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.[1] Federal oversight addressing the disposition of embryos is nearly nonexistent,[2] 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.[3] 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.[4]

In Part II, this Note will examine embryo donation and current regulations. Because the ethical issues surrounding human embryo

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1. *See infra* note 26 and accompanying text.
2. *See infra* notes 28–35 and accompanying text.
3. *See infra* notes 5–6 and accompanying text.
4. *See* discussion *infra* Part VI.

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.[5] To create a human embryo, a female egg and male sperm are joined through in-vitro fertilization ("IVF") prior to implantation.[6] This method is normally used if a couple is unable to conceive naturally.[7] When sperm and egg are successfully joined, the resulting embryo is the genetic offspring of the couple.[8] 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."[9] 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.*

7. Couples also choose IVF to screen for genetic diseases. Joe Palca, *Screening Embryos for Disease* (NPR radio broadcast Dec. 20, 2006), *available at* http://www.npr.org/templates/story/story.php?storyId=6653837.

8. ASRM: FAQ, *supra* note 6.

9. David I. Hoffman et al., *Cryopreserved Embryos in the United States and Their Availability for Research*, 79 FERTILITY & STERILITY 1063 (2003).

cryopreservation for future pregnancies.[10] Almost all cryopreserved embryos are kept at the couple's fertility clinic, unless storage space is lacking or necessity dictates otherwise.[11]

Human embryos may be donated directly or anonymously.[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.[13] Cryopreserved embryos are able to be used for the patient's fertility treatment,[14] donated to research[15] or another patient,[16] destroyed, or used for quality assurance purposes.[17] Potential parents are usually encouraged to sign pre-procedural agreements indicating their

10. *Id. See* Kass v. Kass**,** 696 N.E.2d 174, 175 (N.Y. 1998) ("Cryopreservation serves to reduce both medical and physical costs because eggs do not have to be retrieved with each attempted implantation, and delay may actually improve the chances of pregnancy."). Cryopreservation freezes the embryo to preserve it until it is needed. Hoffman, *supra* note 9, at 1066.

11. Hoffman, *supra* note 9, at 1066. The majority of fertility clinics have the ability to cryopreserve embryos. *Id.*

12. GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS 36–38 (2007), *available at* http://www.fda.gov/cber/gdlns/tissdonor.pdf [hereinafter ELIGIBILITY DETERMINATION].

13. 21 C.F.R. § 1271.90 (2006). *See* ELIGIBILITY DETERMINATION, *supra* note 12, at 39–44. Generally, testing is conducted to ascertain the presence of HIV, Hepatitis B, Hepatitis C, Human Transmissible Spongiform Encephalopathy, Treponema Pallidum, communicable disease risk associated with xenotransplantation, Chlamydia Trachomatis, and Neisseria Gonorrhea in semen or other reproductive cells such as oocytes. *Id*. at 14–21. Any potential recipient of the cryopreserved embryos must be advised that "screening and testing of the donors were not performed at the time of cryopreservation of the reproductive cells or tissue, but have been performed subsequently." *Id*. at 43.

14. Cryopreservation allows for future attempts at pregnancy. *See* Hoffman, *supra* note 9, at 1066.

15. Federal law prohibits the use of federal funds for "(1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero . . . ." JUDITH A. JOHNSON & ERIN WILLIAMS, STEM CELL RESEARCH, CON. RESEARCH SERV. Rep., at 3–7 (2004), *available at* http://www.fas.org/spp/civil/crs/RL31015.pdf.

16. Organizations like Project Snowflakes connect couples who are willing to donate their cryopreserved embryos with couples in need of human embryos. Snowflakes Embryo Adoption Program, http://www.nightlight.org/snowflakeadoption.htm (last visited Apr. 7, 2008).

17. *See* Hoffman, *supra* note 9, at 1063, 1066. According to a 2002 study, the vast majority of the nearly 400,000 cryopreserved embryos are designated for patient treatment, while a very small percentage (2.8%) of the total is available for research. *Id.*

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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18. *See* Ethics Committee of the American Society for Reproductive Medicine, *Disposition of Abandoned Embryos*, 82 FERTILITY & STERILITY S253 (2004).

