Avoiding EMBRYOS “R” US: Toward a Regulated Fertility Industry

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I. INTRODUCTION

Envision a couple discovering that their embryos, stored in a fertility clinic for future implantation, have been sold for research purposes without their consent. Or worse, that the fertility clinic sold or gave their embryos to another couple—a couple that has now birthed the unwitting donors’ biological child. Federal oversight addressing the disposition of embryos is nearly nonexistent, making the opportunity for such scenarios to occur uncomfortably likely, with little legal recourse for the harmed couple.

Assisted reproductive technology (“ART”) has created a booming fertility industry. One ART method has given couples the possibility to have biological children through implantation of embryos created outside the womb. With this advancement come many opportunities for misuse or inappropriate disposition of human embryos. This Note proposes that the utilization of human embryos and the organizations that hold them should be closely regulated to ensure that the parents of an embryo are the ones who decide the embryo’s final disposition and are protected from exploitation.

In Part II, this Note will examine embryo donation and current regulations. Because the ethical issues surrounding human embryo...
procurement are similar to issues in organ or tissue procurement, statutory regulations of organ and tissue procurement provide a useful framework for the creation of embryo donation policies and regulations. Thus, Part III will discuss organ procurement and its regulations while Part IV will do the same for tissues. Part V analyzes the impact of following either system in the context of human embryo procurement. Finally, Part VI proposes recommendations for regulating human embryo procurement that protect both donor and embryo.

II. EMBRYO PROCUREMENT AND REGULATION

A. Procurement of Embryos

ART is used to implant human embryos, fertilized outside the woman’s womb, into a woman for a couple to birth a biological child. To create a human embryo, a female egg and male sperm are joined through in-vitro fertilization (“IVF”) prior to implantation. This method is normally used if a couple is unable to conceive naturally. When sperm and egg are successfully joined, the resulting embryo is the genetic offspring of the couple. The number of human embryos produced through an ART process often exceeds the “number that can be prudently transferred to the patient at one time.”

Couples can store non-transferred human embryos through

5. See Society for Assisted Reproductive Technology, Assisted Reproductive Technologies, http://www.sart.org/Guide_AssistedReproductiveTechnologies.html (last visited Apr. 7, 2008) (“[ART] includes in vitro fertilization embryo transfer (IVF-ET), gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer (ZIFT), tubal embryo transfer (TET), and frozen embryo transfer (FET)” and “[t]hese techniques also apply to oocyte donation and gestational carriers.”).

6. ASRM: Frequently Asked Questions About Infertility, http://www.asrm.org/Patients/faqs.html#Q5 (last visited Apr. 7, 2008) [hereinafter ASRM: FAQ]. IVF bypasses the fallopian tubes and implants the embryo directly into the woman’s uterus. Id. The approximate cost for such a procedure is $12,400. Id. IVF accounts for about 99% of ART procedures. Id.


8. ASRM: FAQ, supra note 6.

cryopreservation for future pregnancies.\textsuperscript{10} Almost all cryopreserved embryos are kept at the couple’s fertility clinic, unless storage space is lacking or necessity dictates otherwise.\textsuperscript{11}

Human embryos may be donated directly or anonymously.\textsuperscript{12} Unlike other human reproductive products that are required by the Food and Drug Administration (“FDA”) to be screened and quarantined prior to donation, the FDA exempts most testing requirements for embryos and oocytes used for reproductive services originating between sexually intimate partners.\textsuperscript{13} Cryopreserved embryos are able to be used for the patient’s fertility treatment,\textsuperscript{14} donated to research\textsuperscript{15} or another patient,\textsuperscript{16} destroyed, or used for quality assurance purposes.\textsuperscript{17} Potential parents are usually encouraged to sign pre-procedural agreements indicating their
selection between the alternatives. 18 If a couple did not create such an agreement and cannot be contacted, the cryopreserved embryos are considered abandoned. 19 In such cases, fertility clinics continue to cryopreserve the embryos or destroy the abandoned embryos. 20 The total number of cryopreserved embryos in United States fertility clinics is estimated to be approximately 400,000. 21

Explosive interest in embryonic stem cell research and desperate couples desiring to have a birthed child give cryopreserved embryos real economic value. 22 In fact, purchasing an embryo may be much less expensive than undergoing the entire fertility process. 23 Unlike tissue and organs donation, embryo donation is largely unregulated and easily manipulated by a highly profitable fertility industry, 24 which currently rakes in $3.3 billion dollars annually. 25 At most, states like California provide some protection against embryo misappropriation without parental consent. 26

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19. Id. The ASRM ethics committee opined that an embryo can be considered abandoned if “more than five years have passed since contact with a couple, diligent efforts have been made by telephone and registered mail to contact the couple at their last known address, and no written instruction from the couple exists concerning disposition.” Id. at S253.
21. Hoffman, supra note 9, at 1068.
22. E.g., Rob Stein, ‘Embryo Bank’ Stirs Ethics Fears: Firm Lets Clients Pick Among Fertilized Eggs, WASH. POST, Jan. 6, 2007, at A1, available at http://www.washingtonpost.com/wp-dyn/content/article/2007/01/05/AR2007010501953.html. Abraham Center of Life charges $2,500 per embryo for embryos that are tailor-made, which have an increased value. Id.
23. Id. Even with implantation costs, purchasing an embryo would be cheaper than the average cost of going through in vitro fertilization. Id.
26. See CAL. PENAL CODE § 367g (West 2007). California’s misappropriation law was a result of the University of California, Irvine, Center for Reproductive Health fertility scandal. Melanie Blum, Embryos and the New Reproductive Technologies, http://www.surrogacy.com/legals/embryotech.html (last visited Apr. 7, 2008). Physicians at the fertility clinic thawed and implanted embryos into other couples without parental knowledge or consent. Id. As many as five-hundred couples may have been victims of embryo misappropriation through sale or transfer without permission. Id. California’s legislators responded by passing § 367g. Id. See generally Judith D. Fischer, Misappropriation of Human Eggs and Embryos and the Tort of
B. Existing Regulations of Embryo Procurement

