

2008

Assessing the Market for Human Reproductive Tissue Alienability: Why Can We Sell Our Eggs But Not Our Livers?

Brenda Reddix-Small

Follow this and additional works at: <https://scholarship.law.vanderbilt.edu/jetlaw>



Part of the [Medical Jurisprudence Commons](#)

Recommended Citation

Brenda Reddix-Small, Assessing the Market for Human Reproductive Tissue Alienability: Why Can We Sell Our Eggs But Not Our Livers?, 10 *Vanderbilt Journal of Entertainment and Technology Law* 643 (2020)
Available at: <https://scholarship.law.vanderbilt.edu/jetlaw/vol10/iss3/7>

This Article is brought to you for free and open access by Scholarship@Vanderbilt Law. It has been accepted for inclusion in Vanderbilt Journal of Entertainment & Technology Law by an authorized editor of Scholarship@Vanderbilt Law. For more information, please contact mark.j.williams@vanderbilt.edu.

Assessing the Market for Human Reproductive Tissue Alienability: Why Can We Sell Our Eggs But Not Our Livers?

Brenda Reddix-Small*

ABSTRACT

Currently, an unregulated marketplace for assisted reproductive technology exists in the United States. For some people suffering from infertility, the ability to purchase human reproductive tissue, eggs, and sperm yields a maximum benefit when examined in a market context. Buyers, sellers, supply and demand, and technological advances all operate in a robust marketplace to provide the infertile with a supply of human eggs for reproduction with minimum state and federal regulatory control. Conversely, the buying and selling of all other human organs and tissues is prohibited in the United States by several federal statutes. The National Organ Transplant Act (NOTA) and the Uniform Anatomical Gift Act (UAGA) provide for complete statutory prohibitions against obtaining valuable consideration in exchange for human organs.

This article examines the lack of regulatory controls in the assisted reproductive field by identifying the technologies available to the infertile, reviewing the market forces that operate to preclude federal regulatory control and assessing the governmental and societal restrictions that prevented regulation in the human assisted reproductive technology field. The introduction reviews the scientific and technological advances of the twentieth century that led to the

* Visiting Professor, Franklin Pierce Law Center, Concord, NH. LL.M., Franklin Pierce Law Center, 2006; J.D., Georgetown Law Center, 1976; B.A., Economics, Brown University, 1973. I would like to thank Pierce Law Center and the Faculty and staff for their support and invaluable assistance. I would especially like to thank my family and friends for their unending supply of encouragement and support.

creation of a robust reproductive marketplace and the expectations of citizens for life improvements based on science.

The article first explores the historical and technological context of legislation that currently operates to regulate scientific technologies but excludes reproductive technology. Second, the article explores the minimal legislation enacted to regulate reproductive technology, the Fertility Clinic Success Rate and Certification Act of 1992, and the three federal agencies under the Department of Health and Human Services (the Center for Disease Control and Prevention, the Food and Drug Administration, and the Centers for Medicaid and Medicare Services), which provide insignificant oversight. The article proceeds to examine the market forces that operate to preclude federal regulatory control: the lobbying arms and representative agents of the fertility clinics, the pharmaceuticals, and the physicians providing reproductive services. This examination of the market forces affecting the reproductive field includes an analysis of the market dynamics of supply and demand and shifts toward increased demand based on technological advances and the resulting impact on consumers. The article concludes with the opinion that the transfer of human reproductive tissue has not received comparable regulatory control to other human tissue transfer because of the economic interests of the dominant force market players, the governmental failure to address the ethical issues of a rapidly emergent technology, and the capture of administrative agencies by the dominant market forces.

TABLE OF CONTENTS

I.	INTRODUCTION.....	647
A.	Technology	651
B.	Historical and Technological Context.....	652
C.	Congressional History	654
D.	The Fertility Clinic Success Rate and Certification Act of 1992.....	657
E.	Human Tissue Transference	664
F.	Regulatory Oversight of Human Reproductive Tissue Transfer.....	667
G.	Private Actors and Regulators	672
H.	The Marketplace	676
I.	Capture by Dominant Market Forces.....	681
II.	CONCLUSION	689

Through a lack of regulatory legislation, America is accepting a laissez-faire climate or free-market¹ approach towards collaborative reproduction involving the tissue transfer of human eggs for procreation.² With practically every aspect of human-to-human tissue transfer in the United States regulated,³ the lack of regulatory control

1. Cheryl Erwin, *Utopian Dreams and Harsh Realities: Who Is In Control of Assisted Reproductive Technologies in a High-Tech World*, 9 J. GENDER RACE & JUST. 621, 626 (2006). Erwin contends that our current laws regulating assisted reproductive technology (ART) developed from a collection of federal laws that are best described as market-driven. *Id.* She argues that the United States' "market-based regulation has not left the industry without any regulation," but that the scant regulation may be considered appropriate in a market focused more on "the patient's ability to choose or refuse ART treatment as the most appropriate form of regulation in a pluralistic democracy." *Id.* Erwin argues for greater dissemination of knowledge about the new ART technologies. *Id.*

2. See Helen M. Alvaré, *The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 1 (2003) ("There is little regulation of collaborative reproduction—the use of the eggs, sperm, or embryos of a third party to create a child biologically unrelated to at least one intending parent."). Alvaré contends that collaborative reproduction implicates the rights of children and should be adjusted from the perspective of children's rights. *Id.*

3. See DEBORA L. SPAR, *THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION* (2006) (reviewing the technology and bioethical implications of reproductive services from a market analysis perspective). Spar's thesis is that each area involved in "the making of babies" (e.g., infertility counseling, *in vitro* fertilization, gestational surrogacy, and adoption) has spawned a growing market for eggs, sperm, and, potentially, embryos. While adoption is regulated and baby selling is almost universally prohibited, the other markets are largely unregulated. *Id.*; see also National Organ Transplant Act of 1984, 42 U.S.C. §§ 273-274e (2000) (providing a framework for the distribution of organs and tissues for transplant purposes and establishing an Organ Procurement and Transplantation Network, which is required to provide criteria for allocating organs, "maintain a twenty-four-hour telephone service to facilitate matching organs with individuals included in the list," "assist organ procurement organizations in the nationwide distribution of organs equitably among transplant patients," adopt quality standards for the acquisition and transportation of donated organs (including standards for preventing infected organs), and "provide information to physicians and other health professionals regarding organ donation"); 42 U.S.C. §§ 274k-274m (2000) (establishing the C.W. Bill Young Cell Transplantation Program, successor to the National Bone Marrow Donor Registry, for "the purpose of increasing the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow"); Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 BYU L. REV. 107, 123-24 (2001) (asserting that, despite its prolonged existence and popularity, human egg donation as a form of noncoital or assisted reproduction exists within a paucity of legislation, and noting that the "[l]egislation that does exist is variable and ambiguous" and includes only "three categories: 1) gamete donor medical screening guidelines, 2) clinic reporting requirements, and 3) insurance coverage guidelines"); *id.* at 128 ("Beyond the few state and federal [*in vitro* fertilization] statutes and the highly variable and ambiguous state statutes that regulate the sale of human body parts, there is no legislation in the United States that regulates the practice of oocyte donation."); David L. Weimer, *Public and Private Regulation of Organ Transplantation: Liver Allocation and the Final Rule*, 32 J. HEALTH POL. POL'Y & L. 9 (2007) (examining the availability of transplant organs, including kidneys, livers, hearts, lungs, pancreases, and intestines, and the process by which they are allocated, and citing the Organ Procurement

over human egg donation in particular, and assisted reproductive technology (ART) in general, speaks volumes about the acceptance of a free market approach to ART.⁴

An unregulated marketplace for ART operates outside of the United States' safeguards usually applied to new technology. Why is almost all human tissue transfer federally regulated except for the transfer of human eggs (or sperm)?⁵ Although people can buy or sell human eggs or sperm, human organ alienability for profit is strictly prohibited and heavily regulated by federal and state laws.⁶

Any examination of the current level of regulatory controls in ART should include: (1) identifying the predominant ART technologies available; (2) examining the market forces that operate to preclude federal regulatory control; and (3) reviewing the pertinent administrative legal regime that permits such scant regulatory controls.

I conclude that the transfer of donor eggs does not receive comparable regulatory control because of the convergence of (1) the economic interests of the dominant force market players (consumers and suppliers), (2) the governmental failure to address the ethical issues of a rapidly emergent technology, and (3) the capture of administrative agencies by the dominant market forces.

and Transplantation Network and the U.S. Department of Health and Human Services as the primary rule-making bodies regarding the allocation of transplant organs).

4. See Alvaré, *supra* note 2, at 5-6 ("Collaborative reproduction . . . includes the various processes by which 'intending parent(s)' use the embryos or gametes (sperm or eggs), of one or more donors to conceive a child that the intending parents will legally rear. A child born through collaborative reproduction is not the biological offspring of both intending parents, though he may be the biological child of one intending parent." (footnote omitted)).

5. This paper is prompted by the question: why can you purchase human eggs but not a human liver?

6. See 42 U.S.C. § 274e (generally prohibiting the buying and selling of human organs, and defining "human organs" to include "the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof)," and stating that "[i]t shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation"); see also Charles C. Dunham IV, *"Body Property": Challenging the Ethical Barriers in Organ Transplantation To Protect Individual Autonomy*, 17 ANNALS HEALTH L. 39, 41 n.12 (2008) ("Currently, federal and state statutes specifically forbid the sale of human organs." (citing 42 U.S.C. § 274e; CAL. PENAL CODE § 367f (West 1999); MD. CODE ANN., HEALTH-GEN. § 5-408 (LexisNexis 2005); MICH. COMP. LAWS ANN. § 333.10204 (West 2001); N.Y. PUB. HEALTH LAW § 4307 (McKinney Supp. 2007))).

I. INTRODUCTION

The advances in scientific research and technology in the twentieth century created progressively higher expectations for the alleviation of disease and sickness in the American human population.⁷ Increasingly, in the United States, publicized advances in scientific discoveries have led to heightened perceptions by the public that life could be extended, epidemics could be eliminated, and perhaps death could be cheated, for a time.⁸ All of the old fears for

7. See THOMAS HAGER, *THE DEMON UNDER THE MICROSCOPE: FROM BATTLEFIELD HOSPITALS TO NAZI LABS, ONE DOCTOR'S HEROIC SEARCH FOR THE WORLD'S FIRST MIRACLE DRUG 3-4* (2006) (recounting how antibiotics and new drugs were developed from "sulfa," which changed the way Americans viewed diseases.). As Hager notes:

People in my parents' generation, as children, could and all too often did die from strep throats, infected cuts, scarlet fever, meningitis, pneumonia, or any number of infectious diseases. I and my classmates survived because of antibiotics. My parents as children, and their parents before them, lost friends and relatives, often at very early ages, to bacterial epidemics that swept through American cities every fall and winter, killing tens of thousands. The suddenness and inevitability of these epidemic deaths, facts of life before the 1930s, were for me historical curiosities, artifacts of another age. Antibiotics virtually eliminated them.

Id. at 3.

8. See ALAN LIGHTMAN, *THE DISCOVERIES: GREAT BREAKTHROUGHS IN 20TH CENTURY SCIENCE 371* (2005) (commenting on the process through which James Watson, Francis Crick, Maurice Wilkins, and Rosalind Franklin deciphered the genetic code of DNA). Lightman argues:

The full impact of the discovery of the structure of DNA has not yet been measured. . . . The first "gene therapy," a process of curing disease by modifying a person's DNA, occurred in 1990 for severe combined immune deficiency (SCID). . . . It is impossible to say what lies in the future. The knowledge of DNA and how to modify it could help cure disease, alter personality and behavior, create new life forms, produce new kinds of computers, produce creatures half animal and half machine.

Id.; see *Researchers Isolate Human Stem Cells in the Lab: Breakthrough Could Lead to Treatments for Paralysis, Diabetes*, CNN.COM, Nov. 5, 1998, <http://www.cnn.com/HEALTH/9811/05/stem.cell.discovery/> (reporting that researchers "have successfully grown human stem cells in a laboratory, a major advance that could one day help in organ transplantation, gene therapy and treatment of such maladies as paralysis, diabetes and AIDS"). See generally CHRISTOPHER THOMAS SCOTT, *STEM CELL NOW: FROM THE EXPERIMENTATION THAT SHOOK THE WORLD TO THE NEW POLITICS OF LIFE 3-4* (2006) (reporting on the public attention that occurred after the scientist James Thomson published the first paper where he reported that he had developed the first line of human embryonic stem cells). Scott argues:

The scientific and medical implications contained in this short paper are profound and unambiguous. Embryonic stem cells could be used to generate new tissue and organs for transplantations. Defective and dying tissues caused by diseases such as Parkinson's or diabetes could be replaced with an unlimited supply of specially grown stem cells.

Id. But see JAMES D. WATSON & ANDREW BERRY, *DNA: THE SECRET OF LIFE ix* (2003) ("DNA has moved from being an esoteric molecule only of interest to a handful of specialists to being the heart of a technology that is transforming many aspects of the way

conditions such as heart failure, lung impairments, eyesight loss, epidemic catastrophes, and pandemic scourges were met with scientific theory, research, and, ultimately, curatives. Human infirmities, as varied as growth imperfections and even infertility, were attacked and conquered by the new science. Genetic deficiencies that subjected humans to the luck of the draw were predicted to fall before the juggernaut of science and technology.⁹

These rapid advances in technology created new markets to meet the demand for human tissue and body parts needed to implement the scientific discoveries.¹⁰ The intellectual property protection regime in the United States expanded and offered protection for technological innovation in areas ranging from pharmaceutical compositions to DNA patents.¹¹ Between the 1950s

we all live. With that transformation has come a host of difficult questions about its impact—practical, social, and ethical.”).

9. See Erwin, *supra* note 1, at 621 (“The twentieth century witnessed an explosion of scientific knowledge and technological achievement. The discovery of insulin in 1922 led to treatments for diabetes. The unique properties of penicillin, discovered in 1928, were called a medical miracle and a ‘magic bullet’ when the drug was used on infected wounds. . . . Other scientific and medical discoveries followed: kidney dialysis, tetracycline, oral contraceptives, and pharmaceutical products that help millions of Americans every day.”).

10. Gregory S. Crespi, *Overcoming the Legal Obstacles to the Creation of a Futures Market in Bodily Organs*, 55 OHIO ST. L.J. 1, 8-9 (1994) (“Several factors have combined over the past few decades to give rise to a tremendous increase in the need for bodily organs that can be transplanted into recipients suffering from organ failure. First, and most importantly, there have been dramatic advances in the technology of organ transplantation. The refinement of surgical techniques, the invention of sophisticated surgical support and life-maintenance equipment such as respirators, ventilators, and dialysis machines, and the development of highly effective immuno-suppressant drugs have combined to make organ transplantation a common and almost routine procedure with a high survival rate. At least twenty-five different bodily tissues and fluids have been transplanted in human beings, including key internal organs such as kidneys, hearts, livers, and pancreases. Second, a variety of nutritional and medical factors have interacted to increase average lifespans, and older persons obviously face higher probabilities of organ failure.” (footnotes omitted)).

11. Andrew Chin, *Research in the Shadow of DNA Patents*, 87 J. PAT & TRADEMARK OFF. SOC’Y 846, 846 (2005) (recognizing the existence and level of patenting proliferations). Chin argues:

Since the U.S. Supreme Court’s 1980 *Diamond v. Chakrabarty* decision, in which the Court ruled that a genetically-altered bacterium is a “nonnaturally occurring manufacture or composition of matter” eligible for a U.S. patent, the issuance of patents on genetic material has become commonplace. Decisions of the Federal Circuit, established in 1982, have consistently held that ‘isolated and purified’ DNA molecules excised from genes are patentable if they are useful, novel, nonobvious and adequately disclosed.

