

FOUR

REGULATING EGG DONATION: A COMPARATIVE ANALYSIS OF REPRODUCTIVE TECHNOLOGIES IN THE UNITED STATES AND UNITED KINGDOM

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While rapid scientific development of egg donation technology has made it possible to elude infertility and to expand options for means of procreation, it has also thrust policy makers advanced societies in the midst of a raging debate that involves several ethical concerns. This paper describes and contrasts the respective regulatory approaches of the United States and the United Kingdom towards egg donation, and explores their potential implications for policy making in both countries.

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INTRODUCTION

Procreation is a fundamental human drive. The image of happy parents holding a healthy baby pervades our society, from Gerber commercials to TV sitcoms. However, as infertility rates continue to rise, couples are increasingly turning to egg or sperm donation to achieve the elusive goal of parenthood¹. The American Society for Reproductive Medicine (ASRM) states, “The use of egg donation as a therapy for infertility continues to increase every year and accounted for 12% of all Assisted Reproductive Technology cycles in 2003, the most recent year for which statistics are available.” (ASRM 2007). The donation of gametes (eggs and sperm) raises profound ethical issues and demands the attention of policymakers. As a newer and more dangerous technology, egg donation is especially concerning and therefore will be the focus of this paper’s discussion. Though there have been extensive policy discussions in the United States about the use of oocytes (human eggs) in research, there has been a pronounced absence of a similar discussion around donation for reproductive purposes.

Egg donation raises challenging questions about the role of the state in regulating procreation and the appropriate balance of individual and collective societal rights. Two countries, the United States and the United Kingdom, have taken polar opposite approaches to regulating egg donation and thus serve as interesting case studies for the topic of appropriate regulation of this reproductive technology. The United States has an active market for gametes and meets the demand for infertile couples seeking treatment, but has ignored the contentious issues surrounding egg donation and has failed to implement any policies to monitor or restrict the practice. The United Kingdom has implemented very strict regulations that attempt to address myriad ethical concerns with respect to gamete donation. However, in so doing it has greatly reduced the availability of donor eggs and disadvantaged infertile couples seeking treatment.

The distinct approaches of the two nations favor different groups and ethical frameworks. One action to improve the regulation of both nations would be to adopt a new “clinical trial” framework for considering egg donation, thus removing the primary issue of human commodification while also maintaining payment commensurate with sacrifice. Regardless of the regulatory approach, rising demand makes it clear that egg donation will be increasingly common in both nations and worthy of proactive policy action.

BACKGROUND INFORMATION ON GAMETE DONATION

History of Egg Donation

The practice of egg donation began in the early 1980s. The first successful in vitro fertilization (IVF) procedure took place in 1978 in the United Kingdom (Shanley 2002), and the first pregnancy using donated eggs was reported in Australia in 1983 (Steinbock 2004). The practice developed as an alternative to sperm donation and other fertility treatments for couples that could not conceive a child. In general, egg donation is used by women with three types of reproductive problems: women who lack functioning ovaries, women who cannot achieve pregnancy for some reason through IVF, and women who use donated eggs for genetic reasons.

The demand for egg donation has increased along with a continuing trend of women waiting longer to become mothers. As they get older and start trying to have children, many women are dismayed to find that their fertility has decreased and that they can no longer conceive, at which point they turn to IVF and egg donation to achieve a pregnancy. The likelihood of a fertilized egg implanting (and thus achieving a pregnancy) is related to the age of the woman who produced the egg. According to the Centers for Disease Control and Prevention, the probability of a live birth resulting from IVF with egg donation is approximately fifty-one percent, and remains steady as a woman ages through her forties. Without egg donation, the live birth rate resulting from IVF steadily falls as a woman ages. Hence, demand for eggs has continually risen since the process became widely available. In 2004, donor eggs were used in approximately 15,175 cycles, resulting in approximately 7,588 births (CDC 2004). In the United Kingdom, 7,350 cycles of IVF were done using donated eggs in 2003, leading to 782 successful births (Human Fertilisation and Embryology Authority 2006). It is interesting to note that, according to these statistics, the United States has a much better birth rate for IVF and egg donation than the United Kingdom. The U.S. price of eggs ranges considerably; a price of around five thousand dollars is most common, but donors can be paid up to fifty thousand dollars or even more (Hopkins 2006).

