COMMENT

AN INFORMATION PRIVACY APPROACH TO REGULATING THE MIDDLEMEN IN THE LUCRATIVE GAMETES MARKET

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1. INTRODUCTION

An ad in an upstate New York college newspaper reads: "Egg Donor Sought. Attractive, Intelligent, Jewish, SAT score 1370 (or equivalent), 21-29 years of age, at least 5'4" tall and no more than average weight. Compensation—$75,000."1 In a Baghdad hospital, a twenty-two year old taxi-driver awakens to find that he is "one kidney lighter and $1,400 ... richer after a three-hour operation."2

In today's global economy, both human reproductive cells and kidneys traverse supply chains that span multiple borders. However, because various national laws regulate or forbid transactions of body parts,3 and the extraction and transplant processes require

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1 See Missy Kurzweil, Op-Ed, Egg Donor Sought Don't Miss Out, CORNELL DAILY SUN, Sept. 21, 2004, available at http://www.cornellsun.com/node/12494 (quoting an advertisement that appeared in the same publication the day before).


3 There are myriad markets for human body parts, including body parts for medical research and education (i.e., Moore's hairy cell line and cadavers for first year medical students), postmortem tissues which can be reprocessed into surgical products necessary for operations, blood and DNA. See generally MICHELE GOODWIN, BLACK MARKETS: THE SUPPLY AND DEMAND OF BODY PARTS 160 (2006) (discussing the underground body broker trade); R. Alta Charo, Skin and Bones:
highly technical skills, the typical transaction in the human body parts market is rarely an arms-length one. Rather, the market operates through complex networks of both legitimate and illegal intermediaries such as tissue banks, clinics, processing companies, and brokers. These intermediaries need not directly handle the transfer of the body part. However, in arranging the transaction, they play a direct role in transferring personal information—often

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**Post-Mortem Markets in Human Tissue, 26 NOVA L. REV. 421 (2002) (discussing the medical research and processing product end uses for human tissue retrieved at death).** However, the scope of this Comment is limited to transactions in which body parts are largely unaltered, and exchanged with the intent of being used for their original or natural use. Further, the focus will be on body parts exchanged between living persons; even though cadavers are a common source of body parts, it is presumed that one does not maintain information privacy interests past death. But see Clay Calvert, *The Privacy of Death: An Emergent Jurisprudence and Legal Rebuke to Media Exploitation and a Voyeuristic Culture*, 26 LOY. L.A. ENT. L. REV. 133, 134 (2006) (distinguishing information privacy from the emerging privacy of death jurisprudence in which relatives of the decedent are wrangling over “what others see about the death of [their] late family members”).

4 This Comment focuses on the information privacy aspects of commodifiable body parts—that is, largely unaltered human body components which are currently exchanged in both legitimate and black markets. While information derived from body parts such as the cell line derived from Moore’s hairy cell leukemia sample have value, exchanges of such information amongst researchers are encapsulated in the form of such intellectual property as trade secrets and patents. Moreover, the value of the proprietary rights in such information stems at least in part from the researchers’ efforts and manipulation of the source material. Despite this Lockean argument, one must recognize that “[t]here is substantial research value both in unidentified material (i.e., material that is not linked to an individual) and in material linked to an identifiable person and his or her continuing medical record.” R. Alta Charo, *Legal Characterizations of Human Tissue, in Transplanting Human Tissue: Ethics, Policy, and Practice* 101, 112 (Youngner et al. eds., 2004) (emphasis added). “Sometimes, however, it is necessary to identify the source of the research sample, because the research value of the material depends on linking findings regarding the biology of the sample with updated information from medical or other records pertaining to its source.” Id. at 113.

5 To clarify, the parties to the arms-length transaction are the source (“donor”) and ultimate recipient of the body part.

6 This Comment refers to banks, clinics, and brokers interchangeably.

7 For the purposes of this Comment, personal information is defined as any piece of information which can potentially be used to uniquely identify, contact, or locate a single person. This includes but is not limited to financial information such as social security and taxpayer numbers, genetic and biometric data, addresses, and health information. Privacy concerns arise when there are breaches and abuse of the collection, storage, transfer, and uses of this uniquely identifiable information. This definition is partially molded from the definition in the European Union Data Directive and the OECD Privacy Guidelines. Council Directive 95/46/EC, art. 2, 1995 O.J. (L 281) 31; *OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data*, (Sept. 23, 1980), available at
of a highly sensitive nature—relating to the body part’s source and recipient. At a minimum, medical information necessary for determining compatibility between the source and recipient (such as blood type) passes through the network of middlemen. Financial, genetic and other medical information are also often collected and processed. Moreover, in the case of gametes, because consumers place a premium on obtaining information above and beyond bare-bones medical data, family histories and personality trait information are also routed through the supply chain. In a global market of suppliers, personal information is increasingly bundled with the exchanged body parts. This development, coupled with advances in medical and information technology, has propelled a privacy construction of the human body into the public consciousness.

http://www.oecd.org/document/18/0,2340,en_2649_34255_1815186_1_1_1_1,00.html [hereinafter OECD Privacy Guidelines].