Few statutes address human embryo procurement. Most pertain to either the legal status of embryos or the rights of a husband, wife, or other party to legal custody of a cryopreserved embryo in the event of divorce, death, or other circumstance. Custodial rights of these parties are often governed by contract law. However, at least two states have forbidden monetary compensation for embryos.


27. Id. at 392. See Alvare, supra note 24, at 25–35.

28. See, e.g., Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992) (concluding “that preembryos are not, strictly speaking, either ‘persons’ or ‘property,’ but occupy an interim category that entitles them to special respect because of their potential for human life” and that parents do not have a property interest, per se, but rather have an interest in ownership because of their “decision-making authority concerning disposition of the preembryos, within the scope of policy set by law.”). Louisiana is the only state that explicitly includes embryos, including those created through ART, as a judicial person. La. Stat. Ann. § 9:124 (2006). See also Planned Parenthood v. Casey, 505 U.S. 833, 869 (1992) (finding that the State has the power to restrict abortions after fetal viability, which indicates that personhood probably begins after a fetus is viable); Roe v. Wade, 410 U.S. 113, 162 (1973) (concluding that the term “person” does not include the unborn fetus); Susan L. Crockin, Commentary, What Is an Embryo?: A Legal Perspective, 36 Conn. L. Rev. 1177 (2004) (critically analyzing and discussing Dr. Kiessling’s What Is an Embryo?); John A. Robertson, In the Beginning: The Legal Status of Early Embryos, 76 Va. L. Rev. 437, 450–55 (1990) (discussing the legal status of embryos).

29. See In re Marriage of Witten, 672 N.W.2d 768 (Iowa 2003) (holding that agreements entered into at the time IVF is commenced are enforceable and binding, subject to the right of either party to change his or her mind regarding disposition of embryos and if donors cannot reach a mutual decision on disposition, then no transfer, release, disposition, or use of the embryos can occur without the signed authorization of both donors); A.Z. v. B.Z., 725 N.E.2d 1051 (Mass. 2000) (holding that an ex-husband’s interest in avoiding procreation outweighed a wife’s interest in having more children using cryopreserved embryos, and public policy dictates that husbands not be forced to become parents against their will); J.B. v. M.B., 783 A.2d 707 (N.J. 2001) (holding that ordinarily the party wishing to avoid procreation should prevail); Kass v. Kass, 696 N.E.2d 174 (N.Y. 1998) (stating that parties should be encouraged to specify their wishes in writing for issues such as reproductive choice and the court should enforce the advance agreements by using the plain meaning of the document); Litowitz v. Litowitz, 48 P.3d 261 (Wash. 2002) (holding pre-embryos would be thawed as stated in the cryopreservation contract with the fertility clinic). Current precedent has recognized that the rights to procreate and to not procreate are significant, but generally the party that does not want to procreate is afforded protection. Id. See also Ellen Waldman, The Parent Trap: Uncovering the Myth of ”Coerced Parenthood” in Frozen Embryo Disputes, 53 Am. U. L. Rev. 1021 (2004) (discussing cases about the disposition of cryopreserved embryos, and whether the judicial precedent of avoiding unwanted genetic links between adults and biological children at all costs is appropriate).

30. See Kass, 696 N.E. 2d at 180. Common law principles of contract should be used to determine the intent and plain meaning of advance directive writings by the pro-genitors. Id.
altogether, over half of the states have restricted sale of human embryos for research, and one state explicitly allows the sale of embryos.

Fertility clinics offering ART are under very few statutory regulations regarding the creation, storage, or profit-making capabilities of the human embryos created in their clinics. Even the Fertility Clinic Success Rate and Certification Act, passed by Congress to require fertility clinics to publish their pregnancy success statistics and certify laboratories handling embryos, does not give investigators authority over clinical practices. The few standards that do exist are mostly derived from research review boards or non-binding ethics committee guidelines.


35. Id. See ENCYCLOPEDIA OF REPRODUCTIVE TECHNOLOGIES 320–22 (Annette Burfoot ed., 1999) (Fertility Clinic Success and Certification Act has little control over any medical aspect of ART in fertility clinics).

