

Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States

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I. INTRODUCTION

Scholars of differing political affiliation and the President's Council on Bioethics have called for regulation of assisted reproductive technology (ART) that would emulate many aspects of the regulatory system of the United Kingdom, in particular that of the Human Fertilisation and Embryology Authority. Specifically, scholars and the Council have argued that research in the U.S. involving gametes and human embryos lacks consistent oversight.¹ While the Centers for Disease

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¹ See THE PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION AND RESPONSIBILITY: THE REGULATION OF NEW TECHNOLOGIES, at ch. 9-10 (2004), available at <http://www.bioethics.gov/reports/reproductionandresponsibility/index.html> (criticizing patchwork framework for regulation of ART in U.S. and suggesting comprehensive regulation, including permanent monitoring and oversight arrangements); Erik Parens & Lori Knowles, *Reprogenetics and Public Policy: Reflections & Recommendations*, HASTINGS CTR. RPT. (Supp. Jul. - Aug. 2003), available at <http://www.thehastingscenter.org/publications/reports.asp> (advising creation of commission, Reprogenetics Technology Advisory Committee, to propose legislation to Congress). See, e.g., Lori Andrews, et al., *Cloning Position Paper of the IIT Institute for Science, Law, and Technology Working Group On Reproductive Technologies*, 8 S. CAL. INTERDISC. L.J. 87, 99 (1998) (advocating the U.S. ban human cloning and explaining that the loss of possible benefits of cloning as a result of such a ban could be avoided by crafting legislation similar to that of the United Kingdom's licensing of clinics involved in reproductive technologies); James F. Childress, *An Ethical Defense of*

Control and Prevention (CDC) produces an annual ART success rate report,² submission of data is guaranteed only by the promise that non-responders will be noted as such in the appendix of CDC's report, and most ART clinics publish success rates on the Internet in a much more recognized forum: website advertising. Moreover, U.S. law does not require licensing or accreditation of infertility programs and few regulations govern embryo research.³ While the large majority of clinics report their success rate data, and many follow practice standards and apply for accreditation from private agencies, these practices are strictly voluntary.⁴ Clinics failing to report their success rates face no legal consequence.

In contrast, Great Britain's Human Fertilisation and Embryology Authority (HFEA) has complete authority over fertility clinics and human embryo research in

Federal Funding for Human Embryonic Stem Cell Research, 2 YALE J. HEALTH POL'Y L. & ETHICS 157, 163 (2001) (stating that a public body similar to that used in the U.K. may be needed in the U.S. for regulating embryonic stem cell research); Cynthia B. Cohen, *Unmanaged Care: The Need to Regulate New Reproductive Technologies in the United States*, 11 BIOETHICS 348 (1997); Weldon E. Havins & James J. Dalessio, *The Ever-Widening Gap Between the Science of Artificial Reproductive Technology and the Laws Which Govern that Technology*, 48 DEPAUL L. REV. 825 (1999); Robert L. Stenger, *The Law and Assisted Reproduction in the United Kingdom and the United States*, 9 J.L. & HEALTH 135, 159 (1994-1995) (arguing that Britain's Human Fertilization and Embryology Act of 1990 can offer guidance to states within the U.S. in their attempts to formulate legislation on assisted reproductive technology); Kara L. Belew, Comment, *Stem Cell Division: Abortion Law and its Influence on the Adoption of Radically Different Embryonic Stem Cell Legislation in the United States, the United Kingdom, and Germany*, 39 TEX. INT'L L.J. 479, 519 (2004) (stating that the U.S. and Germany will have to change their laws and regulations concerning stem cell research to something similar to the U.K. framework if either country wants "to stay on the forefront of biomedical technology."); Melissa S. Burchell, Note, *America's Struggle to Develop a Consistent Legal Approach To Controversial Human Embryonic Stem Cell Research and Therapeutic Cloning: Are the Politics Getting in the Way of Hope?*, 32 SYRACUSE J. INT'L L. & COM. 133, 158-61 (2004) (arguing that the U.S. should revise its regulations on stem cell research and therapeutic cloning, modeling them after the U.K.'s); Sherri A. Jayson, Comment, *"Loving Infertile Couple Seeks Woman Age 18-31 to Help Have Baby. \$6,500 Plus Expenses and a Gift": Should We Regulate the Use of Assisted Reproductive Technologies by Older Women?*, 11 ALB. L.J. SCI. & TECH. 287, 311 (2001) (discussing legislation regulating age of women undergoing ART). Compare Suzanne H. Rhodes, Comments, *The Difficulty of Regulating Reproductive and Therapeutic Cloning: Can the United States Learn Anything From the Laws of Other Countries?*, 21 PENN. ST. INT'L L. REV. 341, 355 (2003) (recommending that the U.S. "follow the lead" of the U.K. and other countries and place a ban on reproductive cloning), with Arthur C. D'Andrea, Note, *Federalizing Bioethics*, 83 TEX. L. REV. 1663 (2005) (arguing that regulation of human cloning should be done on a state, not national level).

² The publication of the reports is considerably delayed. The 2002 data was not published until 2004. See DIV. OF REPROD. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION, & SOC'Y FOR ASSISTED REPROD. TECH., AM. SOC'Y FOR REPROD. MED., 2002 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS (2004), available at <http://www.cdc.gov/ART/ART02/index.htm> [hereinafter 2002 ART RATES].

³ The existing federal regulation limits federal funding for embryo research. On August 9, 2001, President Bush announced that federal funds for human embryonic stem cell research would be limited to 64 stem cell lines that were in existence as of the date of the announcement. In May 2005, The U.S. House of Representative approved a bill to expand federal financing for embryonic stem cell research to permit financing studies involving human embryos in frozen storage at fertility clinics if they would otherwise be discarded. To date, the Senate has not passed comparable legislation.

The States have been more active in regulating assisted reproduction. In particular, fourteen states have laws pertaining to human cloning. See National Conference of State Legislatures, *State Human Cloning Laws*, (2005), available at <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm> (charting state laws regulating the cloning of human embryos as of June 21, 2005). Legislation that would regulate ART and the use of frozen embryos has been introduced in ten states. See National Conference of State Legislatures, Genetics Legislation Database, available at <http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm> (last visited Oct. 26, 2005).

⁴ See 2002 ART RATES, *supra* note 2, at 5-6 (stating that clinics known to be in existence without reporting success rate data were merely listed as nonreporters, in compliance with U.S. law).

the United Kingdom.⁵ All clinics and labs using gametes or human embryos must receive a license from the HFEA.⁶ British clinics and embryo laboratories follow clear guidelines for data reporting, advertising, confidentiality, and clinic practices, which the HFEA enforces through powers granted by the British Parliament. While some American clinicians would argue that the HFEA restricts the freedom of clinics and researchers, the HFEA has shown the ability to adapt its policies to reflect changing technology while maintaining its moral bedrock: protecting the welfare of the child.

In her benchmark comparison of British and American policy governing infertility, Gladys White⁷ argued quite explicitly that the British system is a good guide for U.S. policy. She based her argument on a review of U.K. policy and in particular on a visit to the HFEA in London. White's pro-HFEA position has become a staple argument in bioethics and legal scholarship. In this paper, we compare the two systems in greater detail, taking issue with the conclusions drawn by White and others. In Part II, we compare the role of the HFEA in the United Kingdom to the authority and limitations of several agencies and organizations in the United States. These are the Centers for Disease Control and Prevention (CDC), the American Society for Reproductive Medicine (ASRM), the Society for Assisted Reproductive Technology (SART), the American College of Obstetrics and Gynecology (ACOG), the Food and Drug Administration (FDA), and the Department of Health and Human Services (DHHS). Relying heavily on our review of the existing policies and on Dr. McGee's comparative analysis of the HFEA and American institutions—conducted for the Commonwealth Foundation during 2000-2002⁸—we address the roles of these organizations and the HFEA in legislation, data collection, licensing, and regulation of fertility clinics and embryo research. Our comparison reveals the patchwork and essentially unenforceable nature of the American regulatory system, and the centralized, effectual authority of the HFEA.

In Part III, we examine the effect that trans-Atlantic discourse has had on recent regulatory policy shifts and important ethical debates in reproductive medicine. Specifically, we analyze the feasibility of importing a U.K.-style system to the U.S. and the strengths and roots of the current U.S. system. We explore specific regulations regarding reproduction technology including embryonic stem cell research, in vitro fertilization (IVF), and novel infertility treatments (ooplasmic transplantation and egg freezing) involving the use of human cells, tissues, semen, and oocytes. We then examine the role of ethical discourse in the regulation of ART by studying the ways in which the U.K. and U.S. seek to prevent multiple births.

In part IV, we conclude that the basis for differences in policy between the U.S. and the U.K. is rooted in each nation's history of dealing with reproduction, and that a system of the sort advocated by White, the HFEA, and most recently by Leon Kass and the U.S. President's Council on Bioethics would be extremely difficult to implement in the U.S.

⁵ The Human Fertilisation and Embryology Authority, *About the Human Fertilisation and Embryology Authority*, <http://www.hfea.gov.uk/AboutHFEA> (last visited Oct. 23, 2005).

⁶ See Human Fertilisation and Embryology Act, 1990, c. 37, § 11, sched. 2 (Eng.), available at http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900037_en_1.htm#end (Select "Schedule 2" link).

⁷ Gladys B. White, *Crisis in Assisted Conception: The British Approach to an American Dilemma*, 7 J. WOMEN'S HEALTH 321, 327 (1998).

⁸ On file with author (Glenn McGee).

II. COMPARATIVE ANALYSIS: AN OCEAN BETWEEN US

A. LEGISLATION

1. United Kingdom

The Human Fertilisation and Embryology Act of 1990 (HFE Act) forms the basis for all U.K. legislation regarding fertility clinics and embryo research.⁹ It describes the functions and procedure of the Human Fertilisation and Embryology Authority (HFEA), the conditions requiring licensing for fertility clinics and related research, and specific regulations governing the creation, storage or use of human gametes and embryos.¹⁰ Significantly, the HFE Act authorized the formation of the HFEA, the first statutory body of its kind in the world. It grants the HFEA several general functions, outlined in the 2004 HFEA annual report.¹¹ The HFEA is primarily responsible for the licensing and monitoring of clinics that perform IVF, donor insemination and/or human embryo research, and the regulation of gamete and embryo storage.¹² In addition, the HFEA produced a Code of Practice with guidelines on licensed activities¹³ and keeps a register of information on donors, treatments, and children born through ART.¹⁴ It also publicizes its role, gives advice and information, and reviews new developments in the field.¹⁵

2. United States

Those scholars advocating a U.S. shift to a U.K. model offer only a brief, disparaging account of U.S. legislation regarding fertility clinics and embryo research.¹⁶ This reflects the fact that no comprehensive policy governs ART in the U.S. The law that most closely parallels the HFE Act is the U.S. Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA).¹⁷ The FCSRCA mandates that infertility clinics submit ART success rate data and describes the responsibilities of the CDC in regard to data reporting and licensing.¹⁸ Specifically, the CDC must (1) publish annual success rates for pregnancies achieved via ART technology, and (2) develop a model program for the licensing of embryo laboratories for adoption by the states.¹⁹ The FCSRCA legislation, however, does not go nearly as far as the

⁹ See generally Human Fertilisation and Embryology Act, 1990, c. 37 (Eng.).

¹⁰ *Id.* §§ 3–15.

¹¹ HUMAN FERTILISATION & EMBRYOLOGY AUTH., FACING UP TO THE CHALLENGE: HFEA ANNUAL REPORT 2003/04 (Thirteenth Annual Report) at 5 (2004), available at <http://www.hfea.gov.uk/HFEAPublications/AnnualReport> [hereinafter FACING UP TO THE CHALLENGE].