8 The OECD Privacy Guidelines also distinguish between sensitive and nonsensitive personal data based on whether the nature of the data is treated as inherently sensitive; the drafters give medical records as an example. Id. See also James T. Sunosky, Privacy Online: A Primer on the European Union’s Directive and United States’ Safe Harbor Privacy Principles, 9 CURRENTS INT’L TRADE L.J. 80, 86 (2000) (noting the importance and sensitivity of “personal information specifying medical or health conditions, racial or ethnic origin, [or] political opinions”).

9 A kidney is only useful or valuable to the recipient insofar as its source has compatible ABO blood group and an adequate number of similar human leukocyte antigens (“HLA”) and other minor antigens. See International Association of Living Organ Donors, Inc., Living Kidney Donation: Now . . . About Your Health, http://www.livingdonorsonline.org/kidney/kidney4.htm (last visited Nov. 17, 2007) (explaining how the HLA test determines compatibility).


11 See Sandra Barney, Accessing Medicalized Donor Sperm in the US and Britain: An Historical Narrative, 8(2) SEXUALITIES 205, 212 (2005), available at http://sexualities.sagepub.com/cgi/reprint/8/2/205.pdf (reporting as an example that Fairfax Cryobank offers discounted sperm on the grounds that the donor had provided less information than that contained in a typical donor profile, which encompasses such information as “the condition of the donor’s male relatives’ hair, his favorite animal . . . and his self-reported musical abilities”).

12 As recently as January 17, 2007, President George W. Bush “urged Con-
This Comment argues that an information privacy-based approach\textsuperscript{13} to regulating the middleman in the gametes market will facilitate a harmonized approach for the existing quasi-grey market\textsuperscript{14} in reproductive tissue. An information privacy approach will also address the currently neglected cross-border data transfer issues in the human body part trade. Moreover, because this approach eschews the varying and sometimes conflicting cultural and religious perceptions of ownership that ensnare a property interest-based approach,\textsuperscript{15} it may serve as a regulatory model beyond the gametes context for a plausible active tissue and organ market. Section Two sets forth the concept of an information privacy interest in the human body, as distinct from the property interest. Section Three examines the gametes market, and the human tissue regulatory landscape in the United States and abroad. The information privacy issues of the global gametes trade are also scrutinized. In Section Four, the information privacy regulatory approach is developed, using the Organization of Economic Cooperation and Development Privacy Guidelines as a framework. Section Four then contemplates which existing international bodies

\textsuperscript{13} An information privacy approach focuses on “precluding the dissemination or misuse of sensitive and confidential information.” Dorothy J. Glancy, Privacy on the Open Road, 30 OHIO N.U. L. REV. 295, 321 n.101 (2004) (quoting Hill v. Nat’l Collegiate Athletic Ass’n, 865 P.2d 633, 654 (Cal. 1994)).

\textsuperscript{14} “Quasi-grey” is an appropriate adjective because while some jurisdictions prohibit the outright sale of gametes (i.e. monetary consideration in exchange for the gametes), they permit compensation for the provider’s time and efforts—and absent government-imposed caps, this compensation can range from $4,500 to $50,000. See María Cristina Caballero, Spar Takes on Boom in Baby Biz: Harvard Business School Professor Delves into ‘Commerce of Conception,’ HARV. U. GAZETTE, Mar. 16, 2006, available at http://www.news.harvard.edu/gazette/2006/03.16/01-babybiz.html (describing the field of reproductive technologies as a booming economic sector, in spite of the “denials of authorities and the difficulty for most to conceive of a child as a commercial product”); see also Kerry Howley, A Market in Morals, THE AMERICAN, Jan. 26, 2007, available at http://www.american.com/archive/2007/january-0107/a-market-in-morals/ (“If you’re a European citizen, chances are you’re of origin either prescribes compensation for donor eggs, [or] prohibits the anonymous sale of sperm . . . . But reproductive freedom may lie just a high-speed train away, over a border and into a different legal regime.”).

\textsuperscript{15} See infra Section 2.
are best suited to administer this approach. After concluding that the divergent cultural and moral views of gametes make such a promulgation impossible, Section Four argues that within the United States, the Food and Drug Administration should be responsible for applying this regulatory approach to the typical middleman in the gametes market: the sperm and ova banks. Finally, Section Five briefly contemplates the extension of the information privacy regulatory approach for a hypothetical legitimate organs market.

2. PRIVACY AND PROPERTY INTERESTS IN THE BODY

The concepts of bodily autonomy and ownership are inherent in the principle of "spatial privacy," which concerns physical access to one's body and personal spaces. As Professor Anita Allen explains:

> The human body, like information, is an object of privacy.... The general rule within legal doctrine is that, in the absence of consent, intentionally harmful or offensive physical contact with another is tortuous battery; uninvited entry onto another's property is trespass; and intrusion into another's [sic] seclusion, especially by searching, prying, or remote surveillance, is an invasion of privacy.  

