Lessons Learned from Great Britain's Human Fertilization and Embryology Act: Should the United States Regulate the Fate of Unused Frozen Embryos

Lee Kuo
LESSONS LEARNED FROM GREAT BRITAIN’S HUMAN FERTILIZATION AND EMBRYOLOGY ACT: SHOULD THE UNITED STATES REGULATE THE FATE OF UNUSED FROZEN EMBRYOS?

I. INTRODUCTION

Assisted reproductive technology, a general term encompassing various methods of helping infertile couples to conceive children, has received more than its share of media attention over the past years. Recently, the media has focused on controversies involving governmental regulation of the reproductive technology industry.

On August 1, 1996, in compliance with a federal statute, fertility clinic operators in Great Britain destroyed more than 3,000 frozen embryos. Doctors removed the embryos from their freezing containers, allowed them to thaw, and then destroyed the embryos with a few drops of alcohol. Many desperate “mothers” scrambled to save their embryos; however, most of them were unsuccessful.

The Catholic Church called the event a “prenatal massacre.” Italian doctors offered to “adopt” the embryos by purchasing and transporting them to Italy for implantation into women willing to receive them. Fertility experts and health officials criticized the destruction. Anti-abortionists called August 1, 1996 a “day of

1. See Human Fertilisation and Embryology Act, 1990, ch. 37 (Eng.).
2. See Cindy Schreuder, Embryo Issue From American View, Unlike Britain, We Have Little Regulation, CHI. TRIB., Aug. 4, 1996, at Cl.
4. See Kathy Marks, Woman Ends Fight to Save Embryo, DAILY TELEGRAPH (London), Aug. 9, 1996, at 8. See also Cameron Simpson, Call for Changes to Law on Embryos; Church Steps in as Clinics Prepare to Dispose of Frozen Stocks, HERALD (Glasgow), Aug. 1, 1996, at 4.
5. See Ibrahim, supra note 3.
6. See id.
7. See Simpson, supra note 4.

1027
national shame."\(^8\)

Great Britain is not alone in the spotlight of this controversy. In May 1995, improprieties at a prominent fertility clinic at the University of California, Irvine (UCI) were exposed.\(^9\) Three doctors at that clinic allegedly transferred embryos from one patient to another without either patient's consent or knowledge.\(^10\) In the eighteen months since UCI's fertility scandal unfolded, the clinic closed, its three doctors were indicted, more than 80 civil lawsuits were filed, and a one million dollar settlement has been paid to two couples.\(^11\) This incident spawned an immediate response from California legislators.\(^12\)

Another incident involved Rhode Island's only fertility clinic. In September 1995, two couples filed suit against Women and Infants Hospital for allegedly losing nine embryos.\(^13\)

Assisted reproductive technology has commanded society's attention since the birth of the first "test tube baby" in 1978.\(^14\) Since that time, the United States and Great Britain have both made headlines for their roles in the unfortunate fate of some embryos. The method and extent of regulation to address these concerns, however, differ greatly in each country.

Great Britain's regulations are codified in the Human Fertilization and Embryology Act of 1990.\(^15\) This extensive act contains forty-nine sections and runs fifty pages.\(^16\) The United States, by contrast, has passed very limited legislation. The legislation pertains almost exclusively to data collection in the field.\(^17\) This Comment analyzes the regulatory practices of the United States

---

8. See Ibrahim, supra note 3.
10. See id.
15. See Human Fertilisation and Embryology Act, 1990, ch. 37 (Eng.).
16. See id.
17. See Stenger, supra note 14, at 137.
Regulating Frozen Embryos

1997] Regulating Frozen Embryos 1029

and Great Britain, assesses the fallout from the mass "thawing" in Great Britain, and recommends that the U.S. federal government not regulate the fate of unused cryopreserved embryos. This recommendation considers the constitutional rights of individuals as well as practical legislative and technological issues.

Part II of the Comment describes the processes of in vitro fertilization and cryopreservation. Part III discusses the current U.S. approach to regulating assisted reproduction. Part IV focuses on Britain's Human Fertilization and Embryology Act, which mandates destruction of frozen embryos after ten years of storage. Part V discusses the aftermath of the destruction of cryopreserved embryos in Britain. Finally, Part VI presents issues for the U.S. government to consider and recommends that the federal government not regulate the fate of unused frozen embryos.

II. THE PROCESSES OF IN VITRO FERTILIZATION AND CRYOGENIC PRESERVATION OF EMBRYOS

In vitro fertilization (IVF) is a medical procedure that affords infertile couples an opportunity to conceive a child. To better understand the legal implications of IVF, the following describes the basic medical procedures involved in the cryopreservation of IVF embryos.

The IVF procedure takes approximately two weeks to complete. First, the woman receives hormonal medication to hyperstimulate her ovaries to produce an increased number of eggs. A second medication is then injected, stimulating a "hormonal surge"

18. "Cryopreservation" and "frozen" are used synonymously in this Comment. The process of cryopreservation will be discussed in detail in Part II.
22. See id.
that causes ovulation in approximately thirty-six hours.\textsuperscript{23} The next step involves removal of the eggs by either laparoscopy or ultrasound–guided transvaginal aspiration.\textsuperscript{24}

A laparoscopy can be performed approximately thirty–four hours after ovulation, and on an outpatient basis, under general anesthesia.\textsuperscript{25} Two or three small incisions are made in the abdomen, through which a laparscope and a hollow needle are inserted. The needle is used to retrieve the eggs.\textsuperscript{26}

Physicians utilize an ultrasound machine to perform ultrasound–guided transvaginal aspiration.\textsuperscript{27} The physicians insert the suctioning needle through the abdomen and bladder, or through the vagina.\textsuperscript{28} Ultrasound–guided transvaginal aspiration may be preferable for patients with abdominal adhesions.\textsuperscript{29} Unlike laparoscopy, the procedure is less expensive and does not require general anesthesia.\textsuperscript{30}