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.

20. *Id. See generally* Heidi Forster, *The Legal and Ethical Debate Surrounding the Storage and Destruction of Frozen Human Embryos*, 76 WASH. U. L.Q. 759 (1998).

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.*

24. *See generally* Helen M. Alvare, *The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective*, 40 HARV. J. ON LEGIS. 1, 25–31 (2003) (discussing the "dearth of regulation," with the regulatory interests dealt with unevenly on a state by state basis).

25. Steven Kotler, *The God of Sperm*, LA WEEKLY NEWS, Sept. 26, 2007, *available at* http://www.laweekly.com/news/news/the-god-of-sperm/17290/?page=1.

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.[27] Most pertain to either the legal status of embryos[28] 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.[29] Custodial rights of these parties are often governed by contract law.[30] However, at least two states have forbidden monetary compensation for embryos

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Conversion: A Relational View, 32 LOY. L.A. L. REV. 381 (1999) (discussing the embryo misappropriation scandal and the resulting passage of § 367g).

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,[31] over half of the states have restricted sale of human embryos for research,[32] and one state explicitly allows the sale of embryos.[33]

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,[34] 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.[35] The few standards that do exist are mostly derived from research review boards or non-binding ethics committee guidelines.[36]

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31. Florida and Louisiana explicitly prohibit the sale of embryos. FLA. STAT. ANN. § 873.05 (LexisNexis 2006); LA. REV. STAT. ANN. § 9:122 (2006). Although Indiana classifies the sale of embryos as a felony, it provides an exception for those using the embryo for reproductive purposes. IND. CODE § 35-46-5-3 (2007).

32. State Embryonic and Fetal Research Laws, http://www.ncsl.org/ programs/health/ Genetics/embfet.htm (last visited Apr. 7, 2008).

33. VA. CODE ANN. § 32.1-289.1 (2006) (exempting ova from general ban on sale of body parts in Virginia).

34. Fertility Clinic Success and Certification Act, 42 U.S.C. § 263a-1 (2002).

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.[37] Organs can be donated by both the living and the deceased and is a voluntary decision.[38] Living donors are often blood relatives who donate one or more of their organs to a family member.[39] Decedent donors enter the organ donation process after they are declared brain dead.[40] 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.[41] If so, the specialist then speaks to the decedent's family about the possibility of organ donation.[42] 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.[43]

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37. Amy Vadenbroucke, *HIV and Organ Donation: Illinois' Solution to Organ Donation Shortages*, 9 DEPAUL J. HEALTH CARE L. 1285, 1287–91 (2006) (discussing the development and history of organ donation, including federal and state laws).

38. *Id. See generally* Medline Plus: Organ Donation, http://www.nlm.nih.gov/medlineplus/organdonation.html (last visited Apr. 7, 2008). Approximately 50% of kidney transplants and 8% of liver transplants are from live donors. Gary Becker & Julio Jorge Elías, *Introducing Incentives in the Market for Live and Cadaveric Organ Donations* 3 (George Stigler Center for the Study of the Economy and the State, Working Paper, 2003), *available at* http://home.uchicago.edu/~gbecker/MarketforLiveandCadavericOrganDonations_Becker_Elias.pdf.

39. One method of increasing kidney transplants is exchanging donated kidneys of two willing donors with the appropriate blood-type of the other loved one's transplant patients. Josh Fischman, *Mix, Match, and Switch: Kidney Exchanges Between Strangers Are Helping to Ease the Organ Shortage*, US NEWS & WORLD REP., Oct. 8, 2006, *available at* http://www.usnews.com/usnews/health/articles/061008/16organ.htm.

40. Life Gift, Understanding Donation: Organ Donation Process, http://www.lifegift.org/lifegift/info/organ_donation_process/ (last visited Apr. 7, 2008) (describing the organ donation process of deceased donors from prior to death to completion of the transplant operation) [hereinafter Life Gift].

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).