Procuring gametes, blood and other bodily material necessarily requires some degree of physical access to one's body and personal space. As long as the source and recipient of the body parts consent to this physical access by the doctor performing the extraction and transplant, spatial privacy is not a concern. However, the harvesting of gametes also implicates genetic information because gametes are, by definition, cells which hold half

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17 *Id.*

18 Some methods of extracting body parts are more intrusive than others—sperm, for instance, may be harvested without actual physical intrusion with needles. *See IDANT Labs., Frequently Asked Questions*, http://www.idant.com/fertilityServices/faqs.htm (last visited Nov. 17, 2007) (specifying a preference for specimens obtained by manual stimulation).
the genetic information needed for human procreation. Genetic information entails an information privacy interest because "[t]o request a family history or . . . the results of genetic tests is to ask about personal information" that an individual may feel it important to secure from access by others. Further, genetic information is intrinsically linked to our identities because it is unique to us, dictates our appearance, reveals links to past and present relatives, and influences the disposition of our health and that of our offspring. Thus, information privacy reflects an individual's ability to control the manner in which others access and use the information that is intertwined with his personhood.

Professor Sonia Suter accordingly distinguishes between property and privacy on the basis of control: property connotes control within the marketplace, while privacy connotes control over access to the individual self. Central to the Anglo-Saxon construct of "property" is the notion that something may be detached and alienable from the self. On the other hand, privacy revolves around the connection, or relationships we build and define through the amount we grant to others, of access to our selves. Nonetheless, property and privacy interests are not mutually exclusive. Some scholars and the drafters of the Genetic Privacy Act justifying the creation of property interests in personal informa-

19 Sonia M. Suter, Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy, 72 Geo. Wash. L. Rev. 737, 738 (2004) ("Genetic information includes information contained within the DNA in our cells, information present in family histories, information evident in visible traits such as eye color and gender, and information present in medical records.").

20 See Merriam-Webster Online Dictionary, http://www.m-w.com/dictionary/gamete (last visited Nov. 17, 2007) (defining gamete as "a mature male or female germ cell usually possessing a haploid chromosome set [which contains half the genetic information] and capable of initiating formation of a new diploid individual [whose cells contain full genetic information] by fusion with a gamete of the opposite sex") (citations omitted).


22 Suter, supra note 19, at 738-39.

23 Id. at 739 ("[Privacy] empowers us by giving us control over the manner in which others will use the information and the right to decide whether we want to learn this information about ourselves.").

24 See id. at 737 (distinguishing between property and privacy on the grounds of whether something is alienable from the self).

25 See id. at 769 ("Property provides control over a commodity; privacy provides control over the self and relationships that constitute the self.")

tion because property rights function as a proxy for control over access to the information.\textsuperscript{27} However, given the miniscule transaction costs involved in controlling access to the information,\textsuperscript{28} this justification is weak. Absent regulation mandating specific types of record collection, it is relatively cheap for the individual to restrict access. Specifically, the individual can limit the amount of information voluntarily disclosed or choose to disclose only to a third party person or firm that is contractually obligated to safeguard that disclosed information from unauthorized access. Property rights in personal information do not boost one’s control over access to the information.\textsuperscript{29} Thus, it is information privacy interests that ensure that no third parties may assume the gate-keeping role in guarding access to oneself.

3. THE GAMETE MARKET

The scope of personal information collected in tandem with the gametes varies with the extraction and supply processes and regulations governing the gamete banks’ practices. An overview of gamete procurement processes and the international nature of the gamete market reflects the value of and risks posed to the personal information of the gamete provider.

\textsuperscript{27} See Suter, supra note 19, at 754 (“Control is central to informational privacy, and ‘property’ works as a proxy for such control.”) (internal citations omitted). Graeme Laurie explicates further:

Confidentiality is concerned with security of information.... To be confidential, information must be in a state of limited access from individuals, groups, bodies and institutions generally. Confidentiality is characterised by a relationship involving two or more individuals, one or more of whom has undertaken—explicitly or implicitly—not to reveal to third parties information concerning the other party to the relationship.

\textsuperscript{28} The costs of controlling access include costs relating to limiting collection of the data and safeguarding the stored data from unauthorized access with encryption technology. See generally Ben Malisow, Valuing Secure Access to Personal Information, SECURITYFOCUS, Aug. 19, 2004, http://www.securityfocus.com/infocus/1797 (explaining the ease with which personal information can be bought without permission).

\textsuperscript{29} See Jessica Litman, Information Privacy/Information Property, 52 STAN. L. REV. 1283, 1293 (2000) (“If ownership of private property is power, however, calling privacy rights ‘property rights’ offers the promise of magically vesting the powerless with control over their personal data.”).
3.1. Process of Harvesting Sperm and Ova

3.1.1. Sperm — From Source to Delivery

The procurement process for sperm is long but technically simple. Although sperm may be extracted through electroejaculation or surgery, such techniques are generally reserved for infertile men; sperm is generally obtained through manual stimulus by the provider. The sperm is typically stored via cryopreservation, in which vials of the semen samples are diluted with cryoprotectants and lowered into liquid nitrogen freezers where they are slowly cooled at rates of between 1°C/min and 100°C/min. Frozen at the low temperature of around -196°C, any biochemical activity in the sperm, including those triggering cell death, is stopped, therefore enabling storage of sperm for years. When a consumer purchases sperm (the unit being “straws” or vials), the straw is removed from the freezer and thawed in a warm water bath of up to 37°C. It is then delivered to the consumer and

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33 The sperm bank portions out semen samples on the basis of sperm count (concentration) and percent motility. See Oregon Health & Sci. Univ. Infertility Lab, Semen Cryopreservation: Patient Information, http://www.fertilityoregon.com/lab/process.htm#number (noting that each semen sample will yield up to 1.8 milliliters in a vial).