36. See American Society for Reproductive Medicine, http://www.asrm.org (last visited Apr. 7, 2008). The American Society for Reproductive Medicine ethics committee has created minimum guidelines for consent. Ethics Committee of the American Society for Reproductive Medicine, Donating Spare Embryos for Embryonic Stem-Cell Research, 78 Fertility & Sterility 957, 959 (2002). First, the consent process “should inform donors of the nature of embryonic stem cell derivation” and information about the research project, its potential commercial and medical applications, and confidentiality policies. Id. Second, the decision to donate embryos for research should occur after infertility needs are met or after discontinuation of therapy, unless the couple has explicit written instructions for future use of embryos. Id. at 959–60. Third, a person other than the fertility treatment specialist should make any request for donations and make clear that it is not necessary for continued medical care. Id. Individuals requesting donation should make clear that the embryos will not be transferred to a woman’s uterus and reveal any financial incentives for the research. Id. Fourth, embryos “should not be bought or sold with a monetary exchange” but “[r]easonable fees may be charged for laboratory processing or for handling, storage, or transport of embryos.” Id.
III. ORGAN DONATION AND REGULATION

A. Organ Procurement Process

Organ transplantation is an established medical practice giving many transplant recipients a chance for an otherwise impossible life. Organs can be donated by both the living and the deceased and is a voluntary decision. Living donors are often blood relatives who donate one or more of their organs to a family member. Decedent donors enter the organ donation process after they are declared brain dead. Once brain death occurs, an organ donation specialist comes to the treatment facility and determines whether the decedent would be a good candidate for organ donation. If so, the specialist then speaks to the decedent’s family about the possibility of organ donation. If the family decides to donate, then the decedent’s vital statistics are entered into a national registry to match the decedent’s organs to transplant recipients.

41. Id.
42. Id. See also Brian Vastag, Need for Donor Organs Spurs Thought and Action, 287 JAMA 2491 (2002) (discussing ideas of how to increase organ donation through use of presumptive scripts educating mourning families about the value of donation).
Families choose to donate for a variety of reasons, often because they derive comfort from the thought that their loved one’s body can be used to help others. The transplant recipient’s surgery team will then remove the organ(s) from the donor and transplant them into the recipient. Organ transplantation has become increasingly successful over the years, giving life to many who would otherwise not recover from life-terminating or debilitating illnesses.

**B. Organ Transplantation and Donation Law**

1. National Organ Transplantation Act

The donation of heart, kidney, pancreas, lungs, liver, and any other human organ specified by regulation as a solid organ is federally regulated under the National Organ Transplant Act (“NOTA”), enacted in 1984. NOTA heavily regulates the organ procurement industry, stipulating the methods of procurement, storage, and allocation of organs. NOTA criminalizes the sale of any human organ or tissue for profit. Violators face up to $50,000 fees and a maximum of five years in prison.

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45. Life Gift, supra note 40.
50. Id.
In addition to several other provisions,\textsuperscript{51} NOTA created the Organ Procurement and Transplantation Network (“OPTN”), a national network facilitating organ donations around the country.\textsuperscript{52} OPTN matches organ donors with a patients’ need for organ transplantation through an established allocation system.\textsuperscript{53} To do so, OPTN uses organ procurement organizations (“OPO”), which are certified non-profit, tax-exempt entities, with stringent guidelines for oversight and implementation.\textsuperscript{54}

OPOs identify organ donors, recover and process the organs, and prepare them for transplantation.\textsuperscript{55} Each OPO is designated to cover a particular area of the United States with a total of fifty-eight OPOs throughout the country.\textsuperscript{56} The Department of Health and Human Services (“DHHS”) designated the United Network of Organ Sharing


\textsuperscript{53} 42 U.S.C. § 274(b)(2) (2000); \textit{Dead Bodies}, supra note 51. Potential transplant recipients are first ranked according to objective medical criteria such as blood or tissue type, size of organ, medical urgency, and time already spent on the waiting list. OPTN: Organ Procurement Transplantation Network, Donation and Transplantation, http://www.optn.org/about/transplantation/transplantprocess.asp (last visited Apr. 7, 2008). Then potential recipients are ranked according to policy criteria that differ for each type of organ. UNOS, supra note 43. See also United Network for Organ Sharing: Organ Donation and Transplantation, http://www.unos.org/PoliciesandBylaws/policies.asp?resources=true (last visited Apr. 7, 2008).

\textsuperscript{54} 42 U.S.C. § 273 (2000). An OPO must prove its ability to maintain fiscal stability, must be certified every four years, and must have a defined service area sufficient to assure maximum effectiveness with staff able to complete such requirements to become a member of the Organ Transplantation Network. \textit{Id.} OPOs must also have an advisory board composed of members representing (a) hospitals, tissue banks, and voluntary health associations; (b) the public; (c) physicians in the field of histocompatibility; (d) physicians with a speciality in neurology; and (e) a surgeon who has knowledge of organ transplantation with the authority to recommend procedures for organ procurement and transplantation. \textit{Id.}


\textsuperscript{56} Katz, supra note 55, at 955.
(“UNOS”)\textsuperscript{57} to become the private non-profit organization that maintains OPTN.\textsuperscript{58}

2. Uniform Anatomical Gift Act

Although the method of procurement is federally regulated, the post-mortem process of donation is governed by individual states. All fifty states and the District of Columbia have enacted some version of Model Uniform Anatomical Gift Act (“UAGA”).\textsuperscript{59} Unlike the guidelines of NOTA, which are limited to organ procurement in practice, the UAGA also includes tissue donation.\textsuperscript{60} UAGA’s purpose is to overcome competing interests standing in the way of anatomical gifts at the time of death and increase the number of anatomical donations through policy-made incentives.\textsuperscript{61} It does so by setting standards of documentation for medical professionals to follow in the event of a death and to provide guidelines for gaining consent for organ and tissue procurement.\textsuperscript{62} Like NOTA, UAGA provides significant guidance to OPOs through regulations and oversight.

C. Organ Sales of Living or Deceased Donors is Inappropriate

With both living and deceased donors, procurement of organ donations raises ethical concerns.\textsuperscript{63} For living donors, the risks of a

\textsuperscript{57} UNOS, supra note 43.