¹² *Id.*

¹³ HUMAN FERTILISATION AND EMBRYOLOGY AUTH. CODE OF PRACTICE 6TH EDITION (2003), available at <http://www.hfea.gov.uk/HFEAPublications/CodeofPractice>.

¹⁴ The Human Fertilisation and Embryology Authority, *supra* note 5.

¹⁵ *Id.*

¹⁶ See, e.g., Burchell, *supra* note 1, at 139-42 (describing federal regulation of embryonic stem cell research in the U.S. as inconsistent and contradictory); Childress, *supra* note 1, at 162–63 (contrasting the U.K.’s “strict regulation of reproductive technologies” with the “limited and uneven” regulation in the U.S.). But see PRESIDENT’S COUNCIL ON BIOETHICS, *supra* note 1, at 47–50 (discussing extensively current regulation of ART).

¹⁷ Fertility Clinic Success Rate and Certification Act of 1992, Pub. L. No. 102-493, 106 Stat. 3146 (codified at 42 U.S.C. §§ 263a-1 to a-7 (2000)).

¹⁸ 42 U.S.C. §§ 263a-1 to a-5 (2000).

¹⁹ *Id.* §§ 263a-2(a)(1), 263a-5(1)(A).

HFE Act. It fails to give the CDC the authority to enforce the data-reporting requirement, and simply outlines a voluntary system of licensing that has not been implemented or enforced.²⁰

The States have been more active than the federal government in using legislation to regulate the use of human embryos. State activity appears minimal, however, when contrasted with HFEA's oversight. Some states have regulated the use of human embryos for research purposes; others have banned human cloning.²¹ No state has created an agency with powers like the HFEA or regulated ART in any other significant manner.²²

B. DATA REPORTING

1. United Kingdom

The HFEA began collecting data in a register of information on August 1, 1991.²³ Its registry is now the largest of its type in the world.²⁴ The HFEA maintains data on everyone who receives ART treatment, donates embryos, or is born through ART in licensed British fertility clinics.²⁵ The HFEA updated its register in 1998, and now provides non-confidential ART success rate data on its website.²⁶ In order to ensure data reliability, the HFEA implemented a five-year auditing program.²⁷ Over the course of the program, which ran from October 1996 until January 2002, the HFEA audited data from 106 licensed clinics.²⁸ The HFEA is presently engaged in a large strategic project to improve the Register,²⁹ which holds data on cycles of licensed treatments, following a review that identified technical problems and challenged the rigor of the data.³⁰ Specifically, as the HFEA Chief Executive, Dr. Maureen Dalziel, noted in the 2002 Annual Report:

²⁰ See PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1, at 50.

²¹ For a list of state laws regulating the cloning of human embryos, see NATIONAL CONFERENCE OF STATE LEGISLATURES, STATE HUMAN CLONING LAWS (2005), <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm> (charting state laws regulating the cloning of human embryos as of June 21, 2005). Legislation that would regulate ART and the use of frozen embryos has been introduced in nine states. See NATIONAL CONFERENCE OF STATE LEGISLATURES, GENETICS LEGISLATION DATABASE, <http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm> (select "ART/Frozen Embryos"; then enter search) (last visited Oct. 26, 2005).

²² See PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1, at 51-54 (outlining state regulation of ART and concluding that "There are few state laws that bear directly on assisted reproduction.").

²³ FACING UP TO THE CHALLENGE, *supra* note 11, at 12, 41.

²⁴ *Twelfth Annual Report And Accounts 2002/03, 2003 HUMAN FERTILISATION AND EMBRYOLOGY AUTH.* 16, <http://www.hfea.gov.uk/HFEAPublications/AnnualReport/Twelfth%20HFEA%20Annual%20Report.pdf> [hereinafter *Twelfth Annual Report*].

²⁵ FACING UP TO THE CHALLENGE, *supra* note 11, at 5.

²⁶ Human Fertilisation and Embryology Auth., <http://www.hfea.gov.uk> (last visited Oct. 20, 2005).

²⁷ *Eleventh Annual Report And Accounts 2002, 2002 HUMAN FERTILISATION AND EMBRYOLOGY AUTH.* 7, <http://www.hfea.gov.uk/HFEAPublications/AnnualReport/2002%20HFEA%20Annual%20Report.pdf> [hereinafter *Eleventh Annual Report*].

²⁸ *Id.*

²⁹ FACING UP TO THE CHALLENGE, *supra* note 11, at 9.

³⁰ *Eleventh Annual Report, supra* note 27, at 18.

The HFEA's information technology shortcomings are being addressed and comprehensive information management systems are being put in place to ensure that meaningful information can be extracted from data entered into the Register. It is frustrating that we are again unable to publish detailed information on treatment cycles in this Annual Report.³¹

By 2004, the HFEA reported progress in developing a comprehensive Data Register and had undertaken a Historic Audit Project to guarantee the accuracy of treatment information.³²

In addition to using data to monitor treatments and provide information, the HFEA maintains a confidential registry of information for the sake of children born from ART treatment.³³ Its registry includes patient and partner names, patient reference numbers, treatment dates, and details of sperm and egg donors.³⁴ This personal information is kept confidential except for children over the age of 18 (or over 16 if they are going to marry), who may be told whether or not they were born via ART.³⁵ In this way, the HFEA aims to ward off a situation where two people marry without knowing that they are genetically related.

2. United States

In the U.S., the process of data collection demands a thorough review. U.S. law³⁶ requires clinics to submit ART success rate data for publication by the CDC, but the process is essentially voluntary and non-reporting clinics suffer little or no consequences.

From 1992 to 2004, the responsibility for data collection rested largely on the Society for Assisted Reproductive Technology (SART),³⁷ a private organization of ART clinical programs and an affiliate of the American Society for Reproductive Medicine (ASRM).³⁸ SART has been keeping an ART success rate database since 1986.³⁹ Although the CDC took over publishing ART success rate reports in 1995,⁴⁰ SART remained the driving force behind the CDC's publications.

SART is individually incorporated for tax purposes, but SART members are meant to be ASRM members also.⁴¹ Clinics that join SART pay a \$300 yearly membership fee, a \$500 registry fee for data collection services, and additional

³¹ *Id.*

³² FACING UP TO THE CHALLENGE, *supra* note 11, at 9.

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ 42 U.S.C. § 263a-1 (2005).

³⁷ The homepage for SART is located at <http://www.sart.org/home.html>.

³⁸ ASRM is a professional society. The homepage for the ASRM is located at <http://www.asrm.org>.

³⁹ Med. Research Int'l, *In vitro Fertilization/Embryo Transfer in the United States: 1985 and 1986 Results from the National IVF/ET Registry*, 49 FERTILITY & STERILITY 212 (1988).

⁴⁰ See generally Centers for Disease Control and Prevention, *Assisted Reproductive Technology: All Reports*, at <http://www.cdc.gov/ART/ARTReports.htm> (showing links to published ART reports beginning with the 1995 ART report through the 2002 ART report).

⁴¹ See American Society for Reproductive Medicine, *The ASRM Invites You To Apply For Membership*, <http://www.asrm.org/Professionals/Membership/member.html> (showing that affiliations with like organizations is a benefit of membership in ASRM); American Society for Reproductive Medicine, *Specialty Societies*, <http://www.asrm.org/Professionals/Membership/member.html> (showing that SART is affiliated with ASRM). See also Society for Assisted Reproductive Technology, *What Does SART Do Anyway?*, at <http://sart.org/whatis.html> (demonstrating close affiliation with ASRM).

\$4.00 per cycle.⁴² SART requires its members to submit and verify annual ART success rate data and their other membership requirements.⁴³ SART members must receive inspection and accreditation by an outside agency every two years, and must meet all SART/ASRM ethical practice, laboratory and advertising guidelines.⁴⁴

In 2004, the CDC announced a change in its data collection contractor and in approved data reporting systems for 2004-2008. It contracted with Westat to perform the services previously performed by SART under Westat's web-based National ART Surveillance System (NASS).⁴⁵ Even under the CDC's contract with Westat, SART members may continue to enter their data into the SART system.⁴⁶ SART then transfers its data into the Westat system so that clinics maintain compliance with the federal mandate.⁴⁷ The CDC has not yet published a report based on the Westat data.

Regardless of whether they are SART members or not, federal law requires *all* ART clinics to report and verify ART success rate data annually.⁴⁸

Unlike the U.K., where data collection is simply a part of the licensing process, data collection in the U.S. is its own entity. To complete the process, clinics must submit verified data about every ART cycle performed and maintain medical records in their own files for validation purposes.⁴⁹ Until 2004, SART collected all submitted data and compiled a database that the CDC used to publish its annual report. The CDC oversaw SART, in part by selecting a percentage of clinics for random verification inspections which SART conducted with CDC supervision. In 1999, validation site visits took place at 29 of 370 reporting clinics.⁵⁰ Based on its review of the 2000 data, SART conducted 40 validation visits in 2003, 20 visits in 2004, and 39 visits in 2005.⁵¹ The CDC will presumably continue its inspection of clinics under its new contract with Westat.

⁴² E-mail communication from Joyce Zeitz to author Alicia Ouellette (October 5, 2005) (on file with author).

⁴³ Society for Assisted Reproductive Technology, *supra* note 41 (last visited Sept. 23, 2005).

⁴⁴ *Id.* SART requires all its member laboratories to be accredited by a SART approved program. All laboratory accreditation programs approved by SART follow the Clinical Laboratory Amendments of 1988 (CLIA). CLIA requires certification at least every two years. BROOKS A. KEEL & TAMMIE K. SCHALUE, *Quality Control and Accreditation*, in A COLOR ATLAS FOR HUMAN ASSISTED REPRODUCTION 277-78 (Pasquale Patrizio et al. eds., 2003); Clinical Laboratory Amendments of 1988, 100 Pub. L. No. 578, 102 Stat. 2903 (1988) (codified at 42 U.S.C. § 263(a)).

⁴⁵ Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs, 70 Fed. Reg. 5187, 5188 (Feb. 1, 2005).

⁴⁶ Angenlique Lopez, *RLT PG Representative to SART*, REPRODUCTIVE TECHNOLOGIST PROFESSIONAL GROUP NEWSLETTER (American Society of Reproductive Medicine), Summer 2005 at 3, available at http://www.asrm.org/Professionals/PG-SIG-Affiliated_Soc/rltpg/rltpg_summer2005_newsletter.pdf.

⁴⁷ *Id.*

⁴⁸ 2002 ART RATES, *supra* note 2, at 4.

⁴⁹ Victoria Clay Wright, et al., *Assisted Reproductive Surveillance – United States 2001*, MORBIDITY AND MORTALITY WEEKLY REPORT (April 30, 2004), at <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5301a1.htm>. See also PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 1, at 47-50.

⁵⁰ Soc'y for Assisted Reprod. Tech. & The Am. Soc'y for Reprod. Med., *Assisted Reproductive Technology in the United States: 1999 Results Generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry*, 78 FERTILITY & STERILITY 918, 919 (2002).

⁵¹ Interview with Joyce Zeitz, Executive Administrator, Society for Assisted Reproductive Technology (June 25, 2003); E-mail communication from Joyce Zeitz to author Ouellette dated October 5, 2005 (on file with author).

The CDC has sought to make clear that it maintains "ultimate authority" over the validation process and the annual report.⁵² It explained its decision to contract with SART for data collection and validation as follows:

CDC's authority to publish and disseminate the annual report is not being ceded to SART, but rather SART is serving as a valuable resource from which CDC can obtain the necessary information to fulfill its statutory obligation Prior to the decision to partner with SART, CDC reviewed the SART reporting database and system and found that it provided the necessary information to publish an annual report as required by FCSRCA. Rather than duplicate SART's reporting system and thereby burden ART clinics, CDC has contracted with SART to annually obtain a copy of their clinic specific database.⁵³

The CDC offered no explanation when it awarded the data collection contract to Westat in 2004.⁵⁴ Our discussion will focus on data collected by SART since the agency has not yet published a report based on data collected by Westat.