43. Life Gift, *supra* note 40; *see also* United Network for Organ Sharing: Organ Donation and Transplantation, http://www.unos.org/whatwedo/organcenter.asp (last visited Apr. 7, 2008) [hereinafter UNOS]. UNet is the national online database run by the UNOS. *Id.* The system registers patients for transplants, matches donated organs to waiting patients, and manages the

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.[44] The transplant recipient's surgery team will then remove the organ(s) from the donor and transplant them into the recipient.[45] Organ transplantation has become increasingly successful over the years, giving life to many who would otherwise not recover from life-terminating or debilitating illnesses.[46]

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.[47] NOTA heavily regulates the organ procurement industry, stipulating the methods of procurement, storage, and allocation of organs.[48] NOTA criminalizes the sale of any human organ or tissue for profit.[49] Violators face up to $50,000 fees and a maximum of five years in prison.[50]

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data of all patients, before and after their transplants. *Id.* It is currently used by all of the nation's organ transplant programs, OPOs, and tissue typing laboratories working to efficiently share a limited number of donated organs among many patients. *Id.*

44. Ohio Donor Registry, Stories, http://www.donatelifeohio.org/beahero/storiesfrom registrants/index.aspx (last visited Apr. 7, 2008).

45. Life Gift, *supra* note 40.

46. Life Gift, *supra* note 40. *See generally* Lauran Neergaard, *Doctors Explore Use of Mismatched Hearts*, WASH. POST, Feb. 12, 2007, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2007/02/12/AR2007021200833.html (explaining that babies have received mismatched heart transplants to increase their survival rate by taking advantage of a lag in their immune system); Roni Rabin, *Prospect of Womb Transplant Raises Hopes and Red Flags*, N.Y. TIMES, Jan. 30, 2007, at F5 (discussing the beginning of uterine transplants for women).

47. 42 U.S.C. §§ 273–274e (2000).

48. 42 U.S.C. § 273 (2000).

49. 42 U.S.C. § 274e(b) (2000).

50. *Id.*

In addition to several other provisions,[51] NOTA created the Organ Procurement and Transplantation Network ("OPTN"), a national network facilitating organ donations around the country.[52] OPTN matches organ donors with a patients' need for organ transplantation through an established allocation system.[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.[54]

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

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51. NOTA also provides a twenty-four hour phone service to facilitate the distribution of organs equitably among transplant patients and maintains procurement and screening standards of potential organs donated through UNOS and OPTN. 42 U.S.C. § 274(b)(2)(C) (2000). UNOS provides the twenty-four hour service staffed by organ placement specialists. United Network for Organ Sharing: Organ Donation and Transplantation—What We Do, http://www.unos.org/whatWeDo/organCenter.asp (last visited Apr. 7, 2008). NOTA aims to improve organ donation practices by increasing the number of donors, informing the public of donation needs, maintaining high procurement standards, and successfully matching transplant patients with available organs in a timely manner. *See* 22A AM. JUR. 2D *Dead Bodies* § 92 (2003) [hereinafter *Dead Bodies*]; 42 U.S.C. § 274c(2) (2000).

52. *See* OPTN: Organ Procurement Transplantation Network, http://www.optn.org (last visited Apr. 7, 2008).

53. 42 U.S.C. § 274(b)(2) (2000); *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 types 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).

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. *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. *Id.*

55. 42 U.S.C. § 273 (2000). *See* Robert A. Katz, *The Re-gift of Life: Can Charity Law Prevent For-Profit Firms From Exploiting Donated Tissue and Nonprofit Tissue Banks?*, 55 DEPAUL L. REV. 943, 955–56 (2006).

56. Katz, *supra* note 55, at 955.

("UNOS")[57] to become the private non-profit organization that maintains OPTN.[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").[59] Unlike the guidelines of NOTA, which are limited to organ procurement in practice, the UAGA also includes tissue donation.[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.[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.[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.[63] For living donors, the risks of a

57. UNOS, *supra* note 43.

58. Jeffrey A. McDaniel, Note and Comment, *A Decent Proposal? Fundamental Fairness in an "Un-commercial" Organ System*, 19 J.L. & COM. 327 (2000) (explaining the organ sharing network system and calling for stricter regulations for uniform and fair distribution of organs).

59. UNIF. 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*.

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).

61. UNIF. ANATOMICAL GIFT ACT prefatory note.

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).

