. In fact, between 2000 and 2006, Nadya gave birth to six children, including a set of twins, as a result of fertility treatments.⁹⁰ Those five live births represented just over twenty percent of the total live births to women under thirty-five at the clinic in question during the six-year span.⁹¹ This led many to believe that Nadya’s doctor was using her to, “boost his stats and improve his standing in the highly competitive and lucrative fertility field.”⁹² More disturbing is the revelation that Nadya was implanted with

six embryos for each of the pregnancies.⁹³ The implantations were a clear violation of professional guidelines that state patients under the age of thirty-five should consider implantation of only one embryo, and should not be implanted with more than two embryos.⁹⁴ Under no circumstances do the guidelines recommend implanting more than five embryos at any stage.⁹⁵

Even though Nadya's doctor violated the guidelines he received no penalization other than the media and professional backlash. Although Nadya's doctor was expelled from membership in ASRM and SART, there is nothing stopping him from continuing to practice.⁹⁶ The high danger to both Nadya and her unborn children was at odds with the low repercussions for Nadya's doctor. That tension is present in the guidelines themselves, which state first that, "[h]igh-order multiple pregnancy (three or more implanted embryos) is an undesirable consequence (outcome) of assisted reproductive technologies (ART). Multiple gestations lead to an increased risk of complications in both the fetuses and the mothers."⁹⁷ Only two paragraphs later the guidelines state that, "[s]trict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient's own unique circumstances."⁹⁸ Clearly ASRM and SART have traditionally supported a deregulated industry that allows the greatest flexibility for doctors, clinics, and patients. Yet at the same time these professional societies encourage safe and ethical practices. Cases like Nadya's, where a doctor manipulates the process in order to report greater success rates, demonstrate the need for a more consistent and compliance oriented regulatory environment in which there are true penalties for dangerous procedures.

In the UK, the Authority has similar guidelines for fertility clinics in terms of actual numbers. The law mandates that in a single cycle no more than two embryos can be implanted for women under forty, and no more than three for women over forty.⁹⁹ Also, at a minimum, clinics must keep individual records explaining the reasons for implanting three embryos and have a "multiple births minimisation strategy."¹⁰⁰ In cases where multiple embryos are implanted into a woman who meets the criteria for single embryo transfer, the clinic must also include an explanation for the action and a note "confirming that the risks associated with multiple pregnancy have been fully discussed with the patient."¹⁰¹ Failure to comply can result in any of the informal and formal penalties discussed in the previous section.

B. Sex-Selection & Preimplantation Genetic Diagnosis

Another controversial issue is sex-selection and preimplantation genetic diagnosis (PGD). PGD is defined as the process of testing to see whether a specific mutation from one or both parents has been transmitted to an embryo.¹⁰² First, it is important to distinguish between sex-selection for medical reasons and sex-selection for non-medical reasons. Sex-selection for medical purposes allows parents to prevent the transmission of sex-linked genetic diseases.¹⁰³ ASRM explicitly approves of preimplantation sex-selection when used for medical reasons because of its ability to limit disease and suffering and the inherent lack of gender bias.¹⁰⁴

In the UK, HFEA not only specifically bans sex-selection for non-medical reasons, but it also states that an embryo may only be tested to determine if the embryo has a "gene, chromosome, or mitochondrial abnormality" that would impact whether it would result in a live birth or when there is

a particular risk of the embryos having such an abnormality.¹⁰⁵ PGD can only be carried out in two specific instances. The first is when there is a "particular risk" that the embryo will have a "genetic, mitochondrial or chromosomal abnormality" that will result in a "serious disability, illness or medical condition."¹⁰⁶ In that situation PGD is used to determine whether the embryo has the specific genetic abnormality. The second situation in which PGD is allowed in the UK is for medical sex-selection. In that case PGD is allowed "where there is a particular risk that any resulting child will have or develop a gender related serious disability, illness or medical condition."¹⁰⁷ In that situation the Authority must first determine that the condition in question affects only one sex or disproportionately affects one sex more than the other.¹⁰⁸ These are mandatory requirements that all fertility clinics in the UK are required to follow.

The arguments in favor of sex-selection for non-medical reasons center on reproductive choice. The logic is that individuals should be allowed to make their own choices when it comes to bearing children and that choosing the sex of a child is a natural extension of that right.¹⁰⁹ Other arguments in favor of sex-selection include, "social goods such as gender balance or distribution in a family with more than one child, parental companionship with a child of one's own gender, and a preferred gender order among one's children."¹¹⁰ In a 2001 report published in *Fertility and Sterility*, ASRM concluded that preconception, "sex selection aimed at increasing gender variety in families may not so greatly increase the risk of harm to children, women, or society that its use should be prohibited or condemned as unethical in all cases."¹¹¹ Preconception sex-selection is distinct from PGD because it takes place before the egg is fertilized, often in the form of sperm separation.