Process of Egg Donation

Egg donation is a complicated procedure and requires extensive time and discomfort for the person donating her eggs as well as the woman receiving them. For approximately three months, the two women take hormone medication to synchronize their menstrual cycles². Once synchronization is achieved, the woman who is to donate eggs receives hormone injections to stimulate ovulation. For three weeks she takes a hormone to inhibit eggs from ripening or being released, and then she switches hormones in the fourth week to “hyperstimulate” the ovary and cause the release of an abundance of eggs, often a dozen or more.

The eggs are then retrieved using laparoscopy or ultrasound. Ultrasound has become the preferred method for donation in recent years, as it only requires local anesthesia. The doctor locates the egg follicles through the use of the ultrasound, and then inserts a needle through the vaginal wall to reach the ovarian follicles, using suction to capture the eggs.

Once removed, the eggs are placed in a culture dish with sperm, usually that of the egg recipient’s partner but potentially from another donor. The eggs are then observed for signs of fertilization, and those that appear fertilized are placed in an incubator. Finally, two to four of these pre-embryos are placed into the uterus of the woman who will bear the child. If one of the embryos successfully implants, a pregnancy is achieved (Steinbock 2004).

As is evident from the above description, egg donation is an involved and time-consuming procedure. It is unpleasant, at times painful, and can have short and long-term health consequences for the donor. Donors experience medication side effects like mood swings, breast tenderness, headaches, hot flashes, vaginal dryness, fatigue, sleep problems, and body aches (Egg Donation Information Project 2006). Rarely, fertility drugs can cause a risk of ovarian hyperstimulation syndrome, in which the ovaries swell and fluid builds up in the abdominal cavity. If mild, the symptoms will recede after the woman’s next menstrual period. However, in the rare instances that the syndrome is severe both of the donor’s ovaries may have to be

removed, and the condition may potentially be fatal. Ovarian hyperstimulation occurs in about six percent of IVF cycles (Pearson 2006). In the long term, there is also some evidence associating the use of fertility drugs like those used in egg donation with an increased risk of uterine cancer, though significant scientific debate continues over that conclusion. A 2005 study collected the medical records of more than 12,000 women who received ovulation-stimulating drugs between 1965 and 1988, and found that those women were 1.8 times more likely to develop uterine cancer (Althuis, et al. 2005). However, many women now take different ovulation-stimulating drugs today than they did in the 60s, 70s, and 80s. Researchers have only had about a decade to examine the effects of the current drugs, which may not become evident until the women taking them are older (Pearson 2006).

ETHICAL ISSUES IN EGG DONATION

The process of egg donation raises myriad ethical issues. Some of the ethical questions involve the adequate implementation of policies allowing egg donation, such as informed consent, the right to privacy, and the ability of children to determine their lineage. Other ethical issues involve the fundamental act of donation, especially any monetary payment that may be included in that donation. These issues balance the potential commodification of people with a society's desire to alleviate suffering and promote individual choice. As Donald Evans writes:

It is a difficult question which provokes rival camps to present arguments concerning the nature of persons, slavery (the selling of people), commodification of people (manufacturing people), the body as property and so on, on the one hand, and the freedom of people to make independent choices, the relief of suffering, the greatest happiness of the greatest number and so on the other hand" (Evans 1995).

Though it will be impossible to fully explore all of the ethical issues associated with egg donation in this paper, some of the most prominent questions are briefly described below.

Informed Consent

Informed consent may be one of the clearest ethical issues raised by egg donation since it is relatively non-controversial. As defined above, egg donation entails physical and emotional risk. Any donor should be cognizant of those risks before agreeing to donate, or there is a risk of exploitation or coercion. Additionally, policies should promote ongoing research on risks and publicize any findings. That research is necessary to ensure the relative safety of the donors.