34 Cryoprotectant is a vitrification solution that lowers the freezing temperature and increases the viscosity of the semen sample so as to prevent damage to the cellular membranes from crystal formation damage. See Critser et al., supra note 32, at 147 (naming glycerol buffered with egg yolk-citrate medium as an example).

35 See id.


37 Oregon Health & Science University Infertility Lab, supra note 33.
her physician to begin the impregnation process using assisted reproductive technologies.\textsuperscript{38}

By contrast, the administrative aspect of bringing sperm "fit for consumption" to the market is complex. An immense quantity of medical and personal information is collected and analyzed by sperm banks as part of their daily operations.\textsuperscript{39} Before undergoing the actual procurement procedures, the sperm provider candidate must undergo a preliminary and informal screening process that scrutinizes his basic health,\textsuperscript{40} height, weight, age,\textsuperscript{41} and educational background.\textsuperscript{42} Candidates who pass this round are then instructed


\textsuperscript{39} The information collected fulfills this purpose in at least three ways. First, the bank analyzes it to detect the susceptibility of the provider's DNA to genetically-linked diseases. Failure to do so would be akin to selling defective goods with potentially dire health implications for the progeny conceived using the sperm. \textit{See} Johnson v. Cal. Cryobank, 124 Cal. Rptr. 2d 650 (Cal. Ct. App. 2002) (involving a suit for failure to disclose the risk that a child conceived from the sperm sold by California Cryobank was at high risk of developing autosomal dominant polycystic kidney disease, a genetically transferable life-threatening condition).

Second, the information is an essential price valuation tool as banks can prioritize the providers based on the immaculateness of their personal and family health records, and other desirable traits such as green eyes. \textit{See} \textit{Buying Babies, Bit by Bit}, THE ECONOMIST, Dec. 23, 2006, at 117 [hereinafter \textit{Buying Babies}] (reporting that one sperm bank also offers "exclusive worldwide rights to a donor for $75,000").

Third, the information itself is commoditized as part of the goods and services the bank delivers to consumers. \textit{See} id. at 118 ("Basic information about donors [at California Cryobank]-height, weight, colouring, occupation comes free [with purchase of the specimen], but further information must be paid for. A facial-features report, listing such attributes as 'nostril flare' (narrow, average or large), costs $12 . . . .")

\textsuperscript{40} Basic medical questions during this screening process are intended to filter out any prospective providers with known genetically-linked diseases such as cancer or diabetes.

\textsuperscript{41} California Cryobank justifies the age restriction thusly:

Donors must be between the ages of 19 and 39. According to the Cryobank's medical director, Cappy Rothman, MD, "While a man's fertility does not automatically decline after the age of 39, men under that age are more likely to consistently produce superior quality of sperm necessary for successful freezing and thawing." The American Association of Tissue Banks sets age 39 as the maximum age for donors.

\textsuperscript{42} Educational information is a function of market demand, since most con-
to submit paperwork on sexual history, drug use, and additional non-health information such as "what would send [one] . . . to an ATM at three in the morning." While the paperwork often involves filling out lengthy questionnaires reminiscent of ones common to online dating web profiles, middleman banks are quite vigilant in collecting and conducting a thorough medical background check. Mindful of its legal liability, its public image, and consumer confidence, California Cryobank requires candidates to:

[C]omplete a three-generation medical and genetic history (better known as the "long profile"), meet with several people for interviews, including [a] genetic counselor, have a complete physical exam and have various laboratory tests [that screen for sexually transmitted diseases including gonorrhea, cytomegalovirus (herpes), hepatitis, HIV, cystic fibrosis, Creutzfeldt-Jakob disease, and syphilis].

Candidates also must provide multiple semen samples to the middleman bank. The clinic analyzes the quality and viscosity of...
the semen to determine whether to accept the sperm provider into a full-time donor program. It is not always clear whether the information or specimens collected from "rejected" sperm providers are destroyed or disposed of, and if so, how.

The screening process continues even after the sperm provider enters a contractual agreement with the middleman clinic. All sperm is stored for at least six months under quarantine while the sperm providers undergo health monitoring and testing every three months.