There are several arguments against engaging in sex-selection for non-medical reasons. One concern is that there is a 'slippery slope' once parents are given control over "nonessential characteristics of children."¹¹² If parents can decide the gender of their child, why not eye or hair color? Another argument is that engaging in sex-selection encourages gender discrimination and could in fact lead to sex ratio imbalances. In terms of sex-selection for "social reasons" HFEA specifically bans all "practices designed to ensure that a resulting child will be of a particular sex."¹¹³ This includes both PGD and preconception sex-selection.

ASRM's guidelines regarding sex-selection have not stopped fertility clinics and doctors in the US from exploring the notion of using PGD to select the gender and even other physical traits of a child. In fact, the Fertility Institutes clinic in Los Angeles advertises that it can guarantee the gender of a child, stating that, "If you want to be *certain* your next child will be the gender you're hoping for, be aware that *no other method comes close* to the reliability of PGD. While traditional sperm-screening techniques have a success rates of 60-70%, only PGD offers *virtually 100% accuracy*."¹¹⁴ Sex-selection, which is offered for both fertile and infertile couples, is quoted as costing \$18,490.¹¹⁵

Although there is not yet any mention of it on the website, the Fertility Institutes also recently said that it would begin offering services to help couples select other physical traits in their unborn children.¹¹⁶ The clinic claims that the service has been requested by several couples.¹¹⁷ A survey conducted by the New York University School of Medicine revealed that of 999 people seeking genetic counseling most supported PGD to screen for certain genetic diseases.¹¹⁸ This reflects the stance taken by ASRM and

other professional organizations. Notably, however, ten percent of patients surveyed said they would use genetic testing to determine athletic ability and another thirteen percent supported genetic testing to ensure superior intelligence.¹¹⁹ The director of the Fertility Institutes is quoted as saying that “[t]his is cosmetic medicine. Others are frightened by the criticism, but we have no problems with it.”¹²⁰

C. Controversial Techniques and Research

Another interesting issue that arises with regulation is the use of experimental or investigational techniques. In the UK, the Authority works with professional and scientific organizations to develop policy regarding fertility treatment and human embryo research.¹²¹ HFEA and the Authority specifically regulate what is allowed in terms of research techniques. Currently much of the new research revolves around preventing the transmission of genetic defects and diseases.¹²² In the US, the use of experimental ART techniques is not regulated. Instead professional societies offer guidance. ASRM defines experimental procedures as such until there is sufficient published medical evidence as to their, “risks, benefits, and overall safety and efficacy.”¹²³ ASRM warns that experimental or investigational procedures should not be marketed as established or routine.¹²⁴

Despite guidelines, doctors in the U.S. do turn to experimental procedures in extreme cases. In 1993, Susan and Bill McNamara began to see a fertility specialist after they were unable to conceive on their own.¹²⁵ They faced a myriad of fertility issues. Bill’s sperm count was extremely low, Susan had a misshapen uterus that would require major surgery to hold a fetus, and Susan was literally allergic to Bill’s sperm.¹²⁶ The McNamaras turned to a technique known as co-culture, when human embryos are grown in the uteruses of other species or on fallopian tube cells.¹²⁷ The practice began in the late 1980s, but went unnoticed by the Parental Drug Association (PDA) until 2002 when it began sending letters telling clinics to stop the unapproved use of co-culture.¹²⁸ Even co-culture using human cells poses the risk of transmission of infectious disease from the cell line to the embryo.¹²⁹ Despite the risks of disease transfer from animal to human, the PDA did not ban co-culture, but instead requires clinics to fill out an Investigational New Drug (IND) application.¹³⁰ The PDA also recommended life-long monitoring, including reporting unusual symptoms and abstaining from blood and tissue donation, for co-culture children and families.¹³¹ On the upside, Susan and Bill were able to have three children as a result of co-culture. On the other hand, at least one of their children has a birth defect that may have been caused

by the use of ART to conceive.¹³² In contrast to the more permissive stance taken by the PDA, in 1990 the HFEA specifically banned placing an embryo in any animal.¹³³