Maximizing Public Health

Egg donation raises issues of individual rights versus societal welfare. Donors choose to undergo the risks of an invasive surgical procedure, but doctors and policymakers may question whether placing a young, fertile donor at risk for harm is justifiable for the benefit of an older, infertile patient. This question is especially problematic because, as discussed above, the long-term side effects to egg donors are still being studied.

Distributive Justice

Egg donation is generally a reproductive option only available to the wealthy. At base, an egg donation cycle costs approximately twenty thousand dollars. Only five thousand dollars is likely to go to the egg donor; the rest of the money goes to the clinic and various other administrative fees (Steinbock 2004). Within the wealthy class of people that can afford this payment, additional distinctions of access are made between those who are willing to spend more or less money on the process. Families willing to spend more on purchasing oocytes have more choice in the characteristics of the woman providing the eggs. Though demand is generally being met for eggs in the United States, there is a potential for women who can afford higher payments for advertising and agency fees to be more likely to receive treatment.

Additionally, highly educated white women with blond hair and blue eyes are most likely to get the highest payments for their eggs, while demand for eggs from women of color has been low (Steinbock 2004). This allows some women to have market access and denies others that same opportunity. Those who are able to sell their eggs are frequently already advantaged by society, while the system reinforces the status of disadvantaged groups. One of the best-known examples of the commercialization of egg donation is Ron Harris's website, www.ronsangels.com, which offers models as egg donors. Donor eggs are auctioned online to "would-be parents willing to pay up to one hundred and fifty thousand dollars in hopes of having a beautiful child." (Goldberg 1999). Clearly, those women have exceptional market access. That access is denied to others, raising issues of distributive economic justice.

Right to Privacy vs. Right to Ancestral and Family Knowledge

Many women donate eggs assuming they will never meet the child or children created from those eggs. However, numerous scholars have challenged that practice of anonymity, charging it denies the right of the child to know his or her origins. Some people note that repeat anonymous egg donation likens the transfer of genetic material to giving blood, even though one has the potential to create new life and the other does not. Scholar Mary Shanley notes, "It seems inappropriate to distance ourselves from our gametes and the procreative potential of our body in the same way we distance ourselves from our blood or organs that can sustain, but not generate a new life." (Shanley 2002). On the flip side, ensuring children created by IVF the ability to learn the identity of their genetic mother puts donors in the uncomfortable position of knowing they may be contacted by their genetic children eighteen years after they donated eggs.

Issues with Non-Corporeal Procreation

Some people argue that in-vitro fertilization and egg or sperm donation are inherently wrong because they remove the process of procreation from the sexual act. These arguments generally stem from religious beliefs that the purpose of the sexual act is procreation, and that procreation should only result from a sexual act. "Egg donation represents another rather large step into turning procreation into manufacturing," says the University of Chicago's Leon Kass. "It's the dehumanization of procreation." (Lopez 1998). Proponents of this argument would outlaw these reproductive technologies altogether.

Human Commodification and the Body as Property

Perhaps the most fundamental ethical issue in the egg donation debate is that of the egg market and the commodification of egg transfer. When eggs, sperm, and embryos can be bought and sold, there is a fine line between buying and selling gametes and buying and selling life itself. The legal implications of treating the body as property are problematic at the least, and raise issues of slavery and the uncomfortable question of how to value a life. The egg donation market in the United States has attempted to solve this problem by ostensibly paying for a woman's time and effort, not the eggs themselves. However, it seems clear that payment disparities exist because of physical and mental characteristics of the egg donors, and thus their eggs, and not the different valuation of their time. Notwithstanding these distinctions, market mechanisms may not be the best regulatory approach toward egg donation, because the market does not currently incorporate externalities like overall public health, or the inability of a child to know its genetic lineage, as described above.