If suitable eggs are retrieved, the father will provide a sperm sample.\textsuperscript{31} Technicians combine the eggs and sperm, and wait to see if fertilization occurs.\textsuperscript{32} If fertilization occurs, the embryos are allowed to divide for about three days until they reach the two to eight–cell stage.\textsuperscript{33} The embryos are then either implanted immediately in the patient or cryopreserved for later implantation.\textsuperscript{34}

Cryopreservation is achieved by freezing the embryos in liquid nitrogen at negative 195 degrees centigrade.\textsuperscript{35} After freezing, the embryos are carefully stored and may later be thawed for im-

\begin{footnotes}
\textsuperscript{23} See Perry & Schneider, supra note 21, at 467.
\textsuperscript{24} See id.
\textsuperscript{25} See id.
\textsuperscript{26} See id.
\textsuperscript{27} See BONNICKSEN, supra note 20, at 149.
\textsuperscript{28} See id.; Perry & Schneider, supra note 21, at 467.
\textsuperscript{29} See Perry & Schneider, supra note 21, at 467.
\textsuperscript{30} See BONNICKSEN, supra note 20, at 149.
\textsuperscript{31} See Perry & Schneider, supra note 21, at 467.
\textsuperscript{32} See AFS, supra note 20, at 378.
\textsuperscript{33} See John A. Robertson, In the Beginning: The Legal Status of Early Embryos, 76 VA. L. REV. 437, 441 (1990); BONNICKSEN, supra note 20, at 150.
\textsuperscript{34} See Perry & Schneider, supra note 21, at 468.
\textsuperscript{35} See id.
\end{footnotes}
Regulating Frozen Embryos

plantation in a recipient's uterus.\textsuperscript{36}

Combining IVF and cryopreservation of embryos allows postponing embryo implantation until the negative effects of the ovarian-stimulating hormone have passed.\textsuperscript{37} Furthermore, cryopreservation of embryos for later use is far less expensive than extraction and fertilization of eggs on each successive attempt at IVF.\textsuperscript{38}

Although IVF is considered a medical miracle, it is controversial. Over 100 special commission reports worldwide concentrated on the ethical and legal issues raised by IVF.\textsuperscript{39} Both the United States and Great Britain have attempted to address these controversies, but the two countries have very different approaches to regulating IVF and cryopreservation.

III. THE UNITED STATES APPROACH TO REGULATION

\textit{Davis v. Davis}\textsuperscript{40} was the initial U.S. case that prompted concern for the fate of unused embryos. In that case, frozen embryos were at the center of a custody battle during a divorce proceeding.\textsuperscript{41} Initially, Mary Sue Davis sought custody of the embryos for future implantation.\textsuperscript{42} During the course of the proceedings, however, Mary Sue remarried and wanted to donate the embryos to a childless couple.\textsuperscript{43} Junior Davis objected to granting Mary Sue custody because he did not want to become a parent outside the bounds of marriage.\textsuperscript{44}

The Tennessee Supreme Court denied Mary Sue's request for custody. In support of its denial, the Court stated that no prior agreement had been made, and Mary Sue had other reasonable

\begin{itemize}
  \item \textsuperscript{36} See \textit{id}.
  \item \textsuperscript{37} See \textit{id}. Ovarian-stimulating hormones temporarily reduce the ability of the uterine lining to accept the fertilized embryo. See Machelle M. Seibel, \textit{A New Era in Reproductive Technology: In Vitro Fertilization, Gamete Intrafallopian Transfer, and Donated Gametes and Embryos}, 318 NEW. ENG. J. MED. 828 (1988).
  \item \textsuperscript{38} See Perry & Schneider, supra note 21, at 468.
  \item \textsuperscript{39} See Bartha M. Knoppers & Sonia LeBris, \textit{Recent Advances in Medically Assisted Conception: Legal, Ethical and Social Issues}, 17 AM. J.L. & MED. 329 (1991).
  \item \textsuperscript{40} 842 S.W.2d 588 (Tenn. 1992).
  \item \textsuperscript{41} See \textit{id} at 589.
  \item \textsuperscript{42} See \textit{id}.
  \item \textsuperscript{43} See \textit{id} at 590.
  \item \textsuperscript{44} See \textit{id} at 589.
\end{itemize}
ways to become a parent. For many commentators, the next question was the fate of the frozen embryos.

A. Federal Regulations

Few U.S. federal regulations exist on the issue of assisted reproductive technology. Moreover, none of these regulations deal with unused embryos.

One example of federal regulation is the National Institutes of Health Revitalization Act of 1993. It created research centers designed to study contraception, infertility, and the transplantation of fetal tissue.

The Fertility Clinic Success Rate and Certification Act of 1992 calls for annual reporting to the Centers for Disease Control of pregnancy success rates achieved by assisted reproductive technology programs. The Act also calls for the development of a model program for certifying embryo laboratories. This law never went into effect, however, because of funding problems. If the law had gone into effect, compliance would have been voluntary and no penalties would have been assessed for failing to report or for reporting falsely.