Another procedure that has raised concern is intracytoplasmic sperm injection (ICSI). ICSI involves injecting a single sperm directly into a human egg.¹³⁴ In contrast, typical IVF involves placing an egg in a petri-dish with thousands of sperm and letting fertilization occur on its own.¹³⁵ ICSI is generally used to help couples with male fertility issues, such as low numbers of or poor quality sperm.¹³⁶ One risk of ICSI is that the egg will be irreparably damaged by the needle.¹³⁷ Additionally some doctors believe that ICSI children have slightly higher chances of having sex chromosome abnormalities passed on through defective sperm.¹³⁸ In contrast to co-culture, ICSI is a widely used procedure that is no longer considered an experimental procedure by ASRM.¹³⁹ In the UK, HFEA requires that clinics provide couples using ICSI with information regarding the risks, including, “a reduced number of eggs being available for treatment (compared to IVF), due to eggs being immature or damaged by the process of ICSI”¹⁴⁰ and that, “children conceived [will have] . . . inherited genetic, epigenetic or chromosomal abnormalities (including cystic fibrosis gene mutations, imprinting disorders, sex chromosome defects and heritable sub-fertility).”¹⁴¹ ASRM recommends that couples dealing with male infertility be counseled before using the ICSI technique to conceive.¹⁴²

Despite the risks of experimental procedures like co-culture, and less experimental procedures like ICSI, proponents of a de-regulated infertility industry argue that each individual patient has different needs and responds differently to treatment. The question becomes whether it is fair to outlaw or regulate certain practices that might allow a couple to have a baby when they otherwise could not. In September 2009, ASRM published a report addressing the issue of fertility treatment for couples with little or no chance of success.¹⁴³ The article recognized that, “[m]isunderstandings may arise when couples and/or individuals seek to initiate or continue treatment regarded by practitioners as having either a very low or virtually nonexistent chance of success.”¹⁴⁴ Although ASRM concluded that in cases of futility, it is unethical to continue treatment, it stressed that clinics should remain flexible based on the individual patient and potential differences of opinion among doctors.¹⁴⁵

D. Embryo Mix-ups

Recently several cases of embryos being accidentally implanted into the wrong woman have raised concerns

“The number of multifetal pregnancies has been on the rise for years. In fact, between 1980 and 2000, the rate of infants born in triplet or higher order went from thirty-seven to 181 for every 100,000 births.”

“Without help from insurance, IVF can cost between \$10,000 and \$15,000 per cycle... The high prohibitive cost of fertility treatments in the U.S. means, in most cases, that only the wealthy have access.”

over laboratory policies in both the US and the UK. In the US, the most recent incident involved an Ohio woman who received the embryo of another couple.¹⁴⁶ The Ohio couple hoped to use their remaining frozen embryos to have a fourth child, but was informed early in the pregnancy that there had been a mix-up.¹⁴⁷ The American Fertility Association (AFA), a non-profit professional organization, issued several statements in response to the incident. In their legal statement, the AFA addressed only the custody issues at stake and did not discuss possible repercussions for the clinic.¹⁴⁸ It is unclear exactly what those repercussions, if any, would be.

Another case involved a New Orleans hospital where it was discovered that as many as 100 couples were affected by a labeling error.¹⁴⁹ Although a spokesperson said there was no reason to believe that any embryo was actually implanted in the wrong woman, the program described the problem as a “significant labeling issue.”¹⁵⁰ In addition to the possibility that embryos were wrongly implanted, several frozen embryos were lost or accidentally destroyed.¹⁵¹ At least two couples whose embryos were lost have since filed suit. One of the couples was told that even if their embryos were found, it was determined that required screenings for sexually transmitted diseases had not been done prior to freezing.¹⁵² In a San Francisco case, all of a couple’s embryos were destroyed without their consent when it was discovered that the embryos were implanted with the wrong sperm.¹⁵³ A lawyer for the couple said that, “There is no regulation of these fertility clinic laboratories where the particular jobs like fertilizing eggs or preparing embryos for transfer are done. If there was better regulation, I think we would not have these kinds of problems.”¹⁵⁴

These problems are not unique to the US. From 2007 to 2008, the Authority reports that two embryo or gamete mix-ups occurred.¹⁵⁵ In 2004, a clinical embryologist in London became concerned when she discovered errors in patient notes, including missing signatures and security checks.¹⁵⁶ She was ignored by her superiors and eventually contacted the HFEA, which determined that although she had breached patient confidentiality by bringing the evidence to light, she nevertheless acted in the best interests of her patients.¹⁵⁷ The hospitals in question responded by introducing new procedures to ensure proper labeling.¹⁵⁸

Current HFEA guidelines classify an embryo misidentification or mix-up as a “serious adverse event” for which responsible parties must provide the Authority with a report analyzing the cause and effects of the event.¹⁵⁹ The Authority can then take corrective

measures. Recently, the Authority has begun to publish incident reports on its website.¹⁶⁰ Previously, the Authority made the determination not to publish these reports because, “[w]e wanted to build trust, to assure centres that our aim was to learn and promote higher standards, not to punish human error.”¹⁶¹ In these reports, embryo mix-up ups are classified as grade “A” incidents, which are the most serious offenses. Despite new reporting guidelines, the issue of embryo mix-ups in the UK has created tension between affected couples and the Authority, which is hesitant that stricter guidelines “will drive our patients abroad for treatment because our clinics are more severe.”¹⁶² Despite such tension, the fact that there is a central body to investigate and report these incidents provides better consumer information and gives clinics added incentive to follow regulations.