The commodification of eggs also inevitably leads to discussions of eugenics, since there is a notion that people can have the best eggs their money can buy. This notion is played out by the premium prices paid to donors with Ivy League educations, who have fair skin and blue eyes, and who satisfy any number of other qualities desired by the prospective buyers, from athletic ability to religion to general disposition. Though any genetic researcher will dispute the belief that obtaining eggs from a woman with those characteristics will necessarily lead to a child with those qualities, prospective parents are willing to pay for them nonetheless.

Adoption vs. IVF

Finally, a seldom-discussed ethical issue related to egg donation from a policy perspective is whether to promote the practice of egg donation when many children are available for adoption. Numerous psychological studies have outlined the suffering of parents who are unable to conceive their own child (Massachusetts General Hospital Center). How far should public policy go to alleviate that suffering? To what extent is it a human right to be able to procreate? When numerous children are growing up in foster care while loving families are trying desperately to have a baby, how can social welfare be maximized? The way a society addresses those questions will determine its policy responses to the practice of egg donation.

HISTORY OF EGG DONATION POLICIES IN THE UNITED STATES

The extensive potential ethical issues surrounding egg donation would lead one to assume that there would be a strong policy framework in place or at least an active public debate about the creation of such a policy. However, to date the United States has been characterized by a significant lack of regulation regarding reproductive technology. The nation's general approach has been to let the private market regulate egg donation and to make all controls voluntary. There has been extensive public debate about the use of eggs and embryos for embryonic stem cell research, but far less discussion of their use for reproductive purposes. The United States does not require infertility clinics to be licensed by law, and no uniform standards exist about proper methods for egg donor recruitment and care.

Reproductive technology is one of the least regulated medical specialties in the United

States, and physicians and researchers are relatively free to formulate their own policies about procedural standards and ethical questions. However, researchers have not felt compelled to form standards to date, probably because, as opposed to embryonic stem cell research, there has not been a lot of public demand for such standards. The American Society for Reproductive Medicine offers a voluntary accreditation program for infertility clinics³, but the information on the program is only available to members, so their ethical standards are unclear.

Far from restricting egg donation, U.S. policy encourages donation by offering tax deductions for the practice. The Internal Revenue Service ruled in 2003 that a woman seeking egg donation may claim a medical tax deduction for the costs of obtaining and paying for an egg donor (Laffie 2004). The Food and Drug Administration regulates sperm and egg donations, but simply requires they be screened for communicable disease. Some insurance companies offer fertility insurance, but that insurance varies widely in specific coverage. Usually, fertility insurance does not cover the costs of IVF or egg donation. Three states- Illinois, Massachusetts, and Rhode Island- have laws requiring insurance companies to have partial or full coverage of IVF treatments, which cover part of the costs of egg donation (Jain, Harlow & Hornstein 2002).

Therefore, in the absence of federal or voluntary guidelines, the legal system has begun to fill the regulatory void. For instance, high-profile child custody cases involving egg and sperm donation have drawn attention to the inadequacy of the current regulatory framework to govern complicated new family structures where a child might have four to five parents with varying legal and social standing. In the high-profile *Buzzanca v. Buzzanca* case, a child in California was born in 1995 from an embryo created from donated eggs and sperm implanted in a surrogate mother. The couple having the child, or more appropriately, paying for the child to be had, filed for divorce one month before the child was to be born. The couple then went to court over whether or not the husband would have to pay child support for the new baby, at which point the surrogate mother decided she would sue for custody as well. The egg and sperm donors then both sued, saying their eggs/sperm had been used without their permission. After a three-year court battle during which the child was in custody limbo, an appeals court gave the wife custody and decided the husband is the legal father, making him responsible for child support". By contracting for a medical procedure resulting in the birth of a child, the court ruled, a couple incurs the legal status of parenthood" (Lopez 2006). Whether permission was given for the use of the eggs and sperm was not decided. Overall, courts have ruled that the parent who has contracted to create the child has custody, as was decided in the seminal *Johnson v. Calvert* surrogacy case in 1993 (Pinkerton 2001).