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.[64] 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.[65] 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.[66] However, in 2004 and 2005, the number of living donors exceeded deceased donors.[67] 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.[68]

1. Selling Organs Devalues Intrinsic Human Worth

The sale of organs places economic value upon human body parts.[69] 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).

65. *See, e.g.*, Scott Carney, *Indians Buy Organs With Impunity*, WIRED NEWS, Feb. 8, 2007, *available at* http://www.wired.com/news/technology/medtech/0,72675-0.html?tw=wn_index_14. Flamholz, *supra* note 63, at 339–40.

66. Flamholz, *supra* note 63, at 341–42.

67. Jane E. Brody, *For Living Donors, Many Risks to Weigh*, N.Y. TIMES, Sept. 4, 2007, at F7.

> In 2004 and 2005, the number of organ donations from living donors surpassed those from dead donors. And although dead donors are once again more common, many people risk surgery and the loss of an organ to save the lives of people they love—and increasingly of strangers, as well.

Id.

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.[70] Organ commodification encourages separating human bodies from our personhood, identity and personality[71] and result in "strip[ping] the human body of its proper dignity" because human beings automatically connect bodies to "human personality and identity."[72] Payment for human organs threatens the basic principle that individuals should not become fungible products that are used to benefit others.[73] 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.[74] At the very least, organ sale symbolically violates personhood.[75] As a result, many international

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

> Congress apparently was galvanized into action banning the sale of human organs and tissues largely in response to a plan by H. Barry Jacobs, who established a company in Virginia to broker human kidneys . . . Jacobs . . . intended to broker kidneys from healthy, living donors at an agreed-upon price to which Jacobs would add $2,000 to $5,000 for his services. Jacobs testified before Congress that he also intended to bring Third World indigents to the United States so that the company could sell their kidneys. Congress responded by banning the sale of human organs and tissues.

Id. The World Health Organization ("WHO") guidelines, which emphasize voluntary donation, non-commercialization, and a preference for cadavers over living donors heavily influence worldwide legislation and policies for transplantation. World Health Organization, *Human Organ and Tissue Transplantation*, http://www.who.int/ethics/topics/human_transplant/en/ (last visited Apr. 7, 2008).

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,

> [I]t follows that respect for the human person would also be intrinsically tied to respect for the human body and its parts. . . . Because human dignity is intrinsically linked to human embodiment, treating the body and its parts as commodities would be to strip the human body of its proper dignity.

Id.

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.

75. *See* Stephen Wilkinson, *Commodification Arguments for the Legal Prohibition of Organ Sale*, 8 HEALTH CARE ANALYSIS 189 (2000), *available at* http://www.springerlink.com/

bodies[76] and almost every country have taken the position that the sale of organs is ethically unacceptable.[77]

Proponents of organ sale claim that commodification is a weak argument. They distinguish respect for personhood[78] from individuals using their bodies in a useful manner.[79] 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.[80] As an example, proponents point to the employment context where human labor is used as a fungible good without decreasing human dignity or value.[81] Proponents also argue that the organ recipient's

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content/w267652725386043/fulltext.pdf.

76. International bodies include the Transplantation Society, WHO, and the Council of Europe. *See* The Transplantation Society, *Policy and Ethics*, http://www.transplantation-soc.org/policy.php (last visited Apr. 8, 2008); World Health Organization, *Human Organ and Tissue Transplantation*, http://www.who.int/ethics/topics/human_transplant/en/ (last visited Apr. 8, 2008); Parliament and Council Directive 2004/23, *Setting Standards of Quality and Safety for the Donation, Procurement, Testing, Processing, Preservation, Storage and Distribution of Human Tissues and Cells*, art. 12, 2004 O.J. (L 102) 48 (EC), *available at* http://www.who.int/ethics/en/ ETH_EU_Directive_2004_23_EC.pdf.