Id. (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309-10 (1980)). It should be noted, however, that Chin attempts to rebut the assertions and well-established doctrines allowing the patenting of DNA molecules. See *id.* at 904-05. He contends that critics of DNA patenting could “demonstrate that the patenting of DNA molecules will have the effect of retarding the identification and sequencing of [too] many other useful DNA

and the 1980s, the biotechnology-pharmaceutical industry in the U.S. grew exponentially, fueled in part by the technological advances of the twentieth century and the innovative patenting environment encouraged in the United States beginning in the 1970s.¹² In the late twentieth century, the infertility “solving” market in the United States began generating considerable interest due to the acknowledged numbers (estimated from ten to fifteen percent of the adult population) of infertile people:¹³ infertility met big business. The drive to reproduce is tremendous. It is axiomatic that, for the human race, reproduction is high on the list of survival priorities. When confronted with the inability to procreate, the anxious, infertile person will often pay tremendous sums to alleviate this problem.¹⁴ As a result, the use of ART¹⁵ to address infertility became a \$3 billion industry in the United States by the late 1990s.¹⁶

Meanwhile, new technologies for the curing of disease and the repairing of injuries continued to fuel market demand for human

molecules.” *Id.* Such a demonstration, if successful, could condemn DNA patenting as inimical to “progress.” *Id.* at 905.

12. See Bayh-Dole Act, 35 U.S.C. §§ 200-212 (2000) (giving universities, businesses, non-profit groups, and other recipients of federal research funds intellectual property rights over their resulting inventions); see also Stevenson-Wydler Technology Innovation Act of 1980, 15 U.S.C. §§ 3701-3718 (2000) (attempting to promote technology by establishing organizations to stimulate technology and recognizing individuals who make significant technological contributions); Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373 (2007) (criticizing the Bayh-Dole Act, discussing its effect on universities and industries, and examining its role in the subsidization of the biotechnology industry and the advancement of technology).

13. See SPAR, *supra* note 3, at 1 n.1 (“Estimating infertility statistics is notoriously difficult. Ten percent is the figure suggested by the American Society for Reproductive Medicine.” (citations omitted)); American Society for Reproductive Medicine, Frequently Asked Questions About Infertility, <http://www.asrm.org/Patients/faqs.html> (last visited Apr. 7, 2008) [hereinafter ASRM FAQ] (“Infertility affects about 6.1 million women and their partners in the U.S.—about ten percent of the reproductive-age population.” (citing CTRS. FOR DISEASE CONTROL AND PREVENTION, NATIONAL SURVEY OF FAMILY GROWTH (1995), available at <http://www.cdc.gov/nchs/about/major/nsfg/nsfg1-5doc.htm>)).

14. See SPAR, *supra* note 3, at 1-2.

15. “ARTs,” “Assisted reproductive technology,” and “reproductive technologies” are terms used to identify techniques developed “to facilitate [the] fertilization of human gametes in order to enable pregnancy.” Lyria Bennett Moses, *Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization*, 6 MINN. J. L. SCI. & TECH. 505, 512 (2005); see also Peter Lutjen et al., *The Establishment and Maintenance of Pregnancy Using In Vitro Fertilization and Embryo Donation in a Patient with Primary Ovarian Failure*, 307 NATURE 174 (1984); Alan Trounson & Linda Mohr, *Human Pregnancy Following Cryopreservation, Thawing and Transfer of an Eight-Cell Embryo*, 305 NATURE 707 (1983).

16. See SPAR, *supra*, note 3, at 3 (“In 2004, more than one million Americans underwent some form of fertility treatment, participating in what had become a nearly \$3 billion industry . . .”).

tissue and body parts.¹⁷ As the new human tissue/body parts marketplace developed, questions about commodification, commercialization, and ethical concerns were raised.¹⁸ In response to these concerns, legislative regulatory controls were widely imposed in the fields of organ transplants, tissue transplants, and the use of human body parts for experimentation and research.¹⁹

Surprisingly, the ART marketplace was subject to a negligible amount of regulatory control in comparison with other tissue transfer marketplaces in the economy. In fact, the present regulatory system could be characterized as fragmented with unenforceable private fertility clinic standards and an uninvolved federal government that previously ignored issues related to fertility.²⁰

17. See Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 222-23 (2000) ("Due to dramatic advances in medical technology and scientific knowledge, the potential worth—both economic and non-economic—of the body of one individual to others has never been higher.").

18. See Marjorie M. Shultz, *Questioning Commodification*, 85 CAL. L. REV. 1841, (1997) (reviewing MARGARET JANE RADIN, *CONTESTED COMMODITIES: THE TROUBLE WITH TRADE IN SEX, CHILDREN, BODY PARTS, AND OTHER THINGS* (Harvard Univ. Press 1996)). Radin offers a critique of the contemporary trend in American culture toward the use of market models and market rhetoric in treating persons and experiences as commodities. *Id.* at 1841. Radin perceives this commodification process "in our discourse, our concepts, our self-understanding, our politics, our law, and, of course, in our commercial markets," and contends that this commodification impoverishes our selfhood. *Id.* at 1841-42. See generally *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 497 (Cal. 1990) (Arabian, J., concurring) (describing the problem of selling one's body tissue for profit as an inclement degradation of "the human vessel—the single most venerated and protected subject in any civilized society").

19. See Mahoney, *supra* note 17, at 177-78. The Uniform Anatomical Gift Act as originally drafted was silent on the issue of whether human sources of organs (or their survivors or estates) could receive payments. The question of direct payments to organ sources or to their survivors was resolved with the passage of the National Organ Transplant Act ('NOTA') in 1984, which prohibited payments for any organ to be used for transplantation. In addition, many state statutes forbid payments for transplantable organs. The critical shortages of many transplantable organs have sparked extensive and well-publicized debates over whether applicable law should be changed to permit the offering of compensation to tissue sources or to their surviving relatives.

Id. (footnotes omitted).

20. See SPAR, *supra* note 3; Jean Macchiaroli Eggen, *The "Orwellian Nightmare" Reconsidered: A Proposed Regulatory Framework for the Advanced Reproductive Technologies*, 25 GA. L. REV. 625, 692 (1991) ("[T]he current system [of fertility regulation] is a de facto incremental regulatory system by virtue of the federal government's limited attention, the medical profession's development of [their own] guidelines and the states' activity in areas of perceived critical state interest.").

A. Technology

Assisted reproductive technologies are the direct result of technological change. An all-encompassing definition of technology may be difficult to frame. Usually it involves all

“of those material objects, techniques and knowledge that allow human beings to transform and control the inanimate world.” A broader definition would include control of the animate world, such as: “man’s use of devices or systematic patterns of thought and activity to control physical phenomena in order to serve his desires with a minimum of effort and a maximum of efficiency.”²¹

The ART market developed as science and innovation met the laws of supply and demand in the American marketplace in the midst of rapid technological change.²²

21. Moses, *supra* note 15, at 512 (quoting RON WESTRUM, TECHNOLOGIES AND SOCIETY: THE SHAPING OF PEOPLE AND THINGS 7 (1991); RALPH PARKMAN, THE CYBERNETIC SOCIETY 3 (1972)).

22. Certain terms used in this article are interchangeable, such as “collaborative reproduction” and “assisted reproduction technology.” Other terms are given specific scientific definitions that are utilized in the medical reproductive field and adopted in statutory or common law.

Assisted reproductive technology describes various techniques that can be used to assist women in becoming pregnant. For purposes of this article, the term is used to describe various medical technologies used to create offspring through means other than coital reproduction. See Paula J. Manning, *Baby Needs a New Set of Rules: Using Adoption Doctrine To Regulate Embryo Donation*, 5 GEO. J. GENDER & L. 677, 682-83 (2004) (offering definitions of the various ART techniques). Originally, ART was implemented as fertilization in a test tube where ovum and sperm were commingled to produce a fertilized egg. Egg donation is defined as a reproductive process where one or more eggs (human ova) are removed from a donor and transferred to a recipient. Artificial insemination is the assisted insemination of sperm, whether belonging to the intended parent or a donor, into the uterus for impregnation.

In *in vitro* fertilization (IVF), eggs are surgically removed from the ovary and mixed with sperm outside the body in a Petri dish. *In vitro* literally means “in glass.” After about forty hours, the eggs are examined, and eggs that have become fertilized by the sperm and are dividing are then placed in the woman’s uterus. See *id.*; ASRM FAQ, *supra* note 13; see also Kimberly Berg, Note, *Special Respect: For Embryos and Progenitors*, 74 GEO. WASH. L. REV. 506, 506 n.1 (2006) (“ART includes all fertility treatments in which both eggs and sperm are handled. In general, ART procedures involve surgically removing eggs from a woman’s ovaries, combining them with sperm in the laboratory, and returning them to the woman’s body or donating them to another woman. They do NOT include treatments in which only sperm are handled (i.e., intrauterine—or artificial—insemination) or procedures in which a woman takes drugs only to stimulate egg production without the intention of having eggs retrieved.” (quoting CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP’T OF HEALTH & HUMAN SERVS., 2002 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 3 (2002), available at <http://www.cdc.gov/ART/ART02/PDF/ART2002part1.pdf>)). Citing the balancing of contractual theories and the need for protections of procreative liberties, Berg contends that courts faced with disputes between divorcing couples over the disposition of frozen embryos should adopt an “absolute veto” approach whereby the party asserting a right to avoid procreation should always prevail. *Id.* at 517-21.

B. Historical and Technological Context

In current assisted reproductive procedures, multiple fertilized eggs are transferred, and multiple births are often the result. There has not been any definitive longitudinal studies of the live births to determine whether a disproportionate number have suffered developmental problems. Quite often, not all of the fertilized eggs are transferred, producing embryos preserved in frozen hydrogen for future use. The viability of these embryos has not been determined.²³

In most states, gametes (eggs and sperm) are bought and sold outright unlike other body tissues. Agencies and brokers actively recruit young women as egg donors.²⁴ These donor eggs are then marketed to infertile couples or individuals seeking *in vitro* fertilization (IVF).²⁵ Typically, the customers can view photos of the donors and learn about their physical attributes, history, medical profile, accomplishments, intellectual acumen, and psychological profile.²⁶ Some agencies even provide live interviews with potential

23. See Phillip C. Cato, *The Hidden Costs of Fertility*, 20 ST. JOHN'S J. LEGAL COMMENT. 45, 52 (2005); see also Charles P. Kindregan, Jr. & Maureen McBrien, *Embryo Donation: Unresolved Legal Issues in the Transfer of Surplus Cryopreserved Embryos*, 49 VILL. L. REV. 169, 170-71 (2004) ("Hundreds of thousands of cryopreserved embryos lie frozen in fertility banks throughout the United States. They are the by-products of infertility treatments that began in the early 1970s. . . . Couples typically fertilize about a dozen eggs in vitro and freeze the extra embryos that are not immediately implanted." (footnotes omitted)).

24. See Kari L. Karsjens, *Boutique Egg Donations: A New Form of Racism and Patriarchy*, 5 DEPAUL J. HEALTH CARE L. 57, 62 (2002) ("Recruitment practices range from private 'egg brokers' to medical centers with affiliated fertility clinics to freestanding, independent fertility centers."); see also IntraMed America, <http://www.integramed.com/inmdweb/?gclid=CP3KkNeDzZICFQIgPAodpEewHg> (last visited Apr. 7, 2008) (providing a national network of fertility centers).

25. Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 ARIZ. L. REV. 45, 49 (2007) ("Agencies recruit women as potential egg donors and actively market their eggs to infertile couples who wish to purchase ova for *in vitro* fertilization and, hopefully, the creation of a baby."). Korobkin opines that the "nearly unanimous opinion in the medical research and public policy communities that tissue donors should be subject to a no-compensation rule is misguided and that purchasing tissues for biomedical research should be both legal and socially acceptable." *Id.* at 47; see *supra* note 22 (providing a definition of IVF); see also ASRM FAQ, *supra* note 13 ("In IVF, eggs are surgically removed from the ovary and mixed with sperm outside the body in a Petri dish ('in vitro' is Latin for 'in glass'). After about 40 hours, the eggs are examined to see if they have become fertilized by the sperm and are dividing into cells. These fertilized eggs (embryos) are then placed in the women's uterus, thus bypassing the fallopian tubes.").

26. Korobkin, *supra* note 25, at 49; see Karsjens, *supra* note 24, at 62; see also Baum, *supra* note 3, at 117 (describing the egg donation process and insisting that "[w]hichever process is used, individual donor selection is usually driven by the donor's genetic, physical, psychological, and intellectual characteristics, which . . . may or may not have any bearing on the resultant offspring's characteristics").

egg donors.²⁷ "Donors who are selected . . . typically receive between \$2,500 and \$10,000 for one ovulation cycle."²⁸

The next medical step in this process is relatively straightforward from a technical point of view. Now that physicians understand and have perfected the technique for fertilizing eggs and transferring the resulting embryo back into a womb, all that is needed is to coordinate the donor female's and the donee female's reproductive cycles. The drug Pergonal, or its equivalent, is used to cause super ovulation in the donor, and progesterone or an equivalent drug is used to prepare the recipient's womb for pregnancy.²⁹

The donor is subjected to a three-week course of hormone therapy, which includes daily injections to stimulate the ovaries to produce the eggs. The donor makes several trips to the doctor's office during this time to determine whether the eggs are "ripe."³⁰ At the appropriate time, the eggs are harvested. The procedure involves an ultrasound probe during which the eggs are removed from the ovaries with a needle.³¹

The private agencies that match the donors to the recipients usually receive a fee for their services. Sperm donation operates differently. Sperm banks serve as intermediaries that pay donors directly for providing sperm to the bank. The amount paid for sperm is considerably less: from \$25 to \$100 per donation, although acceptable sperm undergoes a typical markup to as much as \$275 to \$400 per vial.³²

27. Korobkin, *supra* note 25, at 49.

28. *Id.*; see Andrew Wancata, *No Value for a Pound of Flesh: Extending Market-Inalienability of the Human Body*, 18 J.L. & HEALTH 199, 221 (2003-2004) ("Indeed, sperm and ova have become market commodities, reaching bids from prospective purchasers as high as \$15,000 and \$50,000, respectively. The Advanced Fertility Center of Chicago has published that its current charge for a complete egg donation cycle is \$18,200, which includes 'the donor's fee of \$5,000.'" (footnotes omitted)). The estimates for egg donations vary widely. This author visited the Massachusetts Institute of Technology on April 29, 2007, and saw an egg donor solicitation advertisement promising only \$5,000 per successful implantation of the egg.

29. See SPAR, *supra* note 3, at 20, 24; Baum, *supra* note 3, at 117-18 (describing the synchronization of the donor's and recipient's menstrual cycles and the hormonal manipulation required to reach the intended results).

30. See SPAR, *supra* note 3, at 43.

31. See *id.*; see also Baum, *supra* note 3, at 118.

32. See Korobkin, *supra* note 25, at 50; see also SPAR, *supra* note 3, at 39 ("All these banks, however operate along similar financial lines. Donors are wooed through promotional material scattered around college campuses or other attractive locales. They contribute a fixed number of times over a relatively short period and receive around \$75 per specimen. Each specimen yields between three and six vials of sperm, and each vial sell for \$250 to \$400—a gross markup for the banks that averages roughly 2,000 percent.")