3.1.2. Ova – From Source to Delivery

The technical procurement of ova is far more complicated because the egg follicles must be punctured with a needle and their contents extracted. Further, in contrast to the vast quantities of sperm that can be released per ejaculation, the female body only naturally matures and releases one egg per month. Since men-

50 California Cryobank generally looks for sperm providers who have “five times the normal range” of sperm count per ejaculation on the grounds that a portion of sperm is lost in the freezing and thawing process. Stoler, supra note 42. The rationale for selecting “robust sperm” is that such sperm is more likely to be effective and survive the cryopreservation storage process. See Donor Semen Quality Varies Within and Between Banks, FERTILITY WEEKLY, Aug. 5, 2002 (summarizing studies which show that the freezing and thawing process of cryopreserved sperm is “usually associated with diminished viability, motility, and functional ability of the sperm” although “[s]perm susceptibility to cryodamage appears to vary between individuals and often between samples of a given donor”) (internal quotations omitted).

51 The Author was unable to find any sperm bank and broker websites, or applications to donate, addressing disposal (as opposed to retention) of the rejected gametes and candidate profile information. California Cryogenics, however, does destroy all records of sperm donors once their samples are sold. See US Sperm Banks Fret About Government Meddling, BioEDGE, Oct. 3, 2007, http://www.australasianbioethics.org/Newsletters/268-2007-10-03.html.

52 A typical contractual agreement contains three parts: (1) authorization for release of semen; (2) personal and financial health; and (3) frozen donor semen purchase agreement, which outlines the terms and conditions for utilizing donor semen specimens. California Cryobank, Client Accounts, http://www.cryobank.com/spbanknonphys.cfm?page=45 (last visited Jan. 3, 2007) (stating that both the client orientation and client agreement forms must be completed and signed prior to placing orders).

53 Id.

strual cycles vary from person to person, egg providers are subject to hormonal injections such as Lupron to suppress and thereby synchronize their cycles with those of the recipients. This is followed by ovarian hyper-stimulation treatment, which involves daily hormonal injections that trigger the follicles to mature and release a dozen or more eggs at a time. The next step is an injection of human chorionic gonadotropin. Thirty-six hours later, the egg provider will “undergo the egg retrieval under mild sedation” in which a needle will be inserted through the vaginal wall to reach the ovarian follicles, and apply suction to extract the ova with the guide of an ultrasound image.

It is far more difficult to “bank” extracted eggs than to “bank” sperm. Until December 31, 2005, when the first baby conceived with a frozen egg from a commercial ova bank was born, middleman clinics merely sold broker services by facilitating information exchange between those interested in giving eggs and those receiving them. This was because cryopreservation technology

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55 Lupron effectively “shuts down the ovaries so that no eggs ripen or are released.” Mary Lyndon Shanley, Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs, 36 LAW & SOC’Y REV. 257, 264 (2002); see also Duke Fertility Services, Medications: Lupron, DUKEHEALTH.ORG, http://www.dukehealth.org/Services/Fertility/Resources/Medications/Lupron (last visited Oct. 25, 2007) (describing Lupron as effectively turning one’s ovaries off so that the physician can “control the amount of ovarian stimulation by the amount of medication”).

56 See Egg Donation Inc., Donor Info, http://www.eggdonor.com/?section=donor&page=process (last visited Mar. 15, 2007) [hereinafter EggDonor.com] (“Once the doctor has synchronized the cycles, you will begin receiving daily injections of Gonad-f. Fertinex or Follistim to stimulate your ovaries. Ultrasound examinations are then used to evaluate your ovaries’ response to the stimulation treatment and blood tests performed to monitor your estradiol level.”).


58 EggDonor.com, supra note 56.

59 See Shanley, supra note 55.

60 Univ. of Kentucky, First Baby Delivered from Commercial Frozen Donor Egg Bank, LAT L. WKLY., Jan. 27, 2006, at 249 (reporting on the ground breaking birth of Avery Lee).

61 See Mayumi Saito, Here Comes the Egg Biz: Ova Operations Open in Japan, http://findarticles.com/p/articles/mi_m0NTN/is_44/ai_108881982 (last visited Oct. 25, 2007) (reporting that in 2003, a newly opened branch of a South Korean ovam bank in Tokyo would arrange for recipients to browse the egg provider pro-
for eggs has lagged behind that for sperm. The developmental stages of the oocytes into ova vary and oocytes are far more sensitive to the "multiple steps involved in the cryopreservation procedure, such as CPA [cryoprotectant agent] addition/removal, cooling, and warming." Oocytes are susceptible to osmotic and ionic stress damage resulting from the cryoprotectant agent's permeation through their membrane, and to aneuploidy resulting from exposure to low temperature. The new technology that enabled the birth of Avery Lee on December 31, 2005, involves use of a "more rapid freezing technique... in which the water in the egg is replaced with a cryo-protectant that prevents egg damage." Nonetheless, the high water content in the mature cells—the eggs—makes "freezing and thawing them a delicate procedure that has a [mere] 20 percent chance of success." This low rate of success explains why many middleman clinics currently bypass the cryopreservation phase, and merely arrange the transaction between the ova provider and recipient.

files, and even meet up to two providers "in person before making a final choice" to undergo the medical procedure.

See id. (reporting that in 2003, "freezing human eggs for clinical applications [was] premature" due to a lack of safe methods).

The distinction between oocytes and ova is that the former are immature egg cells that mature into the latter. Critser et al., supra note 32, at 149-51.