Every clinic that reported data for the first CDC report (1995) was a SART member.⁵⁵ Over time, however, the percentage of non-SART members reporting data to SART has increased. Six percent (6%) of clinics that reported data in the CDC's 2000 data report⁵⁶ were not SART members. This likely reflects efforts by both the CDC and SART to include all existing clinics in the report. In the CDC's recent CDC 2002 data report, 8.7% of clinics were not SART members.⁵⁷

Since the start of the CDC/SART joint reporting effort in 1995, a high percentage of all programs in the U.S. providing ART services have submitted data on procedures performed in their practices.⁵⁸ In 1999, 370 of the 399 listed clinics, or 92.7%, reported verified data.^{59, 60} The number of non-reporting clinics documented by the CDC has decreased from 30 of 390 in 1998, to 29 of 399 in 1999, and 25 of 408 in 2000.^{61, 62, 63} While many consider it a successful reporting

⁵² Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310, 53,311 (Sept. 1, 2000).

⁵³ *Id.*

⁵⁴ See Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs, 70 Fed. Reg. 5187, 5188 (Feb. 1, 2005).

⁵⁵ Soc'y for Assisted Reprod. Tech. & The Am. Soc'y for Reprod. Med., *Assisted Reproductive Technology in the United States and Canada: 1995 Results Generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry*, 69 FERTILITY & STERILITY 389 (1998).

⁵⁶ DIV. OF REPROD. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION ET AL., 2000 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 71 (2002), *available at* <http://www.cdc.gov/reproductivehealth/ART/ARTReports.htm> [hereinafter 2000 RATES].

⁵⁷ 2002 ART RATES, *supra* note 2, at 69.

⁵⁸ See, e.g., 2002 ART RATES, *supra* note 2, at 71, 509–510. Out of 428 total listed clinics, approximately 91% of them submitted data.

⁵⁹ See Reporting of Pregnancy Success Rates From Assisted Reproductive Technology Programs, *supra* note 52, at 53,312–13.

⁶⁰ DIV. OF REPROD. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION ET AL., 1999 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 6, 469–70 (2001), *available at* <http://www.cdc.gov/reproductivehealth/ART/ARTReports.htm> [hereinafter 1999 RATES].

⁶¹ DIV. OF REPROD. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION ET AL., 1998 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 5, 445–46 (2000), *available at* <http://www.cdc.gov/reproductivehealth/ART/ARTReports.htm> [hereinafter 1998 RATES].

⁶² 1999 RATES, *supra* note 60, at 6, 469–70.

trend, a significant cohort of programs continues to defy the law by not reporting verified ART success rates. For instance, eight of the non-reporting clinics in 1999 were also listed as non-reporting in 1998, and four of the eight were listed as non-reporting in 1997 as well.^{64, 65, 66} Nearly half of the 25 non-reporting clinics in 2000 also did not report data in 1999.^{67, 68} One clinic, The Genetics & IVF Institute (GIVF) of Fairfax, VA, was listed as non-reporting in 1996, 1997, 1998, 1999, and 2000.^{69, 70, 71, 72, 73} This is especially disturbing because GIVF is a particularly large and well-known clinic. They have received national attention for pioneering the "Micro sort," sperm-sorting technology⁷⁴ and advertise nationally on the Google search engine and in the New York Times Magazine.⁷⁵

The long list of non-reporting clinics (and an increasing number of repeat non-reporters) in the CDC's annual report illustrates the essentially voluntary nature of data-reporting, even when it is mandated by federal law. According to Richard J. Sherins, M.D., director of the GIVF Division of Andrology (Male Infertility), a number of factors may lead a clinic to not report ART success rates. These include the lack of solid criteria to correctly identify the etiology of infertility, an imprecise separation of clinical indications, and the inherent bias in the reporting structure toward pregnancy rates as the sole arbiter of a clinic's success (even though other criteria may be useful to the public as they choose an ART clinic).⁷⁶ In fact, being listed as a non-reporting clinic in the CDC's annual report is the *only* consequence for failing to report ART success rate data.⁷⁷

Moreover, the CDC gives only a vague reference to those clinics that fail to report data but are not listed in the CDC report at all, even as non-reporting.⁷⁸ According to the CDC, their report includes "almost all" clinics that used ART in the year covered by the report.⁷⁹ The list of ART clinics has grown with each annual report,⁸⁰ indicating that the CDC is continually tracking down clinics that have not

⁶³ 2000 RATES, *supra* note 56, at 6, 501–02.

⁶⁴ 1999 RATES, *supra* note 60, at 469–70.

⁶⁵ 1998 RATES, *supra* note 61, at 445–46.

⁶⁶ DIV. OF REPROD. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION ET AL., 1997 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 404–05 (1999), *available at* <http://www.cdc.gov/reproductivehealth/ART/ARTReports.htm> [hereinafter 1997 RATES].

⁶⁷ 2000 RATES, *supra* note 56, at 501–02.

⁶⁸ 1999 RATES, *supra* note 60, at 469–70.

⁶⁹ DIV. OF REPROD. HEALTH, CTRS. FOR DISEASE CONTROL & PREVENTION ET AL., 1996 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 359 (1998), *available at* <http://www.cdc.gov/reproductivehealth/ART/ARTReports.htm>.

⁷⁰ 1997 RATES, *supra* note 66, at 405.

⁷¹ 1998 RATES, *supra* note 61, at 446.

⁷² 1999 RATES, *supra* note 60, at 470.

⁷³ 2000 RATES, *supra* note 56, at 502.

⁷⁴ Gina Kolata, *Researchers Report Success in Method to Pick Baby's Sex*, N.Y. TIMES, Sept. 9, 1998, at A1.

⁷⁵ See Claudia Kalb & Karen Springen, *Brave New Babies*, NEWSWEEK, Jan. 26, 2004, at 45.

⁷⁶ Interview with Richard J. Sherins, M.D., Director of the GIVF Division of Andrology, The Genetics & IVF Institute (April 2003).

⁷⁷ SART members may lose their membership, but SART is "not a punitive society." See Sandra Carson, President ASRM, Keynote Address at the Meeting of the President's Council on Bioethics (March 7, 2005), *available at* <http://www.bioethics.gov/transcripts/march03/mar7full.html>.

⁷⁸ See, e.g., 2002 ART RATES, *supra* note 2, at 5–6.

⁷⁹ *Id.* at 5.

⁸⁰ Compare 2002 ART RATES, *supra* note 2, at 509–510 (listing 37 non-reporting clinics), with 2000 RATES, *supra* note 56, at 501–502 (listing 25 non-reporting clinics).

previously been listed as operating ART programs. However, the fact that the list of non-reporting clinics begins with a request that consumers contact the CDC if they know of any clinics missing from the report, leads one to conjecture that enforcement is inconsistent at both the non-reporting and inclusion levels.

C. LICENSING

1. United Kingdom

According to the HFE Act, the HFEA has the authority to license British fertility clinics and research laboratories using gametes or human embryos.⁸¹ The HFE Act clearly sets out three licensing categories: licenses for fertility treatment, licenses for embryo storage, and licenses for research on human embryos or gametes.⁸² Section 1 of Schedule 2 specifies that clinics require a license to create embryos in vitro, store embryos, use human gametes, test embryos before implantation, implant embryos in a woman, test sperm viability, or conduct research on human embryos or gametes.⁸³ None of these practices require a license in the U.S.

Importantly, the HFE Act⁸⁴ authorizes the HFEA to *enforce* the licensing requirements. The HFEA has the authority to refuse, revoke, or suspend a license and to submit violators of the HFE Act to the Director of Public Prosecutions.⁸⁵ Those convicted of license violations may be charged with a prison term of up to ten years and a fine.⁸⁶ For less serious cases, the HFEA may issue a license, contingent upon a clinic meeting certain HFEA conditions or completing a review.⁸⁷ At the very least, the licensing process allows for the HFEA to make recommendations to improve clinic practices without issuing conditions or revoking a clinic's license.⁸⁸

The U.K. Parliament also retains some power over the licensing process, most notably in regard to licenses for research on human embryos. In a recent and well-publicized case, Parliament used its power to extend the HFEA's ability to grant licenses for embryo research.⁸⁹ Before the decision by Parliament, the HFEA could issue a license for research on embryos or gametes only for the study of infertility, congenital disease, miscarriages, contraception techniques, or pre-implantation testing for genetic abnormalities.⁹⁰ As of January 2001, the HFEA can issue licenses for research on embryo development or "serious disease," or for the treatment of serious disease.⁹¹ While the terminology might cause some confusion, these licenses

⁸¹ Human Fertilisation and Embryology Act, 1990, c. 37, § 11(1)(b) (Eng.), *available at* <http://www.opsi.gov.uk/acts/acts1990.htm>.

⁸² *Id.* sched. 2.

⁸³ *Id.*

⁸⁴ *Id.* §§ 39–40.

⁸⁵ ELEVENTH ANNUAL REPORT, *supra* note 27, at 6–7.

⁸⁶ Human Fertilisation and Embryology Act, 1990, c. 37, § 41(1) (Eng.), *available at* <http://www.opsi.gov.uk/acts/acts1990.htm>.

⁸⁷ *Id.* §§ 12–13.

⁸⁸ *Id.* §§ 23–24.

⁸⁹ *New Embryo Research Regulations*, HUMAN FERTILISATION AND EMBRYOLOGY AUTHORITY UPDATE (London), Feb. 2001, at 2, *available at* <http://www.hfea.gov.uk/HFEAPublications/HFEAUpdate>.

⁹⁰ HUMAN FERTILISATION AND EMBRYOLOGY AUTH., NINTH ANNUAL REPORT AND ACCOUNTS 2000 25 (2000), *available at* <http://www.hfea.gov.uk/HFEAPublications/AnnualReport> [hereinafter NINTH ANNUAL REPORT].

⁹¹ *New Embryo Research Regulations*, *supra* note 89, at 2.

for research on "serious disease" essentially allowed for the first legal stem cell research in the U.K.⁹²

In terms of process, a research program must first obtain approval from a Research Ethics Committee (equivalent to Institutional Review Boards in North America) before applying for a license from the HFEA.⁹³ It must then submit an application explaining the objectives and protocols of the study, why the study requires the use of human gametes or embryos, and why the study is necessary.⁹⁴ Completed applications are peer reviewed and returned to the applicant for comments before the license committee reviews them.⁹⁵ For successful applications, the HFEA conducts inspections and reviews progress reports and a final report.⁹⁶

The 2003-2004 HFEA Annual Report includes a list of licensed research projects and a list of peer reviewers.⁹⁷ The HFEA granted research licenses to 124 of 156 applicants between 1991 and August 31, 2004.⁹⁸ The majority of these were research licenses for the treatment of infertility.⁹⁹ It will be interesting to see how the make-up of licensed research projects changes given the availability of licenses for the study of "serious disease."

The process of licensing programs for the creation or storage of embryos differs slightly from the process of licensing for research.¹⁰⁰ Recently, the HFEA began to issue three-year treatment and storage licenses in response to the growing number of well-established fertility clinics that had demonstrated consistent adherence to the Code of Practice.¹⁰¹ For licensed clinics, a full inspection takes place every third year prior to license renewal, and interim inspections take place during the other two years. These changes demonstrate the HFEA's efforts to save time and make the licensing process more cost-effective.