77. *See, e.g.*, AUSTEN GARWOOD-GOWERS, LIVING DONOR ORGAN TRANSPLANTATION: KEY LEGAL AND ETHICAL ISSUES, ix–xi (1999) (discussing several countries' policies on organ procurement, including Tables of Legislation of relevant legislation about organ and tissue donation); DAVID PRICE, LEGAL AND ETHICAL ASPECTS OF ORGAN TRANSPLANTATION, x–xiv, 369 (2001) (Table of legislation regarding organ and tissue laws worldwide). Some countries, however, turn a blind eye to any organ commercialization activities despite the wide-spread prohibition of such activity. WILKINSON, *supra* note 68, at 101, 104–07 (discussing China's practice of executing prisoners to harvest organs). This has created an international black market for organs. *See* DAVID J. ROTHMAN, *Bodily Integrity and the Socially Advantaged*, *in* ORGAN AND TISSUE DONATION, *supra* note 71, at 35, 37. The most notorious black markets are located in India and China where potential organ recipients from all over the world travel to receive often unethically procured organs. *See id*.; World Health Organization, *Human Organ and Tissue Transplantation*, http://www.who.int/ethics/topics/human_transplant/en (last visited Apr. 8, 2008).

78. Respect for personhood requires treatment of each person as a "unique individual" having "incommensurable value." Wilkinson, *supra* note 75, at 196.

79. Wilkinson uses the example of recognizing a friend as highly useful for their household skills and recognizing the person as intrinsically valuable. Wilkinson, *supra* note 75, at 196.

80. Wilkinson, *supra* note 75, at 197–98.

81. Wilkinson, *supra* note 75, at 197–98. *See also* Stephen Wilkinson & Eve Garrard, *Bodily Integrity and the Sale of Human Organs*, 22 JOURNAL OF MEDICAL ETHICS, 334, 337 (1996).

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]

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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 Merz, *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.[86] Any decision to donate organs should be voluntary,[87] but financial incentives can compromise the voluntariness of donors.[88] Vulnerable populations, particularly living donors, bear the brunt of this risk of undue inducement.[89]

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.[90] However, those who

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

87. The Transplantation Society proposed that "[t]he person who gives consent to be a live organ donor should be competent, willing to donate, free of coercion, medically and psychosocially suitable, fully informed of the risks and benefits as a donor, and fully informed of risks, benefits, and alternative treatment available to the recipient." The Transplantation Society Policy & Ethics, http://www.transplantation-soc.org/policy.php (last visited Apr. 8, 2008). Consent is an ethical necessity, analogous to consent requirements for research subjects. CARL COLEMAN ET AL., THE ETHICS AND REGULATION OF RESEARCH WITH HUMAN SUBJECTS apps. D, E, F (2005). The Belmont Report and the Nuremberg Code require voluntariness of human research subjects because of the risks associated with research. *Id.* at apps. D-1, F-3. Organ procurement from live donors should follow similar standards. Peter P. Reese et al., *Creating a Medical, Ethical, and Legal Framework for Complex Living Kidney Donors*, 1 CLINICAL J. AM. SOC. NEPHROL. 1148, 1148–53 (2006). A recent press release by the WMA condemned China's practices that violate vulnerable populations. Press Release, World Medical Association, World Medical Association demands China stops using prisoners for organ transplants (May 22, 2006), *available at* http://www.wma.net/e/press/2006_4.htm.

88. Robert D. Truog, *The Ethics of Organ Donation by Living Donors*, 353 NEW ENGL. J. MED. 444, 445 (2005).

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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visited Apr. 11, 2008). *Cf.* NORA MACHADO, USING THE BODIES OF THE DEAD: LEGAL, ETHICAL AND ORGANIZATIONAL DIMENSIONS OF ORGAN TRANSPLANTATION 192 (1998) ("[D]onation motivated by altruism is a means of assuring quality control . . . .).

91. *See* Sadaqat Jan, *Poor Pakistanis Donate Kidneys for Money*, WASH. POST, Nov. 12, 2006, *available at* http://www.washingtonpost.com/wp-dyn/content/article/2006/11/12/AR2006111200375.html; Nima Sarvestani, *Iran's Desperate Kidney Traders*, BBC ONLINE, Oct. 31, 2006, *available at* http://news.bbc.co.uk/2/hi/programmes/this_world/6090468.stm.