In 2003, the average price paid by the infertile was approximately \$12,400 per cycle, "only slightly more than the inflation-adjusted price" of \$6,000 in 1986.³³ An infertile couple or individual may expend upwards of \$50,000 to \$100,000 attempting to obtain a successful pregnancy.³⁴ Apparently, this is not too much to pay for the desperate clientele seeking to "have a baby" with certain characteristics.³⁵ Certainly the price incentives are sufficient to make the "ART baby business" a lucrative one.

C. Congressional History

In 1979, President Jimmy Carter appointed an Ethics Advisory Board (EAB) to address research issues involving ART, specifically *in vitro* fertilization.³⁶ On May 4, 1979, the board issued a report stating that it was "acceptable from an ethical standpoint to undertake and fund research involving human IVF and embryo transfer subject to various qualifications."³⁷ The EAB dodged the issue of the morality of human embryo research and research for IVF purposes by stating "the human embryo is entitled to profound respect; but this respect does not necessarily encompass the full legal and moral rights attributed to persons."³⁸ The Carter, Reagan, and first Bush administrations subsequently denied funding for this Board.³⁹ Federally funded research on embryos had to be approved by this board, and without the board's approval, federally funded research on embryos was virtually eliminated.⁴⁰

33. See SPAR, *supra* note 3, at 33.

34. *Id.* at 46.

35. See generally *id.* (discussing a couple that placed an ad seeking "a Caucasian woman 'with proven college level athletic ability' willing to 'give the gift of life and love'").

36. Moses, *supra* note 15, at 539.

37. *Id.* (citing Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer, 44 Fed. Reg. 35,033, 35,056 (June 18, 1979)).

38. *Id.* (quoting 44 Fed. Reg. at 35,056). "The Board recommended that a model or uniform law be drafted dealing with the legal status of children born as a result of IVF." *Id.*

39. *Id.* "This Board approval requirement was removed in 1993." *Id.* (citing National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, § 121, 107 Stat. 122, 133 (1993)).

40. See *id.*; cf. Eggen, *supra* note 20, at 684-85 ("[T]he Board approved such research with the following provisos: '1. The research complies with all appropriate provisions of the regulations governing research with human subjects . . . ; 2. The research is designed primarily: (A) to establish the safety and efficacy of embryo transfer and (B) to obtain important scientific information toward that end not reasonably attainable by other means; 3. Human gametes used in such research will be obtained exclusively from persons who have been informed of the nature and purpose of the research in which such materials will be used and have specifically consented to such use; 4. No embryos will be sustained *in vitro* beyond the stage normally associated with the completion of implantation (14 days

In this environment, devoid of significant federal or state funding, from 1980 to 1992, private funding increased.⁴¹ Without government funding and subsequent oversight, privately funded researchers were free to push the frontiers of ART, expanding and improving techniques.⁴² Improved medical technology, coupled with increased knowledge, fueled increasing consumer demand for the emerging fertility services. EAB approval for federally funded research in this area was totally eliminated by 1996.⁴³ Thus, the lack of initial federal funding for embryonic and genetic research created a vacuum of federally sponsored research that was filled by private entrepreneurs, private research facilities, and medical universities in the fertility industry.⁴⁴

after fertilization); and 5. All interested parties and the general public will be advised if evidence begins to show that the procedure entails risk of abnormal offspring higher than those associated with natural human reproduction.” (quoting 44 Fed. Reg. at 35,057)).

41. See Judith F. Daar, *ART and the Search for Perfectionism: On Selecting Gender, Genes, and Gametes*, 9 J. GENDER RACE & JUST. 241, 255 n.36 (2005) (“There are no federal laws or regulations that directly prohibit the use of embryos in privately funded research protocols. Thus, current research in PGD [(preimplantation genetic diagnosis)] is largely supported by private benefactors.”).

42. See Gabriel S. Gross, Comment, *Federally Funding Human Embryonic Stem Cell Research: An Administrative Analysis*, 2000 WIS. L. REV. 855, 883 (“Stem cell research will occur in the private sector regardless of whether it is funded by the federal government. Through private funding, the research will proceed, potentially unregulated by the government and unknown to the public at large. Federal funding confers a distinct benefit to scientific research, that of strictly enforced oversight processes that are absent from privately funded work. Furthermore, making the vast resources of the federal government available to ES cell researchers will diminish scientists’ reliance on private funds, creating a powerful incentive for independent research organizations to conform to federal ethical guidelines.”).

43. See Susan L. Crockin, *The “Embryo” Wars: At the Epicenter of Science, Law, Religion, and Politics*, 39 FAM. L.Q. 599, 620 (2005) (outlining the federal disengagement from genetic and fertility research by explaining the history of the EAB and subsequent Dickey Amendment through the latter Bush administration). “Under the Clinton administration, the Dickey Amendment was interpreted to mean research was permitted so long as federal funding was not used to create the stem cell lines, because creation of the lines would involve destruction of embryos.” *Id.* The Dickey Amendment is a rider that was attached to a Department of Health and Human Services appropriations bill in 1996. *Id.* (citing Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA), Pub. L. No. 104-99, Title I, § 128, 110 Stat. 26, 34 (1996)).

44. See Note, *Guiding Regulatory Reform in Reproduction and Genetics*, 120 HARV. L. REV. 574 (2006) (examining the social, political, and economic forces that produced the modern day divergence between genetic research which utilized the techniques in reproductive medicine and the reproductive medicine field). The note acknowledges that

the two fields have spawned very different regulatory regimes. Assisted reproduction is now dominated by private firms that provide reproductive services, including fertility treatments, to parents willing to pay, operating under only a minimal set of guidelines with little formal oversight. In contrast, most genetic research remains tightly regulated by overlapping federal agencies, with funding subject to the approval and oversight of review boards that scrutinize the ethical, safety, and policy concerns of new research.

The National Institutes of Health (NIH), an administrative agency under the auspices of the Department of Health and Human Services (DHHS), decided that “federal funds could be used for research using donated surplus IVF embryos remaining after infertility treatments.”⁴⁵ Congress immediately “attached a rider [(the Dickey Amendment)] to a Department of Health and Human Services (DHHS) appropriations bill, which effectively prohibited federal funding for any research in which a human embryo is destroyed.”⁴⁶ The amendment was attached before any funding was granted for research. The Dickey Amendment has been attached to every subsequent DHHS appropriations bill. The Clinton administration interpreted the Dickey Amendment broadly, permitting research with federal funding as long as the “funding was not used to create the stem cell lines, because creation of the lines would involve destruction of embryos.”⁴⁷

NIH implemented those regulatory guidelines, which remained until 2001. Those guidelines provided that “federal funds could be used for the study of stem cells derived from excess human embryos remaining after infertility treatments, so long as the extraction of the stem cells from the IVF embryos was privately funded and completed

Id. at 574 (footnotes omitted). The note identifies stem cell research on embryos as an example of the tightly controlled research. *Id.* The note concludes that there is a “convergence between reproductive medicine and genetic research creat[ing] dilemmas for current regulation” but strongly argues that any reform should “consider the past forces that have contributed to today’s regulatory divide,” for example, the funding prohibitions and lack of governmental oversight in one area in the face of strong market forces. *Id.* at 596. The note further argues that potential tools for reform should consider the implications of past policy decisions and consider

that funding-oriented regulation may be effective for early-stage research, that there may be a large cultural capacity to absorb new technologies, and that safety concerns ought to be heightened in the face of strong market forces [T]hese insights, drawn from the hard experience of history, should offer useful guidance as today’s speculative ethical debates develop into concrete realities.

Id.

45. Crockin, *supra* note 43, at 620; see Christine L. Feiler, Note, *Human Embryo Experimentation: Regulation and Relative Rights*, 66 *FORDHAM L. REV.* 2435, 2449 (1998) (“The NIH Panel believed that the public’s interest in obtaining beneficial information from these experiments warranted performance of (and federal funding for) embryo experimentation—even where it involved the deliberate creation of research embryos.”).

46. Crockin, *supra* note 43, at 620 (citing Omnibus Consolidated and Emergency Supplemental Appropriations Act (OCESAA), Pub. L. No. 104-99, Title I, § 128, 110 Stat. 26, 34 (1996)).

47. *Id.*; see also National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 65 *Fed. Reg.* 51,976 (Aug. 25, 2000) (withdrawn by National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, 66 *Fed. Reg.* 57,107 (Nov. 14, 2001)).

prior to the NIH funded research.”⁴⁸ In August 2001, President George W. Bush announced a narrower construction of the Dickey Amendment, allowing federal funds to be used for research on existing stem cell lines only.⁴⁹ The latter Bush Administration’s realignment of the definition of embryos potentially restricted any further federal government funding of research on stem cell lines.⁵⁰

Currently, any research on stem cell lines remains in the unregulated realm of private research and private funding. The ultimate effect of the initial (1979) prohibition against federal funding of research led to a possibly unintended result. The absence of governmental oversight and funding of embryonic and genetic research, combined with the lack of public debate on the assisted reproductive technologies, freed private enterprises to pursue advancing ARTs and test new, emergent applications on their customers.⁵¹

D. The Fertility Clinic Success Rate and Certification Act of 1992

In 1988, the DHHS reconstituted the EAB.⁵² The federal government failed to issue or present new oversight regulations for private research during the eighties. In 1990, in the wake of renewed interest in regulation, a bill was passed authorizing the Secretary of Health and Human Services to issue regulations for the certification of embryo laboratories, and establishing certification standards and

48. Crockin, *supra* note 43, at 620.

49. See David Adamson, *Regulation of Assisted Reproductive Technologies in the United States*, 39 FAM. L. Q. 727, 729-30 (2005) (“On August 9, 2001, President George W. Bush announced criteria for federal funding of stem cell research, limiting it to sixty-four stem cell lines in existence at that time.”).

50. See Crockin, *supra* note 43, at 620-21.

51. See generally Korobkin, *supra* note 25, at 45 (“President Bush’s policy permits federal funding of research on human embryonic stem cell . . . lines only if they were created prior to August 2001 and only if they were derived from embryos created without financial compensation. The Stem Cell Research Enhancement Act, passed by Congress but vetoed by President Bush in July 2006, would have expanded the scope of federal funding but maintained the no-compensation requirement” for “any person who donates tissues for stem cell research, including eggs, sperm, adult cells, or frozen early-stage embryos stored at *in vitro* fertilization . . . clinics.”).

52. Ethics Advisory Board; Notice of Establishment, 53 Fed. Reg. 35,232 (Sept. 12, 1988); see also Gross, *supra* note 42, at 862 (“In response to the introduction of human *in vitro* fertilization in the 1970s, the Department of Health, Education and Welfare (HEW—now the Department of Health and Human Services) appointed an Ethical Advisory Board (EAB), to consider and review all applications or proposals involving human IVF.”). The EAB was allowed to die during subsequent administrations before being revived in 1988. *Id.* at 863.

procedures.⁵³ The bill contained a success rate reporting requirement as a precondition of certification.⁵⁴ The bill, known as the Fertility Clinic Success Rate and Certification Act of 1992 (Fertility Success Rate Act, or the FCSRCA), represents governmental regulation at its weakest.⁵⁵

Although the FCSRCA was enacted in 1992, it was not implemented until the DHHS actually funded its implementation in 1996.⁵⁶ The two critical components of the Fertility Success Rate Act include certification and statistical reporting of success.⁵⁷ The reporting requirement for ART clinics involves the reporting of annual pregnancy success rates.⁵⁸ The Act required the success rates of the reporting clinics be made available to the public. In addition, clinics

53. See Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to -7 (2000).

54. *Id.* § 263a-1(a).

55. See Siddharth Khanijou, *Multifetal Pregnancy Reduction in Assisted Reproductive Technologies: A License To Kill?* 8 DEPAUL J. HEALTH CARE L. 403, 410-11 ("In response to this concern, [questions about the accuracy of the reporting of fertility clinics] Congress passed the Fertility Clinic Success Rate and Certification Act of 1992 and directed the Center for Disease Control (CDC) to collect and publish information regarding fertility center success rates. However, this mandatory reporting requirement serves no regulatory purpose and clinics continue to maximize pregnancy rates by transferring too many embryos per cycle. Information regarding a clinic's success rates, originally intended to serve a consumer-oriented purpose, has had the regrettable side-effect of promoting unethical business practices" (footnotes omitted)); see also Alicia Ouellette et al., *Lessons Across The Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J.L. & MED. 419, 422-23 (2005) ("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. . . . The FCSRCA legislation, however, does not go nearly as far as the HFE Act [a regulatory statute operating in the United Kingdom]. 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." (footnotes omitted)). See generally Crokin, *supra* note 43.

56. See 42 U.S.C. §§ 263a-1 to -7; 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, 843-44 (1999); see also Reporting of Pregnancy Success Rates from Assisted Reproductive Technology Programs, 65 Fed. Reg. 53,310 (Sept. 1, 2000) (setting forth the reporting requirements under the FCSRCA).

57. See Havins & Dalessio, *supra* note 56, at 843-44 (noting the reporting and certification components of the Act and opining that the certification component of the statute was designed to "maximize the quality of IVF, assure consistent application of established procedures, and guarantee accurate reporting"); Jennifer L. Rosato, *The Children of ART (Assisted Reproductive Technology): Should the Law Protect Them from Harm?*, 2004 UTAH L. REV. 57, 63 ("The information serves a worthwhile consumer-oriented purpose: it allows intended parents to make knowledgeable choices about the fertility center they will use.").

58. 42 U.S.C. § 263a-1(a).

failing to report their rates would be publicly exposed for consumers to see.⁵⁹

The reporting and certification requirements were enacted to combat exaggerated claims of success rates by clinics. Thus, the reporting requirements were created to serve the consumer and provide knowledge about the fertility centers success rates with pregnancy and birth. The certification requirements were crafted with the intention of improving the quality of IVF and the procedures used.

The Act defines “assisted reproductive technology” to mean

all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).⁶⁰

The Fertility Success Rate Act also directs the Secretary of Health and Human Services to “develop a model program for the certification of embryo laboratories . . . to be carried out by the States” (which has yet to be adopted).⁶¹

The fertility clinics’ reporting and certification data is collected by the Center for Disease Control and Prevention (CDC), which is under the DHHS. The success data includes actual pregnancies (which may not result in actual births) and live births.⁶² The CDC then reports these statistics to the public. Insignificant sanctions are imposed on a fertility clinic that fails to report its success rates or actual pregnancies.⁶³ The failure to report simply causes the clinic to be listed on the CDC Web site as non-reporting.⁶⁴

59. 42 U.S.C. § 263a-5(1)(A); *see also* Rosato, *supra* note 57, at 64.

60. 42 U.S.C. § 263a-7(1); *see also* 42 U.S.C. § 263a-7(2) (defining an “embryo laboratory” as “a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation”).

61. 42 U.S.C. § 263a-2.

62. *See* CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEPT OF HEALTH & HUMAN SERVS., ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 6 (2004), *available at* <http://ftp.cdc.gov/pub/Publications/art/2004ART508.pdf> [hereinafter ARS SUCCESS RATES].

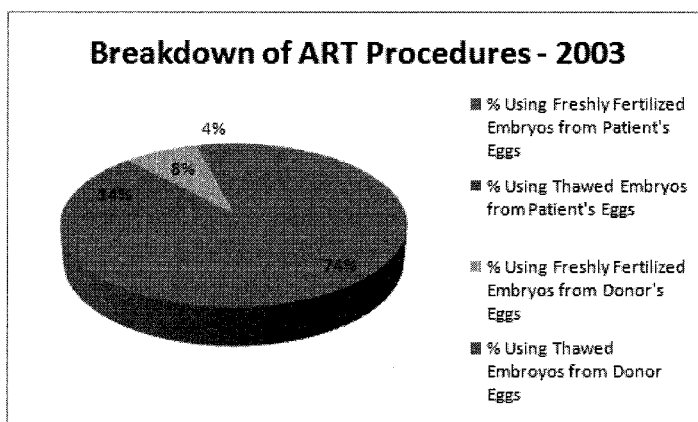
63. The FCSRCA requires only an annual reporting of clinic success rates, a listing of clinics that do not report, and the development of a model certification program. 42 U.S.C. §§ 263a-1 to -7 (2000).