V. Access/Fairness

An additional issue that comes up in the regulation debate is deciding who should have access to ART. When Nadya Suleman gave birth to octuplets, much of the uproar surrounded the fact that she was an unemployed single mother on disability assistance with six children in addition to the eight infants.¹⁶³ Beyond the medical issues discussed in the previous section, Suleman’s case upset people in terms of her ability to mother and provide for all fourteen children.¹⁶⁴ The public sentiment was that Suleman never should have been allowed to conceive using ART procedures. These issues go to the heart of the access dilemma. Should there be limitations on who has access to ART? If so, who should decide?

There are definite access issues on both sides of the regulatory model. In the US, access to IVF depends on whether an individual or couple can either afford the procedures on their own or whether their private insurance plan happens to cover certain ART procedures, most commonly IVF.¹⁶⁵ A few states have passed laws regarding insurance coverage for certain ART procedures. For example, in Arkansas, all insurers that cover maternity benefits are also required to cover IVF.¹⁶⁶ The law exempts HMOs and also has strict eligibility requirements.¹⁶⁷ Arkansas also requires that the patient’s eggs be fertilized with her spouse’s sperm.¹⁶⁸ Clearly, this eligibility requirement makes it considerably more difficult for same-sex couples to access IVF and other ART procedures. It also discriminates against single women seeking to have children. On a more positive note, the law promotes safety and best practices by requiring that the IVF procedure be performed in facilities certified by the Arkansas Department of Health.¹⁶⁹

In Illinois, insurance policies that provide coverage to more than twenty-five individuals and that already provide pregnancy benefits are required to cover the diagnosis and treatment of infertility.¹⁷⁰ The coverage includes a wide variety of ART, including IVF, artificial insemination, and gamete intrafallopian transfer. The Illinois law also requires that facilities meet the standards set forth by either ASRM or the American College of Obstetricians and Gynecologists.¹⁷¹ Although the law does not require that patients be married, it does require that patients have “used all reasonable, less expensive and medically appropriate treatments and [are] still unable to get pregnant or carry a pregnancy.”¹⁷² The implication is that a same-sex couple seeking fertility treatments will not receive coverage unless infertility is medically established. Both New York and California require some insurers to cover treatment for infertility, but specifically exclude IVF from the mandate.¹⁷³

The wide variety of state laws makes ART procedures more accessible in some states than others. It also means that, in some states, fertility clinics are required to follow best practice guidelines in order to accept payment from insurance companies, but there is no consistent mandate. The concern over mandating insurance coverage for ART procedures goes beyond cost concerns. In fact, one estimate suggests that even if usage of IVF rose 300 times when added to an employer health plan, the average premium would only increase by nine dollars a year.¹⁷⁴ The thought is that despite the high costs of IVF, the fraction of the population that needs the treatment is still relatively low.¹⁷⁵

The debate about covering IVF also focuses on cost effectiveness. Despite the popularity of the procedure, success rates are still relatively low and vary greatly across clinics. A 2007 survey of all SART member clinics revealed that for women under thirty-five, about forty percent of cycles using fresh embryos from non-donor oocytes resulted in live births. Thirty-four percent of cycles using thawed embryos resulted in live births for the same population.¹⁷⁶ The numbers are significantly lower for women over thirty-five, with a live birth percentage rate of just over thirty percent for both fresh and thawed embryos.¹⁷⁷ Given these success rates, the question becomes whether it is cost effective for insurance companies to cover IVF. Moreover, should companies be allowed to limit access for older women who are less likely to get pregnant? Some state insurance mandates do address the age issue. For example, Connecticut law requires that the covered individual be under the age of forty.¹⁷⁸ In New York, patients have to be between the ages of twenty-one and forty-four.¹⁷⁹