2. United States

While licensing has become well established and even streamlined in the U.K., no U.S. law requires licensing or accreditation of ART programs or embryo laboratories. Though SART conducted verification site visits as part of its data reporting process, the inspections have no connection to licensing or accreditation.¹⁰² SART members must submit evidence that they have received accreditation to fulfill their membership requirements, but an approved outside agency and not SART itself grants accreditation.¹⁰³ Non-SART members have no obligation to SART or the CDC to receive such accreditation.

⁹² Andy Coghlan & Emma Young, *Landmark vote clears the way for stem cell research in Britain*, NEW SCIENTIST, Jan. 6 2001, at 99.

⁹³ HUMAN FERTILISATION AND EMBRYOLOGY AUTH., *supra* note 13, § 10.6, at 93.

⁹⁴ FACING UP TO THE CHALLENGE, *supra* note 11, at 13.

⁹⁵ HUMAN FERTILISATION AND EMBRYOLOGY AUTH., *supra* note 13, § 10.10, at 94.

⁹⁶ ELEVENTH ANNUAL REPORT, *supra* note 27, at 11.

⁹⁷ FACING UP TO THE CHALLENGE, *supra* note 11, 20 apps. 4-5.

⁹⁸ *Id.* at 14.

⁹⁹ *See Id.*

¹⁰⁰ Human Fertilisation and Embryology Act, 1990, c. 37, §§ 2-3, sched. 2 (Eng.), available at <http://www.opsi.gov.uk/acts/acts1990.htm>.

¹⁰¹ ELEVENTH ANNUAL REPORT, *supra* note 27, at 6.

¹⁰² Interview with Joyce Zeitz, Executive Administrator, Society for Assisted Reproductive Technology (June 25, 2003).

¹⁰³ Society for Assisted Reproductive Technology, *supra* note 43, at ¶ 9.

Section 3(a) of the FCSRCA of 1992¹⁰⁴ specifies that the CDC shall develop an embryo laboratory certification program "to be carried out by the States" and that it "shall encourage [state] officials to assist the State in adopting such a program." Although the resulting model certification program, published in July 1999,¹⁰⁵ includes standards for quality assurance, personnel competency, and record keeping, the CDC cannot require clinics to meet these standards in practice. As of July 2005, no state had adopted the CDC's program.¹⁰⁶

Since no state has implemented the model certification program, it is impossible for any clinic to obtain certification according to the CDC's standards. Therefore, as a public service, the CDC has decided to document accreditation by the College of American Pathologists (CAP), the Joint Commission of Accreditation of Healthcare Organizations (JCAHO), and the New York State Tissue Bank Accreditation Program (NYSTB) in its annual success rate report.¹⁰⁷ These three organizations provide accreditation of the *laboratories*, and the *clinic* is responsible for the data reporting procedures described previously.¹⁰⁸ These are nonfederal programs that the CDC does not oversee, and they are also the three accreditation programs approved by SART.¹⁰⁹ In the U.S., ART clinics may use multiple embryology laboratories.

According to the CDC's 2002 report, 92% of 391 reporting clinics had accreditation from CAP, JCAHO, or the NYSTB, with accreditation pending for an additional 4% of clinics.¹¹⁰ This is a significant increase from just four years prior, when only 67% of 360 reporting clinics had accreditation from any of the three agencies, with accreditation pending for an additional 8% of clinics.¹¹¹

Unlike in the U.K., there are no legal consequences for non-accredited U.S. programs. In addition, there is also "no consumer-recognized seal of approval or standard symbol that conveys that any minimum standards of quality have been met."¹¹² The rapid increase in accreditation since White's 1998 analysis depicts the changing landscape of the decentralized U.S. regulatory system; driven by commercial success and consumer behavior, the ART clinics have responded to the increasingly informed and educated consumer, a response not previously generated by unenforced federal mandates.

The newly educated consumer should not be viewed as a coincidental byproduct of increasingly widespread internet use. In 2000, SART began a public relations campaign called "Setting the Standards for ART." The campaign press release acknowledged SART's intent to create an image of SART as the guardian of quality

¹⁰⁴ Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-2(a) to (b) (2005).

¹⁰⁵ Implementation of the Fertility Clinic Success Rate and Certification Act of 1992: A Model Program for the Certification of Embryo Laboratories, 64 Fed. Reg. 39,374, 39,386 (July 21, 1999).

¹⁰⁶ The President's Council on Bioethics, Discussion Document, U.S. Public Policy and the Biotechnologies that Touch the Beginnings of Human Life: A Detailed Overview, at text accompanying notes 85-86 (June 3, 2003), available at <http://www.bioethics.gov/background/biotechnology.html>.

¹⁰⁷ See 2002 ART RATES, *supra* note 2, at 69. See also THE NEW YORK STATE TASK FORCE ON LIFE AND THE LAW, EXECUTIVE SUMMARY OF ASSISTED REPRODUCTIVE TECHNOLOGIES: ANALYSIS AND RECOMMENDATIONS FOR PUBLIC POLICY, at Certification and Licensure (Oct. 2001), <http://www.health.state.ny.us/nysdoh/taskfce/execsum.htm>.

¹⁰⁸ 2002 ART RATES, *supra* note 2, at 69-70.

¹⁰⁹ 2002 ART RATES, *supra* note 2, at 69-70; Society for Assisted Reproductive Technology, *supra* note 43, at ¶9.

¹¹⁰ 2002 ART RATES, *supra* note 2, at 71.

¹¹¹ 1998 RATES, *supra* note 61, at 47.

¹¹² White, *supra* note 7, at 323.

assurance.¹¹³ The campaign sought to raise consumer confidence in dealing with fertility clinics belonging to SART and to increase recognition of the fact that SART members adhere to strict membership standards. SART hopes that the label "SART member" will convey a message of quality and safety to consumers. This message is appropriate since SART members must have accreditation from at least one of CAP, JCAHO, or the NYSTB.¹¹⁴

Of course, the quality and safety of an accredited fertility clinic or embryo laboratory depends upon the standards of the accrediting agency. Since CAP accredits the majority of accredited programs listed in the 2002 CDC report, it is imperative that CAP set strict standards for accreditation. CAP has published its standards, which include specifications regarding lab directors, personnel, facilities, inspections and quality assurance.¹¹⁵ Specifically, CAP requires the lab director to have appropriate education and experience with relevant procedures.¹¹⁶ CAP also required that personnel, resources, and facilities correspond to the size of the program.¹¹⁷ CAP conducts periodic on-site inspections and clinics supplement this with self-inspections.¹¹⁸ Clinics must correct any deficiencies and report any corrective action taken.¹¹⁹ In addition, clinics must put in place an ongoing quality assurance program to evaluate quality of care, analyze data as a method of quality control, and complete proficiency testing.¹²⁰

CAP's program does not differ significantly from the HFEA's licensing program in these standards, which also includes specific requirements, on-site inspections, evaluations, and recommendations for improvement.¹²¹ The general process of licensing and accreditation is roughly the same for the two organizations, although specific regulatory differences exist. The key difference is that British law *requires* licensing, while U.S. clinics choose to seek accreditation voluntarily.

D. REGULATION

1. United Kingdom

Programs applying for licensing from the HFEA must comply with both the HFE Act and the most recent edition of the Code of Practice.¹²² Both documents describe acceptable and unacceptable practices for infertility treatment and embryo research in the U.K.¹²³ Restrictions and prohibitions are clearly stated, and are subjected to HFEA revision and review.¹²⁴ Moreover, both reflect the need for

¹¹³ Press Release, Society for Assisted Reproductive Technology, Society for Assisted Reproductive Technology Embarks on New, Aggressive Campaign Aimed at Setting Higher Standards, Greater Awareness of Reproductive Medicine (Oct. 25, 2000) (on file with authors), available at <http://www.obgyn.net/infertility/infertility.asp?page=/infertility/articles/sart>.

¹¹⁴ Society for Assisted Reproductive Technology, *supra* note 43, at ¶ 9.

¹¹⁵ See COLL. OF AM PATHOLOGISTS, STANDARDS FOR LABORATORY ACCREDITATION (2000), available at http://www.cap.org/apps/docs/laboratory_accreditation/lapstandards.pdf.

¹¹⁶ *Id.* at 1-3.

¹¹⁷ *Id.*

¹¹⁸ *Id.* at 5.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 4-5.

¹²¹ See FACING UP TO THE CHALLENGE, *supra* note 11, at 7.

¹²² See HUMAN FERTILISATION AND EMBRYOLOGY AUTH., *supra* note 13, at 9-10; Human Fertilisation and Embryology Act, 1990, c. 37, § 3(1) (Eng.), available at <http://www.opsi.gov.uk/acts/acts1990.htm>.

¹²³ See HUMAN FERTILISATION AND EMBRYOLOGY AUTH., *supra* note 13, at 9-10.

¹²⁴ See *Id.* at 10.

flexibility in the regulation of ART. The Code of Practice was revised and republished in 1993, 1995, 1998, 2001, and 2004.¹²⁵ Parliament amended the HFE Act to grant licenses for stem cell research.¹²⁶ The Act serves as the basis for the HFEA's continual evaluation of developments in the field.

The HFEA addresses the policy issues raised by changes in ART in frequent updates and its annual report looks forward to key issues expected in the upcoming year. For instance, the Policy Update for the HFEA 2002 Annual Report¹²⁷ offers background information and HFEA policy on pre-implantation genetic diagnosis (PGD), tissue typing within PGD to identify embryos that are "tissue compatible" with an existing child, aneuploidy screening, embryo transfer, donor information, the Human Reproductive Cloning Act 2001, Intrea-Cytoplasmic Sperm Injection (ICSI), and stem cells from human embryos. The HFEA's decisions on these issues have primary importance to British infertility programs, since in many cases the HFEA has the authority to grant or deny licenses for novel treatments, such as PGD or egg freezing.

The HFEA's regulatory reach on policy issues has a direct impact on choices available to British citizens seeking procreative options. For example, the HFEA permits couples to use technology to conceive a child who is genetically appropriate for use as an organ donor for an older sibling,¹²⁸ but does not allow couples to use IVF to conceive triplets.¹²⁹

2. United States

No regulatory agency in the U.S. has as comprehensive a list of policy issues to evaluate as in the U.K., and most of these issues—with the exception of cloning and gamete, embryo and tissue storage—lack federal regulation all together. The existing regulation in the U.S. focuses on quality control. The FDA oversees clinical studies of new medicines, but has asserted "jurisdiction over human cells used in therapy involving the transfer of genetic material by means other than the union of gamete nuclei."¹³⁰ As discussed above, the CDC oversees the task of gathering and publishing data on ART success rates.¹³¹ States discipline fertility specialists for using unscrupulous practices.¹³²

Regulation on sensitive policy matters concerning ART is virtually nonexistent at a federal level. Debate rages in Congress about appropriate regulation of stem cell research for therapeutic purposes, but almost no debate exists about regulating assisted reproduction.

¹²⁵ The HFEA maintains all six editions of the Code of Practice on its website. HFEA, <http://www.hfea.gov.uk/HFEAPublications/CodeofPractice> (last visited October 26, 2005).

¹²⁶ Human Fertilisation and Embryology Act, 1990, c.37, § 11, sched. 2 (Eng.), available at <http://www.opsi.gov.uk/acts/acts1990.htm>.

¹²⁷ See ELEVENTH ANNUAL REPORT, *supra* note 27, at 16–17.

¹²⁸ See FACING UP TO THE CHALLENGE, *supra* note 11, at 15.

¹²⁹ See *id.* at 19.

¹³⁰ K.C. Zoon, Human Cells Used in Therapy Involving the Transfer of Genetic Material, FDA Center for Biologics Evaluation and Research Letter to Sponsors/Researchers (July 6, 2001), available at <http://www.fda.gov/cber/ltr/cytotrans070601.htm>.