64. *Id.* § 263a-5(1)(A) (requiring that the Secretary publish and distribute to the States and public the “pregnancy success rates reported to the Secretary under section 263a-1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name

Nothing in the Fertility Success Rate Act attempts to regulate the standards, quality, or ethical issues, including compensation for donors, involving ART and the use of donor eggs.⁶⁵ The Act, in fact, contains a specific provision forbidding such regulations: "In developing the certification program, the Secretary may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs."⁶⁶

The data obtained from the CDC Web site contains information related specifically to success rates and delivery rates.⁶⁷ The information and data collected comes from a contract entered into between the federal government and the associative organization SART (Society for Assisted Reproductive Technology) for the collection of the data.⁶⁸ While this collection methodology is not empirically incorrect, it does underscore the close and collaborative arrangements between the fertility industry providers and the federal government.⁶⁹

Figure 1⁷⁰



of each such program and each pregnancy success rate which the program failed to report"); *see also* Rosato, *supra* note 57, at 64.

65. *See* 42 U.S.C. §§ 263a-1 to -7.

66. 42 U.S.C. § 263a-2(i)(1).

67. Victoria Clay Wright et al., *Assisted Reproductive Technology Surveillance—United States, 2003*, MORBIDITY AND MORTALITY WKLY. REP., May 26, 2006, <http://www.cdc.gov/mmwr/preview/mmwrhtml/ss5504a1.htm>.

68. *See id.* ("CDC contracted with the Society for Assisted Reproductive Technology (SART) to obtain data from ART medical centers located in the United States."); *see also* What Is SART?, <http://www.sart.org/WhatIsSART.html> (last visited Apr. 8, 2008).

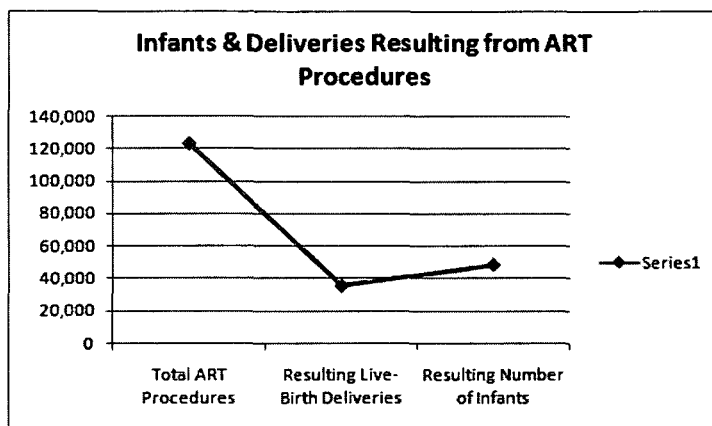
69. *See* Wright et al., *supra* note 67.

70. *See id.*

The statistics reported by the CDC provide a telling, but incomplete, picture about the costs and societal implications of ART. As shown in figure 1, nationwide, seventy-four percent of ART procedures used freshly fertilized embryos from the patient's eggs, fourteen percent used thawed embryos from the patient's eggs, eight percent used freshly fertilized embryos from the donor's eggs, and four percent used thawed embryos from donor eggs.

In interpreting the data, one has to measure the success rate of ART when using the patient's eggs as compared to the success rate of ART when using a donated egg.⁷¹

Figure 2⁷²



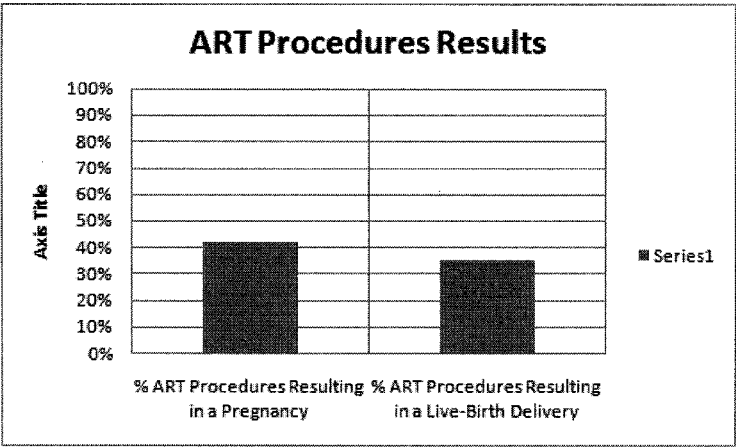
As shown in figure 2, in the year 2003, the latest year in which statistics have been released for compilation in the completed reports, "a total of 122,872 ART procedures were reported to the CDC." As a result of these procedures, 35,785 live-birth deliveries occurred and 48,756 infants were born.⁷³

71. *Id.*

72. *See id.* ("Whether an ART procedure resulted in a pregnancy and live-birth delivery varied according to . . . the patient's age, the type of ART procedure performed, the number of embryos transferred, and embryo availability (an indicator of embryo quality).").

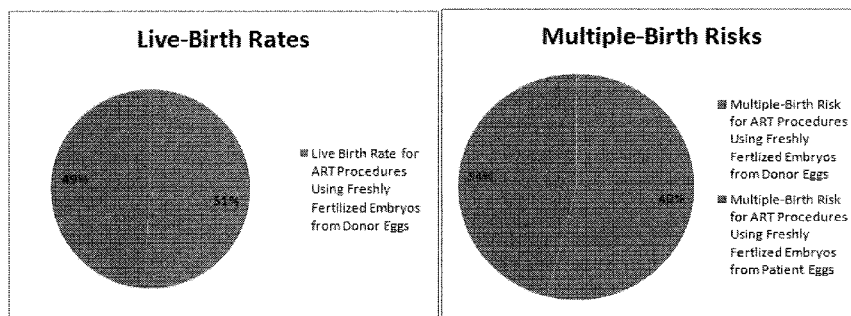
73. *Id.* Live-birth deliveries include multiples born to the mother (twins and triplets).

Figure 3⁷⁴



“Of [the] 48,756 infants born through ART procedures, 51% were born in multiple-birth deliveries.”⁷⁵ “The multiple-birth risk was highest for women who underwent ART transfer procedures using freshly fertilized embryos from either donor eggs (40%) or their own eggs (34%).”⁷⁶ Strong predictors of multiple birth risk include the “[n]umber of embryos transferred, embryo availability (an indicator of embryo quality), and [the] patient’s age.”⁷⁷

74. *Id.*
75. *Id.*
76. *Id.*
77. *Id.*

Figures 4 and 4A⁷⁸

“The highest live-birth rates were observed among ART procedures using freshly fertilized embryos from donor eggs (51%).”⁷⁹ Yet the highest multiple birth risks in the ART procedures were accounted for in those using freshly fertilized embryos from the donor’s eggs.⁸⁰

The CDC’s abstract highlights the problems of multiple births:

Patients who undergo ART treatments are more likely to deliver multiple-birth infants than women who conceive naturally. Multiple births are associated with increased risk for mothers and infants (e.g., pregnancy complications, premature delivery, low-birthweight infants, and long-term disability among infants).⁸¹

The Fertility Success Rate Act, with its reporting statistics, paints a troubling picture. The ART procedures do not guarantee a successful delivery of a live infant, and they come with a risk of multiple births. The best success rate for a live birth from ART appears to occur with donated eggs. If success is measured by both a live birth and a reduced incidence of multiple births, then a new reporting paradigm has to be created. Yet there are no attendant regulatory controls to curtail overzealous implantation techniques or risky techniques. More troubling is the reality that there are no regulatory measures to ensure that the reporting is accurate. Clinics that fail to report are merely listed on the site as non-reporting.⁸²

78. See *id.* (“ART-related multiple births represent a sizable proportion of all multiple births nationwide and in selected states. Efforts should be made to limit the number of embryos transferred for patients undergoing ART. In addition, adverse infant health outcomes (e.g., low birthweight and preterm delivery) should be considered when assessing the efficacy and safety of ART.”).

79. *Id.*

80. *Id.*

81. *Id.*

82. See *supra* notes 63-64 and accompanying text.

There does not appear to be any reporting of the consequences of adverse [if any] reactions resulting to the donors from any of the procedures to retrieve the eggs. Nor is there any attention paid to the number of times eggs are retrieved from donors in any given locale. The federal government has enacted a weak reporting statute for ART clinics.⁸³ Correspondingly, through policies and political expediency, the federal government has not proscribed the sale and transfer of human gamete material. Instead, the result is that women can be paid for donating eggs, and the regulation of ART is left to the private players.

E. Human Tissue Transference

The second half of the twentieth century ushered in scientific advances that allowed the successful transplant of a human organ into a human being. These advances began with the transplant of a human kidney, followed swiftly by a successful heart transplant in South Africa.⁸⁴ In stark contrast to the market for reproductive tissue transfer, the organ transfer donation marketplace is highly regulated by the federal government.

The transfer of organs and human tissue is regulated by federal and state statutes that forbid the payment of monetary compensation to the donors of human organs.⁸⁵ The federal statute that directly forbids monetary compensation payment is the National Organ Transplant Act (NOTA).⁸⁶ NOTA regulates the procurement and transplantation of human organs.⁸⁷ More specifically, NOTA prohibits the buying or selling of organs for valuable consideration.⁸⁸

83. See Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1(a) (2000) (outlining the reporting requirements for ART clinics).

84. See S. Gregory Boyd, *Considering a Market in Human Organs*, 4 N.C. J. L. & TECH. 417, 420-21 (2003) (contending that the modern computer was invented more than a decade before the first successful human organ transplant occurred, and noting that "[t]he first kidney was transplanted in 1951, the first lung in 1963, the first intestine in 1964, the first liver in 1965, the first pancreas in 1966, and the first heart in 1967" (footnotes omitted)); see also Crespi, *supra* note 10, at 11 n.46 ("In 1954 doctors performed the first successful kidney transplant. In 1967 Dr. Christian Barnard made history by performing the first human heart transplant." (citations omitted)); Wancata, *supra* note 28.

85. Wancata, *supra* note 28, at 213; see Charles M. Jordan, Jr. & Casey J. Price, *First Moore, Then Hecht: Isn't It Time We Recognize a Property Interest in Tissues, Cells, and Gametes?*, 37 REAL PROP. PROB. & TR. J. 151, 159 n.35 (2002) (listing the statutes of the states which have adopted the Uniform Anatomical Gift Act (UAGA) in some form and asserting that all fifty states and the District of Columbia have adopted some version of the 1987 version of the UAGA).

86. National Organ Transplant Act of 1984, 42 U.S.C. §§ 273-274e (2000).

87. *Id.*

88. *Id.* § 274e.

It does not include blood, sperm, or ova in its definition of organs.⁸⁹ NOTA was rushed through Congress in the 1980s to avoid what Congress perceived as a rush to create for-profit marketing of human organs.⁹⁰

All fifty states now have some form of statutory prohibition against the sale of or compensation for human organs.⁹¹ The National Conference of Commissioners adopted the Uniform Anatomical Gift Act (UAGA) in 1968, and subsequently revised it in 1987 and 2006.⁹² The UAGA allows anyone over eighteen years of age to make or refuse an anatomical gift.⁹³ Similar to NOTA, the UAGA also forbids the purchase or sale of body parts for transplantation or therapy if the removal is intended to occur after death. This Act (adopted by all fifty states and District of Columbia) was designed to facilitate the transplantation of hearts and kidneys.⁹⁴ It does, however, encourage the “voluntary, uncompensated donation of human organs.”⁹⁵ The “fear of commodification” of the human body underlies support for the prohibition on organ sales.⁹⁶ During the hearings in the Senate before

89. *Id.* § 274e(c)(1); *see also* Jordan, Jr. & Price, *supra* note 85, at 157 (“[T]he statute specifically defines the term ‘organ,’ and the statute does not interpret an organ to include blood, sperm, and ova.”); Korobkin, *supra* note 25, at 47 n.12 (“The legislative history of the NOTA specifically states that that statute’s prohibition of sales ‘is not meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor.’” (quoting S. REP. NO. 98-382, at 16-17 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 3975, 3982)).

90. *See* Wancata, *supra* note 28, at 213-14 (“In enacting NOTA, Congress intended to prevent for-profit marketing of human organs. Interestingly, this legislation was rushed through Capitol Hill due to the plans of a Virginia physician to arrange a commercial market in human kidneys. . . . The proposition shocked many and was met with immediate congressional dissent, including then-Tennessee Senator Albert Gore, Jr., [who] vehemently contended that ‘putting organs on a market basis is abhorrent to our system of values.’” (footnotes omitted)).

91. *See supra* note 85 and accompanying text.

92. UNIF. ANATOMICAL GIFT ACT § 1 et seq. (West 2008).

93. *Id.* § 2(a).

94. *Id.*; *see also* Crespi, *supra* note 10, at 14-15 (“NOTA . . . created the National Organ Procurement and Transplantation network as a vehicle for matching organ donors with those who need transplants.”); Jordan, Jr. & Price, *supra* note 85, at 158 (“In an effort to facilitate the transplantation of hearts and kidneys, the National Conference of Commissioners on Uniform State Laws adopted the Uniform Anatomical Gift Act.”).

95. Wancata, *supra* note 28, at 214.

96. *See id.* at 215 (“[C]ompensation to organ donors has been widely attacked as espousing the notion that people may become viewed as market commodities.”). The fear is that, if human body parts are granted full property rights, “we would become slaves, not in a market for our bodies, but in a market for body parts.” *Id.* (quotation marks omitted) (footnote omitted). For an annotation of cases concerning the validity of state and federal acts, *see* Marjorie A. Shields, *Validity and Application of Uniform Anatomical Gift Act*, 6 A.L.R. 6TH 365 (2005).

NOTA was passed, the Committee Report in Congress identified the commodification issue as a reason for the need for this bill.⁹⁷

NOTA is the primary federal law regulating the procurement, distribution, and transplantation of human organs.⁹⁸ The Act provides regulatory direction on both organ procurement and donation. It is a complete statutory prohibition against obtaining valuable consideration in exchange for human organs.

NOTA also created the Organ Procurement and Transplantation Network (OPTN), which facilitates, through privately and government-funded organizations, the waiting lists, protocols, and procurement procedures for organ donation and transplantation.⁹⁹ The Act provides for fines up to \$50,000 and/or five years in jail as punishment for selling organs.¹⁰⁰ More restrictive than the UAGA, NOTA prohibits the selling of organs during the life and after the death of the donor if the sale could be interpreted to affect interstate commerce.¹⁰¹

Although NOTA prohibits the sale of organs, estimates show a billion dollar unregulated industry in the transfer of human tissues through middle men and brokers.¹⁰² All manner of persons are engaged in this perfectly legitimate grey market.¹⁰³ NOTA prohibits the donor or his family from receiving valuable consideration in exchange for tissue or an organ, but the participants can receive costs for tissue retrieved, stored, rendered, and transplanted, as well as a reasonable fee as the tissue moves from one broker to another.¹⁰⁴

97. S. REP. NO. 98-382, at 17 (1984), as reprinted in 1984 U.S.C.C.A.N. 3975, 3982 ("The Committee believes that human body parts should not be viewed as commodities . . .").