In response to these rulings, numerous states have instituted laws defining parental rights and responsibilities in regards to egg and sperm donation and surrogacy, including Colorado, Louisiana, North Dakota, Oklahoma, Oregon, Texas, Utah, Virginia, Washington, and Wyoming (National Conference of State Legislatures 2005). California and New York have begun to address the issue of informed consent by implementing laws defining what an egg donor must be told before agreeing to donate, and mandating signed consent agreements. The state of New York has taken more action than any other, by forming the New York State Task Force on Life and the Law, which released a report in 1998 finding that egg donors were frequently not adequately informed about the process and risks of egg donation. The report states, "The Task Force's review of egg donor consent forms from programs in New York State revealed wide

variability in the nature and detail of information regarding the medical risks of donation. In some programs, IVF patients and egg donors are given different risk data on the same medications and procedures” (New York State Taskforce on Life and the Law). The Task Force report then recommends, “Information about the potential risks associated with all phases of egg donation should be given to prospective donors before screening tests have been performed and before the donor has been matched to a recipient” (New York State Taskforce on Life and the Law). Though New York then proceeded to an informed consent law, the majority of the country remains unregulated. Also, New York has outlawed direct payment for gametes and embryos; instead, egg donors are paid for their time and discomfort. California also has an advisory committee on the use of eggs in embryonic stem cell research as a result of Proposition 71. The committee recently released guidelines that prohibit the sale of eggs and only allow for a donor’s monetary costs to be covered (California Institute for Regenerative Medicine). However, the recommendations do not apply to eggs used to facilitate reproduction.

HISTORY OF EGG DONATION POLICIES IN THE UNITED KINGDOM

The United Kingdom has taken the opposite approach from the United States in regulating egg donation. From early on, the United Kingdom established regulatory agencies and procedures governing virtually every aspect of egg donation in both the public and private sectors. The birth of Louise Brown, the first child conceived through in-vitro fertilization in 1978, spurred U.K. lawmakers to form an advisory committee chaired by philosopher Mary Warnock to consider the ethical repercussions of in-vitro fertilization and other reproductive technologies. In 1984, the Warnock Committee recommended that the British government establish a government licensing authority for reproductive technologies, and that the buying and selling of gametes and embryos be prohibited. These recommendations were made in the context of substantial interest on the part of the U.K. public with regards to regulating the process of IVF and gamete donation. The Warnock Report notes that they received written and oral evidence from hundreds of interested individuals and organizations (Warnock, 1984). Public debate raised many of the ethical issues described above and added others, such as the unlikely, but possible, inter-marrying of unknown half-siblings. Six years later, virtually all of the Warnock Committee’s recommendations were translated into the Human Fertilization and Embryology Act (HFE Act) of 1990.

The HFE Act, Section 12E, states, “No money or other benefit shall be given or received in respect of any supply of gametes or embryos unless authorized by Directions.” The Act stipulates that certain expenses can be covered for donors, including travel and medical expenses, and compensation for lost wages. However, no additional compensation can be given. In essence, this treats the time spent donating sperm and the time spent donating eggs equally.

The HFE Act also created the Human Fertilization and Embryology Authority (HFEA), which enforces the prohibition of gamete commodification, facilitates the voluntary transfer of both sperm and eggs for the purposes of research or infertility treatments, licenses all fertility clinics and research labs, and maintains a database of all sperm/egg donors, recipients, and children conceived through these reproductive technologies. The HFE Act addresses many of the ethical issues associated with egg donation, including commodification, informed consent, and the relative importance for public policy to facilitate procreation. On the latter point, “the Act

implicitly acknowledges that facilitating the creation of children is a good to the child itself, to its parents (whose suffering is alleviated) and to society at large (who may benefit from scientist's increased understanding of human reproduction)" (Plomer & Martin-Clement 1995).