¹³¹ 42 U.S.C. §§263a-1—263a-5.

¹³² See, e.g., Katherine Seligman, *License Revoked for Embryo Mix-Up*, S.F. CHRON., March 3, 2005, at B4 (reporting that the Medical Board of California revoked the license of San Francisco-based fertility specialist Dr. Steven Katz, who implanted the wrong embryo in a patient and failed to inform her of the mistake until more than two years later).

The lack of regulation at the federal level is a direct result of U.S. emphasis on personal autonomy and the sanctity of privacy. These rights make it difficult for states to issue restrictive policies on ART.¹³³ Furthermore, the political stakes surrounding the volatile issue of abortion in the U.S. cause reluctance by policy makers to deal with issues regarding human embryos created through ART.¹³⁴ Sovereignty complications also arise, with some issues requiring attention on the state level.¹³⁵

Several scholars offer excellent accounts of the legal status of ART in the U.S.¹³⁶ Havins and Dalessio describe the relevant constitutional protections, statutory protections, federal and state regulations and court rulings.¹³⁷ This body of legislation and court cases demonstrate that regulations on ART lack consistency and are rarely well developed in any particular state. For example, Havins and Dalessio point out that Louisiana is the only state with a law regarding the destruction of frozen embryos (destruction is forbidden), an issue that is clearly regulated by the HFEA.¹³⁸ Often, U.S. law fails to reflect important distinctions in biological techniques and fails to match the rapid pace at which reproductive technologies are developing, a challenge met by the HFEA.

The private capitalistic health care system further drives the lack of regulation. Given the important role SART plays in data reporting and in requiring accreditation among its members, one might expect SART to contribute to the creation of policy in the U.S. SART, however, is committed to *self-regulation* of ART and embryo labs.¹³⁹ One SART slogan states that “prevention is the best medicine” with regard to government regulation.¹⁴⁰ Indeed, SART’s campaign to represent the highest standards in ART demonstrates an effort to maintain regulatory control, while simultaneously improving the quality of infertility programs and research. SART members value their ability to individualize their patient treatment depending on the specific circumstances. They fear government regulation would limit their flexibility in utilizing innovative ART procedures and techniques, thereby compromising patient care and access.¹⁴¹ A recent study conducted by Frankel and Morris¹⁴² echoes this sentiment clearly. Their survey of 370 SART fertility clinic

¹³³ See Kathryn Venturatos Lorio, *The Process of Regulating Assisted Reproductive Technologies: What We Can Learn from Our Neighbors—What Translates and What Does Not*, 45 LOY. L. REV. 247, 266 (1999).

¹³⁴ Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect them From Harm?*, 2004 UTAH L. REV. 57, 73-74 (2004) (arguing that the politics of abortion preclude meaningful regulation of ART in the United States).

¹³⁵ See D’Andrea, *supra* note 1, at 1698 (noting that devolving law making powers to the states recognizes “the tension between the principle of ‘one law for all’ and the need to accommodate a ‘bewildering variety of religious and belief systems.’”).

¹³⁶ See, e.g., Havins & Dalessio, *supra* note 1.

¹³⁷ Havins & Dalessio, *supra* note 1, at 828–31; R. Alta Charo, *Children by Choice: Reproductive Technologies and the Boundaries of Personal Autonomy*, NATURE CELL BIOLOGY & NATURE MEDICINE (Fertility Supp. 2002), available at www.nature.com/fertility.

¹³⁸ LA. REV. STAT. ANN. § 9:129 (1991); Havins & Dalessio, *supra* note 1, at 837-38.

¹³⁹ Sandra Carson, President, American Society for Reproductive Medicine, Chief, Baylor University Assisted Reproductive Technology Program, Remarks at the Meeting of the President’s Council on Bioethics (March 7, 2003), available at <http://www.bioethics.gov/transcripts/march03/mar7full.html>.

¹⁴⁰ See <http://www.sart.org> (The Benefits of Membership).

¹⁴¹ See generally ASRM/SART Statement on Responsibility and Reproduction, March 30, 2004, available at <http://www.asrm.org/Washington/Bulletins/vol6no22.html>.

¹⁴² See Mark.S. Frankel & Parisa Morris, *A View From the Field on Food and Drug Administration Regulation: Report of a 2002 Survey of U.S. Fertility Clinics*, 79 FERTILITY & STERILITY 1060 (2003).

members reveals that 133 of 221 responding clinics viewed the FDA's assertion of jurisdiction over human cells used in therapy involving the transfer of genetic material to be inappropriate.¹⁴³ The clinics objecting to the FDA's assertion of jurisdiction explained that "cytoplasm is not a drug," that the FDA was interfering with the doctor patient relationship, and that the FDA's intervention would compromise future health benefits by "imposing an unnecessary restraint on the process of medical science."¹⁴⁴

SART, however, is not an accrediting agency itself and has no control over non-members. Indeed, the greatest punishment that SART can impose on its own members is to revoke their membership status.¹⁴⁵ This does nothing to improve the quality of a clinic for which membership status is not important. SART recognizes these limitations on its ability to make changes in the field and attempts to overcome them by working closely with government agencies and continually recruiting new members.¹⁴⁶ But SART alone cannot deal with the problems of poor-quality clinics and practices.

Without regulation, certain problems will continue to plague the field of ART and embryo research in the U.S. The problems include:

- Poor quality clinics will remain open and will propagate morally questionable and/or sloppy clinical practices, whether on purpose or unintentionally. Some of these cases will make headlines while others will go unpublicized.
- The availability, reliability, and clarity of ART success rate data will continue to be poor so that consumers will have difficulty determining the quality of individual clinics.
- Clinics that "cut corners" on voluntary data reporting, advertising, and practice guidelines will achieve commercial success at the expense of better quality clinics with whom they compete.
- Poor quality clinics will harm the reputation of the field of ART as a whole.

These problems demand attention through governmental regulation or other means. The goal of any such regulation must be to get rid of low-quality clinics, improve available ART success rate data for consumers, and eliminate morally questionable and sloppy practices. Lorio adds that regulations are necessary to ensure safety and health, protect the welfare of children born from ART, and avoid putting off difficult ethical questions for the future.¹⁴⁷ In any case, regulation in the U.S. must keep in mind the rapid pace of technology development and reflect the individual nature of infertility treatment.

III. RESULTS: THE IMPACT OF CROSS-ATLANTIC DISCOURSE

A. REGULATORY PARADIGM SHIFTS?

The U.K. model for regulating ART is mature: comprehensive, unified, and heavy handed. The U.S. model is in its infancy: haphazard, decentralized, and

¹⁴³ *Id.* at 1061.

¹⁴⁴ *Id.*

¹⁴⁵ See Carson, *supra* note 139.

¹⁴⁶ Interview with Joyce Zeitz, Executive Administrator, Society for Assisted Reproductive Technology (Aug. 7, 2001).

¹⁴⁷ Lorio, *supra* note 133, at 248.

deferential to autonomous decisions by professionals and consumers. Despite the calls to emulate the U.K. model in the U.S., we predict that the U.S. system is unlikely to follow the path of the HFEA. Instead, differing cultural values and U.S. Constitutional guarantees will drive a uniquely U.S. solution which focuses at a federal level on quality control and consumer protection, leaving ethical and moral line-drawing to individual patients, providers, and professional medical bodies.

To be sure, the U.K.'s model of central control over artificial reproduction has some significant advantages over the patchwork of U.S. state and federal regulation that essentially leave the U.S. fertility industry unregulated. U.K. consumers have access to better information about individual clinics and providers. They are better protected from unscrupulous practices of unethical providers who have made headlines and eroded confidence in the U.S. system. The benefits to consumers translate to confidence in a system that allows the HFEA to answer difficult ethical questions and draw uniform lines applicable across the U.K. This model eliminates the public hand wringing and debate that dominate U.S. discourse on human reproduction.

That said, the wholesale importation of the U.K. model to the U.S. is neither possible nor wise given the American values, history, and culture. The U.K. system does not accommodate the moral diversity that exists in the U.S., where profound disagreement over the moral status of the embryo exists. The current system—comprised of oversight by professional groups, sporadic state regulation, and significant deference to individual consumer choice—although imperfect, allows for moral diversity on ethical and policy issues. Any attempt to impose national uniformity in the absence of moral consensus over ART policies will monopolize precious time on the national docket (as the ongoing battle over stem cell research for therapeutic purposes demonstrates), and is unlikely to resolve the ethical dilemmas. Rules imposed in the U.S. by an HFEA-type regulatory body appointed by an executive elected by a bare majority of the population would face fierce court challenges and political opposition.

A second reason for expecting less federal—and more state and private—activity around ART issues in the U.S. is politics. The lack of national moral consensus has made federal policy making extremely difficult, since no set of advocates has been able to assemble a stable majority coalition to support their views and enact legislation and financial support consistent with them. As a result, federal influence over many ART policies has been limited. Since advocates of different views are not evenly distributed geographically, however, individual states have frequently been able to implement their own, widely divergent, policies in place to deal with at least some ART issues.

This pattern of “federalism by default” is perhaps most clear in the debate over embryonic stem cell research. Despite considerable attention to these issues over the course of the last fifteen years by two separate Presidentially appointed bioethics commissions and several different scientific advisory panels, as well as considerable Congressional discussion, there is little consensus about the appropriate scope and financing for this research.¹⁴⁸ Debate in Washington has generally not addressed the permissibility or legality of embryonic stem cell research, but has rather focused on the narrower question of what stem cell “lines” should be eligible to receive federal

¹⁴⁸ See generally PCBE: *Monitoring Stem Cell Research: Chapter 2 “Current Federal Law and Policy”* (January 2004), THE PRESIDENT’S COUNSEL ON BIOETHICS, available at <http://www.bioethics.gov/reports/stemcell/chapter2.html> (describing a history of federal policy in this area).

financial support through the National Institutes of Health and other federal agencies.¹⁴⁹ The use of federal funds to create embryos for research purposes or to destroy embryos has been routinely prohibited in appropriations bills since the mid-1990s through the so-called Dickey amendment.¹⁵⁰ Subsequent debate, however, has relied on arguments that this prohibition does not extend to research using stem cell lines created with other funding sources.¹⁵¹ The Clinton Administration advocated an expansive view of this argument, which would have encouraged researchers to fund the creation of stem cell lines from other sources and then apply for federal funds to continue research on these “pre-existing” lines.¹⁵² The Bush Administration, by contrast, has limited federal funding support to the small number of lines existing before 2001, although the precise legal status of this directive is unclear.¹⁵³ The House recently passed legislation that would expand federal support to cell lines derived from embryos created, but not used, for *in vitro* fertilization.¹⁵⁴ Many Senators also support the legislation, including Majority Leader William Frist.¹⁵⁵

¹⁴⁹ See, e.g., Rick Weiss, *Bill Renews Fight on Stem Cells; House, Senate Measures Would Loosen Bush's Research Curbs*, WASH. POST, Feb. 17, 2005, at A6; Rick Weiss, *Approved Stem Cells' Potential Questioned*, WASH. POST, October 29, 2004, at A3; Ceci Connolly, *2 GOP Senators Defend Bush on Stem Cell Research*, WASH. POST, August 13, 2004, at A2; CNN.com Specials, *The Stem Cell Debate*, <http://www.cnn.com/SPECIALS/2001/stemcell/> (last visited Oct. 26, 2005).