92. Reese et al., *supra* note 87, at 1150; Kallich & Merz, *supra* note 83, at 147–48.

93. Kallich & Merz, *supra* note 83, at 144–45; Machado, *supra* note 90.

94. *See* Barbara Indech, *The International Harmonization of Human Tissue Regulation: Regulatory Control Over Human Tissue Use and Tissue banking in Select Countries and the Current State of International Harmonization Efforts*, 55 FOOD & DRUG L.J. 343, 345–46 (2000) (discussing considerations for procurement of tissue from live donors).

95. *See* Ohio Organ and Tissue Procurement, Donation Process, http://www.donatelifeohio.org/aboutdonation/donationprocess/ (last visited Apr. 11, 2008) [hereinafter Donate Life Ohio].

96. *See, e.g.*, Regeneration Donor Services, Medical & Funeral Professionals, http://www.rtidonorservices.com/en/professionals/professionals.aspx (last visited Apr. 11, 2008). *See generally* Katz, *supra* note 55, at 959–61 (providing general information about tissue recovery and types of recoverable tissues).

97. John J. Zodrow, *The Commodification of Human Body Parts: Regulating the Tissue Bank Industry*, 32 SW. U. L. REV. 407, 407, 411–12 (2003) (discussing the tissue procurement process, types of tissue recoverable including corneas, veins, nerves, bone, cartilage, tendons, skin, and marrow). The amount of recoverable tissue from one body exceeds the number of recoverable organs. *Cf. id.*

tissue can be procured several hours after the patient's death and can be stored for longer periods of time.[98] Generally, donated tissue must be procured within twenty-four hours of the donor's death.[99]

After determining that the decedent is a suitable donor, the tissue bank or OPO specialist asks the family members about their willingness to donate.[100] The tissue bank or OPO representative may or may not tell the family about the bank's non-profit status.[101] 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.[102] As uses for donated tissue began to grow, additional tissue banks were started by physicians, researchers, and hospitals for use in their local communities.[103] Over time, tissue banks were primarily non-profit entities that varied in size, with the largest tissue banks connected to medical institutions.[104] In 1976, the American Association of Tissue Banks ("AATB")[105] was created to ensure quality standards, increase number of donations, support scientific exchange of ideas and provide adequate support for the tissue banks.[106] The AATB is the only organization that accredits tissue banks; however, tissue banks are not required or expected to be accredited.[107]

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.

101. *See generally* Katz, *supra* note 55, at 959–61.

102. Jason L. Williams, Note, *Patient Safety or Profit: What Incentives Are Blood Shield Laws and FDA Regulations Creating for the Tissue Banking Industry?*, 2 IND. HEALTH L. REV. 295–96 (2005).

103. Zodrow, *supra* note 97, at 411.

104. Williams, *supra* note 102, at 296–300; Zodrow, *supra* note 97, at 411–12.

105. AATB: American Association of Tissue Banks, http://www.aatb.org (last visited Apr. 11, 2008).

106. Williams, *supra* note 102, at 296–300. Zodrow, *supra* note 97, at 411–12.

107. Williams, *supra* note 102, at 297. Zodrow, *supra* note 97, at 412–13.

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 Act[110] 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

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108. Zodrow, *supra* note 97, at 412–13.

109. Indech, *supra* note 94, at 343 (quoting Human Tissue Intended for Transplantation, 21 C.F.R. § 1270 (1999)) (emphasis added).

110. 42 U.S.C. §§ 201–300 (2000).

111. FDA/CBER Testing HCT/P Donors for Relevant Communicable Disease Agents and Diseases, http://www.fda.gov/cber/tissue/prod.htm (last visited Apr. 11, 2008).

112. DEP'T OF HEALTH AND HUMAN SERVS., FOOD AND DRUG ADMIN., PUBL'N NO. FS 01-4, FDA'S CENTER ON THE FRONT LINE OF THE BIOMEDICAL FRONTIER (2002), *available at* http://www.fda.gov/opacom/factsheets/justthefacts/4cber.pdf; Indech, *supra* note 94, at 347.

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.[116] 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.[117] 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.[118] 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.[119]

Tissue procurement and use is not as strictly regulated as organ donation.[120] Thus, most community tissue banks send their tissues to be processed at a processing company and collect a recovery fee from the processing company.[121] Processing companies can be either profit or non-profit, but a growing number are profit earning corporations.[122] For-profit tissue processing companies make

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.