\textsuperscript{59} UNIFORM ANATOMICAL GIFT ACT (amended 2006), 8A U.L.A. (Supp. 2007). This statute was first promulgated in 1968, revised in 1987, and most recently amended in 2006. Id.

\textsuperscript{60} Compare id, prefatory note (referring to organ, eye, and tissue donations) with 42 U.S.C. § 274b(d)(2) (2000) (referring only to organ donations).

\textsuperscript{61} UNIFORM ANATOMICAL GIFT ACT prefatory note.

\textsuperscript{62} Id. See also Richard Perez-Pena, Turning the Grief-Stricken Toward Organ Donation, N.Y. TIMES, Jan. 16, 2007, at B1 (noting that the number of New York organ donors has increased by training nurses to talk to grieving families about donation).

\textsuperscript{63} See also David I. Flamholz, Note and Comment, A Penny for your Organs: Revising New York’s Policy on Offering Financial Incentives for Organ Donation, 14 J.L. & Pol’y 329, 339–40 (2006); Michele Goodwin, Altruism’s Limits: Law, Capacity, and Organ Commodification, 56 RUTGERS L. REV. 305 (2004) (addressing organ and tissue donation and the limits of altruism and the subsequent private (illegal) donation processes that abound, and also comparing slavery to organ procurement programs).
serious medical procedure and the harm inflicted by the actual donation process weigh against medical professionals’ duty to not harm their patients. In addition, the use of living donors may create incentives to take advantage of individuals who are poor, desperate, young, or mentally incompetent and incapable of truly consenting to such a procedure. Because of the ethical issues surrounding living donors, deceased donor organ transplantation is the preferred method of donation, despite its own ethical issues such as organ shortage. However, in 2004 and 2005, the number of living donors exceeded deceased donors. As a result of lawmakers’ response to significant fears, particularly with respect to living donors, organ procurement and donation agencies in the United States are legally required to be non-profit entities and are absolutely prohibited from selling organs.

1. Selling Organs Devalues Intrinsic Human Worth

The sale of organs places economic value upon human body parts. The widely held belief that selling human body parts promotes devaluation of an individual’s personhood and intrinsic

64. Flamholz, supra note 63, at 339–40 (discussing ethical concerns for organ donation from living and deceased donors).
66. Flamholz, supra note 63, at 341–42.
68. See supra notes 47–50 and accompanying text. One commentator has found five reasons to prohibit organ sale: (1) It causes harm to organ vendors; (2) Free donation expresses and promotes social solidarity, while allowing paid donation damages these values; (3) Organ donor consent is likely to be invalid; (4) Prospective organ vendors would be coerced into selling their organs; and (5) Organ vendors would be exploited. STEPHEN WILKINSON, BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE 103 (2003). This Note will only focus on the effect of commodification on society’s view of the human body, undue influence and the validity of consent, and equitable dispersing of organs.
69. Id. at 101–07.
value led to the non-profit status of OPOs. Organ commodification encourages separating human bodies from our personhood, identity and personality and result in “strip[ping] the human body of its proper dignity” because human beings automatically connect bodies to “human personality and identity.” Payment for human organs threatens the basic principle that individuals should not become fungible products that are used to benefit others. Commodification would result in potential organ recipients—and the donors (dead or alive) themselves—viewing the donor as mere body parts to be sold or procured for personal gain. At the very least, organ sale symbolically violates personhood. As a result, many international

70. Fred H. Cate, Human Organ Transplantation: The Role of Law, 20 IOWA J. CORP. L. 69, 80 (1994). Cate states,


71. For example, "An attacker cannot plausibly plead: 'I did not intend to hurt you, but only your body.'" Carson Holloway, Monetary Incentives for Organ Donation: Practical and Ethical Concerns, in ORGAN AND TISSUE DONATION 143, 152 (Bethany Spielman ed., 1996). "Bodies are more than mere objects insofar as they are intimately related to persons." Wilkinson, supra note 68, at 53 (emphasis added).

72. Bernard Teo, Is the Adoption of More Efficient Strategies of Organ Procurement the Answer to Persistent Organ Shortage in Transplantation? 6 BIOETHICS 113, 125 (1992). Teo states that because we connect human bodies to human personality and identity,

73. Holloway, supra note 71, at 152; Wilkinson, supra note 68, at 44–48. One example of wrongful commodification is slavery, where a person is not valued for their humanity but only for their ability to work.

74. Holloway, supra note 71, at 152.

bodies, and almost every country have taken the position that the sale of organs is ethically unacceptable.

Proponents of organ sale claim that commodification is a weak argument. They distinguish respect for personhood from individuals using their bodies in a useful manner. Respect for personhood, according to the theory, could be maintained while commercializing organs as long as the ability to be useful is not isolated from knowledge that the individual is an intrinsically valuable person. As an example, proponents point to the employment context where human labor is used as a fungible good without decreasing human dignity or value. Proponents also argue that the organ recipient’s...
attitude toward a donor, as a means of personal gain, is identical regardless of compensation.82

2. Sale of Body Parts May Unfairly Distribute Limited Organs Based on Income Rather than Necessity

Many legal scholars, among others, have argued that relying solely upon the altruistic nature of humans is not enough to meet the demand for organ donation at this time.83 However, allowing sale of organs to compensate for the lack of organs also introduces a high likelihood of inequitable distribution of organs.84 The poor will rarely receive an organ transplant and bear the brunt of donation while the wealthy will receive organs but rarely donate.85