Without help from insurance, IVF can cost between \$10,000 and \$15,000 per cycle.¹⁸⁰ For women under thirty-five, this means that the average cost to get pregnant is more like \$34,000 because it generally takes more than one cycle. For women over forty, that price tag can exceed \$100,000. The high prohibitive cost of fertility treatments in the US means, in most cases, that only the wealthy have access. In her article discussing access and regulation, June Carbone argues that access to fertility treatments allows wealthier women to wait longer to have children and accumulate greater wealth and education.¹⁸¹ In contrast, “[f]or the poor, and particularly poor African Americans, waiting may instead mean permanent childlessness . . . The cost of the new reproductive technologies places them out of the reach of poorer women.”¹⁸²

In the UK, the NHS will cover ART procedures, but has strict regulations as to who is eligible and how many times a person can receive treatment.¹⁸³

The NHS website explains that, “[f]ertility treatment, funded by the NHS, currently varies across the UK. In some areas, waiting lists for treatment can be long. The criteria you must meet in order to receive treatment can also vary.”¹⁸⁴ These variations are regional, based on what is known as the ‘postcode lottery’. The term ‘postcode lottery’ describes “seemingly random countrywide variations in the provision and quality of public services.”¹⁸⁵ Despite the existence of the NHS, there is not a standard of care and instead access to infertility services depends on where you live.

The website includes a section on seeking out private treatment, which for a cycle of IVF is estimated to cost between £4000 and £8000.¹⁸⁶ The NHS will typically cover one IVF cycle per eligible couple.¹⁸⁷ Although eligibility determinations are made locally by primary care trusts (PCTs)¹⁸⁸, the basic eligibility criteria is that the woman is between the ages of twenty-three and thirty-nine and that either the reasons for infertility have been identified or the couple has been experiencing fertility problems for at least three years.¹⁸⁹ The guidelines also note that priority is typically given to couples without other children.¹⁹⁰ Despite the fact that the NHS covers fertility treatments, many couples in the UK end up using private services and are left in a similar position to their American counterparts.¹⁹¹ That is, access to fertility treatments often times ends up relying on wealth despite the existence of nationalized health care.

One problem is the lack of standards across PCTs. PCTs have the freedom to set their own eligibility requirements. Different PCTs have different criteria for eligibility. For most, the maximum age of eligibility is thirty-nine, but some PCTs have a maximum age of thirty-seven.¹⁹² Another variation in criteria is the minimum length of relationship or period of infertility. The minimum ranges from one to three years, while some simply require that the relationship be “stable.”¹⁹³ At least forty-six PCTs require infertile women to give up smoking in order to be eligible for treatment.¹⁹⁴ Some even require that the woman’s partner also be a non-smoker. More troubling are some of the other “social criteria” that PCTs set to exclude certain women, including weight, sexual preference, and whether the individual or their partner have other children.¹⁹⁵ According to one report, fifty-four percent of PCTs bar access to IVF for couples that have other children, including when the partner not seeking to get pregnant has children from a previous relationship.¹⁹⁶ In one case, a woman trying to conceive was told that if she found a partner other than her husband of three years, who had children from a previous relationship, she would be immediately eligible for NHS funded IVF.¹⁹⁷ At least six PCTs explicitly deny IVF access to same-sex couples, while most others have an unspecified policy.¹⁹⁸

In 2004, The National Institute for Health and Clinical Excellence (NICE) recommended that infertile women be given three free cycles of IVF.¹⁹⁹ According to a 2008 article, only nine of 151 PCTs followed that recommendation. Four were not offering IVF at all (that number is now down to one).²⁰⁰ According to the article, “[e]ven where IVF treatment is funded, there is wide variation in the eligibility criteria set by different PCTs . . . across the whole of South Central . . . only women aged between 36 and 39 are eligible and only if neither partner has any children from a previous relationship. . . In many areas women under the age of 25 cannot have free IVF, while [some] women will not be treated until they reach the age of 35.”²⁰¹ As discussed, success rates are significantly lower for women over the age of thirty-five. In one case, a couple was denied access to IVF because the woman was only twenty-six years old and the eligibility

requirements stated that the woman had to be between thirty-five and thirty-eight years old.²⁰² In that case the couple had been trying for six years and was told that IVF was their only possibility for conception.²⁰³ If that particular couple lived in a different part of the country, they would have had no problem getting approved for treatment.