¹⁵⁰ The original amendment can be found in Section 128 of P.L. 104-99; it affected NIH funding for FY1996 contained in P.L. 104-91. For subsequent fiscal years, the rider is found in Title V, General Provisions, of the Labor, HHS and Education appropriations acts in the following public laws: FY1997, P.L. 104-208; FY1998, P.L. 105-78; FY1999, P.L. 105-277; FY2000, P.L. 106-113; FY2001, P.L. 106-554; FY2002, P.L. 107-116; FY2003, P.L. 108-7; FY2004, P.L. 108-199; and, FY2005, P.L. 108-447. See CRS Report for Congress, *Stem Cell Research*, n.19, available at <http://fpc.state.gov/documents/organization/51131.pdf>. The amendment states:

(a) None of the funds made available in this Act may be used for —

(1) the creation of a human embryo or embryos for research purposes; or
 (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

(b) For purposes of this section, the term ‘human embryo or embryos’ includes any organism, not protected as a human subject under 45 CFR 46 [the Human Subject Protection regulations] as of the date of enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes [sperm or egg] or human diploid cells [cells that have two sets of chromosomes, such as somatic cells].

¹⁵¹ See, e.g., JUDITH A. JOHNSON & ERIN D. WILLIAMS, CONG. RES. SERV., *STEM CELL RESEARCH* 8 (2005), available at <http://fpc.state.gov/documents/organization/51131.pdf>; George Q. Daley, *Missed opportunities in Embryonic Stem-Cell Research*, 351 NEW ENG. J. MED. 627 (2004); NAT'L BIOETHICS ADVISORY COMM'N, *ETHICAL ISSUES IN HUMAN STEM CELL RESEARCH* 35 (1999), available at <http://www.georgetown.edu/research/nrcbl/nbac/stemcell.pdf>.

¹⁵² See Clinton Administration NIH Guidelines for Embryonic Stem Cell Funding, 65 Fed. Reg. 51,975, (Aug. 25, 2000), reprinted in President's Council on Bioethics, *Monitoring Stem Cell Research*, Appendix D, available at http://www.bioethics.gov/reports/stemcell/appendix_d.html; NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 151, at 35.

¹⁵³ Roger Noll, *The Politics and Economics of Implementing State-Sponsored Embryonic Stem-Cell Research* 21, <http://siepr.stanford.edu/papers/pdf/04-28.pdf>, (June 2005)(Stanford Institute for Economic Policy Research Discussion Paper 04-2820).

¹⁵⁴ Sheryl Gay Stolberg, *Senate's Leader Veers from Bush Over Stem Cells*, N.Y. TIMES, July 29, 2005, at A6.

¹⁵⁵ Ceci Connolly, *Frist Breaks with Bush on Stem Cell Research*, WASH. POST, July 30, 2005, at A1.

The Bush Administration has threatened to veto this bill, and as of this writing it is unclear if the veto can be overridden.¹⁵⁶

In short, federal policy toward embryonic stem cells has been inconsistent and uncertain. Current federal law imposes no restrictions on research funded by private or other non-federal funds, but limits federal support to a small number of pre-existing lines.¹⁵⁷ This limited federal activity has led both supporters and detractors of embryonic stem cell research to seek favorable state legislation on the allowable scope of such research.¹⁵⁸ It has also encouraged disease advocates and researchers to seek less restrictive funding from state and private sources.¹⁵⁹

The resulting state legislation and other activities governing ART technologies have been extremely diverse in scope and intent, ranging from legislation to prohibit and even criminalize certain types of activities, to actively encouraging embryonic stem cell research within state borders and authorizing considerable amounts of state funds to support such research.¹⁶⁰ While no state has enacted anything approaching an HFEA-style comprehensive regulatory framework, it is significant that states have found it easier to legislate in this complex and controversial area than the federal government.

State financial support for stem cell research is particularly significant, since few states have any experience with supporting bio-medical research on a large scale. While some states have supported various kinds of targeted research initiatives at state universities in order to encourage other types of technology,¹⁶¹ almost no states have experience with operating competitive, peer-reviewed research programs in medicine or genetic research. Funding from the National Institutes of Health and other federal agencies has been ubiquitous in biomedical research, so states have not previously felt compelled to support research in these areas.

In spite of this limited experience, several states have approved, and more have proposed, substantial spending from state sources to support stem cell research. California's voter approved initiative, known as Proposition 71, intends to disburse \$3 billion in research funds over ten years.¹⁶² While this is clearly the largest undertaking to date, New Jersey, Illinois, Connecticut, and Massachusetts have also approved stem cell research programs, and similar programs have been proposed in Wisconsin, Maryland, and Pennsylvania, among others.¹⁶³ While the enacted and proposed programs differ in particulars, most envision states spending hundreds of millions of dollars to support research with fewer restrictions than currently applied by federal funding agencies.

¹⁵⁶ *Senate Lacks Vote for Stem Cell Override*, (August 1, 2005), available at http://www.boston.com/news/nation/washington/articles/2005/08/01/senate_lacks_votes_for_stem_cell_override?mode=PF (last visited Oct. 26, 2005).

¹⁵⁷ Address to the Nation on Stem Cell Research, 37 PUB. PAPERS 32 (Aug. 13, 2001).

¹⁵⁸ See generally Noll, *supra* note 153.

¹⁵⁹ See National Council of State Legislatures, *supra* note 3, for an inventory of state legislative activities.

¹⁶⁰ *Id.* For analyses of state legislation and subsequent court action, see Lori B. Andrews, *Legislators as Lobbyists: Proposed State Regulation of Embryonic Stem Cell Research, Therapeutic Cloning, and Reproductive Cloning*, available at http://www.bioethics.gov/reports/stemcell/appendix_e_html; Havens & Dalessio, *supra* note 1.

¹⁶¹ The State Science and Technology Institute publishes weekly digests of State funded technology initiatives on its website, <http://www.ssti.org/Digest/Indices/indexstate.htm>.

¹⁶² California Gives Go-Ahead to Stem Cell Research, <http://www.msnbc.msn.com/id/6384390/> (last visited Oct. 27, 2005).

¹⁶³ For descriptions of state initiatives, see What's New in State Stem Cell Legislation and Funding, http://www.grassrootsconnection.com/state_stem_cell_resources.htm (last visited Oct. 27, 2005).

The arguments in support of these undertakings are as much about economic development and jobs as science. In addition to noting the potential of stem cell research to provide therapy for a wide range of conditions, advocates have also stressed the potential to create jobs and income for state residents and the need to “keep up” with other states and retain scientists and state prestige. A letter from a leading stem cell researcher to a Wisconsin state legislator provides a useful example of this rhetoric:

I was born and grew up in the Midwest, but subsequently studied both on the east and west coasts. I therefore know first hand that there is a strong impression on both coasts that the middle of the country is an intellectual void. If a T.V. sitcom takes place in either L.A. or New York, and the writers want to introduce a character that is a well-meaning yokel, they often put a T-shirt on him with "Wisconsin" printed on the front to establish his character. It has been a great source of pride to me that the publicity surrounding human embryonic stem cells and its universal association with Wisconsin has helped to remove that T-shirt. Please be absolutely clear: any legislation that impacts basic science that is more restrictive than current federal legislation will only help put that T-shirt back on.¹⁶⁴

The perception by state policy makers that they are in competition with other states for jobs, scientists, and prestige—in much the same way as they compete for other economic development activities—will probably produce a level of spending on stem cell research significantly higher than if federal policy on allowable cell lines was less restrictive and funding levels were established through the budget process at the National Institutes of Health. In addition to the \$3 billion passed in California,¹⁶⁵ Illinois proposed a \$1 billion bond issue,¹⁶⁶ New Jersey is planning a \$500 million initiative,¹⁶⁷ Pennsylvania put forward a \$500 million spending plan,¹⁶⁸ Wisconsin proposed a \$375 million initiative,¹⁶⁹ and Connecticut approved a \$100 million spending plan.¹⁷⁰ Even if all of these funds are not spent, it would appear that embryonic stem cells may well receive more funding from state agencies than less controversial stem cell research currently receives from federal agencies.

The ability of state agencies to implement these ambitious undertakings is an open question, since states have little history with managing large-scale research enterprises. States attempting to establish stem cell research programs confront two separate but related classes of administrative and political problems. One set of such problems would occur even if the research subject were less controversial.¹⁷¹ For example, states have to establish procedures for receiving, reviewing, and rewarding

¹⁶⁴ Letter from James Thomson, Professor, University of Wisconsin-Madison Medical School, to Rep. Steve Kestell, Representative, Wisconsin State Assembly, June 28, 2005, available at www.wisbusiness.com/1008/large/050627thomson.pdf.

¹⁶⁵ California Gives Go-Ahead to Stem Cell Research, *supra* note 162.

¹⁶⁶ Illinois Regenerative Medicine Institute Act, H. B. 3815, 94th Gen. Assemb. (Ill. 2005).

¹⁶⁷ Stem Cell Research Bond Act, Assemb. B. 4013, 211th Leg., 2d Reg. Sess. (N.J. 2005).

¹⁶⁸ Stem Cell Research Act, H. B. 864, 189th Gen. Assemb. (Pa. 2005); Amy Worden, *Spotlights on Biology and God*, PHILA. ENQUIRER, Jun. 21, 2005, <http://www.philly.com/mld/inquirer/news/local/states/pennsylvania/11943819.htm>.

¹⁶⁹ Jeana Anderson, *Gov. Unveils \$375m Stem-Cell Initiative*, THE DAILY CARDINAL, Nov. 18, 2004, <http://www.dailycardinal.com/article.php?storyid=809385>.

¹⁷⁰ An Act Permitting Stem Cell Research and Banning the Cloning of Human Beings, S. B. 934, 2005 Gen. Assem., Jan. Sess. (Conn. 2005) (enacted), 2005 Conn. Act. 05-149.

¹⁷¹ The argument in this paragraph is largely drawn from Noll, *supra* note 153.

grants in order to establish large-scale, peer-reviewed research enterprises. These procedures must address such questions as conflicts of interest between reviewers and potential grantees, and the potential conflict between the blind nature of most academic review processes and the requirements of state open meeting laws. States must also establish intellectual property guidelines governing who “owns” products and processes developed through funded research, and who receives revenues from their licensing and sale. Federal law allows academic institutions to keep licensing revenues from products developed with federal financial support in order to encourage the commercialization of research results.¹⁷² State policy makers, however, are likely to insist that a significant share of licensing revenues flow to the state rather than to universities. While none of these problems is insurmountable, it will likely take non-negligible amounts of time for states to negotiate agreements and put procedures into place.

A second, more severe set of potential problems stems from the controversial nature of embryonic stem cell research and its connection to the politically difficult abortion issue. While the debate over embryonic stem cell research is less polarized than the abortion controversy (some pro-life supporters such as the Ronald Reagan family have supported stem cell research, and some pro-choice groups have opposed it¹⁷³) it is also true that most of the opposition, both in the states and in Washington, has come from groups that are also pro-life.¹⁷⁴ Such groups are likely to resort to a wide range of legal and political means to stall or stop state funded stem cell activities on an on-going basis. This suggests embryonic stem cell research is likely to remain controversial, and a potential issue in state elections.¹⁷⁵

There is limited history by which to judge the potential severity of these problems and the ability of state policy-makers to overcome them. However, the little evidence that is available suggests that both types of problems may impede state efforts to establish functioning stem cell research programs. California’s efforts to implement Proposition 71, the first such state sponsored stem cell program, has been preoccupied with research management, litigation by pro-life groups to prevent the state from issuing bonds to support the research, and other start-up questions.¹⁷⁶ In similar fashion, the New Jersey initiative has had to deal with disagreements over spending priorities, methods for project selection, and other research management questions.¹⁷⁷ A planned state bond issue has been postponed until after the 2006 election for fear of creating a conservative backlash against the program.¹⁷⁸

In contrast to the regulation of unresolved moral issues surrounding ART, increased U.S. regulation of data collection and quality control is consistent with U.S. values and the country’s history in dealing with reproduction and medical

¹⁷² *Id.*

¹⁷³ See Andrews, *supra* note 8.