82. Wilkinson, supra note 75, at 194–95.
83. See Steve P. Calandrillo, Cash for Kidneys? Utilizing Incentives to End America’s Organ Shortage, 13 GEO. MASON L. REV. 69 (2004) (encouraging payment for organ donations); Joel D. Kallich & Jon Metz, The Transplant Imperative: Protecting Living Donors from the Pressure to Donate, 20 IOWA J. CORP. L. 139, 144 (1994); Christy M. Watkins, A Deadly Dilemma: The Failure of Nations’ Organ Procurement Systems and Potential Reform Alternatives, 5 CHI.–KENT J. INT’L. & COMP. L. 1 (2005) (discussing several alternatives to increase the number of donated organs and the history of organ donor procurement); Gail L. Daubert, Note and Comment, Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably, 50 ADMIN. L. REV. 459 (1998) (describing the current system of organ distribution, discussing problems with that system, and suggesting that a government rationing system is necessary); Flamholz, supra note 63, at 329 (outlining NOTA and AUGA and state laws relating to organ donation and then offering suggestions to increase the number of donated organs); Shelby E. Robinson, Comment, Organs for Sale? An Analysis of Proposed Systems for Compensating Organ Providers, 70 U. COLO. L. REV. 1019 (1999) (discussing ethical and practical considerations regarding monetary compensation to organ providers); Laurel R. Siegel, Comment, Re-engineering the Laws of Organ Transplantation, 49 EMORY L.J. 917 (2000) (proposing that Congress amend NOTA to include pilot programs that could increase the number of donated organs).
84. It is argued that organs are already inequitably distributed. Proponents of commercializing organ procurement argue there are ways to make distribution equitable in a manner other than non-payment. Adam J. Kolber, A Matter of Priority: Transplanting Organs Preferentially to Registered Donors, 55 RUTGERS L. REV. 671 (2003); Daubert, supra note 83; McDaniel, supra note 58; Robinson, supra note 83.
85. Most Indians who sell kidneys do so to pay off debts. Lawrence Cohen, Where it Hurts: Indian Material for an Ethics of Organ Transplantation, 38 ZYGON 663 (2003) (arguing that most people who sell their organs (mainly kidneys) in India do so in order to pay already existing debts and most “donors” are back in debt soon after the operation); Madhav Goyal et al., Economic and Health Consequences of Selling a Kidney in India, 288 JAMA 1589, 1589–93 (2002).
3. Income from Organ Donation May Create Undue Inducement for Donation from Vulnerable Populations

If commercialization of organ procurement were acceptable, it would prey upon indigent members of our society or the Third World as a source of organs. See supra notes 77 and 85 and accompanying text; Flamholz, supra note 63, at 329, 339–40. Any decision to donate organs should be voluntary, but financial incentives can compromise the voluntariness of donors. Vulnerable populations, particularly living donors, bear the brunt of this risk of undue inducement.

Inappropriately influenced decisions to sell organs by live donors may disproportionately affect low-income individuals because of financial need. A high number of low-income or vulnerable individuals responding to requests for organs might also raise questions about the quality of donated organs. However, those who

86. See supra notes 77 and 85 and accompanying text; Flamholz, supra note 63, at 329, 339–40.


89. Joel D. Kallich & Jon Merz, supra note 83 at 139, 144. China often relies upon executed prisoners for organs, particularly hearts and kidneys. See Rothman, supra note 77, at 35, 37. Although not publicly admitted, the government may sanction the death penalty based on organ transplant demand. Id.; Wilkinson, supra note 68, at 44–49; Garwood-Gowers, supra note 77, at 149, 184–85 (discussing the high likelihood of coercion for organ procurement in vulnerable populations such as psychiatric patients, children, and mentally incompetent and U.S. cases of living donors who are adult incompetents); Price, supra note 77, at 367.

90. Fortunately, the fear of sub-par donated organs from impoverished individuals is tempered by the requirements that have been put in place for living donors. These requirements include physical fitness, good general health, and no high blood pressure, diabetes, cancer, kidney disease, or heart disease. Transplant Living: Organ Donor and Transplant Information for Patients, http://www.transplantliving.org/livingdonation/facts/qualifications.aspx (last
desire to procure organs may be tempted to ignore such concerns because of their immediate need. 91 Unlike deceased donors, living donors are exposed to unknown medical risks involved in organ removal. 92 In such cases, true consent for organ donations should be questioned. 93 All of these issues—consent, coercion, and quality of donors—discourage commercializing organs via compensation.

IV. TISSUE DONATION PROCUREMENT AND REGULATION

A. Procurement of Tissues

Tissue donors can be living or deceased. 94 In the hospital context, deceased tissue donation is almost identical to organ donation. 95 Outside of the hospital context, tissue banks receive information from a variety of sources, including the coroner, funeral home directors, or medical examiners, for potential tissue donors. 96 Approximately one-half of prospective donors are rejected, but the tissue of those that are suitable is recovered without delay. 97 Unlike organ procurement,
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Tissue can be procured several hours after the patient’s death and can be stored for longer periods of time. Generally, donated tissue must be procured within twenty-four hours of the donor’s death. After determining that the decedent is a suitable donor, the tissue bank or OPO specialist asks the family members about their willingness to donate. The tissue bank or OPO representative may or may not tell the family about the bank’s non-profit status. If the family chooses to donate, the tissue bank undergoes the retrieval process.