118. One of the largest tissue product companies is Cryolife, a leader in processing heart valves and other tissue products, with $40 million in worldwide 2006 sales of one of its more popular products. Cryolife-CorporateProfile, http://phx.corporate-ir.net/phoenix.2html?c=80253&p=irol-homeProfile&t=&id=& (last visited Apr. 11, 2008). Osteotech and Lifecell are two other tissue processing companies making millions in net revenues yearly. Osteotech-Financial Highlights, http://www.osteotech.com/finhi.htm (last visited Apr. 11, 2008); Lifecell, Annual Report (2004), http://lifecell.com/downloads/annual/2004%20Annual%20Report%20with%2010-K.pdf. Lifecell reported product revenues from cadaveric tissues used for plastic reconstructive surgery, burn victims and others of $32.9 million in 2002, $38.6 million in 2003 and $58.7 million in 2004. Lifecell, *supra*. Osteotech claims to be a global leader in processing human bone and connective tissue for transplantation and receives close to $100 million in net revenues in 2003–2005. Osteotech, *supra.* It is estimated that the total amount of revenue for tissue processing companies is over $1 billion. *See* Williams, *supra* note 102, at 297–99.

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.[123] This new tissue processing system has dramatically changed the face of tissue banking from one of altruism to that of significant profit.[124]

C. The Effect of Profit on Tissue Banks

Revenue earning tissue processing companies have changed the completely charitable nature of the tissue donation industry,[125] but they have also garnered great technological advancements for medical uses of the donated tissue.[126] Donated tissue is often used for allografts,[127] such as cryopreserved heart valves for patients with defective heart functions,[128] demineralized bone matrices for spinal fusion surgeries,[129] and acellular dermal tissue to replace skin for burn and cancer victims without the patient's body rejecting the new skin.[130] Acellular dermal tissue can also be used for cosmetic surgery, such as the reduction of wrinkles.[131] These are just a few of the

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Technologies, Osteotech, Is Otis, and CryoLife. Robin R. Young, FDA Issues Final Good Tissues Practices Rule, http://www.healthpointcapital.com/research/2004/11/29/fda_issues_final_good_tissue_practices_rule/ (last visited Apr. 11, 2008).

123. Williams, *supra* note 102, at 297–99.

124. *See generally* Katz, *supra* note 55, at 943–52.

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.

126. *See generally* Katz, *supra* note 55, at 963–67.

127. LifeLink Tissue Bank, Frequently Asked Questions and Answers, http://www.lifelinktb.org/index.cfm/fuseaction/index.cfm?fuseaction=Patients.FAQs (last visited Apr. 11, 2008) (defining allograft as a "tissue (i.e. bone, ligaments, heart valves) recovered from a human donor for transplantation into another person.").

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.).

129. Bone Graft Options for Spine Fusion Surgery, http://www.spine-health.com/topics/surg/bone/bone02.html (last visited Apr. 11, 2008) (donor allograft bones work well in the upper spine (neck) area). *See also* Osteotech, The Grafton Advantage, http://www.osteotech.com/prodgrafton.htm (last visited Apr. 11, 2008) (observing that Osteotech currently dominates as the demineralized bone matrix supplier, but is facing growing competition).

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.[132] Many of these processes are patented by large commercial tissue processors that are unable to keep up with the growing demand[133] and gain significant profit from selling the products to hospitals.[134]

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.[135] 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.[136] There is mixed speculation about

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visited Apr. 11, 2008).

132. Tissue Services, http://www.lifecell.com/tissue (last visited Apr. 11, 2008). Cadaveric tissue can be used in the following ways:

> [T]issue transplants make possible skin grafts for thousands of critically burned patients and others in need of soft tissue repair; donated corneas avert or correct blindness; donor heart valves help repair cardiac defects or damage; bone, cartilage and tendon grafts help restore function in people who would otherwise be incapacitated or disabled.

Id.

133. Aaron Smith, *Tissue From Corpses in Strong Demand: Market for Allografts Keeps Growing, Outpacing Supply*, CNN MONEY, Oct. 5, 2005, *available at* http://money.cnn.com/2005/10/04/news/midcaps/allograft/index.htm.