Id. Further sensitivity may stem from the hormonal treatments (e.g., Lupron, which is a gonadotropin-releasing hormone agonist) which influence the development of the germinal vesicle (fully grown) oocytes. Germinal vesicle oocytes are particularly sensitive because maturation causes the germinal vesicle to break down and "meiotic spindles [to] form in the cytoplasm, which makes them more vulnerable to the detrimental effects of cryopreservation processing." Id.

Aneuploidy is a condition in which the number of chromosomes is abnormal due to extra or missing chromosomes; this may lead to chromosomal genetic disorders including Down syndrome and Turner syndrome. See Ulrich Melcher, Aneuploidy, in MOLECULAR GENETICS 1211, 1211 (2003), http://opbs.okstate.edu/%7Emelcher/MG/MGW1/MG1211.html (explaining that human genetic diseases may result from trisomy or monosomy, with Down syndrome being a prominent example of the former).

Critser et al., supra note 32, at 149-51. See also Michael J. Tucker, Human Oocyte and Embryo Cryopreservation, IVF.COM http://www.ivf.com/boston.html (describing the general concern over increased aneuploidy potential due to freezing and thawing process of mature oocytes).

Univ. of Kentucky, supra note 60.

Id.


See EggDonor.com, supra note 56 ("Once your Application has been approved, you will be entered into our egg donor database and available to be
As advances in cryopreservation technology make the retrieve-freeze-thaw procedure more viable for commercial ova banking, it is inevitable that ova providers will be subjected to information practices similar to those in sperm banking. Similar to sperm providers, ova provider applicants already have to provide information on their family history, medical history (including child bearing history), sexual activity, drug and medication usage, educational background, philosophy on life, and any special characteristics.\textsuperscript{71} Their profiles, along with photographs, are also uploaded to a database that consumers may browse.\textsuperscript{72} Additionally, ova providers are prescreened to ensure that age restrictions are met\textsuperscript{73} and are subject to assessment by a professional with regard to their psychological and medical suitability. With an increasing chance of successful conception using cryogenically frozen eggs, middleman clinics are increasingly storing the actual genetic information itself (contained in the gametes) in tandem with the personal information of the ova providers.\textsuperscript{74}

3.2. The International Gametes Market, Information Transactions, and Regulation

3.2.1. Overview of the International Gametes Market

Sperm and ova banks are the antithesis of barber shops\textsuperscript{75} in that

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\item \textsuperscript{71} Advanced college degrees such as master’s or doctorate degrees, Asian and Jewish ancestry, career-oriented professionals, and unique artistic or creative talents comprise special characteristics. Egg Donation Inc., Donor Info, http://www.eggonline.com/?section=donor&page=info (last visited Oct. 25, 2007).
\item \textsuperscript{73} EggDonor.com, supra note 56 (justifying the restriction on adult status to ages between 21-30 and time of optimal biological condition).
\item \textsuperscript{74} Id.
\item \textsuperscript{75} In literature on globalization, barbers are a popular example of service
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the customer bases need not be tied to the physical location of the headquarters or labs. While many middlemen operate labs or clinics in different states or countries,\textsuperscript{76} most banks will ship cryopreserved sperm in special vials packed in liquid nitrogen\textsuperscript{77} to mailing addresses around the world.\textsuperscript{78}

Despite the fragility of ova in relation to the cryopreservation storage process, international ‘mail-order’ egg donation also exists. Dr. B.C. Heng reports that scarcity of egg providers in developed countries has prompted “some fertility clinics . . . to source oocyte providers tied to a physical location. Put differently, barber shops are necessarily local: since few people would find it cost-effective to fly to another country for a haircut since the cost of the flight would be greater than any savings from wage differentials. \textit{See}, \textit{e.g.}, \textsc{Charles Derber, People Before Profit: The New Globalization in an Age of Terror, Big Money, and Economic Crisis} 139 (2002) (noting the local and small-scale characteristics of barber shops).


\textsuperscript{77} The “Frequently Asked Questions” page on Xytex’s website explains:

Each unit of semen arrives frozen in a screw-cap vial. Each vial is clipped to a metal support rod (called a “cane”) to facilitate vial removal from a refrigerated “tank” (or “dry shipper”). The tank is refrigerated with liquid nitrogen trapped in spongy material to prevent spillage, hence the name “dry shipper.” Outside of the tank are shipping documents including product description and other non-frozen material such as insemination appliances, “Summary of Records” and a packet of documents for the inseminated patient.


\textsuperscript{78} While some banks will ship the sperm specimen directly to the customer, others will only ship to people or places with medical authority, such as a physician, authorized medical staff, or institutions approved for therapeutic treatment with donor semen. \textit{Compare} California Cryobank Sperm Bank—Reproductive FAQs, http://www.cryobank.com/reprofq.cfm?page=5 (last visited Dec. 7, 2007) (“The specimens are guaranteed in the dry shipper tanks for 7 days from the date shipped.”) and Xytex Patient Page, \textit{supra} note 77 (“[S]hipments will only be sent to your medical specialist who has signed a Supply Agreement with Xytex”).
donors from poorer countries . . . .”