B. Historical and Current Tissue Banking Oversight

The first tissue bank in the United States was maintained by the United States Navy. As uses for donated tissue began to grow, additional tissue banks were started by physicians, researchers, and hospitals for use in their local communities. Over time, tissue banks were primarily non-profit entities that varied in size, with the largest tissue banks connected to medical institutions. In 1976, the American Association of Tissue Banks (“AATB”) was created to ensure quality standards, increase number of donations, support scientific exchange of ideas and provide adequate support for the tissue banks. The AATB is the only organization that accredits tissue banks; however, tissue banks are not required or expected to be accredited.

Today, the Food and Drug Administration (“FDA”) under the DHHS regulates the tissue-based products and consequently directly

98. Id. at 411–12.
99. Id. Tissue recovery times depend upon the type of tissue being recovered but range from several hours after death to a full day. Id.
100. Donate Life Ohio, supra note 95.
103. Zodrow, supra note 97, at 411.
104. Williams, supra note 102, at 296–300; Zodrow, supra note 97, at 411–12.
106. Williams, supra note 102, at 296–300. Zodrow, supra note 97, at 411–12.
affects the tissue banking industry.108 Under the FDA and DHHS, regulated tissues that are able to be donated include:

Any tissue derived from a human body, which 1) [i]s intended for transplantation to another human for the diagnosis, cure, mitigation, treatment, or prevention of any condition or disease; 2) [i]s recovered, processed, stored or distributed by methods that do not change tissue function or characteristics; 3) [i]s not currently regulated as a human drug, biological product, or medical device; 4) [e]xcludes kidney, liver, heart, lung, pancreas, or any other vascularized human organ and; 5) [e]xcludes semen or other reproductive tissue, human milk, and bone marrow.109

The FDA’s regulatory power is derived from the DHHS, which is charged by the Public Health Service Act110 to ensure that tissues are not defective or contaminated during processing or transplantation.111 Although the FDA has played different roles in its regulation of the tissue procurement industry, reducing risks to public health is one of its primary objectives.112 The most significant regulation enforced by the FDA classifies tissue that has been more than minimally altered, used for non-homologous use, or has been combined with another article, as a drug or medical device that has more stringent requirements due to public health reasons.113 However, most cases involving tissue are regulated only to the extent that prevents communicable diseases.114

Just as the regulatory construction for tissue procurement has changed over the years, so has the tissue banking industry.115 The

113. Williams, supra note 102 at 301.
114. Id. at 302.
115. Williams, supra note 102, at 297–99.
industry has seen explosive growth from its historical community-based tissue banking model and its non-profit roots. Although the sale of tissue is still strictly prohibited by federal law, current legislation allows profit to be made in the processing of donated tissue. This has created a little-known multi-billion dollar profit-earning industry dependent primarily upon the altruistic donation of tissues to hospitals and other tissue banks. These tissue processors, many of them publicly traded companies, create products from the donated tissue that are used in a variety of ways and are highly profitable.

Tissue procurement and use is not as strictly regulated as organ donation. Thus, most community tissue banks send their tissues to be processed at a processing company and collect a recovery fee from the processing company. Processing companies can be either profit or non-profit, but a growing number are profit earning corporations. For-profit tissue processing companies make

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116. Williams, supra note 102, at 297–99. “For example, 350,000 human tissue products were transplanted in 1990; however, more than 800,000 tissue products were transplanted in 2002.” Id. at 298.

117. Williams, supra note 102, at 297–99. This differs from organ processing companies, that must be non-profit entities. Although 42 U.S.C. § 274e defines organs to include tissue and the statutes referring to OPO’s do not redefine organs, it seems that the government does not enforce or interpret the definition of human organs to include tissue, and thus it does not require the same standards for tissue regulation as it does for organ donation. 42 U.S.C. § 273 (2000); see also Katz, supra note 55, at 946–47.


119. Williams, supra note 102, at 297–99. Cryolife, Osteopath, and Lifecell are all publicly traded multimillion dollar revenue earning tissue processing companies. See supra note 118.

120. 42 U.S.C. § 274e (2000). NOTA only includes tissue donation in the statutory language relating to sale of body parts. Id. See supra note 117.

121. Williams, supra note 102, at 297–99.

122. The largest suppliers of implantable human tissue are MTF Foundation, Regeneration
significant revenue by selling “tissue service” to hospitals. This new tissue processing system has dramatically changed the face of tissue banking from one of altruism to that of significant profit.

C. The Effect of Profit on Tissue Banks

Revenue earning tissue processing companies have changed the completely charitable nature of the tissue donation industry, but they have also garnered great technological advancements for medical uses of the donated tissue. Donated tissue is often used for allografts, such as cryopreserved heart valves for patients with defective heart functions, demineralized bone matrices for spinal fusion surgeries, and acellular dermal tissue to replace skin for burn and cancer victims without the patient’s body rejecting the new skin. Acellular dermal tissue can also be used for cosmetic surgery, such as the reduction of wrinkles. These are just a few of the

123. Williams, supra note 102, at 297–99.
125. Tissue processing companies often partner with community banks so that they can have reliable access to human body tissues. Williams, supra note 102, at 299.
128. LifeLink Tissue Bank, About Tissue Donation, http://www.lifelinktb.org/index.cfm/fuseaction/Patients.About (last visited Apr. 11, 2008) (“Heart valves are used in cardiovascular surgery for patients with valvular disease.”); see also Cryolife: Corporate Profile, http://www.cryolife.com/about/profile/ (last visited Apr. 11, 2008) (Cryolife, a for-profit tissue processing company was the first to develop a commercially viable cryopreserved heart valve.).
130. LifeLink Tissue Bank, About Tissue Donation, supra note 128 (“Transplanted skin is used as replacement tissue over 1,000,000 times per year. Three quarters of this usage occurs in life-saving circumstances such as severe burns.”).
131. AlloDerm by Life Cell is one such cadaveric tissue that is often used for cosmetic and facial reconstructive surgery. Alloderm Defined, http://www.lifecell.com/products/95/ (last
medical advances that have been made by pharmaceutical companies processing donated tissue.  