Additionally, in 2004 the United Kingdom passed a measure to require that children born through egg and sperm donation be able to find out who their genetic parents are once they reach age eighteen. Though controversial, the law went into effect in April 2005, and anyone donating after that date will not be an anonymous donor. The HFEA website now states on its "interested donors" page:

Under the Human Fertilisation and Embryology Act 1990, people could apply to find out if they were conceived using donated sperm, eggs or embryos. They could also check whether they were related to someone they wanted to marry. But they did not have the right to know who the donor was. Over the past few years, attitudes towards donation and people's right to know about their genetic origins have changed. As a result, on 1 April 2005 a new law came into effect, which allows people conceived through donation to find out who the donor was, once they reach eighteen (Human Fertilisation and Embryology Authority).

As would be expected after all of these regulations, the rate of egg donation in the United Kingdom has been considerably lower than that of the United States. Consequently, there is a three to five year waiting period for couples wishing to obtain donated eggs. The HFEA keeps a database of donors and couples seeking a donation, and tries to match up couples seeking treatment with a donor that closely matches their wishes. However, couples are not able to dictate specifics the same way that U.S. couples can. Couples seeking treatment can also skip past others on the waiting list by recruiting fertile women friends and relatives to contribute their eggs to the anonymous donor pool. Under pressure to increase the availability of eggs, the HFEA proposed three other possible sources for eggs in its 2006 report on the subject, including the use of immature eggs obtained from live donors or cadavers, ovarian tissue grafting, and ovarian tissue from aborted fetuses (Human Fertilisation and Embryology Authority). However, the first and third of these options has not yet been proven in a clinical setting, and the second is only useful for a small subset of infertile couples. As a result of the high levels of unmet demand, there has been a dramatic increase of UK citizens flying to the United States to purchase eggs from U.S. women (McGrath 2001).

There is also evidence that regulation in the United Kingdom has caused the country to fall behind in effective IVF treatment. An article last year in *The Times* claimed that, "While Belgium is top, with 40.5 percent of infertility patients becoming pregnant, British clinics manage only a 28.6 percent success rate, eclipsed by countries such as Slovenia and Ukraine" (Rogers 2006). There is a growing concern that the United Kingdom will fall behind in research and fertility treatment efficacy because of its restrictive egg donation policies.

COMPARING THE UNITED STATES AND UNITED KINGDOM APPROACHES

However disparate they may seem, there are some similarities between the United States and United Kingdom approaches. Neither country has discouraged reproductive technologies in favor of increasing adoption rates. In doing so, both countries implicitly determine that the state has an interest in assisting its citizens' quest for their own procreation. Beyond that base similarity, however, the two countries prioritize very different interests in their respective policies.

The absence of regulation in the United States directly benefits two parties: fertility clinics, and infertile couples seeking treatment. Fertility clinics operate with higher profit margins, and make their own policies largely without government oversight. Infertile couples have substantial control over the characteristics of the egg donor, and are able to get an egg donor quickly. U.S. policy thus prioritizes the right of individual choice, the desire to procreate, and the promotion of economic activity. As a result, it disadvantages egg donors in that they are not guaranteed the right to informed consent. It also ignores most of the other thorny ethical issues described above in a laissez-faire approach to market promotion, and denies the public a voice in affecting the issue. Finally, by letting the market drive up prices, it disadvantages the poor by preventing access to the technology. As is historically consistent for U.S. policy, personal choice remains the primary driving force for legislation, or lack thereof. The primary fault in this approach is that it assumes free information in order for the market to adequately function, and there is evidence showing that assumption is invalid. As stated above, the New York State Task Force on Life and the Law found that informed consent was not always obtained from egg donors, and recent medical studies have outlined uncertainties in the long-term medical effects of egg donation. Under these circumstances, free information can be difficult to attain.

The United Kingdom attempts to address the majority of the ethical issues defined above, but in doing so, it drastically restricts supply and fails to adequately compensate donors for their risk and pain. The regulation ensures the informed consent of the donor, but removes most incentives for women to become donors and disadvantages those who choose to go forward with the process. It sets up a regulatory body to track all donors and the children resulting from donation, and therefore prevents intermarrying. By outlawing the sale of eggs, it removes the issues associated with commodification, and neutralizes most of the concerns about eugenics. It removes the role of the market and imposes strict regulations on fertilization clinics, thus increasing the power of the state. It also gives power to the general public, which has a venue to express its opinions and lobby for change. The parties benefiting from these policies include researchers, the children produced from assisted reproduction technologies, the state, the public, and donors who have informed consent who otherwise might not. Obviously, it greatly disadvantages infertile couples seeking treatment.