Moreover, many banks operate thriving web-based “storefronts” on the Internet by selling subscription access to a protected electronic database of sperm provider profiles. The websites also list the rates charged per shipment of a particular “grade” of treated sperm. After submitting an “Authorization for Release of Semen” form or an equivalent signed notice, which indicates that the consumer is receiving care under the supervision of a physician, consumers may complete either an electronic or hardcopy order form for a particular sperm provider’s specimen. The “mail-order” sperm business often crosses international borders. Danish sperm bank giant Cryos, for instance, provides semen for artificial insemination treatment in as many as sixty countries, including Spain, Paraguay, Kenya, Hong Kong and the United States.

Operating a virtual storefront makes economic sense to the middleman, because the service—access and use of genetic information of individuals with particular physical, social, and personal attributes (and experiences)—is a niche one. Consumers are very selective in designing the genetic makeup of their offspring, because they want to maximize the likelihood that their offspring will

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80 Id. (“[F]rozen sperm of the recipient’s male partner is exported abroad through courier mail”).

81 Id.

82 See e.g., Xytex, Sample Donor Profile. http://www.xytex.com/patient_sdp.cfm (last visited Dec. 7, 2007) (providing a sample profile that shows what information is contained in a donor profile).


85 Lizette Alvarez, Spreading Scandinavian Genes, Without Viking Boats, N.Y. TIMES, Sept. 30, 2004, at A4 (listing possible destinations for deposited sperm and indicating that sperm banks may establish new satellite offices in places where its Internet mail-order business demonstrates a sufficient demand in that area).
identify with them and their existing or ideal partners.\textsuperscript{86} Shared ancestry or heritage, similarity of physical features, and common personality traits strengthen the relationships that consumers have with their offspring.\textsuperscript{87} As consumer preferences for access and use of genetic information in perpetuating their progeny vary with individual taste, the success of the web-based fertility business is vested in its ability to address on a global scale the scarcity of gamete providers that meet consumer demand.\textsuperscript{88} In other words, blonde-haired, blue-eyed sperm providers with doctorates in astrophysics and who speak at least one Scandinavian language may be scarce in Japan but are likely available in Denmark.

3.2.2. \textit{International Markets as a Function of Regional Regulatory Landscapes Over Information Disclosure in Britain, Denmark, and the United States}

Local regulations, ranging from laws mandating disclosure of the identity of sperm or ova providers\textsuperscript{89} to outright bans on gamete transfers,\textsuperscript{90} also contribute to the scarcity of supply.\textsuperscript{91} Regulation-

\textsuperscript{86} Although critics warn of designer babies and eugenics, Cryos Managing Director Ole Schou insists that the real impetus is that people want “someone like them, someone they can relate to.” \textit{Id. See also} Caballero, \textit{ supra} note 14 (reporting an increasing demand for ‘designer babies:’ the consumer decides which eggs to purchase based on SAT scores and other desired characteristics).

\textsuperscript{87} Stoler’s interview with California CryoBank’s founder reveals the preferences consumers have for similar ancestry: “Italian women, sometimes they only want full-blooded Italians.” Stoler himself was valued for his Jewish ancestry, which led him to quip that “Jewish women are hard-pressed to find the seeded rye.” Stoler, \textit{supra} note 42.

\textsuperscript{88} Certain attributes, such as blonde hair and blue eyes, tend to be more popular than others. In 2005, the FDA banned “sperm from any European countries with exposure to mad cow disease” causing U.S. sperm banks to “run[] low on donor sperm that can produce . . . Scandinavian babies.” \textit{Mad Cow Ban Leads to U.S. Shortage of ‘European’ Sperm}, \textit{THE CANADIAN PRESS}, Sept. 21, 2007, available at http://www.cbc.ca/story/health/national/2007/09/21/sperm-shortage.html [hereinafter \textit{Mad Cow Ban}].


\textsuperscript{90} Switzerland’s constitution prohibits all commercial transactions that involve human germinal material. Constitution fédérale de la Confédération suisse [Constitution] April 18, 1999, SR 101, RO 101, art. 119(2)(e) (Switz.), available at

\textsuperscript{91} Regulation-
imposed scarcity creates opportunity for enterprising middlemen to respond to the surplus demand by facilitating cross-border transactions.  

http://www.admin.ch/suchen/index.html?keywords=119&lang=en. Australia's Prohibition of Human Cloning Act likewise targets the exchange of gametes for any consideration. L. Bernier & D. Grégoire, Reproductive and Therapeutic Cloning, Germline Therapy, and Purchase of Gametes and Embryos: Comments on Canadian Legislation Governing Reproduction Technologies, 30 J. MED. ETHICS 527, 530 (2004) ([S]ection 23 . . . states that it is an offence to intentionally give or receive value for the supply of human eggs, sperm, or embryos.”). Sweden’s Transplantation Act expressly precludes the operation of sperm and ova brokers by providing “that someone who wilfully [sic] and for profit, collects, donates, receives or acts as an intermediary in respect to biological material from a living or a dead human . . . shall be fined or sentenced to imprisonment for up to 2 years.” Id. “In Norway sperm donation is legal, but egg donation is not—despite today’s technology and medical techniques that make it possible.” BERET BRÅTEN, KILDEN INFORMATION CENTRE FOR GENDER RESEARCH IN NORWAY, MOTHERHOOD CHALLENGED (2006), http://kilden forskningsradet.no/c17224/artikkel/vis.html?id=41266.