Many of these processes are patented by large commercial tissue processors that are unable to keep up with the growing demand and gain significant profit from selling the products to hospitals.

It is hard to know whether these advances would have taken place without the entrance of profit-based companies in the tissue industry. American society encourages ingenuity through capitalism, and without profit as an incentive for medical advancement, the funds and resources necessary to create valuable medical products may not have been provided or used to save many patients’ lives. Also, the belief that tissue is procured through truly voluntary consent is questionable if it is not clear that tissue donors are aware of the profits derived from their altruistic actions.  

California has enacted a statute requiring tissue procurement agencies to reveal to potential donors their intended use of the tissue, and whether monetary profit will be gained from the donor’s altruism.  

There is mixed speculation about
whether the number of donors will decrease if the commercial uses and profits were revealed, particularly because none of the profit is passed to the altruistic donor.\textsuperscript{137} Other states may follow California’s actions\textsuperscript{138} and DHHS proposed a regulation, which was enacted, that requires disclosure about the tissue bank’s profit status.\textsuperscript{139}

\textbf{V. APPLYING ORGAN OR TISSUE PROCUREMENT REGULATIONS TO EMBRYO TREATMENT}

As the existing numbers of cryopreserved embryos grow,\textsuperscript{140} federal statutes should be enacted to protect potential donors and their embryos. The impact of organ and tissue procurement laws provides different levels of protection for the donor.\textsuperscript{141} The differences may be attributed to their respective functions and the typical recipient of such donations. Comparing tissue and organ characteristics and evaluating tissue and organ procurement regulations and effects if applied to human embryo procurement may help create appropriate regulations for human embryo treatment.

Human embryos share characteristics similar to both tissues and organs. Embryo creation outside the womb occurs when all other efforts of procreation have failed;\textsuperscript{142} likewise, organ transplants are considered when no other alternative exists.\textsuperscript{143} Also like organs, human embryos have the power to sustain human life. The capability

markets in human biological materials exist and are unavoidable and instead the conversation should be about the allocation of burdens and benefits of scientific advances).

\textsuperscript{137} Alison Jack & Christopher Womack, \textit{Why Surgical Patients Do Not Donate Tissue For Commercial Research: Review of Records}, 327 BRIT. MED. J. 262 (2003) (stating that in a study of over 3,000 interviews, only 1.2% of responders refused to donate tissue based on its commercial use after donation).

\textsuperscript{138} See Katz, supra note 55, at n.93 (similar bill was supported by twenty-four Wisconsin legislators).

\textsuperscript{139} 70 Fed. Reg. 6086, 6119 (Feb. 4, 2005) (codified as amended at 42 C.F.R. § 486.342(4) (2006)). DHHS’ proposal included requiring the OPO to give the potentially donating family “information (such as profit or non-profit status) about organizations that will recover, process, and distribute tissue” in its proposed legislation. Id.

\textsuperscript{140} See supra notes 17, 20–24 and accompanying text.

\textsuperscript{141} See supra Parts III.B, IV.B.

\textsuperscript{142} See supra note 7 and accompanying text.

\textsuperscript{143} See supra Part III.A. Similar to transplanted organs that replace a vital life-sustaining organ, embryos contain everything necessary to bring forth a human child within its cells. See supra Part II.A.
of human embryos to preserve life without any negative effects to the donor and their unlimited availability is similar to tissue. However, unlike current regulations for organ or tissue donation, screening procedures are less stringent for embryo donation because embryos are created to become genetic offspring of a particular couple regardless of genetic disease.

Selling embryos presents many of the same issues that prompted legislators to prohibit monetary exchange for tissue and organs. Allowing the sale of human embryos is even more troubling because it treats potential offspring as chattel—somewhat similar to the practice of slavery, which existed in parts of the United States prior to the Civil War. This practice devalues the intrinsic worth of humans, commodifies potential children, and might even encourage couples to buy the “best” child for their money. Because couples cannot separate the embryo’s value from its capabilities, arguments made by supporters of organ sale are inapplicable when it comes to the sale of human embryos. Furthermore, if abandoned or misappropriated human embryos are sold, fertility clinics are thus implanting genetic offspring without permission from, or notice to, the donating parents. Finally, economic need or pressure from fertility clinics may unduly influence a decision to sell an embryo.

Public policy required Congress to protect vulnerable organ donors and recipients with strict governance of organ procurement.
Coerced organ donors and desperate recipients are subject to significant medical risks that are easily ignored during times of crisis. Similarly, parents desperate for a birthed child or the economic benefits of selling embryos for research are easily pressured by fertility clinics or others to buy or sell embryos. If human embryos were treated like tissue, profit-earning fertility clinics could encourage donation for the clinic’s own economic benefit, but its target market would be similar to organ recipients—those desperate for a chance to live. Requiring all aspects of organ procurement to be non-profit, with significant oversight, aims to prevent schemes that prey upon the vulnerable; a similar plan could do the same for human embryo procurement.