There is an unacceptable lack of U.S. regulation on reproductive technologies, opening young women to risk and over-emphasizing the needs of the market. The United Kingdom should be applauded for its steps to address the issue. However, in its zeal the U.K. policy makes egg donation an impossibility for many, and drives British women to seek egg donors abroad. The policies of both countries have faults and both need revision. The next section outlines one possible approach that would create more ethical, streamlined regulations for both nations.

RECOMMENDATIONS

Regulate Egg Donation through the Clinical Trial Structure

Both the United States and the United Kingdom have a process already in place that could be used to address many of the concerns raised by egg donation: the clinical trial structure. Clinical trials are used to prove the safety of new medical procedures and drugs. In the United States, the clinical trial process was initially implemented to ensure informed consent in drug testing and the efficacy of new medical procedures. The clinical trial process in both nations includes extensive informed consent procedures and regulated standards for monetary compensation.

By treating egg donation like a clinical trial, a woman could be paid in a manner commensurate with her time and discomfort, but the payment would not be directly related to the egg donated. Like other clinical trials, she would be paid for her time, her inconvenience, and the risk associated with the procedure. Since sperm donation is significantly easier, less risky, and less time-intensive than egg donation, it can be assumed that a lower payment level would be assigned to that task. Thus, this approach avoids commodifying life, but can still leave room for adequate payment for donors.

Additionally, there is already extensive public policy enacted around clinical trials that could be borrowed to create a new framework for reproductive technology regulation. The FDA has extensive guidelines for the proper execution of a clinical trial (United States Food and Drug Administration), most of which are applicable to egg and sperm donation. Since the little federal regulation present in the United States on egg and sperm donation is administered through the FDA, the administrative shift would be minimal. The very term “clinical trial” lends more solemnity to the procedure and gives potential donors a signal that there might be medical repercussions to their actions.

The process of advertising for clinical trials is closely regulated and avoids the emotional pleas and bloated financial promises made in current egg donation ads. In fact, when egg donation was being developed at the University of California, Los Angeles, in the 1970s, it was treated as a clinical trial. The human subjects (or donors) were compensated fifty dollars a day for their time and expenses (Sauer 2001). Though the payment would undoubtedly be higher now, the same structure could hold true.

Though payment would be sufficient in a clinical trial setting, it would still likely be less than some of the high-end payments currently being offered in the United States for eggs. Thus, some of the eugenic and economic disparity issues would be addressed. The Federal Drug Administration states that, “The amount of compensation [for a clinical trial] is determined by the amount of time you will be required to dedicate to the trial, and to the level of discomfort that might be associated with medical or surgical procedures related directly to the study” (United States Food and Drug Administration). People would not be able to pay for eggs of “a higher caliber” and everyone would be put in the same pool, like the system in the United Kingdom. This will lower the current prices faced by couples seeking infertility treatment in the United

States, and allow access to more people, though it would potentially reduce the number of egg donors.

In the United Kingdom, only a minor legal shift would be necessary, at which point the HFEA could begin to offer donors more reasonable payment, which would assist in alleviating the egg supply shortage. Clinical trials are currently run through the United Kingdom Department of Health, so the HFEA would have to be given special regulatory authority to run them in relation to gamete donation, but that should not prove overly difficult. With that change, the United Kingdom would have a policy that both adequately addresses ethical concerns and maximizes the availability of the technology within those constraints.

There are additional steps the U.S. should take to regulate these reproductive technologies. They include:

Create a United States Equivalent of the HFEA

If a clinical trial system is implemented, a separate FDA office on reproductive technologies should be created. There is a strong argument to be made for a centralized authority that maintains information on donors and recipients, both for regulatory and research purposes. Additionally, the government has a responsibility to engage with the ethical issues around egg donation in order to ensure the maximum public good, and this kind of authority would be able to achieve that goal. This office could operate somewhat like the HFEA, in that they could regulate fertility clinics and serve as a repository of information.