One concern is that the failure to fund the recommended treatments will increase instances of multiple births because of the pressure to succeed in the first cycle.²⁰⁴ The lack of funding for multiple cycles of IVF frustrates the Authority's goal of minimizing multiple births. While clinics are required to have minimization strategies, PCTs that refuse to fund the recommended cycles are de-incentivizing the policy choice. This will either result in clinics ignoring guidelines on the number of embryos they implant or in much lower success rates for patients trying to get pregnant. According to the National Infertility Awareness Campaign, "with the move to single embryo transfer, it is even more important to end this totally unacceptable and allow patients access to the treatment promised to them by the government."²⁰⁵

There is also controversy in the UK surrounding the use of surrogates. Not all PCTs will fund IVF for women using a surrogate.²⁰⁶ The regulations are unclear. For example, "guidance from the National Institute for Health and Clinical Excellence states that where reason for the infertility is known patients should be fast-tracked for NHS funded treatment but it goes on to say surrogacy lies outside the remit of guidance."²⁰⁷ The most recent version of HFEA only addresses the illegality of commercial surrogacy arrangements.²⁰⁸ In the UK, commercial facilitation of surrogacy is a crime and persons seeking a surrogate either has to seek out a friend or relative or turn to one of a few non-profits that help match parents with surrogates.²⁰⁹ The US has taken a similarly confusing approach to surrogacy. The laws differ greatly state to state. For example, of the six states that allow surrogacy contracts, three only allow gestational surrogacy²¹⁰ and three only allow for uncompensated surrogacy agreements.²¹¹ In eleven states and the District of Columbia surrogacy is illegal in some or all circumstances.²¹² In cases where a surrogate is necessary, access in both countries, once again, depends on where you live.

VI. Should the US Regulate ART?

Currently policies and regulation of ART in the US are comprised of a combination of minimal federal law, varied state laws, and guidance from professional societies. There are pros and cons to adopting a federal regulatory scheme for ARTs in the US. One of the pros of the UK model is that there is better protection against, "unscrupulous practices of unethical providers who have made headlines and eroded confidence in the US system."²¹³ There is also, "access to better information about individual clinics and providers."²¹⁴ The regulatory model in the UK has led to better consumer protection, which coincidentally was one of the goals that drove the US to enact the FCSRCA. The stated purpose of the bill was to, "provide the public with comparable information concerning the effectiveness of infertility services and to assure the quality of such services by providing for the certification of embryo laboratories."²¹⁵ A more comprehensive regulatory system in the US would likely provide better protection for consumers.

One theory as to why a federal regulatory scheme would be difficult in the US is the idea that there is a "lack of national moral consensus," when it

comes to setting ART policies.²¹⁶ Without federal regulation there is more room for divergent ethical and political viewpoints.²¹⁷ Moreover, "[r]ules imposed in the US by an HFEA-type regulatory body appointed by an executive elected by a bare majority of the population would face fierce court challenges and political opposition."²¹⁸ It would be difficult to have a consistent policy with power shifts from one party to another. The US experience with stem cell research is demonstrative; with policy shifting from funding the creation of stem cells for research during the Clinton Administration to a much more limited policy under Bush.²¹⁹ Now, under the Obama Administration, the pendulum is swinging back towards full support for federal funding of stem cell research.

In the US there is a heavy focus on choice and autonomy when it comes to making health care decisions.²²⁰ There is also general suspicion of government regulation.²²¹ As was evident in the current debate over health care reform, many Americans feel that the government should stay out of personal health care decisions. The US has avoided federal regulation of ART over and over again. In the early 1990s IVF was one of only a few medical procedures to be "explicitly excluded from the standard health benefit package in the Clinton administration's Health Security Act."²²² Also telling is the fact that the one federal law currently in place, by requiring doctors to disclose success rates, has actually ended up putting pressure on doctors to ignore guidelines limiting the number of embryos implanted in order to maximize success at a minimal cost.²²³

The argument against centralized regulation of ARTs focuses on the autonomy of the individual to make his or her own reproductive choices. The bioethicist John Robertson has been instrumental in leading this side of the debate. He believes in "procreative liberty" or what he describes as protecting, "the freedom to contract for the provision, receipt, transfer, and storage of embryos and gametes, when necessary to achieve protected reproductive goals."²²⁴ For him these rights come from the Constitution and are fundamental.²²⁵ As fundamental rights, Robertson believes they should be free from governmental constraint.²²⁶ Most recently Robertson has been involved in the argument over reprobogenetics, or the use of assisted reproduction and genetics to engineer embryos.²²⁷ He argues against a centralized regulatory scheme, claiming that to date the system of "muddling through" has worked for other applications of assisted reproduction.²²⁸

At the same time, without regulation of fertility clinics, doctors are able to ignore or pick and choose which guidelines to follow when it comes to ART procedures. The existence of a Constitutional right does not mean that regulation is impossible or unnecessary. Without a national regulatory agency akin to the Authority in the UK, there is no way to ensure that clinics are following guidelines when it comes to health and safety. Professional societies in the US argue that regulation would limit the type of treatments available to women desperately seeking fertility treatments.²²⁹ They make a personalized medicine argument against strict regulations.²³⁰ They also argue that there is no way for the law to keep pace with technology.²³¹ At the same time, a closer look at regulation in the UK demonstrates that the HFEA does allow treatment options to vary depending on the patient, while requiring documentation and informed consent.²³² Moreover the most recent amendments to HFEA have been able to keep up with technological and social advances.²³³