98. See 42 U.S.C. § 273 (2000).

99. See 42 U.S.C. § 274 (2000); Organ Procurement and Transplant Network, <http://www.optn.org> (last visited Apr. 9, 2008) (reporting that there were 98,793 waiting list candidates for organ transplants as of April 9, 2008, at 17:27 EST).

100. 42 U.S.C. § 274e(b) (2000).

101. See *id.* § 274e(a).

102. See Michelle Oberman, *When the Truth Is Not Enough: Tissue Donation, Altruism, and the Market*, 55 DEPAUL L. REV. 903, 910-11 (2006).

103. See *id.* (commenting on the largely unregulated human tissue market). The market in human tissue sprung up in the late-twentieth and early-twenty-first centuries and involves the procurement of body parts from human cadavers. *Id.* at 903. It involves the "recycling of skin, bone and other body parts" and subsequent sale and resale to various brokers and middlemen. *Id.* "Over the course of the past twenty years, some participants in this market have realized extraordinary profits." *Id.*; see also Robert A. Katz, *The Re-Gift of Life: Who Should Capture the Value of Transplanted Human Tissue*, 18 NO. 4 HEALTH LAW 14, 14 (2006) (chronicling the billion-dollar industry existing in the United States for the recovery of "tissue (e.g., bone, skin, heart valves)" from cadavers and its transfer into living persons).

104. See Oberman, *supra* note 102, at 910.

F. Regulatory Oversight of Human Reproductive Tissue Transfer

Three federal agencies and three separate federal legislative enactments¹⁰⁵ provide some regulatory oversight of the reproductive technology industry.¹⁰⁶ At best, this federal oversight is fragmented, and state regulatory oversight for reproductive fertility services is virtually nonexistent. The DHHS oversees the Food and Drug Administration (FDA),¹⁰⁷ the CDC,¹⁰⁸ and the Centers for Medicaid and Medicare Services (CMS).¹⁰⁹

The FDA has the authority, although limited, to regulate genetic testing.¹¹⁰ The FDA passed regulations to “screen and test cell and tissue donors, in a way that prevents the introduction,

105. See Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to -7 (2000); see also Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (2000) (amending section 253 of the Public Health Service Act); Social Security Act of 1965, Titles XVIII & XIX, 42 U.S.C. §§ 1395-1396v (2000); Adamson, *supra* note 49, at 728-29 (“Numerous general mandatory regulations affect ART in a direct and indirect manner. The Federal Clinical Laboratory Improvement Act of 1988 (CLIA 88) governs endocrinology and andrology laboratories that provide hormonal assays and semen analysis tests, respectively, for IVF. The National Institutes of Health (NIH) and federal research regulations cover all human research, including that performed in IVF laboratories. The Food and Drug Administration (FDA) has regulations that govern SCNT, and other federal government laws restrict research on embryos, SCNT, and stem cell research. The Federal Trade Commission (FTC) has intervened to sanction ART clinics that have marketed or advertised their results in a manner that the FTC considered inappropriate. . . . The Centers for Medicare and Medicaid Services (CMS) sets payment levels for all medical services, including those provided by ART centers. Even though Medicare and Medicaid do not pay for IVF, the setting of reimbursement levels in general has a direct effect on payments by insurance companies and others to ART centers.”).

106. See Adamson, *supra* note 49, at 729 (“These federal policies have had the primary impact of limiting human embryo research and support for reproductive research, including stem cell research.”).

107. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a (2000).

108. 42 U.S.C. §§ 264-272 (2000 & Supp. II 2002); 42 C.F.R. pts. 70-71 (2007).

109. 42 C.F.R. pts. 400-505 (2007).

110. See U.S. Food and Drug Administration, Human Gene Therapy and the Role of the Food and Drug Administration (Sept. 2000), <http://www.fda.gov/cber/infosheets/genezn.htm> (“The U.S. Food and Drug Administration (FDA) is the primary government agency charged with protecting the health of U.S. citizens The FDA’s authority includes any human gene therapy product sold in the United States.”); see also Adamson, *supra* note 49, at 730 (“Regulations affecting genetics also impact ART in an increasing manner, because of the application of preimplantation genetic diagnosis and screening (PGD/S), which is performed by testing cells biopsied from embryos that have been created by IVF. The DHHS oversees genetic tests through the CDC, FDA, CMS and Office for Human Research Protection (OHRP). The CLIA has laboratory oversight, and the NIH oversees genetics research activities.”); Larry Thompson, *Human Gene Therapy: Harsh Lessons, High Hopes*, FDA CONSUMER MAG., Sept.-Oct. 2000, available at http://www.fda.gov/fdac/features/2000/500_gene.html.

transmission, or spread of communicable diseases.”¹¹¹ These minimum health standards became effective on May 25, 2005.¹¹² The FDA exercises jurisdiction over facilities donating, processing, or storing sperm, ova, and embryos through its power to prevent the spread of communicable disease and its power to regulate drugs, devices, and biological products.¹¹³

The CDC has oversight authority over fertility clinics for the purpose of reporting statistics required under the Fertility Success Rate Act.¹¹⁴ As we have seen, however, the Act merely requires the clinics to report their success rates as indicated by actual pregnancies or live births.¹¹⁵ The CDC has no power to sanction the clinics for noncompliance except to list the noncompliant clinics on their Web site.¹¹⁶ The CDC does have oversight authority, based on its enabling statute,¹¹⁷ to regulate the spread of communicable diseases, but it is clear from its regulations that it does not have the authority to do anything more with fertility clinics.¹¹⁸ Note that, for the 2004 report, of the 411 reporting clinics, only twenty-eight were chosen for a site audit to determine that the tabulated success rates were accurate.¹¹⁹

The CMS has oversight authority over non-research laboratories concerning standards, personnel, and guidelines.¹²⁰ A

111. 21 C.F.R. § 1271.145 (2007); *see also* U.S. Food and Drug Administration, Tissues, <http://www.fda.gov/CBER/tiss.htm> (last visited Apr. 8, 2008) (“Human cells or tissue intended for implantation, transplantation, infusion, or transfer into a human recipient is regulated as a human cell, tissue, and cellular and tissue-based product or HCT/P. The Center for Biologics Evaluation and Research (CBER) regulates HCT/Ps under 21 CFR Parts 1270 and 1271. Examples of such tissues are bone, skin, corneas, . . . heart valves, . . . oocytes and semen.”).

112. *See* 21 C.F.R. pts. 210-11, 820, 1271 (2007); Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29,786 (May 25, 2004).

113. *See* Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 68 Fed. Reg. 2689 (Jan. 21, 2003).

114. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to -7 (2000); Centers for Disease Control and Prevention, Division of Reproductive Health: Activities—ART Surveillance System, <http://www.cdc.gov/ReproductiveHealth/DRH/activities/ART.htm> (last visited Apr. 8, 2008).

115. *See* 42 U.S.C. § 263a-1.

116. *See supra* note 64 and accompanying text.

117. 42 U.S.C. §§ 264-272 (2000 & Supp.II 2002).

118. *See supra* note 65 and accompanying text.

119. ART SUCCESS RATES, *supra* note 62, at 5.

120. *See* 42 C.F.R. § 493.2 (2007); Centers for Medicare & Medicaid Services, Medicare Overview, <http://www.cms.hhs.gov/MedicareGenInfo/> (last visited Apr. 8, 2008) (noting that Medicare is a government-sponsored health care insurance program for individuals who have certain disabilities or are over the age of sixty-five and is essentially health care for indigent individuals); Centers for Medicare & Medicaid Services, Clinical Laboratory Improvement Amendments, <http://www.cms.hhs.gov/CLIA/> (last visited Mar.

review of the enabling statute makes it clear that this federal agency has not exercised oversight authority on ART applications. However, the clinics do operate under some form of self-regulation.¹²¹ Because they are not operating within fields classified as research, clinics are generally free to offer new applications and reproductive options, limited only by the practitioner's judgment. The demands of buyers, suppliers, and consumers drive this market. Consumer demand for fertility treatments, coupled with the ability of fertility clinics to develop new reproductive techniques, create strong incentives to offer new applications.¹²²

The CMS has some regulatory authority over medical clinics pursuant to the Clinical Laboratory Improvement Amendments of 1988 (CLIA).¹²³ The CMS has not used its powers under the CLIA, which sets standards for laboratory personnel, quality control, and quality performances to ensure proficiency requirements for molecular genetic testing.¹²⁴ This leaves fertility clinic labs in the self-regulating position of assuring the accuracy and validity of their own tests.

31, 2008) ("The Centers for Medicare & Medicaid Services (CMS) regulates all laboratory testing (except research) performed on humans in the U.S. through the Clinical Laboratory Improvement Amendments (CLIA). . . . The objective of the CLIA program is to ensure quality laboratory testing.").

121. See Note, *supra* note 44, at 578; see also Adamson, *supra* note 49, at 737-38.

122. See Note, *supra* note 44, at 578.

123. See Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (2000); see also Adamson, *supra* note 49, at 728; Christopher D. Zalesky, *Considering Changes to CMS'S National Coverage Decision Process: Applying Lessons Learned from FDA as a Regulator of Access to Healthcare Technology*, 57 FOOD & DRUG L. J. 73, 78 (2002) ("Medicare was established by an act of Congress in 1965. The Health Care Financing Administration (HCFA) (renamed CMS in 2001 by Secretary Thompson) was established in 1977 and is located within DHHS. CMS is responsible for the administration of Medicare and other programs." (footnotes omitted)).

124. See Gail H. Javitt, *In Search of a Coherent Framework: Options for FDA Oversight of Genetic Tests*, 62 FOOD & DRUG L. J. 617, 617 (2007) ("[T]he regulatory environment for genetic testing has not evolved as quickly as has the technology itself."); *Id.* at 624 ("Clinical laboratories, including those that use LDTs [(laboratory developed tests)], are regulated under the Clinical Laboratory Improvement Amendments of 1988, but such oversight focuses on the quality of the laboratory's overall operations and does not evaluate directly the safety and effectiveness of the individual tests performed. Moreover, CLIA has not been fully implemented with respect to genetic testing laboratories, despite the fact that CLIA was enacted to strengthen federal oversight of clinical laboratories and to ensure the reliability of test results." (footnotes omitted)); Empire Medicare Services, Part B NY News: National Government Services Top Claim Submission Errors, <http://www.empiremedicare.com/news/nynews07/062507ngs.htm> (last visited Apr. 11, 2008) ("Congress passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988, establishing quality standards for all non-research laboratory testing performed on specimens derived from humans for the purpose of providing information for the diagnosis, prevention, treatment of disease, or impairment of, or assessment of health. CLIA requires that laboratories performing these types of tests be certified by the Secretary of the Department of Health & Human Services (DHHS)."); see e.g., Zalesky, *supra* note 123, at

Of the three foregoing legislative enactments, the Fertility Success Rate Act,¹²⁵ coupled with the FDA's enforcement powers, provides the only available mechanism for possible meaningful regulation. The Fertility Success Rate Act grew out of a perceived need for a reporting system for consumers rather than a need for a regulatory oversight mechanism.¹²⁶ Congressman Ron Wyden, "[w]ith the support and active participation of the American Society for Reproductive Medicine (ASRM) and its affiliated society, the Society for Assisted Reproductive Technology," developed and passed the Fertility Success Rate Act, referred to as the Wyden Law.¹²⁷

As Dr. Adamson, chair of the National Committee Overseeing ART and a board-certified reproductive endocrinologist, surgeon, and director of Fertility Physicians of Northern California, said:

88 ("Congress enacted CLIA with an interest toward improving the quality of testing performed by clinical laboratories. Under CLIA, DHHS implemented various provisions relating to standards for quality control and determination of 'complexity' for certain commercial in vitro diagnostic products sold for use by clinical laboratories. DHHS delegated this responsibility to CMS. In turn, CMS and FDA agreed that FDA would perform 'complexity categorizations' required under regulations promulgated by CMS to implement CLIA. Under this agreement, FDA was simultaneously to review new laboratory tests for section 510(k) premarket clearance under the Federal Food, Drug, and Cosmetic Act and for complexity classification under CLIA." (footnotes omitted)); *see also* Javitt, *supra*, at 639 ("In addition to the absence of premarket review, there is also little postmarket oversight. While CLIA requires laboratories to be certified and inspected every two years, it does not assess the clinical validity of the tests offered by clinical laboratories; each laboratory director makes a decision about whether to offer a test. CMS officials in the CLIA program have repeatedly asserted that CLIA does not permit oversight of clinical validity. Even if the statute could be so construed, CMS's failure to implement regulations to ensure the analytical validity of genetic tests makes it unlikely, as a practical matter, that the agency would ever seek to regulate their clinical validity absent new legislation requiring it to do so." (footnotes omitted)).

125. Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. §§ 263a-1 to -7 (2000).

126. *See* 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 (July 21, 1999) ("The Fertility Clinic Success Rate and Certification Act of 1992 . . . was intended to provide the public with comparable information concerning the effectiveness of infertility services and to assure the quality of such services by providing for the certification of embryo laboratories."); *see also* Adamson, *supra* note 49, at 731 ("With the support and active participation of the American Society for Reproductive Medicine (ASRM) and its affiliated society, the Society for Assisted Reproductive Technology (SART), [Congressman Ron Wyden] developed and passed the Fertility Clinic Success Rate and Certification Act of 1992 . . ."); Daar, *supra* note 41, at 254-55 ("Congress has enacted just one law regulating the practice of reproductive medicine, the Fertility Clinic Success Rate and Certification Act of 1992. The Act was born out of a concern that fertility clinics were misleading prospective patients about pregnancy success rates in an era when reporting of such data was completely voluntary. . . . The goal of the Act's reporting provisions is to provide consumers with reliable and accurate information about individual clinics' pregnancy and 'take home baby' success rates." (footnotes omitted)).

127. *See* Adamson, *supra* note 49, at 731.

Overall, despite many difficulties in being the first “regulation” directly addressing ART in the United States, the FCSRCA has been considered a success by physicians, patients and the government. Implementation of the FCSRCA has improved over time, helped with research by SART and others, helped improve the clinical practice of ART, provided useful information to patients, and been used by the CDC for publication of papers regarding ART.¹²⁸

However, none of the ART-related statutes has the teeth of the National Donor Act or the prohibitions against selling of the Uniform Gift Transfer Act.¹²⁹

In the Congressional hearings prior to the passage of the Fertility Success Rate Act, none of the discussions involved commodification concerns related to the selling of reproductive tissues.¹³⁰ These Congressional debates are in sharp contrast with the testimony elicited around the passage of NOTA, where entire hearings seemed to revolve around commodification in the face of market forces.¹³¹ This silence around the issue of selling and purchasing

128. *Id.* at 732.