There are numerous reasons for the failure to address issues of human reproduction at the national level. One reason is the volatile issue of abortion, and another is concern over federalism. Both issues are discussed in Section VI of this Comment.
Regulating Frozen Embryos

B. Private Preconception Agreements

Clinics and gamete donors generally determine the fate of embryos through private preconception agreements.58 According to Dr. Joseph D. Schulman, director of the Genetics and IVF Institute in Fairfax, Virginia, “as a matter of policy in virtually all in-vitro fertilization centers, decisions are made by the individual couples.”59 In the United States, most clinics offer to store embryos for a specified period of time. In addition, the clinics ask each couple to provide written direction on what should happen to the embryos if the couple divorces, if one or both partners die, or if they lose touch with the clinic.60 There are usually four options for dealing with unused embryos: storage, destruction, donation to other infertile couples, or use in research.61 If the clinics are unable to contact the couple, they normally try to follow the couple’s written directions.62

A major problem with these agreements is that clients do not truly contemplate the consequences of their decisions.63 The agreements are executed early in the process, well before clients might face the events considered in the agreements.64 Thus, the clients may be bound by agreements that do not reflect their true interests.65 In addition, the clients may not have been fully informed about the issues in the agreement.66

A final problem is that clients are anxious to overcome infertility problems and often consent to these agreements under unconscionable circumstances.67 One commentator notes that “IVF programs and embryo banks may have such monopoly power that

58. See, e.g., Schreuder, supra note 2, at C1.
60. See Schreuder, supra note 2, at C1.
61. See id.
63. See Robertson, supra note 33, at 465. Professor John Robertson argues that preconception agreements for disposition of embryos should not be enforceable because they are analogous to preconception agreements “to abort, not to abort, or to give up for adoption,” which are unenforceable. See id.
64. See id.
65. See id.
66. See id.
67. See id.
the conditions they offer give couples little real choice, making them the equivalent of adhesion contracts. 68

Three elements must exist for a contract to be valid: offer, acceptance of the offer, and consideration. 69 An agreement may still be unenforceable despite proper formation of the contract. 70 Where a properly formed agreement contravenes the public policy of a particular jurisdiction, courts have traditionally found the agreement unenforceable. 71 No court has decided the viability of unconscionability claims with regard to preconception agreements between patients and fertility clinics. 72

IV. THE BRITISH APPROACH TO REGULATION

On July 25, 1978, events in Great Britain spawned worldwide public discussion of IVF. On this day, Louise Brown was born and became the world’s first “test tube” baby. 73

Following the birth of Louise Brown, churches commissioned many committees to study the ethical, legal, social, and political ramifications of IVF. 74 In July 1982, the British Government’s Secretary of State for Social Services announced the establishment of a sixteen-member committee of inquiry. 75 Philosopher Mary Warnock headed the committee, which was composed of theologians, social workers, attorneys, and scientists. 76

---

68. Id.
70. See id.
72. No such cases have been reported yet. At least one court, however, decided in favor of a donor couple based on a preconception agreement. The couple wanted to transfer their embryo to another institution, but the defendant institution refused, arguing that the preconception agreement did not allow for transfer of the embryo. The court held the agreement established an ownership right for the gamete donors, and therefore, a right to transfer the embryos. See York v. Jones, 717 F.Supp. 421, 423-27 (E.D. Va. 1989).
73. See Stenger, supra note 14, at 139.
74. See id. at 140.
75. See id. at 140-41.
76. See id.
Regulating Frozen Embryos

A. The Warnock Report

The Warnock Report was presented to the British Parliament on June 26, 1984. Its findings and recommendations were broad, covering topics ranging from artificial insemination to IVF, from surrogacy issues to research issues. Subsequent legislation incorporated many of the Warnock Report's recommendations.

Specifically, the Report recommended a definite time limit for the storage of frozen embryos because of the unknown effects of long-term storage and the legal and ethical complications that might arise over disposal of embryos whose parents have died, obtained a divorce, or otherwise separated. Furthermore, the Report concluded that it would be "unreasonable and impractical to expect those responsible for storage to maintain all eggs and semen stored indefinitely." The report, therefore, recommended a review of the embryos after five years to assess the couple's wishes, with a maximum of ten years of storage. After the ten-year period, the right to use or dispose of the embryos should pass to the storage authority.

B. The Human Fertilization and Embryology Act

Great Britain's Human Fertilization and Embryology Act of 1990 (HFEA) governs a wide range of assisted reproductive technology activities. One of the HFEA's provisions created the Human Fertilization and Embryology Authority, a statutory licensing authority.

78. See id.
79. See Stenger, supra note 14, at 142.
80. See Warnock Report, supra note 77, at 56.
81. Id. at 55.
82. See id. at 56.
83. See id. Other recommendations include: no right of ownership in a human embryo; when one member of a couple dies, the right to use or dispose of the embryo should pass to the survivor (or to the storage authority, should both die); and when there is no agreement between the couple, the right to determine use or disposal should pass to the storage authority as if the ten year period had expired. See id. at 56-57.
84. See Human Fertilisation and Embryology Act, 1990, ch. 37 (Eng.).
85. See id. § 8.
The major effect of the HFEA is the licensing of persons and premises involved with reproductive technologies. Licenses may be granted for providing treatment services, storage of gametes and embryos, and research. The HFEA also establishes boundaries beyond which treatment and research may not venture, defines technologies to be licensed, and determines the legal status of the resulting children.

The pertinent portion of the HFEA, involving storage of embryos, went into effect on August 1, 1991. Section 14 states that “no gametes or embryos shall be kept in storage for longer than the statutory storage period and, if stored at the end of the period, shall be allowed to perish.” The HFEA originally set the statutory storage period at five years. Any clinic that violates this storage provision runs the risk of losing its license and possible criminal prosecution.

In May 1996, the British government, amid growing concern of the impending mass embryo thawing, amended section 14 of the HFEA. This amendment extended the statutory maximum storage time, as long as both the “mother” and “father” consent to

The Authority shall:

(a) keep under review information about embryos and any subsequent development of embryos and about the provision of treatment services and activities governed by this Act, and advise the Secretary of State, if he asks to do so,

(b) publicise the services provided to the public by the Authority or provided in pursuance of licences,

(c) provide, to such extent as is considered appropriate, advice and information for persons to whom licences apply or who are receiving treatment services or providing gametes or embryos for use for the purposes of activities governed by the Act, or may wish to do so, and

(d) perform such other functions as may be specified in regulations.