¹⁷⁴ See Jessica Reaves, *The Great Debate Over Stem Cell Research*, TIME ONLINE, July 11, 2001, <http://www.time.com/time/health/article/0,8599,167245,00.html>; J.C. Wilke, *I’m Pro-Life and Oppose Embryonic Stem Cell Research*, CULTURE OF LIFE FOUNDATION & INSTITUTE, June 27, 2001, http://sites.silaspartners.com/partner/Article_Display_Page/0,,PTID4211|CHID102753|CIID578206,0.html.

¹⁷⁵ See Noll, *supra* note 153.

¹⁷⁶ For coverage of the implementation of the California initiative, see David Jensen, California Stem Cell Report, <http://www.californiastemcellreport.blogspot.com/> (last visited Oct. 26, 2005). For a description of the most recent suit filed against the stem cell program, see Terri Somers, *Group Files Lawsuit to Halt Research at Stem Cell Institute*, S.D. UNION TRIB., Aug. 6, 2005, at A4.

¹⁷⁷ See Tina Kelley, *In Race Toward Stem Cell Research Institute, New Jersey Stalls*, N.Y. TIMES, July 31, 2005, at 25, §1, col. 2.

¹⁷⁸ See *id.*

innovation more generally. The fact that there is better data available to guide consumer choice for ART clinics in the U.K. than in the U.S. is surprising given the overwhelming demand for consumer information and services in the U.S. healthcare system. The HFEA website provides a Patients' Guide to IVF Clinics and a Guide to Donor Insemination.¹⁷⁹ This guide contains data on the services each clinic provides and their success rates, thus permitting consumers to compare and choose a provider most likely to 'deliver' the desired end-product—a healthy baby. The national U.K. live birth rate per IVF treatment cycle increased from 13.2% in 1992/1993 to 21.8% in 2000/2001.¹⁸⁰ While most of this increase is due to improvements in equipment, techniques and experience of clinicians, market forces driven by outcome data in the public domain will also be particularly influential in the U.S.

U.K. regulation of ART clinics and embryo laboratories has far outpaced U.S. regulation. The form such regulations should take in the U.S., however, remains in question. State-by-state regulation modeled on existing licensing structures for other medical professionals appears possible, but the utter lack of response to the CDC's 1999 model certification program merits further study to determine and excise the cause for its failure.

While the U.K. model offers important lessons on improving quality control and data dissemination, it is less well-suited for resolving difficult ethical and moral disputes in the U.S. Even within the U.K., the HFEA has come under fire by prominent ethicists who question its vitality and usefulness in resolving difficult ethical questions.¹⁸¹

Direct federal legislation or regulation of complex moral issues in the U.S. is even more problematic. One or more of several options may be required to regulate ART in the U.S. given the country's need for flexibility. Federal legislation aside, some options are to¹⁸² issue state level regulations and licensing requirements,¹⁸³ allow court decisions to take the place of official legislation,¹⁸⁴ settle for voluntary, self-imposed regulation,¹⁸⁵ or issue indirect regulations that control funding, insurance, or administrative procedures.¹⁸⁶ The current debate over federal funding for stem cell research and the existing legislation regarding human cloning indicates that indirect regulation¹⁸⁷ is a likely avenue for the U.S. to take regarding ART.¹⁸⁸

That is not to say, however, that federal legislation or regulation is out of the picture. In fact, the FDA is in the process of creating a unified and consistent system regulating all establishments using human cells, tissues, and cellular and tissue-

¹⁷⁹ The Human Fertilisation and Embryology Authority, Patients' Guides are available as pdf files at <http://www.hfea.gov.uk/HFEAPublications/PatientsGuides>.

¹⁸⁰ HUMAN FERTILISATION AND EMBRYOLOGY AUTH., NINTH ANNUAL REPORT & ACCOUNTS 2000 14 (2000), available at <http://www.hfea.gov.uk/HFEAPublications/AnnualReport>; ELEVENTH ANNUAL REPORT, *supra* note 27, at 13.

¹⁸¹ *Fertility Watchdog "incompetent"*, BBC NEWS (Dec. 10 2004), <http://news.bbc.co.uk/1/hi/health/4084365.stm>; Mark Henderson, *An Embryo That Went on Growing*, TIMES ONLINE, <http://timesonline.co.uk/printFriendly/0,,1-210-1524515-355,00.html>.

¹⁸² See generally Havins & Dalessio, *supra* note 1.

¹⁸³ See Jayson, *supra* note 1, at 299–302.

¹⁸⁴ See generally Cohen, *supra* note 1, at 353.

¹⁸⁵ Christine Willgoos, Comment, *FDA Regulation: An Answer to the Questions of Human Cloning and Germline Gene Therapy*, 27 AM. J.L. & MED. 101 (2001).

¹⁸⁶ Lorio, *supra* note 133, at 253.

¹⁸⁷ Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 66 Fed. Reg. 5447 (Jan. 19, 2001) (codified at 21 C.F.R. pts. 207, 807, 1271).

¹⁸⁸ See generally Willgoos, *supra* note 185, at 122.

based products (HCT/P's).¹⁸⁹ The new category, HCT/P's, includes semen, oocytes, and reproductive tissue,¹⁹⁰ and therefore regulates these products for the first time. The regulations include four parts: a rule on donor screening,¹⁹¹ a final rule on registration,¹⁹² a listing of manufacturers,¹⁹³ and a proposed rule for Current Good Tissue Practice (CGTP) for manufacturers.¹⁹⁴ In January, 2001 the FDA published the final version of the legislation on registration and listing, "Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products."¹⁹⁵ The agency is currently evaluating comments from two interim final rules issued on donor screening and CGTP before issuing final versions.¹⁹⁶

Some of the materials regulated by the HCT/P legislation have previously been regulated as drugs, devices, and/or biological products.¹⁹⁷ In addition, the new legislation regulates reproductive cells and tissues for the first time.¹⁹⁸ Given this distinction, the FDA has created a tiered system of regulation. In the legislation, previously regulated products are subject to stricter standards than materials regulated for the first time, such as reproductive cells and tissues. The authority for the regulation of these new products lies in section 361 of the Public Health Service Act (PHS Act).¹⁹⁹ This Act authorizes the FDA to issue the necessary legislation to block the introduction, transmission, or spread of communicable disease.²⁰⁰

The FDA has solicited comments for its proposed rules before issuing final drafts, and SART has commented extensively to the FDA.²⁰¹ According to Joyce Zeitz of SART, the requirements for registration, listing and screening of donors would not place a burden on the field of infertility.²⁰² The impact of the good tissue practice legislation may, however, raise some concerns.²⁰³ The long, detailed proposed rule included guidelines for handling, processing, storage, and labeling of HCT/P's, as well as guidelines for record keeping, receiving complaints, and the establishment of a quality program. For SART, these regulations raise concerns that the FDA may be "overstepping their bounds" and perhaps regulating the practice of medicine.²⁰⁴

According to an analysis of the impact of the proposed CGTP legislation, the FDA requirements are very similar to CAP's accreditation requirements, with a few exceptions. Since the FDA reports that up to 80% of ART facilities, including

¹⁸⁹ 21 C.F.R. § 1271.1 (2005).

¹⁹⁰ *Id.* § 1271.3.

¹⁹¹ *Id.* pt. 1271, subpt. C.

¹⁹² *Id.* pt. 1271, subpt. B.

¹⁹³ 66 Fed. Reg. 5447 (Jan. 19, 2001) (codified at 21 C.F.R. pts. 207, 807, & 1271).

¹⁹⁴ *Id.* pt. 1271, subpt. D.

¹⁹⁵ *Id.* at 29949.

¹⁹⁶ Human Cells, Tissues, and Cellular and Tissue-Based Products; Donor Screening and Testing, and Related Labeling, 70 Fed. Reg. 29949, 29949–29950 (May 25, 2005) (codified at 21 C.F.R. pt. 1271).

¹⁹⁷ See Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 66 Fed. Reg. 5447, 5448 (Jan. 19, 2001).

¹⁹⁸ *Id.*

¹⁹⁹ *Id.* at 5549.

²⁰⁰ Public Health Service Act, 42 U.S.C. § 264 (2005); see also 21 C.F.R. § 1271.1 (2005).

²⁰¹ Interview with Joyce Zeitz, Executive Administrator, Society for Assisted Reproductive Technology (August 8, 2001).

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

clinics and laboratories, meet CAP requirements,²⁰⁵ implementation of the new FDA regulations will not place an undue burden on most clinics. Most clinics, however, will have to make procedural changes in their tracking practices and inspection policies. It is likely that the FDA expects facilities already complying with industry guidelines to have the necessary components of a quality program in place. It is also likely that the FDA expects that clinics with the lowest success rates will improve their procedures in order to meet the CGTP standards, and thereby increase success rates. The agency cites increased success rates and the reduced number of IVF cycles required per live birth as potential economic benefits of the legislation.²⁰⁶ The FDA estimates that implementing the CGTP guidelines will cost just over \$4 million for the industry as a whole, but that reduced IVF failure could save the industry up to \$25 million annually.

At this point, the FDA has only issued an interim final version of the CGTP legislation²⁰⁷ and it is difficult to tell how great the impact will be upon the field of ART. In crafting the final rule, the FDA must be certain to use input from experts, such as SART and the ASRM. Improvement and oversight are important goals, but these goals must be met with input from SART and other agencies and without politicization of the issues or excessive regulation at the expense of quality of care. In addition, the FDA was prudent to make efforts to allow for flexibility in its regulations. The name *Current Good Tissue Practice* indicates that the FDA expects changes in the industry and aims to create regulations that can accommodate improvements in technology. The FDA should maintain this commitment to flexibility in the final rule.

B. ETHICAL DISCOURSE: AVOIDING MULTIPLE BIRTHS

The approaches taken by the U.S. and U.K. toward avoiding multiple births illustrate the different approaches taken to regulation in general. The 2002 HFEA Annual Report noted that multiple births account for 43% (3,479 of 8,100) of individual babies born through ART in the U.K.²⁰⁸ In the U.S., 42% of live births achieved for women under 35 (where multiple births are counted as a single live birth) were multiple births.²⁰⁹ This number decreased as the age of the mother increased, but even for women over 40, for whom the live birth rate is the lowest, 18.3% of live births were multiple births.²¹⁰ These statistics are alarming since multiple births carry serious health risks for both the fetus and the mother, as well as emotional and financial strains.²¹¹

In the U.K., the HFEA has used its authority to limit the number of embryo implantations allowed at one time (per cycle) in an effort to reduce the number of multiple gestations and multiple births resulting from ART technology.²¹² The 6th Code of Practice absolutely prohibits the transfer of more than two eggs or embryos

²⁰⁵ Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments: Inspection and Enforcement, 69 Fed. Reg. 68,612, 68,654 (Nov. 24, 2004).

²⁰⁶ 66 Fed. Reg. 1507, 1544 (January 8, 2001).

²⁰⁷ 69 Fed. Reg. 68,612.

²⁰⁸ See ELEVENTH ANNUAL REPORT, *supra* note 27, at 13.

²⁰⁹ Centers for Disease Control and Prevention, *Contribution of Assisted Reproductive Technology and Ovulation-Inducing Drugs to Triplet and Higher-Order Multiple Births--United States, 1980-1997*, 49 MORBIDITY & MORTALITY WKLY. REP. 535, 535, (June 23, 2000).

²¹⁰ See *Id.* at 537.