129. Neither the Fertility Success Rate Act nor the FDA provides the strong statutory authority or regulatory guidelines for prohibiting unethical conduct and enforcing rules and regulations comparable to those provided in NOTA. *See* 42 U.S.C. §§ 263a-1 to -7; Current Good Tissue Practice for Manufacturers of Human Cellular and Tissue-Based Products; Inspection and Enforcement, 66 Fed. Reg. 1508, 1542-43 (proposed Jan. 8, 2001) (codified at 21 C.F.R. pt. 1271); Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue-Based Products, 63 Fed. Reg. 26,744, 27,744 (proposed May 14, 1998) (codified at 21 C.F.R. pts. 207, 807, and 1271); *id.* at 26,745 (“Even today, FDA’s human tissue regulations do not address the infectious disease risk of donating, processing, and storing reproductive cells and tissue.”); *see, e.g.*, Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399a (2000); Lars Noah, *Assisted Reproductive Technologies and the Pitfalls of Unregulated BioMedical Innovation*, 55 FLA. L. REV. 603, 648-49 (2003) (“Until recently, the FDA had not asserted regulatory jurisdiction over IVF or other fertility procedures. Indeed, scholars who wrote about the regulation of ARTs had paid no attention to the agency, and, when Congress passed the Fertility Clinic Success Rate and Certification Act of 1992, it suggested no role for the FDA. Instead, it directed the CDC to collect information and to develop a model program . . .” (footnotes omitted)); *id.* at 650 (“Nonetheless, in 1998, the FDA announced, and subsequently reiterated, that its proposed rule governing cellular and tissue-based products would apply to ARTs as well . . .”); *id.* at 651 (“More controversially, however, the FDA also asserted jurisdiction over other aspects of ARTs, claiming that it had the authority to subject human reproductive tissues to premarket review—and to demand proof of their safety and effectiveness—in the event that they had undergone more than minimal manipulation.”).

130. *See* H.R. REP. NO. 102-624 (1992); S. Rep. No. 102-452 (1992), *as reprinted in* 1992 U.S.C.C.A.N. 2564. In fact, the FCSRCA contains the following provision: “In developing the certification program, the Secretary may not establish any regulation . . . which has the effect of exercising supervision or control over the practice of medicine . . .” 42 U.S.C. § 263a-2(i)(1).

131. *See* Crepsi, *supra* note 10, at 15 n.75 (“The Senate Report on NOTA merely stated: ‘It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation’ and ‘human body parts should not be viewed as commodities.’ The House Conference Report stated only that NOTA ‘intends to make the buying and selling of human organs unlawful . . .’” (citations omitted)).

reproductive tissue is as loud as the debates on the prohibitions of selling organs during those Congressional hearings.

G. Private Actors and Regulators

Fertility clinics, drug suppliers (hormonal), gamete middlemen (sperm banks, egg donor banks, and brokers), hospital fertility centers, and private practitioners all operate in a dynamic market. They provide services and goods to clientele seeking one ultimate goal: the birth of a baby.¹³²

The ART market creates the rules under which it operates without the need for excessive regulation. The fertility centers are free to compete, offer experimental or advanced technology, and arrange for the transfer or sale of reproductive material outside the regulatory control of the United States government. In this sense, they operate in the purest model of a free-market enterprise. The clinics also participate in the fertility marketplace through their membership in industry organizations.¹³³ These organizations represent the interests of their members by acting as advocacy groups and self-regulators, and, upon close examination, they appear to operate as lobbying groups on behalf of their membership.¹³⁴ These groups, with their collaborative arrangements with the medical suppliers and pharmaceutical companies, are the dominant forces in the ART marketplace.¹³⁵

132. See SPAR, *supra* note 3, at 195-233 (discussing the global market for babies).

133. See Adamson, *supra* note 49, at 735.

134. See What Is SART?, *supra* note 68 ("SART serves as the governmental watchdog for ART. Working in conjunction with the ASRM Public Affairs Office, members of SART have worked diligently to protect our patients and the practice of ART from inappropriate external intrusion and regulation. We have worked successfully to mitigate many of the somewhat onerous requirements that had been initially proposed by the Food and Drug Administration, including the need to quarantine all embryos derived from donor eggs.").

135. See Michael J. Malinowski, *A Law-Policy Proposal To Know Where Babies Come from During the Reproduction Revolution*, 9 J. GENDER RACE & JUST. 549, 550-53 (2006) [hereinafter Malinowski, *A Law-Policy Proposal*] (citing the need for regulations due to the experimental nature of ART, particularly in areas where experimentation and the practice of medicine are so intertwined); see also Adamson, *supra* note 49, at 735 (discussing the role SART and ASRM play in the market by actively lobbying for its members concerns); Donna M. Gitter, *Am I My Brother's Keeper? The Use of Preimplantation Genetic Diagnosis To Create a Donor of Transplantable Stem Cells for an Older Sibling Suffering from a Genetic Disorder*, 13 GEO. MASON L. REV. 975, 986 n.54 (2005-2006) ("Commentators have described the ASRM as 'the lead professional society issuing guidelines for reproductive medicine.'" (quoting Susan M. Wolf, Jeffrey P. Kahn & John E. Wagner, *Using Preimplantation Genetic Diagnosis To Create a Stem Cell Donor: Issues, Guidelines & Limits*, 31 J.L. MED. & ETHICS 327, 329 (2003))); Michael J. Malinowski, *Choosing the Genetic Makeup of Children: Our Eugenics Past—Present, and Future?*, 36 CONN. L. REV.

The American Society for Reproductive Medicine (ASRM) is the primary professional, nonprofit organization for the advancement of the art, science, and practice of reproductive medicine. ASRM, founded in 1944, is the leading market force in the field of reproductive medicine.¹³⁶ ASRM and the Society for Assisted Reproductive Technology (SART), a representative group, have worked to develop and create the Reproductive Laboratory Accreditation Program (RLAP).¹³⁷ This program established standards and performed on-site accreditation every two years for embryo laboratories.¹³⁸ Two-thirds of SART programs are accredited

125, 179-80 (2003) [hereinafter Malinowski, *Choosing the Genetic Makeup of Children*] ("George Annas, a noted bioethicist and law professor at the Boston University School of Public Health who serves on the Ethics Advisory Board of the Society for Assisted Reproductive Technology ('SART') and the American Society for Reproductive Medicine ('ASRM'), refers to assisted reproduction as 'the wild West' of American medicine. ART is poised at the intersection of a highly vulnerable and growing patient group willing to pay directly and expend considerable personal wealth for these services, and a sophisticated, highly competitive commercial sector engaged in aggressive DTC marketing. ART also provides an opportunity for medical professionals to enjoy professional autonomy and reap significant financial returns at a time when physician income and discretion are generally being checked by managed care." (footnotes omitted)); *id.* at 175 ("The alliance-based nature of biotechnology R&D, reflected in the extraordinary integration of biotechnology and pharmaceutical companies, and industry and academia through entanglements of alliance and collaboration agreements, has contributed to the pace of collective advancement in the field of biotechnology and its progeny fields"); Ouellette et al., *supra* note 55 (discussing ASRM and SART members and the collaborative working relationship they have with the CDC, an agency required to regulate the data reporting from the fertility clinics).

136. See American Society for Reproductive Medicine: History and Purpose, <http://www.asrm.org/history.html> (last visited Apr. 12, 2008).

137. See Ouellette et al., *supra* note 55, at 424-25 ("From 1992 to 2004, the responsibility for data collection rested largely on [SART], a private organization of ART clinical programs and an affiliate of the [ASRM]. . . . In 2004, the CDC announced a change in its data collection contractor and in approved data reporting systems for 2004-2008."); What Is SART?, *supra* note 68 ("SART has also worked in conjunction with the Centers for Disease Control, collecting and validating outcome data and requiring accreditation of embryology laboratories.").

138. See Adamson, *supra* note 49, at 732-33 ("SART and ASRM worked with the College of American Pathologists (CAP) to create the Reproductive Laboratory Accreditation Program in 1992. This program stated requirements and performed onsite accreditation every two years for embryo laboratories. Currently two-thirds of SART programs are accredited through this CAP/SART/ASRM program. The other one-third are accredited through New York State or through the Joint Commission on Accreditation of Healthcare Organizations (JCAHO)."); Malinowski, *A Law-Policy Proposal*, *supra* note 135, at 551-52 ("The CDC has contractually outsourced implementation of its responsibilities under the FCSRCA to the Society for Assisted Reproductive Technology (SART) and the American Society for Reproductive Medicine (ASRM)."); Ouellette et al., *supra* note 55, at 424 ("From 1992 to 2004, the responsibility for data collection rested largely on the Society for Assisted Reproductive Technology (SART), a private organization of ART clinical programs and an affiliate of the American Society for Reproductive Medicine (ASRM). SART has been keeping an ART success rate database since 1986." (footnotes omitted)); *id.*

through this program. SART works closely with the FDA in developing regulations and conducts compliance visits in conjunction with the FDA.¹³⁹ This close working relationship creates a question of suspect federal oversight. When coupled with the lack of public debate over ART regulation, the nonexistent federal regulatory framework in the fertility marketplace has to be examined in light of a "capture" hypothesis—where the administrative agency becomes "captive" to regulated entities rather than regulating in the best interests of the public.

at 425 ("SART requires its members to submit and verify annual ART success rate data and their other membership requirements. 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. . . . Regardless of whether they are SART members or not, federal law requires all ART clinics to report and verify ART success rate data annually." (footnote omitted)).

139. See Adamson, *supra* note 49, at 733 ("SART has also worked extensively with the FDA developing their recently enacted regulations."). Adamson, a board certified reproductive endocrinologist and Chair of the National Committee overseeing ART, states:

In addition to these activities with its members, both SART and ASRM have continued to cooperate with and lead initiatives with other organizations and institutions that are stakeholders in ART. These include the CDC, FDA, NIH, FTC, and members of Congress as well as professional organizations such as the American Medical Association (AMA), American College of Obstetricians and Gynecologists (ACOG), the American Bar Association (ABA) and consumer organizations, RESOLVE, the National Fertility Organization, and the American Fertility Association (AFA).

A significant initiative by SART was the development of the National Coalition for Oversight of the Assisted Reproductive Technologies (NCOART). This group started as a subcommittee of SART in 1996 with the mission of bringing together stakeholders in ART to serve as an inter-disciplinary body overseeing the provision of assisted reproductive technology services in the United States. . . . Members in NCOART's twice-yearly meetings are SART (co-chair), RESOLVE (co-chair), ASRM, CDC, FDA and FTC. . . . Although carrying no regulatory authority, NCOART has been an effective forum for the stakeholders in ART.

Id. at 735; see What Is SART?, *supra* note 68 ("The current FDA regulations do represent a work in progress, and SART and its members continue to interact constantly with appropriate officers of the FDA in an effort to make this process more efficient. We play a significant role in interacting with members of Congress and their staff regarding pending legislation which may have a direct impact on our practice. SART keeps its members apprised of relevant publications in the Federal Register through informational alerts via both fax and e-mail. Another organization, the National Coalition for Oversight of Assisted Reproductive Technology (NCOART) was organized by SART and meets on a scheduled basis in an effort to bring together representatives from SART, ASRM, the FDA, CDC, RESOLVE, AFA, the American Association of Tissue Banks, the American Bar Association, and others to discuss mutual issues or concerns. In this way, SART has been able to network effectively in a small-group setting with leaders of consumer groups, professional organizations, and government agencies to exchange ideas and share information and concerns on an ongoing basis."); see also Ouellette et al., *supra* note 55, at 424 ("Although the CDC took over publishing ART success rate reports in 1995, SART remained the driving force behind the CDC's publications." (internal footnote omitted)).

SART's Web site indicates that members include corporations such as Bayer, Merck, Wyeth, Lilly, Brown & Brown Insurance, Columbia Laboratories, Ferring Pharmaceuticals, Ortho Women's Health, Cook Medical, Dowden Health Media, DuraMed, Solvay Pharmaceuticals, and Edm-Serono-Inc.¹⁴⁰ This partial list includes sponsors who not only provide the hormonal drugs, products, and devices to fertility clinics, but who also participate in policy-making decisions of SART—a purported “self-regulating” entity.¹⁴¹

SART represents, by its own admission, eighty-five percent of clinics practicing ART.¹⁴² Members of SART are required to comply with ASRM and SART guidelines.¹⁴³ Failure to do so results in removal from membership in the organization, but no further sanctions are imposed.¹⁴⁴ SART is also extensively involved in data collection, practice guidelines and standards, government interaction, quality assurance, and research. The National Coalition for Oversight of Assisted Reproduction Technology (an outgrowth of these two groups) “brings together representatives from various government agencies and professional, legal, and consumer groups to discuss mutual issues.”¹⁴⁵

Compliance with reporting requirements is determined through on-site validation visits. “These validations are conducted in conjunction with CDC to determine whether the clinic has accurately reported the data required for the yearly report to the CDC.”¹⁴⁶ This self-regulation regime allows for experimentation and research within the clinic, but also fails to prevent a non-reporting clinic from operating. Therefore, violators can continue providing services to patients.

140. See SART, <http://www.sart.org/index.html> (last visited Apr. 12, 2008); see also American Society for Reproductive Medicine: 2007 Corporate Member Council, <http://www.asrm.org/Professionals/Membership/cmc.html> (last visited Apr. 12, 2008).

141. American Society for Reproductive Medicine: 2007 Corporate Member Council, *supra* note 140 (This information was originally on SART's Web site.).

142. What Is SART?, *supra* note 68 (“Our organization includes over 392 member practices, representing over 85% of the ART clinics in our country.”); see Moses, *supra* note 15, at 543 (“SART describes itself as ‘the premier organization of professionals dedicated to the practice of ARTs in the United States.’” (citation omitted)).

143. See Moses, *supra* note 15, at 544.

144. See *id.*

145. *Id.*; see also Adamson, *supra* note 49, at 735.

146. See Adamson, *supra* note 49, at 732 (“However, the CDC is not a regulatory body and does not have the authority to sanction nonreporters other than to report them as such. The results that are reported are validated randomly by annually selecting approximately 10% of the reporting clinics for onsite visits, and by review of the charts and telephone calls to patients to confirm birth outcomes of ART treatment.”).

Most fertility clinics are members of SART,¹⁴⁷ as can be seen from its corporate subscribers list, which is closely aligned with the pharmaceutical and biological products industry. Although this alignment may not be unethical or harmful, groups like SART certainly cannot provide for sufficiently objective review of these clinics in light of their corporate relations.

H. The Marketplace

In the fertility market,¹⁴⁸ the interplay between powerful, dominant participants and the economics of the law of supply and demand supports the conclusion that private enterprises avoided regulation based on (1) capture of administrative agencies by the dominant market players,¹⁴⁹ coupled with (2) the failure of society to address the ethical concerns of private research in ART. This failure occurred during the 1980s, when the politics of abortion and embryonic research effectively silenced the debate over assisted reproductive technology for infertility purposes, eliminated federal funding and oversight of embryonic research, and allowed the private infertility marketplace to develop.¹⁵⁰

For our purposes, dominance is defined as an attribute used to identify those entities whose presence through the purchase or sale of a good affects the supply and demand of a particular resource within a market through access to capital, infrastructure, technology, or

147. What Is SART?, *supra* note 68.

148. See Mahoney, *supra* note 17, at 204 ("The use of the term 'market' can cause misunderstandings similar to those engendered by the phrase 'property rights.' As the twentieth century draws to a close, confidence in the free enterprise system runs high, but enthusiasm for private ordering is tempered by support for the regulation of markets in many goods and services. To state that a market exists in a particular good should not be taken as an assertion that there is—or should be—a free-for-all of unregulated bargains. 'Market' simply denotes transfers for consideration, with buyers and sellers engaging in mutually beneficial exchanges. Many markets are, of course, heavily regulated, with the terms and conditions of permissible bargains between ready and willing participants curtailed. The prevalence of these regulated markets illustrates that the choice is not between a completely unrestricted exchange system on the one hand and a total absence of commercial activity in human tissue on the other." (footnotes omitted)).

149. See Alfred C. Aman, Jr., *Administrative Equity: An Analysis of Exceptions to Administrative Rules*, 1982 DUKE L.J. 277, 326-27 ("The capture doctrine posits [that] an agency [can be] ultimately dominated by the industry it sets out to regulate. The beneficiaries of the regulation—consumers, for example—are short-changed because the agency eventually puts the interests of the regulated ahead of the interests of those whom the agency was established to protect." (footnote omitted)).