86. See Stenger, supra note 14, at 146.
87. See Human Fertilization and Embryology Act § 11.
88. See Stenger, supra note 14, at 147.
89. See id. at 145 n. 75. The administrative arrangements for the HFEA and section 36 concerning surrogacy went into effect on November 7, 1990, while all other provisions except section 30 (parental orders) became effective on August 1, 1991. See id.
91. See id.
92. See id. §§ 18, 41. An offending person is “liable on conviction on indictment to imprisonment for a term not exceeding ten years or a fine or both.” Id. § 41.
93. See Human Fertilisation and Embryology Regulations, 1996, § 2 (Eng.).
Regulating Frozen Embryos storage beyond five years.94

C. British Privacy Law

Under British law, there is little question regarding Parliament's authority to pass legislation such as the HFEA. Unlike U.S. law, English law does not explicitly recognize a right to privacy.95 Privacy rights in Britain, to the extent they exist, are formulated quite differently than in the United States.96 In fact, a popular treatise on privacy rights in Britain does not discuss freedom of choice with respect to sexuality, reproduction, or familial/parental relations.97 Although British law addresses these issues, they do not fall within the rubric of privacy.98 Thus, one commentator has referred to privacy rights in Britain as a "patchwork affair."99

Early British judicial decisions and legislation lacked any notion of privacy.100 This was a reflection of Britain's reserved authority to make laws regulating any aspect of community life.101 Thus, the British citizen has no guaranteed right to seek redress against intrusive government activity.102

Despite government resistance, British citizens have seized upon the concept of privacy as a potential means to obtain judicial relief from unduly burdensome government intrusion.103 Citizens have lobbied Parliament for a statutory right of privacy, argued before the courts for a common law right of privacy, and traveled to Strasbourg, France to obtain a hearing before an international human rights court.104 Unfortunately, these efforts to carve out an

94. See Human Fertilisation and Embryology Regulations, 1996, Schedule (Eng.). Maximum storage periods range from six to thirty-nine years, depending on the woman's age at the time of the procedure. See id.
98. See Krotoszynski, supra note 96, at 1402.
99. Id.
100. See WALTER PRATT, PRIVACY IN BRITAIN 60 (1979).
101. See Krotoszynski, supra note 96, at 1402.
102. See id. at 1403.
103. See id.
104. See id.
effective institutional process to guarantee privacy interests have largely been unsuccessful and the prospects for reform are bleak.105

The primary source of legal rights in Britain is statutory law.106 "Respect for the supremacy of Parliament, fear that rapid change in the law will create uncertainty and a tendency to maintain a positivist jurisprudential outlook preclude British judges from developing social policy."107 These same factors also discourage judges from using broad legal constructs, such as privacy, to grant rights.108

It is possible that the HFEA has not been challenged because British courts do not recognize privacy. British Parliament freely regulates into the realms of privacy, which the U.S. Supreme Court guards against. Abortion represents an illustration of this difference.

"Theoretically, the right to abortion enjoys less protection in Britain than in the United States."109 As opposed to U.S. law, the British Abortion Act110 generally criminalizes abortion in Britain.111 In practice, however, the Act's exception clause swallows the whole Act. The exception clause allows legal abortions for the physical and mental well-being of the mother and in the case of deformed fetuses.112 By liberally construing this provision, courts, with Parliament's tacit approval, have effectively permitted abortion.113

Parliament's deference to a woman's decision to have an abortion has not, however, led to general discussions of rights of privacy.114 Rather, British citizens appear to rely on a principle of governmental self-restraint coupled with a notion of liberty vest-

105. See id.
106. See id. at 1404.
107. Id.
108. See id.
109. See id. at 1408.
110. Abortion Act, 1967, ch. 87 (Eng.).
111. See Krotoszynski, supra note 96, at 1408.
112. See Abortion Act § 1.
113. See Krotoszynski, supra note 96, at 1406.
114. See id.
Regulating Frozen Embryos

In other words, that which Parliament does not prohibit is permitted. Thus, privacy is “protected” by Parliament’s indifference or deliberate inaction. Nonetheless, no procedure exists to prevent Parliament from impinging on privacy rights. “Individual autonomy is subject to summary abrogation by parliamentary fiat.”

In contrast to U.S. courts, British courts consistently refuse to recognize or create any rights of privacy. British judges believe it is “no function of the courts to legislate in a new field.” Because British courts view legal reform as Parliament’s prerogative, it would be anomalous for them to unilaterally create a right of privacy.

One can infer that Parliament had the authority to pass the HFEA because it has the authority to regulate abortion and both issues affect rights to privacy. Furthermore, with plenary power vested in Parliament and a judicial system that automatically defers to Parliament on issues concerning privacy rights, challenges to the HFEA and its provisions on frozen embryos have not been successful.

V. THE IMPACT AND FALLOUT OF THE BRITISH MASS "EMBRYOCIDE"

“In the end, some 3300 embryos—left by couples who had lost touch with the clinic or chose not to come forward—were destroyed . . . a move some critics charged as tantamount to murder. Others, however, said these products of in vitro fertilization were little more than specks of genetic material.”

On August 1, 1996, the lapse of the five-year statutory period

116. See id.
117. See Krotoszynski, supra note 96, at 1409.
118. See id.
119. Id.
120. See id. at 1411.
121. Id.
122. See id. at 1412.
123. To date, court cases have only dealt with mothers seeking to delay destruction of their frozen embryos beyond the five–year limit stated in HFEA.
124. Schreuder, supra note 2, at C1.
for embryo storage sparked a world-wide controversy.\textsuperscript{125} Although embryos had been destroyed before, this was the first time that the law \textit{required} their destruction.\textsuperscript{126} Moreover, it was the first time that such a large quantity of embryos had been simultaneously destroyed.\textsuperscript{127}

Opponents of the HFEA were troubled by the fact that as many as 650 couples did not respond to inquiries about what they wished to do with the embryos.\textsuperscript{128} Over 900 couples could not be contacted.\textsuperscript{129} The total number of embryos destroyed was roughly 6,000, of which 3,300 were the product of parents that could not be reached.\textsuperscript{130}

\section*{A. Ethical Concerns of the HFEA}

Supporters of the HFEA believe that it was ethically sound for the clinics to destroy the embryos because the couple's rights to find happiness by having a child outweigh the embryo's rights.\textsuperscript{131} This is a utilitarian approach to ethics in which maximizing happiness determines rightness.