When it comes to mandating guidelines and licensing for clinics and doctors, the US has much to learn from the UK's centralized regulatory

scheme. But, that does not mean that a completely centralized regulatory body is the only option. States, as opposed to the federal government, typically regulate medical practice.²³⁴ Given the recent debates over federal government intervention into health care, one option in the US is to mandate laws like the recommendations set forth by the CDC. That is, create minimum requirements for the regulation of ART that states can use to create their own laws, so long as those laws do not violate the constitution. A recent study of the Constitutional implications of regulating ART concluded that pursuant to their police powers, States can regulate ART “in order to protect the health, safety, and welfare of their citizens” but that any regulation distinguishing “socially disfavored groups” will be strictly scrutinized.²³⁵ The author makes a compelling argument that states, “are the most natural regulators of procreation,” because with their policing powers states hold, “the kinds of governmental interests that the Supreme Court has held may justify interfering with individual’s reproductive liberty – public welfare, health, and safety.”²³⁶

Another option is to integrate the current self-regulating scheme with federal enforcement. In the US, critics of regulation ask whether a federally regulated regime would be effective without a national health care system akin to that in the UK. The reality is that the Authority in the UK is able to regulate both public and private facilities. Although there are lingering access issues as a result of the NHS, these are not a direct result of the guidelines that regulate safety and best practices. Just as other agencies within the Department of Health and Human Services regulate private industry; it would be possible to create a new agency to regulate the fertility industry. Considering the current role that professional societies play in regulating ART in the US, it makes sense to allow them to continue setting practice guidelines and leading the industry forward. The US should consider creating a regulatory enforcement agency that creates real consequences for clinics and physicians that violate these professional guidelines.

No matter what type of regulatory scheme emerges, the tide in the professional community does seem to be shifting towards support for greater regulation. The controversy over octomom re-ignited the regulation debate in the US. In the wake of the media storm, ASRM issued a press release stating that, “[t]he time has come for policymakers to sit down with the leading experts in the field to explore ways we can codify our standards to give them additional regulatory teeth.”²³⁷ ASRM also revoked the membership of Nadya’s doctor.²³⁸ The statement prompted responses on both sides of the issue. On the one hand, some providers were outraged. The former president of ASRM was quoted as calling the willingness to regulate “ridiculous,” stating that “[e]veryone has the goal of not having multiples, but the more you have a regulatory agency interfere with your ability to practice medicine, the more unintended consequences will occur.”²³⁹ Another doctor expressed that the “invitation” to regulate would have serious consequences for the doctor-patient relationship: “[c]odification of these standards would be a tragic error that would severely restrict the ability of physicians to provide appropriate, individualized medical care to their patients.”²⁴⁰ On the other hand, proponents of regulation praised the statement as long overdue. A representative of the Center for Genetics and Society, a group that advocates for regulation, blamed the problem partly on competition between fertility clinics, and stated that, “[t]here are a lot of fertility doctors who have lots of integrity and are completely responsible, but it’s a situation where, because of the lack of public policy, it creates –

and encourages – bad apples.”²⁴¹ Despite some opposition, the fact that SART and ASRM are moving in a direction that supports greater regulation is a promising step towards addressing the current patchwork of regulations and guidelines in the US. If the federal government does decide to regulate ART, either through a centralized agency like the Authority in the UK or by requiring that States create their own guidelines, it will be important to have the support of these professional organizations that have traditionally set forth practice guidelines.

¹ Human Fertilisation and Embryology Act, 1990 (amended 2008) ch. 37 (Eng.).

² The Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C.A. §263a(1).

³ *Id.* §263a(2).

⁴ *Id.*

⁵ *Id.*

⁶ *Id.* §263i(1- 2).

⁷ A Model Certification Program for Embryo Laboratories, 64 Fed. Reg. 39374 (July 21, 1999).

⁸ *Id.* at 39375.

⁹ *Id.* at 39376.

¹⁰ *Id.*

¹¹ *Id.* at 39379.

¹² *Id.*

¹³ *Id.* at 39382-86.

¹⁴ *Id.* at 39386.

¹⁵ *Id.* at 39382.

¹⁶ http://www.thehumanfuture.org/topics/reproductive_technology/policy.html (last visited Nov. 21, 2009).