As the United States deals with additional issues like whether children should be able to contact their genetic parents, it should utilize the many resources already created on these issues, such as the report from the New York State Taskforce on Life and the Law referenced above. There have already been panels of ethicists formed to discuss reproductive technologies.⁴ The new FDA office should draw from them to maintain an ongoing ethics advisory panel consisting of diverse stakeholders in the issue. The panel could advise on particularly difficult cases the FDA encounters as these technologies continue to evolve.

Ensure an Avenue for Public Involvement

Implementing any kind of regulatory structure will allow citizens a more active voice than they currently have, giving them an avenue to petition for change. Since there has not been a mass public uproar over egg donation to date in the United States, many assume that the majority of U.S. citizens approve of the idea. However, a study done in 1999 on opinions of eighteen to twenty-two year olds on reproductive technologies shows only a forty-four percent approval rating for egg donation (Lasker 2001). Whatever the actual approval ratings, citizens need an avenue to express their opinions over egg donation and the policies that should govern it. The FDA authority should have clear and transparent avenues for public input into its policies. Additionally, it would be very useful to have more polling data on reproductive technologies in order to gauge the appropriate level of regulation on these issues.

Do Not Neglect Adoption

Finally, in order to maximize the public good policy should try to match parents who desperately want to have a child with children who desperately want to have a home. The goal of policy should be to create healthy families; however that can best be achieved. Though there are undoubtedly many couples that would not consider adoption, there may be many others that would. Therefore, the government should continue to promote adoption in every way possible.

CONCLUSION

Egg donation is a complex issue in any country. As described above, there are numerous different ways to address it from a public policy standpoint. The quest to create new life should not be taken lightly; it should be respected as the powerful force it is. Every country has an interest in ensuring the presence of future generations in order to carry on the country's governance and traditions. Couples who are unable to conceive their own child suffer, and their countries should continue to help them in their quest for procreation⁵. So far, the United States has recognized that suffering and has assisted those couples through tax incentives and a laissez-faire attitude toward the gamete donation market. However, the country's confirmation of the importance of procreation has led to policies that disadvantage the children created through the process of egg donation, and potentially the donors as well. The American public has largely ignored the ethical issues involved with egg donation, but that does not mean the government should do the same. Many states, like New York, have begun engaging in a dialogue about egg donation and the ethical dilemmas it can raise. Those discussions should inform a new national initiative to establish federal standards.

Regulations in the United Kingdom disproportionately disadvantage couples that want to have children and cannot. The HFEA regulations have ensured a shortage of donated eggs and the continuing suffering of infertile couples. Because of their stringency, the U.K. regulations may prove ineffective in the long run- in an increasingly globalized world, women will increasingly seek treatment abroad. The United Kingdom must find a more balanced way to regulate in order to create a just policy. The plight of these couples may make public sentiment amenable to a revised policy. Egg donation has societal benefits and ethical risks. The birth of a new baby is a great joy, and the use of egg donation can bring new children into loving families. It is possible for the practice of egg donation to be used in an ethical way. As a society, we must develop moderate policies that allow egg donation but guard against the many ethical quagmires that can result from it. The adoption of a clinical trial framework would be one step towards that goal.

ENDNOTES

¹ As a point of clarification, in this paper I will use the term "egg donor", even though in the United States women usually sell their eggs for profit. The use of the term "donor" results from its standing as the societal norm.

² In recent years, advances have been made to allow frozen embryos to be implanted, thereby removing the difficulty of synchronizing the women's cycles and allowing eggs to be preserved for longer periods of time. However, this process is still very rare.

³ Information on the ASRM's voluntary program can be found at:
<http://www.asrm.org/Media/Practice/practice.html>

⁴ For instance, the Presidents Council on Bioethics or the National Bioethics Advisory Commission.

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