Allowing profitable companies to process tissue and create marketable products from donated tissue has produced great gains in medical technologies. However, tissue procurement laws that allow for profits may also create an incentive for human embryo misappropriation by fertility clinics, which maintain physical control over embryos along with the opportunity for medical advances. If human embryo sales are not prohibited but profits gained by fertility clinics continue to be undisclosed, then there may be a question of true donative intent and an issue of inequitable enrichment.

155. See supra notes 83–84 and accompanying text.
156. See supra note 85 and accompanying text. Medical risks include purchasing organs that do not match the recipient or is in poor condition. Id.
157. See supra note 6 and accompanying text.
158. See supra note 36 and accompanying text; infra notes 159–60.
159. See supra notes 118–19 and accompanying text. It must be noted, however, that tissue cannot be purchased or sold; only processing fees may be collected. Id. Also, tissue donation from cadavers does not present the same level of medical risks as organ or embryo procurement. Id.
160. See supra Part III.B. Strict federal oversight also discourages a black market and the health risks of procuring an organ off of the black market. Id.
161. See supra notes 127–32 and accompanying text.
162. See supra note 26 and accompanying text.
163. See supra notes 135–37 and accompanying text.
VI. PROPOSED REGULATIONS FOR TREATMENT OF UNIMPLANTED EMBRYOS

Potential parents should have control over their cryopreserved embryos, and their decision to donate should not be coerced by financial considerations. In order to do so, fertility clinics, which hold significant control over financially lucrative cryopreserved embryos and are in a position to exploit couples and embryos, must be statutorily regulated. Analyzing fertility clinics and embryo donation with current policies and statutes regulating organ and tissue donation has led to the following conclusions: (1) embryos should not be bought or sold in a monetary exchange, (2) donors’ decisions should be fully informed and truly voluntary, and (3) embryo procurement organizations should be non-profit and conform to standards similar to NOTA.

Sale of human embryos should be illegal, and human embryos should be treated with special respect by their potential donors, as well as the couple or research facility to which they are donated.164 Allowing commodification of embryos is even more damaging than organ sale because human embryo sale ignores any inherent worth embryos hold as genetic offspring of a couple. Whenever an embryo is sold, it commodifies the human embryo by placing its value only on its characteristics.165 This bears a horrific resemblance to slavery, where human beings are consistently dehumanized and valued only for embodying particular characteristics and functions.166

Sale of human embryos encourages exploitation of vulnerable populations, and prohibition of such exchanges would promote the public policy of protecting vulnerable populations. Couples may turn to purchasing human embryos out of desperation for a child and are, therefore, particularly vulnerable to exploitation.167 Prohibiting human embryo sales prevents couples from taking inappropriate medical risks, bidding for the “best” child, or selling their embryos

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164. See supra note 28 and accompanying text.
165. See supra notes 71–72 and accompanying text.
166. See supra note 73 and text accompanying notes 70–74.
167. This is similar to organ procurement which preys upon individuals desperate for an organ and donors desperate for monetary compensation. See supra notes 85–87 and accompanying text.
because of financial straits. Public policy supports statutory regulations that limit the power of fertility clinics, researchers, and potentially purchasing couples over a prospective donor to allow true consent.168

Donation of embryos should be truly voluntary and can be ensured by a standardized consent process that must occur prior to the procedure. In order to facilitate voluntary consent, couples should be specifically asked, after completing fertility procedures, if their original decisions for or against donation remain unchanged. To prevent confusion, this decision should only be changed for one year after the couple’s infertility needs are met. Requests for donation should be made by specialists uninvolved in the treatment of the couple’s infertility needs and with assurances that the decision will not impact medical care in any way. If donating for research purposes, embryo donors should be informed of the embryonic stem cell derivation process, the sources of funding for any research, its potential commercial value and applications, and the confidentiality policies of the fertility clinic. If decisions to donate are contested at a later time, it is appropriate to follow applicable case law.169

Regulating human embryo donation by instituting a statute similar to NOTA protects both donors and recipients. Fertility clinics are largely unregulated and maintain physical control over most human embryos derived from ART processes.170 Fertility clinics acting as embryo procurement and storage organizations should be non-profit, with accreditation requirements and standards that protect donors. Accreditation ensures that embryo procurement organizations are truly non-profit and also that there are adequate protections for potential donors and their embryo(s).

Necessary embryo processing should also be conducted by non-profit organizations to avoid the inequities and inappropriate practices that are growing in the tissue industry with little or no donor knowledge.171 It seems likely that the number of embryo donors who agree to give embryos for research purposes would decrease if the

168. See supra note 36 and accompanying text.
169. See supra note 28 and accompanying text.
170. See supra note 26 and accompanying text.
171. See supra notes 135–39 and accompanying text.
donors knew that their donated embryos were creating a profitable industry for fertility clinics. Any potential financial gain by researchers should be disclosed to the potential donors prior to their consent and should not provide a source of financial gain to the embryo procurement organization. However, similar to tissue and organ procurement organizations, appropriate fees for storage, processing, and transport may be charged if the minimal revenue is used to promote further education about human embryo donation.172

VII. CONCLUSION

Statutory protection for human embryo donation and processing is essential. Donors and human embryos alike need protection from misappropriation or use of embryos against the donors’ wishes. Prohibiting the sale of human embryos and accrediting embryo procurement and storage organizations as non-profit entities under strict regulations will effectively provide the necessary protection.

172. See supra notes 47–51 and accompanying text.