150. See generally SPAR, *supra* note 3; Eggen, *supra* note 20.

skill.¹⁵¹ Dominant participants derive a benefit from either the supply side or the demand side of the market. Dominant market participants in the fertility marketplace include the medical providers, pharmaceutical and technological suppliers, and the infertile customers. Egg donors serve as the living resource for the marketplace. Much like the owners of cattle or livestock, the egg donors are paid for the care and husbandry of their tissue resources.

In a free market,¹⁵² the dynamics of supply and demand are resolved through the price mechanism. Everything has a price and buyers (demand side) obviously want the price to be lower, while sellers (supply side) want the price to be higher.¹⁵³ Changes in demand are affected by personal preferences, population shifts, prices of substitute goods and services, incomes, and forecasts of future prices. Changes in supply can occur because of changes in production capacity, technology, cost structure, prices of substitutes, and forecasts of future prices.¹⁵⁴

Shifts in supply and demand usually occur over lengthy periods of time. Recent shifts in population, delayed child bearing, for example, and the effect on infertility rates have all contributed to increased demand for fertility services. Shifts in supply can occur because of the advancement in technology, the increasing speed in which technologies are applied, and the effectiveness of technology transfer.¹⁵⁵ During the past decade, the fertility market underwent a

151. See Robert D. Cooter, *The Best Right Laws: Value Foundations of the Economic Analysis of Law*, 64 NOTRE DAME L. REV. 817 (1989) (describing the relationship between efficiency and other values underlying laws, and utilitarian functions within the framework of legal analysis). Cooter posits that "the criterion of Pareto efficiency is concerned with satisfying people's preferences." *Id.* at 824. He moves from a discussion of individualistic standards of values that satisfy the preference of individuals to a discussion of "[t]he social atomism of economics, which is 'self-evident' in the study of competitive markets, [and] extends to law and policy." *Id.* The most relevant point is his discussion of externalities. He argues that the extension of this analysis to externalities shows that "the model of perfect competition breaks down when utilities cannot be separated." *Id.* at 826.

152. See ADAM SMITH, *THE WEALTH OF NATIONS* (Aldine Press 1970); see also Alan Devlin, Note, *A Proposed Solution to the Problem of Parallel Pricing in Oligopolistic Markets*, 59 STAN. L. REV. 1111, 1116 (2007) ("Under perfect competition, every producer is a price taker; that is, each firm faces a horizontal demand curve and therefore cannot influence the price at which its good is sold by unilaterally reducing its output. Accordingly, marginal revenue always equals price." (footnote omitted)).

153. See WALTER J. WESSELS, *ECONOMICS* 41-47 (3d ed. 2000).

154. MILTON FRIEDMAN, *CAPITALISM AND FREEDOM* 4 (Univ. of Chicago Press 1962).

155. See SPAR, *supra* note 3, at 15 (citing the effect of delayed childbearing on fertility for the modern woman). "[F]emale fertility peaks at around age twenty-seven and then declines dramatically after thirty-five. . . . An average twenty-eight-year-old woman, for example, has a 72 percent chance of conceiving after a year of effort. An average thirty-eight-year-old, by contrast, has only a 24 percent chance." *Id.*; see also WESSELS, *supra* note

rapid change in the amount of technology available in assisted reproduction.¹⁵⁶ Although it is not immediately clear that this change actually lowered infertility rates, this technology change did help to fuel the increase in demand for services by increasing access to infertility treatment.¹⁵⁷

When the economy has a fixed amount of resources and the economy is using those resources efficiently, society can reap the optimal benefit from marketplace dynamics. Markets, however, can be inefficient as a result of misallocations of scarce resources.¹⁵⁸ In the market for infertility treatment, inefficiencies are often the direct result of decisions made by consumers and producers (e.g., delayed childbearing, artificial supply costs, and monopolies of suppliers).¹⁵⁹ Some economists argue that such decisions necessitate the availability of crucial information in order to ensure consumers are well-informed.¹⁶⁰ Consumers in the fertility marketplace need to know

153, at 52-53 (asserting an economic maxim that technological advances can shift the supply curve).

156. See generally SPAR, *supra* note 3.

157. See Moses, *supra* note 15, at 514 (presenting IVF as an example of "how a technology makes possible many new forms of conduct").

158. See MICHAEL ALLINGHAM, CHOICE THEORY: A VERY SHORT INTRODUCTION 3 (2002) ("The origin of . . . choice is desire and reasoning with a view to an end—this is why choice cannot exist without . . . reason"; or more concisely, 'choice is deliberate desire.' (quoting Aristotle)). Allingham explains choice theory as an exploration of what it means to be rational and, possibly, as a guide to making sensible decisions. *Id.* at 9; see also WESSELS, *supra* note 153, at 3. But see SMITH, *supra* note 152, at 398. Smith viewed competition as economically efficient and saw an "invisible hand" moving in the choices individuals made, which collectively worked to the greater good:

Every individual is continually exerting himself to find out the most advantageous employment for whatever capital he can command. It is his own advantage, indeed, and not that of the society, which he has in view. But the study of his own advantage naturally, or rather necessarily, leads him to prefer that employment which is the most advantageous to the society.

Id.

159. See generally SPAR, *supra* note 3; Moses, *supra* note 15, at 512 ("The introduction of IVF and the development of related techniques are examples of technological change."); *id.* at 508 ("Few technologies arrive unannounced and few remain unchanged over time. Technologies are not unaffected by the shift from new invention to widely used phenomenon. The development of techniques to facilitate the fertilization of human eggs or ova is no exception.").

160. See FRIEDMAN, *supra* note 154, at 4 ("[It] is the role of competitive capitalism—the organization of the bulk of economic activity through private enterprise operating in a free market—as a system of economic freedom and a necessary condition for political freedom."); *id.* at 12-13 ("The basic problem of social organization is how to co-ordinate the economic activities of large numbers of people. . . . Fundamentally, there are only two ways of co-ordinating the economic activities of millions. One is . . . the use of coercion The other is voluntary co-operation of individuals—the technique of the market place. The possibility of co-ordination through voluntary co-operation rests on the elementary—yet

about success rates, but they also need to know what applications are safe. They need to be informed of the possible hazards of any contemplated medical procedure. Ultimately, consumers and society need to be informed about the costs of any medical intervention. Information relating to the cost of externalities, which has an impact on supply and demand, needs to be available to both consumers and society in general.¹⁶¹

In the fertility market there is an imperfect amount of information available to the consumer. The marketplace is unregulated and operates without scrutiny from the usual regulatory oversight of enterprises that affect the health of citizens. It is almost impossible to discern whether the prices paid and the costs of the technology are beneficial or detrimental to society. Factor in the commodification issue(s) on the selling of eggs and the market has a serious downside: the true costs of the ART laissez-faire system remain unknown.

In an efficient market, market dynamics move the price and quantity of goods to a consistent equilibrium. At that point, producers are supplying the quantity that consumers are demanding. The free

frequently denied—proposition that both parties to an economic transaction benefit from it, *provided the transaction is bi-laterally voluntary and informed.*”).

161. See WESSELS, *supra* note 153, at 493-94; see also Michele Goodwin, *Assisted Reproductive Technology and the Double Bind: The Illusory Choice of Motherhood*, 9 J. GENDER RACE & JUST. 1, 16 (2005) (“[I]s that a real option when the results are that 65% of the women who undergo ART do *not* get pregnant? Only 34% of ART efforts result in clinical pregnancies, and the majority of patients will suffer miscarriages, abort, or simply will not conceive. ART patients who become pregnant suffer a higher incidence of miscarriages, Cesarean births, and fetal birth defects.” (footnotes omitted)). Goodwin, in hypothesizing whether the assisted reproductive technology is really a boon for our society, argues that decisions made utilizing a technology without adequate information on the benefits and the risks actually do not provide the consumer with a meaningful choice or viable options. She questions whether using ART is a viable option for the infertile consumer when the success rates of a pregnancy are not well known and often are not that favorable. *Id.*; see Alvaré, *supra* note 2, at 61 (“First, at the very least, the time has come to fund studies about the long term effects—physical, emotional, social—of collaborative reproduction on children.”). Alvaré argues for the protection of the children born of collaborative reproduction and contends that legislators should act to prevent the physical risk ART poses to children, whether the risk occurs at the embryonic or fetal stage. “Before any particular ART process ‘goes commercial,’ it should be more carefully scrutinized, and more animal testing should be conducted.” *Id.* Finally, Alvaré explores the need for more information prior to the utilization of ART selections and the impact of these selections on society.

This approach also necessitates the hard work of deciding the kinds of knowledge that should be available to intending parents, as well as the social implications of those categories of knowledge included. Should we include race? Health and disabilities? Education and employment? All of these categories are fraught with controversy.

Id. at 62.

marketplace is touted as indispensable to the achievement of political freedom. Consumers, though, are not often overly concerned with these "freedom" issues when demanding a good for their own use; the infertile consumer is concerned primarily with her ability to conceive a child at an affordable cost. Issues of commodification are not subjected to widespread public debate or discourse in the fertility industry. Rather, consumers and producers are subject to market forces relating to the demand and supply of viable eggs and sperm for reproduction.

Markets cater to those who have the money to spend. "Even in this era of enthusiasm for free markets, controversy rages over the appropriate boundaries of the free enterprise system—what should be for sale and what should be kept out of the domain of the market?"¹⁶² The price system gives an incentive to produce only the things that people are willing to pay for, and therefore, under a price system, resources are directed toward producing things for those who have money to spend. Within this framework, Professor Margaret Radin argues against commodification, not only of human body parts but also of eggs and sperm.¹⁶³ She refers to the entire placement or use of market rhetoric as commodification.¹⁶⁴ She argues that this market rhetoric for the sale of human reproductive tissue devalues not only the market users but society.¹⁶⁵

162. Mahoney, *supra* note 17, at 164.

163. Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1857 (1987) ("[T]he question [about commodification] asks about the appropriate relationship of particular things to the market, normative theories about the appropriate social role of the market should be helpful in trying to answer it."); *see id.* at 1937 ("To the extent that we must not assimilate our conception of personhood to the market, market-inalienabilities are justified."); *id.* at 1907 ("In my discussion of possible sources of dissatisfaction with thinking of rape in market terms, I suggested that we should not view personal things as fungible commodities. We are now in a better position to understand how conceiving of personal things as commodities does violence to personhood, and to explore the problem of knowing what things are personal." (footnote omitted)). Radin lists surrogacy and baby-selling as part of the contested reproductive commodification issues. *Id.* at 1852, 1856.

164. *Id.* at 1855 ("Market-inalienability often expresses an aspiration for noncommodification. By making something nonsalable we proclaim that it should not be conceived of or treated as a commodity. When something is noncommodifiable, market trading is a disallowed form of social organization and allocation. We place that thing beyond supply and demand pricing, brokerage and arbitrage, advertising and marketing, stockpiling, speculation, and valuation in terms of the opportunity cost of production." (footnote omitted)); *id.* at 1850 ("Something that is market-inalienable is not to be sold, which in our economic system means it is not to be traded in the market.")

165. *Id.* at 1917 ("Yet, taking a slightly longer view, commodification threatens the personhood of everyone, not just those who can now afford to concern themselves about it.")

A related problem with markets involves income and wealth inequity. A review of the self-regulating entities representing the suppliers (ASRM and SART) supports the proposition that there are substantial benefits available for the suppliers of technology and applications in the infertility marketplace.

The immediate problem with the current ART marketplace is that the social costs are largely invisible. We do not have sufficiently accurate information about ART and its effect on the children produced, the women involved in the selling of eggs, the gene pool, or the ethical implications of research lacking the benefits of public discourse. Without regulatory oversight, private parties have not chosen to publish statistical data or information addressing commodification issues, and therefore, numerous questions relating to the market remain unanswered. Does the alienability of human eggs reflect a moral position or a purely economical market stance?

In the United States, the fertility marketplace is currently operating without comprehensive governmental regulation or an extensive reporting system. It is unclear whether this market is truly efficient, or if hidden external costs exist.

I. Capture by Dominant Market Forces

Administrative agencies may be subject to “capture” by the very forces they are designed to regulate. The dominant market forces in ART include the fertility clinics, the physicians, the pharmaceutical companies, the suppliers, the representative organizations, the embryo laboratories, the gamete middlemen and brokers, and the infertile consumer. In the fertility industry, the governmental agencies receive very little input from Congress as to how to regulate.¹⁶⁶ Regulatory agencies (e.g., the FDA, CDC, and DHHS) are

166. See SPAR, *supra* note 3, at 51 (“In the fertility trade . . . private rules reign. The fertility centers themselves set the rules that guide their conduct, working under the auspices of the ASRM In the United States, at least, the federal government is essentially silent, offering only the merest of parameters: fertility centers must report their success rates to the Centers for Disease Control; they must abide by basic laws forbidding malpractice and fraud Outside these boundaries, the centers are free to operate and compete.”). Spar opines: “In most parts of the world, such oversight [national oversight] is already in place. In the United States, by contrast, federal regulation is minimal, confined to a single piece of legislation (the Fertility Clinic Success Rate and Certification Act of 1992) without any means of enforcement.” *Id.* at 34; see also Moses, *supra* note 15, at 542 (“The absence of formal government regulation does not mean that IVF is necessarily the Wild West of medicine. Various professional groups have imposed extra-legal standards relating to professional qualifications and the manner in which procedures ought to be carried out, as well as opinions on what is and is not acceptable.”).

free to develop close and collaborative relationships with the market stakeholders.

The capture hypothesis postulates that the regulatory agencies tend to be "captured" by the industry they regulate and act in the industry's behalf rather than the consumers' . . .

Often, when a regulatory agency is "captured" a price ceiling becomes a price floor forced upon consumers¹⁶⁷

The traditional model of agency behavior identified agencies as apolitical and viewed them as mere tools for implementing the legislative directives of Congress.¹⁶⁸ A revised pluralist model of agency behavior described agencies as "mini-legislatures," weighing the desires of various interest groups equally.¹⁶⁹ The capture theory underscores the proposition that the industries being regulated could actually become the controlling factors in administrative decision-making.¹⁷⁰

Scholars argue that capture theory requires at least three entities: an agency, a Congressional committee or group that oversees the agency, and a dominant interest group.¹⁷¹ "In order to secure favorable regulations, the interest group (so the story goes) will aggressively lobby committee members and provide support, financial or otherwise, for the members' reelection efforts. Those committee members will then pressure the agencies to enact favorable regulations."¹⁷² Ostensibly, "the rest of Congress will be largely oblivious to the activities of that committee and the agency, [and] this 'iron triangle' will inevitably cater to the interest groups' narrow desires to the detriment of the public interest."¹⁷³ Well-organized groups can exert a disproportionate influence over the regulatory process, partly because of their political capital and organizing capacities, and also because of the agencies' ultimate dependence on

167. WESSELS, *supra* note 153, at 428.

168. Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1669, 1669 (1975) ("The traditional model of American administrative law has been centrally concerned with restricting administrative actions to those authorized by legislative directives. Professor Stewart traces the development and disintegration of the traditional model"); *id.* at 1673 ("The requirement that agencies conform to specific legislative directives not only legitimates administrative action by reference to higher authority, but also curbs officials' exploitation of the governmental apparatus to give vent to private prejudice or passion.").