Opponents of infertility treatment argue that children are gifts from God and that IVF is the first step toward genetically engineered children.\textsuperscript{132} This is essentially a deontological approach to ethics in which God prescribes duties.

As one commentator has noted, "consensus is unlikely when proponents of a result based upon a utilitarian calculus face deontologically-based objections."\textsuperscript{133} It is nearly impossible to reach a consensus when one side attempts to justify what the other side finds absolutely unacceptable.\textsuperscript{134}

\begin{thebibliography}{99}
\bibitem{125} See Ibrahim, \textit{supra} note 3; Marks, \textit{supra} note 4; Simpson, \textit{supra} note 4.
\bibitem{126} See Ibrahim, \textit{supra} note 3.
\bibitem{127} See \textit{id}.
\bibitem{128} See \textit{id}.
\bibitem{130} See Simpson, \textit{supra} note 4.
\bibitem{131} See Cochrane, \textit{supra} note 129.
\bibitem{132} See \textit{id}.
\bibitem{133} Stenger, \textit{supra} note 14, at 138.
\bibitem{134} See \textit{id}.
\end{thebibliography}
Some advocates in Britain believe that doctors overstimulate ovaries for convenience, to accelerate the procedure. Thus, these advocates believe the answer is neither to create extra embryos nor to allow cryopreservation of embryos. This is also the Roman Catholic Church’s position. The Church asks that, at a minimum, the embryos be treated with dignity and given a proper funeral.

The British government believes the HFEA’s mandated disposal is justified for fear that prolonged freezing might damage cells. Some proponents of the HFEA argue that the disposal protocol is justified because it is more respectful of embryos than nature. Forty percent of human embryos are “lost flushed down the loo without the parents even being aware that they have conceived.”

B. Practical Concerns of the HFEA

Sad and unfortunate stories abounded during the mass thawing. In Cambridge, a doctor received a faxed letter from a couple living overseas asking him to extend the storage period of their embryos another five years, but the letter arrived twenty-four hours too late. As a result, their embryos were destroyed.

Another couple’s eggs were fertilized by an anonymous sperm donor and the resulting embryos frozen for future use. This couple also wished to extend the storage of the embryos. The anonymous donor, however, could not be traced, and therefore, did not consent to continued storage. The couple considered bringing court action to prevent the destruction, but did not want

135. See Cochrane, supra note 129.
136. See id.
137. See Simpson, supra note 4.
138. See Ibrahim, supra note 3.
139. See Cochrane, supra note 129.
141. See Jojo Moyes, A World of Anguish in an Inch of Glass; “Blanket” Legislation That is Causing Despair, INDEP. (Eng.), at 1.
142. See Simpson, supra note 4.
143. See id.
144. See id.
their private grief to become public.145

Many believe that the HFEA was carelessly drafted because it fails to account for the extent of egg and semen donation and the problems in tracing couples overseas.146 Furthermore, due to the requirement of express consent of both “parents,” opponents of the law predict increasing problems as the destruction of embryos becomes a regular event.147

The practical concerns with such regulations of embryo storage and disposal are clear. Great Britain’s struggle to balance health risks of long term storage with religious and ethical considerations has many lessons to teach other nations. The United States should consider these lessons in deciding whether to regulate this matter.

VI. SHOULD THE UNITED STATES REGULATE THE FATE OF UNUSED FROZEN EMBRYOS: ISSUES TO CONSIDER

Although there has been recent Congressional action regarding infertility and the impact of assisted reproduction techniques, the United States lags far behind many comparable countries in addressing such issues.148 The consensus among most countries is that storage of gametes and embryos should be subject to time limitations.149 This section of the Comment focuses on whether the U.S. federal government should mandate the disposal of frozen embryos after a specified time limitation has expired.

A. The Legal Status of Embryos

The legal status of embryos is an unsettled area of the law.150 But an understanding of the embryo’s current standing in law is central to resolving the issue at hand.151 The main problem in determining the legal status of embryos is striking a balance between respect for human life and concerns of procreative choice and

145. See id.
146. See Moyes, supra note 141.
147. See id.
149. See Knoppers & LeBris, supra note 39, at 332-33.
150. See Perry & Schneider, supra note 21, at 477-88.
151. See Robertson, supra note 33, at 450.
bodily integrity.152

While there are criminal and tort laws that clearly apply to in utero fetuses and embryos, application of these laws to preimplantation embryos is not clear.153 Furthermore, there are three possible designations for preimplantation embryos: persons, property, or entities deserving "special respect."154 Despite these ambiguities, Professor John Robertson posits that the legal status of preimplantation embryos can be determined by examining the locus and scope of decisional authority over embryos.155

The parties with possible claims of decisional authority over preimplantation embryos include the individual gamete donors, the couple jointly, the physicians who created the embryos, and the fertility clinic that has actual possession of the embryos.156 Professor Robertson concludes that of all the parties with potential claims of decisional authority, the couple that donates gametes has the strongest claim.157

First, Professor Robertson argues that whether or not the embryos are rights-bearing entities is separate from the more important question of who has decisional authority over the embryos.158 Therefore, "because the embryo results from the voluntary gametic contribution of two individuals, and represents their potential biologic offspring, they should have joint dispositional authority over the external embryos resulting from their gametes."159

Second, traditions regarding property rights over one's own body parts support the claim of gamete donors.160 Gamete providers are the original owners of their gametes and have a right to decide whether they want to bear offspring.161 "The person de-