²¹¹ Laura A. Scheive et al., *Live-Birth Rates and Multiple-Birth Risk Using In-Vitro Fertilization*, 282 JAMA 1832, 1832, 1837 (1999).

²¹² ELEVENTH ANNUAL REPORT, *supra* note 27, at 16-17.

to a woman of less than 40 years of age. Women aged 40 and over may receive a maximum of three eggs or embryos.²¹³ According to the HFEA, limits on embryo implantations reflect current medical thinking and help avoid serious health risks.²¹⁴

In the U.S., on the other hand, no regulations govern the number of implantations an infertility clinic may perform per IVF cycle. In the absence of regulations, however, the practice committee of the ASRM²¹⁵ issued "Guidelines on Number of Embryos Transferred," a series of recommendations regarding limits on embryo transfers.²¹⁶ Unlike the British Code of Practice, the ASRM guidelines are voluntary, although SART members must follow them, according to their membership requirements.

In addition, the ASRM recommendations, unlike the HFEA regulations, account for the prognosis of the woman receiving embryo transfers.²¹⁷ The authors of the guidelines reject general restrictions like the British regulations because "[s]trict limitations on the number of embryos transferred as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient's own unique circumstances."²¹⁸ For women under age 35 with sufficient embryos for cryopreservation, the ASRM recommends that no more than two good quality embryos be implanted.²¹⁹ This number increases from 3 to 4 and 5 depending on the age of the woman and the status of the available embryos.²²⁰ The guidelines further provide that "additional embryos may be transferred according to individual circumstances" for patients "with two or more failed IVF cycles."²²¹ According to the 1998 CDC report, age is the most important factor influencing live birth rate when a woman uses her own eggs.²²² The ASRM report takes into account the importance of age, as well as embryo quality, cryopreservation opportunities, and the potential for new techniques.²²³

Indeed, not everyone in the U.K. is happy with the HFEA's regulations on multiple implantations. A 46 year-old woman who failed to become pregnant after eight unsuccessful IVF cycles in five years petitioned the courts for an exception to the embryo implantation limit.²²⁴ She and her physician asked the courts to allow

²¹³ HFEA CODE OF PRACTICE, *supra* note 13, at 84.

²¹⁴ Press Release, Human Fertilisation & Embryology Auth., HFEA Strengthens Commitment to Reducing Multiple Births (Jan. 6, 2004), *available at* <http://www.hfea.gov.uk/PressOffice/Archive/1073398264> (quoting Jane Denton, Director of The Multiple Births Foundation: "For some patients the prospect of twins or triplets may seem an ideal way to have the family they long for. But the reality can be very different. Multiple births are associated with premature and low birth-weight babies and the risk of death before birth or in the first week of life is significantly greater. Compared with one baby, long term disability like cerebral palsy is around five times higher for twins and 18 times higher for triplets.")

²¹⁵ See The Am. Soc'y for Reproductive Medicine, *2002 Guidelines for Gamete and Embryo Donation: A Practice Committee Report*, 77 FERTILITY & STERILITY S1 (Supp. 5 June 2002).

²¹⁶ The Practice Committee of the Soc'y for Assisted Reproductive Technology & the Am. Soc'y for Reproductive Medicine, *Guidelines on the Number of Embryos Transferred*, 82 FERTILITY & STERILITY 773 (2004) [hereinafter SART & ASRM].

²¹⁷ *See id.*

²¹⁸ *Id.* at 773.

²¹⁹ *Id.*

²²⁰ The guidelines recommended a maximum of three embryos for women 35-37, four for women 38-40, and five for women over 40. *Id.* at 773-774.

²²¹ *Id.* at 774.

²²² 1998 RATES, *supra* note 61, at 18.

²²³ SART & ASRM, *supra* note 216, at 773.

²²⁴ James Meek, *IVF Doctor Loses Bid to Change Embryo Rule*, THE GUARDIAN, April 25, 2001, *available at* <http://education.guardian.co.uk/news/story/0,5500,478170,00.html>.

the London infertility clinic representing her to implant five embryos in a cycle.²²⁵ Judges upheld the legal authority of the HFEA by twice rejecting her request.²²⁶

The case of multiple births reveals the difficulties of the British and American approaches to ART regulation. In the U.K., the law virtually eliminates the possibility of quadruplet or greater multiple births, which have been occurring in increasing frequency with the improvement of ART.²²⁷ However, the British law fails to take into account the fact that pregnancy success rates through ART decrease significantly for women over 39 (from a 15.2% live birth rate for women 37-38 to a 9.5% live birth rate for women 39-40).²²⁸ The ASRM recommendations, on the other hand, account for the complexity of individual situations but lack the legal status of the HFEA's guidelines. Given their recent date of publication, it remains to be seen whether the new ASRM recommendations will have an effect on decreasing the multiple birth rate in the U.S.²²⁹

IV. CONCLUSIONS: CROSSING THE POND IS ONLY THE BEGINNING

The differences in ART policy between the U.S. and the U.K. stem from deeply anchored roots. The HFEA is successful in the U.K. in part because of the tradition of national control over health care, which is viewed as a public, not a private commodity. Patients and providers in the U.K. accept government regulation of virtually every kind of health care issue. In the U.S. health care is a market commodity. Self-regulation is the longstanding tradition for medical professionals. With the exception of quality control regulation (licensing of providers and clinics, oversight of drugs, devices, and research), the market and professional societies regulate the industry.²³⁰ The creation of a HFEA-type "ethics police" to regulate one aspect of medicine—particularly the type of medicine like reproductive medicine that inherently raises controversial and divisive issues—would be such a dramatic change from the regulation of the rest of medicine that it would be doomed to fail.

HFEA and regulators in other fields of public policy in the U.K. strive to balance the private versus the public interest. The policy on multiple births is an example of this. While prospective parents seeking ART may wish to maximize their chances of conception by consenting to the transfer of larger numbers of embryos, the U.K. policy eliminates that option to protect unborn children from health risks and stress in their families.²³¹

In addition to protecting the welfare of the child, the HFEA policy on multiple births limits the spending of scarce health care dollars. While the public financing of health care in the U.K. cannot independently explain the inflexibility of the rules designed to prevent multiple births, it plays a role. Many couples in the U.K. pay

²²⁵ Rachel Ellis, *Two-Embryo Limit For IVF as Triplet Births Soar*, MAIL ON SUNDAY, July 8, 1996, available at 2001 WLNR 2726015; Robert Verkaik, *Judge Turns Down Woman's Plea to Relax Embryo Limit*, THE INDEPENDENT (London), Apr. 25, 2001, available at 2001 WLNR 6940416.

²²⁶ Meek, *supra* note 224.

²²⁷ *Action to cut IVF multiple births*, BBC NEWS, Aug. 7, 2001, <http://news.bbc.co.uk/1/hi/health/1476646.stm>.

²²⁸ NINTH ANNUAL REPORT, *supra* note 90, at 14.

²²⁹ The most recent analysis is reported in Soc'y for Assisted Reprod. Tech. & The Am. Soc'y for Reprod. Med., *Assisted Reproductive Technology in the United States: 2000 Results Generated from the American Society for Reproductive Medicine/Society for Assisted Reproductive Technology Registry*, 81 FERTILITY AND STERILITY 1 207-20 (2004).

²³⁰ Robert Gatter, *Faith, Confidence, and Health Care: Fostering Trust in Medicine Through Law*, 39 WAKE FOREST L. REV. 395, 424, 436-437(2004).

²³¹ *Id.*

privately for ART,²³² limiting to some extent the spending of scarce public resources. Nonetheless, the National Health Service remains responsible for funding health care and social costs for children born of ART, even if those costs are extraordinary as a result of the actualized risks of privately funded ART procedures. Thus, the national and public nature of the health care system in the U.K. may help explain the general acceptance of HFEA policy decisions.

From a U.S. perspective, the HFEA's approach seems paternalistic, both for the parents and the child. In the U.S., a child born from an embryo implanted under a multiple transfer policy is unlikely to claim that she was harmed by that policy: the alternative would have prevented her from being born in the first place.²³³ Similarly, U.S. parents bear the financial and personal risks of their reproductive decisions and, therefore can legitimately argue that they should be allowed to make informed, autonomous decisions. This authority stems from the right to raise their children as they see fit, and reproductive rights in general. Indeed, parents challenging a U.S. policy prohibiting multiple transfers would have a strong constitutional argument that the right to determine the number of embryos to implant is a protected interest that cannot withstand government regulation.²³⁴

While the HFEA's primary goal must be to act in the public interest, it should adopt a pragmatic approach to regulation and maintain good relationships with fertility clinics and researchers. Such an approach facilitates openness and good practice. Guarantees of independence and close scrutiny are also important to maintain public trust. Regulators within the U.K. have recently been challenged by reductions in public trust following various public health scares.²³⁵ The most notable was Bovine Spongiform Encephalopathy ('Mad Cow' disease), where there were accusations that the regulators were mostly concerned with protecting the interests

²³² Human Fertilisation & Embryology Authority, Patients' Guide to Infertility: Issues to Consider: Will I Get NHS Funding?, <http://www.hfea.gov.uk/ForPatients/Archivedinformation/PatientsGuidetoInfertility/Issuesstoconsider> (last visited Sept. 26, 2005). "Multiple births are associated with premature birth, low birth weight babies, a higher rate of stillbirth and neonatal death, and long-term disability such as cerebral palsy . . . In addition to the health risks to the babies, there are also increased risks for the parents including complications at birth and the possible emotional strain of having to cope with more than one new baby in the family together with potential increased financial constraints."

²³³ "[T]he vast majority of courts have denied the wrongful life cause of action by focusing on the element of harm and holding that life itself cannot constitute injury. Such a holding assumes that life is always preferable to non-life and/or that it is impossible for a trier of fact to measure damages for the harm of life compared to the 'utter void of nonexistence.'" Deana A. Pollard, *Wrongful Analysis in Wrongful Life Jurisprudence*, 55 ALA. L. REV. 327, 328 (2004).

²³⁴ Charo points out that determination of a court challenge to regulation of ART procedures will depend upon the U.S. Supreme Court's view of ART: is the creation of a fetus in a dish entitled to the same special protection from government intrusion as the creation of a fetus through sexual intercourse?

If [the special protection afforded human reproduction is] associated with intimate marital relations, then technologies using third party gametes or hired surrogates may not be protected If it is because the government ought not interfere with physical bodies and reproductive capabilities of its citizens, then there is a far weaker claim of any right to access medical services that depend on extra-uterine maintenance or diagnosis of embryos. But if it is because human reproduction is notable for the profound way in which it reflects individual choices, aspirations and self identity, then there may be a far broader range of reproductive decisions that are free from government intrusion.

Charo, *supra* note 137, at 525.

²³⁵ Darren Shickle, "On a Supposed Right to Lie [to the Public] From Benevolent Motives": Communicating Health Risks to the Public, 3 MED., HEALTH CARE & PHIL. 241 (2000).

of the agricultural community.²³⁶ Regulators must also recognize the ethical concerns many people within society have about certain aspects of ART.

The same challenges for policy makers and regulators exist in the U.S. While the U.S. places emphasis on individual liberty and the free market, it can be difficult for individuals to make fully informed choices in the context of health care. Health care decisions are often complex and the stakes can be extremely high. It may therefore be reasonable for State and Federal regulatory mechanisms to provide some basic guarantees of quality. Even within a libertarian model, autonomous consumers need reliable information on the quality of ART providers. The creation of an HFEA-type “ethics police” would, however, be inconsistent with the U.S.’s history of regulating medicine in general, and reproductive medicine in particular. The challenge on both sides of the water is to ensure an environment that facilitates innovative research and high standards of care at affordable costs, while still providing protection for the vulnerable child, born or unborn.

²³⁶ *Id.* at 246-247.