134. Katz, *supra* note 55, at 943, 963–67.

135. Kevin L. J. Oberdorfer, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 GEO. L.J. 365 (discussing tissue collection and informed consent in research and therapeutic settings and applying it to the facts in *Greenberg v. Miami Children's Hosp. Research Inst., Inc.* 264 F. Supp. 2d 1064 (S.D. Fla. 2003)).

136. CAL. HEALTH & SAFETY CODE § 7158.3(b)(1) (Deering 2006); *see* SHERRY AGNOS, CAL. SEN. OFFICE OF RES., TISSUE DONATIONS: ISSUES AND OPTIONS IN OVERSIGHT, REGULATION AND CONSENT 11 (2003), *available at* http://www.sor.govoffice3.com/ (select "Publications" tab; then follow "By Subject Area" hyperlink; then follow "Health" hyperlink) (stating that unless families are made aware of for-profit or non-profit status, it may be "difficult to assert that genuine informed consent was obtained"). *See also* Katz, *supra* note 55, at 957–59; Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163 (asserting that

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.[137] Other states may follow California's actions[138] and DHHS proposed a regulation, which was enacted, that requires disclosure about the tissue bank's profit status.[139]

V. APPLYING ORGAN OR TISSUE PROCUREMENT REGULATIONS TO EMBRYO TREATMENT

As the existing numbers of cryopreserved embryos grow,[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.[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;[142] likewise, organ transplants are considered when no other alternative exists.[143] Also like organs, human embryos have the power to sustain human life. The capability

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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).

137. Alison Jack & Christopher Womack, *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).

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

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.*

140. *See supra* notes 17, 20–24 and accompanying text.

141. *See supra* Parts III.B, IV.B.

142. *See supra* note 7 and accompanying text.

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.[144] However, unlike current regulations for organ or tissue donation, [145] screening procedures are less stringent for embryo donation[146] because embryos are created to become genetic offspring of a particular couple regardless of genetic disease.[147]

Selling embryos presents many of the same issues that prompted legislators to prohibit monetary exchange for tissue and organs.[148] 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.[149] This practice devalues the intrinsic worth of humans, commodifies potential children, and might even encourage couples to buy the "best" child for their money.[150] Because couples cannot separate the embryo's value from its capabilities, arguments made by supporters of organ sale[151] 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.[152] Finally, economic need or pressure from fertility clinics may unduly influence a decision to sell an embryo.[153]

Public policy required Congress to protect vulnerable organ donors and recipients with strict governance of organ procurement.[154]

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144. *See supra* Parts II.A, IV.A, and notes 97–99 and accompanying text. Tissues do not face shortages as organs do because they do not have to be matched perfectly with the donor and each individual can donate larger amounts of tissue. *Id.*

145. *See supra* Parts III.B, IV.B. Couples are able to test for genetic diseases if they wish, but are often limited in what types of tests are available. *See* Palca, *supra* note 7.

146. *See supra* notes 12–13 and accompanying text. However, if sperm or other type of reproductive tissue is donated, it goes through strict screening measures. *Id.*

147. *Cf. supra* text accompanying note 13.

148. *See supra* notes 68–70 and accompanying text.

149. *See* Part III.C.1. Couples may also "bid" on embryos based on specific qualities and that sounds uncomfortably similar to slavery as well. Halloway, *supra* note 71 and accompanying text; *see also* Stein, *supra* note 22.

150. *See supra* notes 22–24 and accompanying text.

151. *See supra* Part III.C.1.

152. *See supra* notes 23–24 and accompanying text.

153. *See supra* notes 26, 28 and accompanying text.

154. *See supra* notes 47–58 and accompanying text.

Coerced organ donors[155] and desperate recipients are subject to significant medical risks that are easily ignored during times of crisis.[156] Similarly, parents desperate for a birthed child[157] or the economic benefits of selling embryos for research are easily pressured by fertility clinics or others to buy or sell embryos.[158] 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.[159] 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.[160]

Allowing profitable companies to process tissue and create marketable products from donated tissue has produced great gains in medical technologies.[161] 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.[162] 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.[163]

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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

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.