---

152. See id. at 437.
153. See id. at 450-52.
154. See Perry & Schneider, supra note 21, at 477-88; Davis, 842 S.W.2d at 594-97 (concluding that preembryos are not persons or property, "but occupy an interim category that entitles them to special respect because of their potential for human life.").
155. See Robertson, supra note 33, at 452.
156. See id. at 455.
157. See id. at 455-56.
158. See id. at 456.
159. Id.
160. See id. at 457.
161. See id.
cides whether he or she will—through masturbation, egg retrieval, or coitus—make his or her gametes available for examination, gift, or reproduction."162 Thus, a person may have a cause of action for battery if gametes are removed from the body without consent.163 Moreover, gamete donors may have a cause of action for conversion if gametes are used for purposes not contemplated by the donors (e.g., selling them to others or creating cell-lines).164

Finally, as discussed in the following subsection, the decisional authority of gamete donors is constitutionally protected. "If people have a fundamental right to decide to procreate or not, then control of their gametes, including their combined, embryonic form, is necessary to exercise that choice."165

**B. Constitutional Issues**

The lack of federal regulation in the area of assisted reproduction as a whole, and the fate of unused cryopreserved embryos in particular, is mainly due to the volatility of the abortion issue in the United States.166 The major change at the federal level came when abortion became legal in 1973 with the U.S. Supreme Court’s decision in *Roe v. Wade*.167 The Court held that a woman's right to an abortion was unrestricted until viability (the point when the fetus can survive outside the womb).168

The *Roe* court implemented a trimester system whereby the pregnant woman's interests and the state's interests change as the fetus develops.169 During the first trimester of pregnancy, the decision to abort cannot be regulated by the state, but must be left to

162. *Id.*
163. *See id.*
164. *See id.* But c.f. Moore v. Regents of the University of California, 51 Cal.3d 120, 136-37 (1990) (holding that a patient, who *did not expect to retain possession* of his spleen cells, did not have a cause of action for conversion against doctors who created a lucrative cell line from the patient's spleen cells). The argument for property rights over embryos is stronger than rights over organ cells because of the reproductive significance of gametes and the fact that gamete donors, in the IVF context, fully expect to retain possession of their embryos.
165. *See Robertson, supra* note 33, at 460 n.62.
166. *See Stenger, supra* note 14, at 137.
168. *See id.* at 162-64.
169. *See id.*
Regulating Frozen Embryos

the woman.\textsuperscript{170} This demarcation at the first trimester is made because, up to this point, the mortality rate for mothers undergoing abortions is lower than for those undergoing normal childbirth.\textsuperscript{171}

After the first trimester, states may only regulate abortion "to the extent that the regulation reasonably relates to the preservation and protection of maternal health."\textsuperscript{172} After viability, which the Court determined to be in the third trimester (between twenty-four and twenty-eight weeks), the state's interest in the fetus as "potential life" becomes compelling.\textsuperscript{173} The state may prohibit abortion during the third trimester, except when it is necessary to preserve the life or health of the mother.\textsuperscript{174}

In 1992, the U.S. Supreme Court reaffirmed Roe's essential holding in Planned Parenthood v. Casey.\textsuperscript{175} The plurality, however, rejected Roe's trimester analysis and recognized the state's substantial interest in potential life throughout the pregnancy.\textsuperscript{176}

This analysis suggests that the U.S. federal government has an interest in potential life which may extend to preimplantation embryos. Thus, the pressing question is whether the federal government can require disposal of unused embryos.

Under federalism, states have generally had the power to regulate matters such as family law—definitions of marriage, family, parenthood, legitimacy—health and medical procedures.\textsuperscript{177} One commentator has concluded, however, that assisted reproduction deserves the same legal protection as "natural" reproduction.\textsuperscript{178} Under this reasoning, state interference with individual choices to use IVF is not justified.\textsuperscript{179}

The federal government may impose uniform laws when the

\textsuperscript{170} See id at 163-64.
\textsuperscript{171} See id. at 163.
\textsuperscript{172} Id. at 163.
\textsuperscript{173} See id. at 160, 163.
\textsuperscript{174} See id. at 164-65.
\textsuperscript{175} 505 U.S. 833, 845-46 (1992).
\textsuperscript{176} See id. at 837.
\textsuperscript{177} See Stenger, supra note 14, at 138.
\textsuperscript{179} See id.
issue is resolved on the basis of federal constitutional rights.\textsuperscript{180} Thus, the federal government may impose uniformity with regard to the fate of embryos, because their fate invokes federal constitutional rights belonging to the parents, or less likely, to the embryos.

The constitutional issue of disposal of embryos, similar to abortion, turns on an analysis of privacy rights.\textsuperscript{181} The U.S. Supreme Court has traditionally extended the right of privacy to issues of family, marriage and procreation.\textsuperscript{182} An embryo’s fate undoubtedly involves issues of procreation, an area in which the court chooses to protect individual choice.\textsuperscript{183}

Because privacy rights are implied in the Constitution,\textsuperscript{184} it is not entirely clear how far these rights stretch. With abortion, the U.S. Supreme Court balanced freedom of choice against potential life. In the case of frozen embryos, the balancing would be different. With cryopreserved embryos, the court would balance the rights of a potential life along with the procreative rights of the gamete donors, against practical considerations of storage space, the right to create private contracts, and scientific questions of viability after long term storage.

Even under the U.S. Supreme Court’s more recent “undue burden” analysis,\textsuperscript{185} statutes affecting privacy rights must be carefully crafted in order to pass constitutional muster. Under this analysis, the Court examines whether the implicated law presents a “substantial obstacle” to the exercise of a liberty interest.\textsuperscript{186} Procreation is clearly, at minimum, a liberty interest as it has already

\textsuperscript{180} See id.

\textsuperscript{181} In \textit{Roe v. Wade}, the Court based its decision to legalize abortion primarily on the implied right to privacy. 410 U.S. at 153.