169. See Nicholas Bagley & Richard L. Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1284 (2006).

170. See *id.*; see also WESSELS, *supra* note 153, at 428.

171. Bagley & Revesz, *supra* note 169, at 1284.

172. *Id.*

173. *Id.*

good relations with them and on the information that only they can provide.¹⁷⁴

The traditional view of “capture” creates the specter of the “complicity of congressional committees.”¹⁷⁵ It also supposes that congressional committees are composed of persons who exert influence over the agency for the benefit of powerful industry entities.¹⁷⁶ In time, the committee exerts influence over the agency’s values, moving them away from the values of the elected officials and the concerns of the voters who pushed for a regulatory scheme.¹⁷⁷

The next generation of capture theorists posited another theory, sometimes called “interest group domination,” which “argued that regulatory capture was a pervasive pathology of the administrative state” and sought to invoke a public choice capture theory.¹⁷⁸ The explanations for this supposed pathology centered on how agencies worked with various interest groups to obtain information, political support, and guidance.¹⁷⁹ The more closely the agency worked with the groups for information, the more likely, theorists maintained, that capture would occur.¹⁸⁰

As two scholars argued, “‘narrow, well-organized groups’ will, on the whole, ‘capture’ agencies in order to pressure them to enact excessive regulation.”¹⁸¹ However, this viewpoint has been refuted by

174. See *id.* at 1285 (“Well-organized and tightly knit constituencies will inevitably have an organizational advantage over a dispersed public when it comes to providing ‘the two things that a political party needs: votes and resources.’ The political branches will therefore be more attuned to the interest of those narrow interest groups than to the desires of the general public. It follows that, ‘as a rule, regulation is acquired by the industry and is designed and operated primarily for its benefit.’” (footnotes omitted)); David Dana & Susan P. Koniak, *Bargaining in the Shadow of Democracy*, 148 U. PA. L. REV. 473, 497 (“According to ‘capture’ or ‘public choice’ political theorists, however, government regulation does not work this way in practice. Instead, well-organized interest groups—most notably the targets of prospective regulation—often work to secure provisions in regulatory statutes that leave key decisions in the hands of agency regulators. The interest groups then exploit their power with key legislators to secure case-by-case legislative interventions in agency decision making.” (footnote omitted)).

175. See Bagley & Revesz, *supra* note 169, at 1284-85; David B. Spence, *The Shadow of the Rational Polluter: Rethinking the Role of Rational Actor Models in Environmental Law*, 89 CALIF. L. REV. 917, 927 n.29 (2001).

176. Bagley & Revesz, *supra* note 169, at 1285.

177. *Id.*

178. *Id.* at 1285.

179. *Id.*

180. *Id.*

181. See *id.* at 1286 (“This view takes as its core assumption that ‘narrow, well-organized groups’ will, on the whole, ‘capture’ agencies in order to pressure them to enact excessive regulation. The villains of this story are environmental groups like the Sierra Club, labor unions like the Teamsters, and consumer advocacy groups like Public Citizen, all of whom are driven by their narrow ideologies and heedless of any costs to American

both scholars and empirical data alike. "A 1977 Senate Report concluded that regulated industries far outspent public interest groups in lobbying agency decisionmakers, with regulated industries sometimes lavishing anywhere between fifty and one hundred times as much as their public interest counterparts."¹⁸² The reality of an agency being captured by "pro-regulatory" public interest groups, resulting in the creation and implementation of a multiplicity of over-regulation because of capture, simply has not occurred.¹⁸³

Industry groups with the most at stake are more likely to organize because each individual member will have more at stake in avoiding overzealous regulation. Thus, public choice theory asserts that "smaller, better-organized, and better-financed industry groups" will be more successful at achieving group goals in Congress than larger "public interest" groups.¹⁸⁴

Currently, agencies, more frequently than not, utilize "the judgment of private firms they regulate" in order to achieve broad public goals.¹⁸⁵ The capture theory, as it has emerged and as it has been used to support the deregulation frenzy of the administrative agencies of the Reagan era, ignored the true realities of agencies.¹⁸⁶ The agencies were actually more susceptible to being captured by the industry or groups targeted for regulation than by their public interest counterparts.¹⁸⁷

industries. Through their superior organizational mettle, these ostensibly 'public-serving' groups prey on the sensibilities of warm-hearted but fuzzy-headed bureaucrats and congressmen to drive through regulations that are unnecessary, unwise, or simply too costly." (footnotes omitted)).

182. *Id.* at 1288. "Public choice theory, then, suggests that the large 'proregulatory' interest groups against which DeMuth and Ginsburg rail will be consistently outgunned in the legislative and regulatory process by smaller, better-organized, and better-financed industry groups." *Id.* at 1287.

183. *See id.* at 1284 ("[T]heories of agency overregulation often rest on faulty premises and are in any event no more plausible than alternative theories suggesting that agencies will routinely underregulate").

184. *Id.* at 1287.

185. *See* Kenneth A. Bamberger, *Regulation as Delegation: Private Firms, Decisionmaking, and Accountability in the Administrative State*, 56 DUKE L.J. 377 (2006).

186. *See* Bagley & Revesz, *supra* note 169, at 1262.

187. *See* David B. Spence & Frank Cross, *A Public Choice Case for the Administrative State*, 89 GEO. L.J. 97, 114 (2000) (describing a variant on the public choice theory of "capture," which "implicate[s] both values and information as determinants of preferences"). Spence and Cross suggest that the "capture theory focuses on information, suggesting that industry captures an agency by virtue of the pervasive presence of industry and *industry information* in agency policymaking proceedings over the long term." *Id.* This capture theory is largely based on the premise that "the general public eventually loses interest in agency policymaking, leaving only regulated interest groups to participate in the process," which results in the agency adopting the policy preferences of that interest group. *Id.* at 105 n.37.

The capture theory has long had its critics. Specifically, critics argued that the theory was overly simplified and failed to take into account true behavioral economics. Today, proponents of the public choice capture theory would be hard pressed to describe it “as a valid descriptive theory of bureaucratic behavior.”¹⁸⁸ Public choice theory today could actually support a finding of an alternate reality for agency capture. “[W]ell-organized industry groups that stand to gain from a reduction in burdensome regulations will normally provoke an *antiregulatory* response from the administrative state.”¹⁸⁹

The driving concern behind the public choice/agency capture theories remains viable. The concern is that when government officials are given substantial authority over a public issue to make and enforce policy decisions, and the agency group is insulated from the impact of a voting electorate, that agency group may be subjected to extensive pressure from groups that have a particularly strong interest in the consequences of its policy decisions.¹⁹⁰ The lack of regulation by the government of the fertility industry may be a result of both a capture syndrome leading to domination by the ART providers and suppliers, and a failure of the society to address the difficult and complicated issues raised by the new technologies. There are multiple competing and collaborating interests at play in the assisted reproductive technology marketplace.

In the ART marketplace there is scant regulatory control over the provision of services to the public. The medical providers, through their associative organizations (e.g., ARSM and SART), proclaim their affinity for the non-regulatory state of affairs on their Web sites.¹⁹¹ The medical providers also advertise their associative arrangements with the providers of relevant pharmaceuticals and medical technology.¹⁹² Based on the dominant positions of the stakeholders, it

188. *Id.* at 121-22; see also Bagley & Revesz, *supra* note 169, at 1288-89 (“A litany of studies all support the conclusion that ‘regulated parties enjoy much greater presence in agency decisionmaking than do public interest groups and other outside parties.’ Taken together, these studies provide overwhelming empirical support for our theoretical conclusion that if any group has disproportionate access to the administrative state, it is industry.” (footnote omitted)).

189. Bagley & Revesz, *supra* note 169, at 1286.

190. See Mark C. Niles, *On the Hijacking of Agencies (and Airplanes): The Federal Aviation Administration, “Agency Capture,” and Airline Security*, 10 AM. U. J. GENDER SOC. POL’Y & L. 381, 390 (2002) (describing capture as occurring “when a regulated entity—like a large corporation, or more likely an association of corporate interests—succeed, through lobbying or other influential devices, in replacing what would otherwise be the public-policy agenda of the agency with its own private and self-serving agenda”).

191. See SART, *supra* note 140.

192. See *id.* The medical providers are the members of SART and ASRM, the reproductive fertility specialists. The SART Web site contains the names of some of their

is patently clear that strong regulatory control through agency oversight has been usurped by the market participants. The close collaborative working relationships between the agencies and the medical providers in clinical reporting and reviews underscore the influence of the medical providers.

Administrative agencies frequently utilize the judgment of private firms under their regulatory control to achieve public goals and agency legislative mandates. Such regulation can include identifying and reducing risks derived from the storage of financial data and reducing risks related to homeland security.¹⁹³ Broad public policy goals with complex and complicated methods of production are increasingly implemented with wide discretionary outcomes and deference to private firms as to how to interpret and achieve those goals.¹⁹⁴

Such discretion may appear well-suited for complicated societal goals where specific rules often cannot reflect the large number of variables involved in achieving multi-faceted regulatory goals. Allowing private firms such discretion and opportunity to interpret compliance control may be efficient. As one scholar of administrative law stated: "Traditional regulation seeks to achieve particular outcomes by articulating, *ex ante*, universal rules requiring certain conduct or particular technology. Such command-and-control regulation conveys little discretion to regulated parties in implementation; they can either comply with the regulatory requirements, or fail to do so."¹⁹⁵ However, there are drawbacks to this type of regulation. "This type of regulation proves less operative when regulatory goals are more complex. Specific rules often cannot reflect the large number of variables involved in achieving multifaceted regulatory goals, such as reducing the types of risk produced by a combination of factors."¹⁹⁶

The ART marketplace is lightly regulated with a close collaborative relationship between the federal regulatory agencies and the dominant industry groups. The issues involved in the reproductive technology field are multi-faceted. The questions swirling around the technology, the resources, the ethical implications, and the costs are complicated and lack easy solutions.

pharmaceutical providers. I am referring to the 'clinics' and fertility experts who are members of SART as the medical providers for the infertile customer seeking to have a baby.

193. See Bamberger, *supra* note 185, at 377.

194. See *id.*

195. *Id.* at 386.

196. *Id.* at 386-87.

The alignment of the federal regulatory agencies and the dominant ART players may well have its origin in the complexities of the technology and the need for information exchange, particularly when, initially, the political climate had all but eliminated federal oversight and participation in the reproductive research area. The current lack of regulatory control in the ART marketplace seems highly unusual today in light of emergent technologies.

Economists, on the other hand, like to assert that the ordinary individual makes her selections based on a set of rational self-motivating interests.¹⁹⁷ The rational purchaser of eggs will be motivated by her self-interest in a successful outcome. The rational private market supplier of ART will be motivated by its self-interest in generating a profit and in sustaining the marketplace.¹⁹⁸ Thus, it would be logical to assume that the private, dominant market suppliers in ART would be motivated by their self-interest to influence agencies to regulate for the suppliers' benefit. Or, at least, they would arguably push the agencies to avoid "over-regulation" to enhance their market interests.

The current lack of regulation posits more questions for society. If we assume that a specific technological application has a benefit to society, then collectively, as rational decision-makers, we should seek the maximum benefit (*Mb*) of any application of this specific technological advance. To attain *Mb* from the purchase of the application, the infertile consumer wants to achieve a successful outcome at a price she can afford.

197. See Terry L. Anderson, *Markets and the Environment: Friends or Foes?*, 55 CASE W. RES. L. REV. 81, 81 (2004) ("From this analysis follows one of the main tenets of economics: if the marginal benefits are greater than the marginal cost, do it.").

198. See Kathleen Bawn, *Choosing Strategies To Control the Bureaucracy: Statutory Constraints, Oversight, and the Committee System*, 13 J.L. ECON. & ORG. 101 (1997) (discussing marginal benefits and costs of agency action); Steve P. Calandrillo, *Responsible Regulation: A Sensible Cost-Benefit, Risk Versus Risk Approach to Federal Health and Safety Regulation*, 81 B.U. L. REV. 957, 980-81 (2001) ("Economics scholars have devised several tools in the attempt to measure economic efficiency and social welfare. Among the most popular of the various concepts is that devised by Nicholas Kaldor and J.R. Hicks. Kaldor-Hicks efficiency and the corresponding Hicks Compensation Principle acknowledge that there will be 'winners' and 'losers' resulting from any government regulation. The relevant question is whether the gain to the winners outweighs the losses to the losers such that the winners could potentially compensate the losers and still be better off. If the answer to that inquiry is yes, the regulation is deemed to be Kaldor-Hicks efficient. Most economists would say that society is 'better off' with that regulation in place because the size of the nation's overall pie has been expanded, even though some people or groups are left worse off. . . . Thus, in the regulatory context, striving for efficiency generally means that the overall social welfare created by a federal safety regulation should be greater than that existing before the government intervention." (footnotes omitted)).

We all can assume that any new emergent technology carries with it attendant costs. The technologies discussed at the beginning of this article all brought tremendous benefits, but all had attendant costs for their production and introduction into our society. The true costs of an application of technology for an individual look something like this:

$$\text{Total Costs} = \text{Costs (To Individual)} + \text{Costs (To Society including externalities)}$$

So the *Mb* to be obtained has to equal a successful outcome minus the total costs:

$$Mb = \text{Successful Outcome} - \text{Total Costs}$$

$$Mb = SO - \text{Total Costs}$$

$$Mb = SO - [\text{Costs (To Individual)} + \text{Costs (To Society including externalities)}]$$

As long as the marginal benefit to an individual is equal to or greater than the benefit from a successful outcome minus the total costs, the individual should acquire or utilize the new or emergent technology. The same should hold true for a profit-maximizing dominant market participant: as long as the marginal benefit from the use of the technology is greater than or equal to the successful outcome of its use minus the costs, the dominant market participant should use the technology.

This overly simplistic equation should express a salient point for consideration: what happens if the equation is incomplete? If the costs to society are not transparent or the externality costs are not included, then the required calculation cannot be made. If the calculation of the successful outcome should be a derivative of societal norms (which have not been assessed) and the calculation of marginal benefit should include an assessment of the donor or the costs of commodification of the donor's eggs, then the equation is incomplete and possibly invalid.

The collaborative arrangement between the dominant market interests, the infertile consumer, and the government creates information deficits. The asymmetries of information produce an inefficient marketplace. The costs to society and to the individual are not apparent in any calculation of maximum benefit to society or marginal benefit to the consumer. Thus, any decisions based on the available information are flawed due to a lack of completeness. At the same time, society at large has a stake in avoiding commodification of the human being. Yet this approach leaves very little room for a discourse about the marketplace itself or the costs to society.

The infertile consumer is a dominant stakeholder in this market. Consequently, the buying and selling of gametes from women raises serious ethical concerns about commodification. There are also societal interests involved in (1) avoiding the exploitation of the anxious or desperate infertile consumer, and (2) ascertaining the ethical implications of the exploitation of life forms (e.g., the embryonic or reproductive material).

II. CONCLUSION

The question of why egg selling exists may be answered by an examination of the governmental and societal failures to address and respond to ethical issues that arose when ART technology was new and developing. Advancing technology offered tremendous possibilities for life-altering happiness and improved health at the beginning of the twentieth century. In the mid-1980s, the government and society failed to address ART and its ethical implications in the private sector adequately. A political position against embryonic stem cell research precipitated the withdrawal of federal governmental funding and oversight from much of the research and application in the fertility industry. As a result, private fertility enterprise continued its research largely unsupervised and aligned itself with suppliers and technological producers. The convergence of the self-interests of the suppliers and the dominant market forces currently operates to create a situation of agency capture that has precluded governmental regulatory scrutiny of the marketplace. Additionally, states have also neglected to enter into the regulation of the reproductive marketplace. Without societal scrutiny or regulatory intervention, the marketplace remains open for business, but consumers remain vulnerable due to information asymmetries that only effective regulation can overcome.