¹⁷ Alicia Ouellette et al., *Lessons From Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 Am. J.L. & Med. 419, 429 (2005).

¹⁸ Va. Code Ann. Tit. 54.1, § 2971.1 (2009).

¹⁹ La. Rev. Stat. Ann. § 122 (2009).

²⁰ *Id.* § 123.

²¹ *Id.* §§ 126-27.

²² *Id.* § 128.

²³ *Id.* § 130.

²⁴ Lee Kuo, Comment, *Lessons Learned from Great Britain’s Human Fertilization and Embryology Act: Should the United States Regulate the Fact of Unused Frozen Embryos*, 19 Loy. L.A. Int’l & Comp. L.J. 1027, 1028 (1997).

²⁵ Noel Cohen, *Allegations Against Fertility Clinics Draw Calls for Regulation*, 13 NO. 1 Med. Malpractice L. & Strategy 5 (1995).

²⁶ *Id.*

²⁷ S.B. 1555 (c) (Ca. 1996).

²⁸ Cal. Penal Code § 367g (b) (1996).

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³¹ Ethical Treatment of Embryos Act, S.B. 169, 153rd Gen. Assem. Reg. Sess. §19-7-67, (Ga. 2009).

³² Ethical Treatment of Embryos Act, S.B. 169, 153rd Gen. Assem. Reg. Sess. §19-7-61, (Ga. 2009).

³³ Kimberly D. Krawiec, *Why We Should Ignore the “Octomom”*, 104 Nw. U. L. Rev. Colloguy 120, 127 (2009).

³⁴ *Id.*

³⁵ <http://www.health.state.ny.us/nysdoh/taskfce/taskbio.htm> (last visited Nov. 2, 2009).

³⁶ *Id.*

³⁷ *Executive Summary of the Task Force on Life and the Law*, 1, 3-7 (Oct. 2001), available at <http://www.health.state.ny.us/nysdoh/taskfce/execsum.htm>.

³⁸ *Id.* at 6.

³⁹ *Id.* at 16.

⁴⁰ *Id.*

- ⁴¹ *Id.* at 5.
- ⁴² *Id.*
- ⁴³ American Society for Reproductive Medicine, available at <http://www.asrm.org/detail.aspx?id=60>.
- ⁴⁴ *Id.*
- ⁴⁵ Society for Reproductive Technology, www.sart.org/WhatIsSART.html (last visited Oct. 31, 2009).
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- ⁴⁷ Robert A. Rebar, MD, ASRM Responds to Incidents at IVF Clinics (Sept. 25, 2009), available at <http://www.asrm.org/news/article.aspx?id=2223> (last visited Nov. 19, 2009).
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- ⁵⁰ American Medical Association, Opinion 2.055- Ethical Conduct in Assisted Reproductive Technology (adopted June 1996), available at <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2055.shtml>.
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- ⁵⁵ Human Fertilisation Embryology Authority, Warnock Report, <http://www.hfea.gov.uk/2068.html>.
- ⁵⁶ The report was named after its committee chair, Mary Warnock.
- ⁵⁷ Mary Warnock, *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, 75 (1985).
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- ⁵⁹ *Id.* at 76.
- ⁶⁰ *Id.*
- ⁶¹ *Id.*
- ⁶² Human Fertilisation and Embryology Act 1990, §5(1).
- ⁶³ *Id.*
- ⁶⁴ Human Fertilisation & Embryology Authority Compliance and Enforcement Policy, available at http://www.hfea.gov.uk/docs/Compliance_and_Enforcement_Policy.pdf (last visited Dec. 18, 2009).
- ⁶⁵ *Id.* §§3.2 and 3.3
- ⁶⁶ *Id.*
- ⁶⁷ *Id.* §3.4.
- ⁶⁸ *Id.*
- ⁶⁹ Human Fertilisation & Embryology Authority, available at <http://www.hfea.gov.uk/159.html> (last visited Dec. 18, 2009).
- ⁷⁰ Human Fertilisation & Embryology Authority, Changes to legislation 1991-2004, <http://www.hfea.gov.uk/2221.html> (last visited Nov. 11, 2009).
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- ⁸¹ Naomi R. Cahn & Jennifer M. Collins, *Eight is Enough*, 103 Nw. U. L. Rev. Colloguy 501 (2009).
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- ⁸⁴ Krawiec, *supra* note 33, at 123-24.
- ⁸⁵ Carson, *supra* note 82, at 273.
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- ⁹⁶ Reynolds, *supra* note 48.
- ⁹⁷ American Society for Reproductive Medicine and Society for Assisted Reproductive Technology, *supra* note 94.
- ⁹⁸ *Id.*
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