\textsuperscript{183} See, e.g., Griswold, 381 U.S. at 485; Skinner, 316 U.S. at 541.

\textsuperscript{184} See Roe, 410 U.S. at 153.

\textsuperscript{185} See Planned Parenthood, 505 U.S. at 877.

\textsuperscript{186} See id.
been recognized as "one of the basic civil rights of man."\textsuperscript{187}

In \textit{Planned Parenthood}, the Court determined that requiring spousal notification prior to obtaining an abortion presents an undue burden.\textsuperscript{188} The Court based its decision on the premise that the provision was likely to deter abortion as though the government "had outlawed abortion in all cases."\textsuperscript{189} Likewise, requiring destruction of embryos after a maximum storage period presents an undue burden on the gamete donors' exercise of the right to procreation because the destruction of their embryos may foreclose any possibility of conceiving a child.

This constitutional analysis requires further attention in the future.\textsuperscript{190} For the purposes of this Comment, however, it is clear that when regulating the fate of "potential lives," serious concerns that do not arise in Great Britain become critical under U.S. constitutional law.

\section*{C. State Regulations}

Many states have enacted laws that regulate activities and rights associated with assisted reproductive technology.\textsuperscript{191} Most state laws governing assisted reproductive technology pertain to insurance coverage for medical procedures. Some, however, define the rights and duties of parents and physicians,\textsuperscript{192} and others have been enacted in direct response to recent scandals.\textsuperscript{193}

The scandal at the UCI fertility clinic spawned an immediate

\begin{flushleft}
\textsuperscript{187} Skinner, 316 U.S. at 541.
\textsuperscript{188} See \textit{Planned Parenthood}, 505 U.S. at 894-94.
\textsuperscript{189} See id.
\textsuperscript{190} For a compelling analysis based on hypothetical circumstances, see Lisa Hemphill, \textit{American Abortion Law Applied to New Reproductive Technology}, 32 \textit{JURIMETRICS} J. 361 (1992).
\textsuperscript{193} See 1996 Cal. Legis. Serv. 863 (West); 1996 Cal. Legis. Serv. 865 (West).
\end{flushleft}
response from California legislators. As a result, new legislation went into effect on January 1, 1997.\textsuperscript{194} The new law requires "a physician and surgeon who removes sperm or ova from a patient to obtain a prescribed written consent from the patient before the sperm or ova are used for a purpose other than reimplantation in the same patient or implantation in the spouse of the patient."\textsuperscript{195} Furthermore, the law makes it a felony for anyone to "knowingly use sperm, ova or embryos in assisted reproduction technology, for any purpose other than that indicated by the sperm, ova or embryo provider's signature on a written consent form."\textsuperscript{196} The California laws, while responsive to recent controversies, are indicative of the limited extent of regulation by most states in this area.

Louisiana has one of the more comprehensive statutes governing the status of human embryos.\textsuperscript{197} The law regulates ownership of embryos, safekeeping of in vitro embryos, qualifications for clinics, and duties of gamete donors.\textsuperscript{198} The Louisiana law requires that medical facilities meet the standards of the American Fertility Society and the American College of Obstetricians and Gynecologists.\textsuperscript{199} Additionally, the clinic must be directed by a medical doctor licensed to practice medicine in Louisiana. The director must also possess specialized training and skills with respect to in vitro fertilization that conform to the standards of the American Fertility Society and the American College of Obstetricians and Gynecologists.\textsuperscript{200} Most importantly, the physician is deemed temporary guardian of an embryo if the identity of the donors is unknown.\textsuperscript{201} This guardianship status exists "until adoptive implantation can occur."\textsuperscript{202}

Despite the fact that states may have a strong interest in protecting the potential offspring, few of them have enacted laws in

\begin{itemize}
  \item \textsuperscript{194} See id.
  \item \textsuperscript{195} 1996 Cal. Legis. Serv. 863 (West).
  \item \textsuperscript{196} 1996 Cal. Legis. Serv. 865 (West).
  \item \textsuperscript{197} See LA. REV. STAT. ANN. §§ 9:124, 126-28, 130 (West 1996).
  \item \textsuperscript{198} See id.
  \item \textsuperscript{199} See id. § 128.
  \item \textsuperscript{200} See id.
  \item \textsuperscript{201} See id. § 124.
  \item \textsuperscript{202} Id.
Regulating Frozen Embryos

The lack of state laws governing the fate of unused frozen embryos most likely occurs for the same reason there is a lack of federal regulations. While federalism concerns suggest that regulation of assisted reproductive technology be left to the states, if the states choose to regulate, they risk conflicting with individual privacy rights. As Professor Robertson notes, "unless carefully crafted to respect the couple's procreative liberty, state limits on embryo storage are likely to be found unconstitutional."204

D. Other Legislative Options

Commentators have discussed a variety of legislative options. One possibility is to require transfer of unused embryos to willing recipients.205 This option preserves the state's interest in safeguarding health; however, it creates several problems. First, it does not circumvent the constitutional protections afforded to the gamete donors because the law still interferes with their privacy right to procreation. Second, there is a practical problem in that the supply of embryos greatly exceeds the demand for them.206

A second option is to require donation of unused embryos to research.207 While this option may contribute greatly to medical technology advances, it also poses serious problems. Again, the issue of the donors' constitutional rights rears its head. In addition, this option is likely to ignite moral outrage if not carefully regulated and enforced.208

A final option is limiting the number of eggs that may be fertilized.209 The law may allow a physician to decide how many eggs to fertilize based on the number of children that the couple plans

203. One might argue that the states have a strong interest in the health of "potential lives." The American Fertility Society recommends that the maximum storage time for embryos not exceed the reproductive life of a woman who provides the egg. See AFS, supra note 20, at 60S. At least one commentator, however, questions the effectiveness of a law that is meant to protect offspring, when it might prevent their existence. See Robertson, supra note 33, at 495.

204. Robertson, supra note 33, at 495.

205. See Perry & Schneider, supra note 21, at 491.

206. See id.

207. See id.

208. See, e.g., id. at 492.

to have. Limiting the number of fertilized eggs available for implantation is a difficult option because the success rate of the IVF process is unpredictable. If all of the fertilized embryos are unsuccessfully implanted, a couple may have to repeat the entire IVF process again. On the other hand, if IVF succeeds immediately or the couple decides to have fewer children than previously contemplated, a surplus of embryos remains. This surplus, however, leaves legislators with the same problems discussed above.

**F: Technological Advances**

A final consideration is current state of the art and future technological advances. Future techniques and procedures may render the embryo disposal issue moot.

One such possible technique is egg-freezing. It is currently the most effective and promising alternative to embryo-freezing. As in IVF, multiple eggs are removed from the woman for the possibility of fertilization. Instead of immediately fertilizing all of the eggs, however, the doctor selects one egg for fertilization and immediately implants that egg. The remaining eggs are frozen for possible use at a later time.

Although some eggs may become unusable in the freezing and thawing process, this is of little moral or ethical concern because an egg alone is not yet a human being. Additionally, because eggs may be fertilized as needed for immediate implantation, egg-freezing avoids the problem of unused embryos. This procedure is still in the development stages, but as early as 1986, children were born via egg-freezing.

---

210. See Perry & Schneider, supra note 21, at 496.
211. See id.
212. See Browne & Hynes, supra note 209, at 100.
213. See id.
214. See id.
215. See id.
216. See id. See also Human-egg Banks: Frozen to Life, ECONOMIST, May 14, 1988, at 88 [hereinafter Frozen to Life].
217. See Browne & Hynes, supra note 209, at 100. See also Interview: Alan Trounson, OMNI, Dec. 1985, at 83, 126.
218. See Browne & Hynes, supra note 209, at 100.
219. See id.; Frozen to Life, supra note 216.
VII. CONCLUSION

Reminiscent of the Warnock Committee in Britain, a variety of U.S. groups called for a study of current ethical and clinical guidelines in the fertility industry after the scandal at the UCI fertility clinic. Some are calling for more stringent voluntary guidelines. Others desire mandatory standards, with penalties for wrongdoing. Yet others are content with the status quo.

Although scandals and controversies have arisen in Great Britain, the United States, and throughout the world, there is a significant difference between a government mandated “mass embryocide” and unethical or bungling physicians. Whether the federal government should regulate all aspects of the assisted reproductive technology industry is a broad question beyond the scope of this Comment. Instead, the focus here is specifically on the prudence of federally mandated disposal of unused cryopreserved embryos.

Several considerations counsel against a U.S. federal government mandate on the disposal of unused frozen embryos. One reason not to regulate is that the U.S. medical profession, historically, has not looked kindly at outside regulation of the profession. It would also be nearly impossible to create legislation that would satisfy the moral and ethical needs of the industry, the patients, and U.S. society. These concerns, however, can be dismissed as a fear of confronting difficult challenges, rather than as legitimate reasons. There are other considerations, however, that suggest the U.S. government should not require disposal of unused embryos.

First, U.S. constitutional law recognizes the right to choose whether or not to procreate. The British Parliament did not have this concern when it passed the HFEA. If a similar law was passed in the United States there would be, at a minimum, numerous challenges to its constitutionality. These challenges would be suc-

221. See id.
222. See id.
223. See id.
224. See id.
cessful because the U.S. Supreme Court has consistently recognized privacy rights in matters of family and procreation.\textsuperscript{225}

Second, due to rapid technological advances, there is a high likelihood that cryopreservation of embryos will become an obsolete technique, rendering such legislation moot. Because techniques such as egg-freezing are presently a reality, the argument against a federal mandate for disposal of embryos becomes stronger.

Furthermore, concerns about the viability of embryos after prolonged freezing have subsided since the HFEA was drafted.\textsuperscript{226} Many scientists now believe that embryos can be frozen indefinitely.\textsuperscript{227} Thus, even if technology does not render mandatory disposal laws moot, increased knowledge about the current process of cryopreservation does.

Finally, there are many possible alternatives that legislators may consider, only a few of which have been discussed here. While these options have their problems, they do not carry the draconian finality of mandatory destruction.

In the end, the disposal issue is best left to private contract. This option keeps the decision with the individuals, avoiding any invasion of privacy rights. It also allows flexibility to keep pace with advancing technology. For example, if egg freezing were to become the standard infertility procedure, private contracts could easily adjust for the new issues and concerns rather than waiting for legislative action. Finally, any apprehension about the patient's state of mind can be resolved by educating the public. For example, one of the benefits of the UCI fertility clinic scandal is that more infertility patients are now openly discussing pertinent issues with their physicians.\textsuperscript{228} Such increased discussion may relieve concerns about unconscionable adhesion contracts.

Although assisted reproductive technology is a controversial issue, with many areas subject to regulation, government man-


\textsuperscript{226} See Cochrane, supra note 129.

\textsuperscript{227} See id.

\textsuperscript{228} See Diane M. Gianelli, Fertility Scandal Raises Call for Regulation, AM. MED. NEWS, Sept. 11, 1995, at 3.
dated disposal of embryos is difficult to justify. A potential life should not be terminated when it is against the wishes of the mother and father. The bottom line is that any option is better than a government mandate, and the best option is to leave the decision to the parties involved.

Lee Kuo*

* J.D. candidate, Loyola Law School, 1998; B.S. Psychobiology, University of California, Los Angeles, 1992. I dedicate this Comment to my wife Lisa. She is my hero because only a woman with her strength, patience, and love could so gracefully be pregnant with twins (the topic is ironic, isn't it?). Special thanks goes to the editors and staffers who polished the many rough edges of this Comment. I would also like to thank Professor Katherine Pratt for her assistance in developing the topic.