91 See e.g., Sperm Ships for Fertility Seekers, BBC NEWS, Sept. 16, 2005, http://news.bbc.co.uk/2/hi/health/4251634.stm [hereinafter Sperm Ships] (quoting Ole Schou of Cryos as saying, “[i]f you have different regulations on treatments[of gamete transfers,] then you will have trading across borders.”). Even regulation not intended to target the human reproductive technology industry can create scarcity of gametes. The FDA’s prohibition of the importation of sperm from countries with mad cow disease is one such example. See e.g., Mad Cow Ban, supra note 88 (reporting criticism of the ban on the grounds that the human form of mad cow disease—Creutzfeldt-Jakob disease—has never been documented as being “passed on after a sperm donation”); Steven Kotler, The God of Sperm, LA WEEKLY, Sept. 26, 2007, http://www.laweekly.com/news/news/the-god-of-sperm/17290/?page=1 (reporting that Creutzfeldt-Jakob disease is a prion disease and cannot be sexually transmitted, and that the only danger would come from someone actually eating mad cow-tainted frozen sperm).

92 According to Professor Deborah Spar, sperm and ova brokers “capitalize on regulatory gaps. In Germany, all eggs removed from a woman must be transferred back inside her [since egg transfer of any sort is illegal]: But in Russia, these same eggs can be sold or bartered.” Caballero, supra note 14. After extensive media coverage about a Romanian clinic “specialising [sic] in egg cell donation to EU nationals in return for financial compensation,” the European Commission released a report in 2006 surveying the national legislations of 25 member states relating to reproductive cell donation. Health & CONSUMER PROTECTION DIRECTORATE-GENERAL, REPORT ON THE REGULATION OF REPRODUCTIVE CELL DONATION IN THE EUROPEAN UNION 2 (2006), available at http://ec.europa.eu/health/ph_threats/human_substance/documents/tissues_frep_en.pdf. While the European Commission regards payment of substantial fees beyond compensation for expenses and inconveniences related to the donation procedure to obtain human egg cells “to be against the principles expressed in the Directive 2004/23/EC on Tissues & Cells,” the Directive also “provides for a mechanism that will allow for a coherent approach to the authorisation of imports and exports [of gametes].” Id. at 2. This has also opened the doors for creative gamete transfer arrangements, such as mobile fertility clinics on ships which would be “governed by the laws of their own
Middle Eastern countries where sperm donations are taboo.\textsuperscript{94} Similarly, the United Kingdom's prohibition on selling ova\textsuperscript{95} has generated an influx of British women contracting with middleman gencies based in countries with a relatively laissez-faire attitude towards domestic and international gamete transactions (such as the United States).\textsuperscript{96} As the responsible regulatory authority in Britain, the Human Fertilisation and Embryology Authority ("HFEA")\textsuperscript{97} limits the amount of compensation that British egg providers may receive in the form of "reasonable expenses" incurred during the provision process. Compensation for opportunity costs measured in lost earnings is also permitted: "you can claim £55.19 for each full day up to a maximum of £250 per cycle of egg donation or course of sperm donation."\textsuperscript{98} With reasonable ex-

\textsuperscript{94} Italy's 2004 ban was prompted by the Roman Catholic Church's outcry against playing God. See Andrew Wancata, Note, No Value for a Pound of Flesh: Extending Market-Indelibility of the Human Body, 18 J.L. & HEALTH 199, 227 (2003); see also Caballero, supra note 14 ("Italy [has also] passed legislation that prohibits sterile, gay, or single adults from using donor eggs or surrogate mothers.").

\textsuperscript{95} Alvarez, supra note 70. See also Marcia C. Inhorn, A More Open Mind Toward Iran, THE CHRONICLE REVIEW, June 23, 2006, http://www.chronicle.com/weekly/v52/i42/42b01201.htm (comparing Sunni Muslim fatwas prohibiting any form of third-party donation of gametes with Shi'ite cleric Ayatollah Ali Husseine Khamanei's fatwa permitting both sperm and egg donation, the latter of which has led to significant reproductive tourism in Tehran).


\textsuperscript{98} Human Fertilisation and Embryology Authority (HFEA), http://www.hfea.gov.uk (last visited Nov. 15, 2007).

penses reaching no more than £1,000,\textsuperscript{99} compensation is well below the going rate of $8,000 for "average" quality eggs in New York.\textsuperscript{100} It is unsurprising that women with highly desirable physical, personal and intellectual traits from the United Kingdom and other countries with similar (or even more restrictive) bans on ova exchanges for monetary consideration\textsuperscript{101} are vying to exchange their gametes for $35,000–50,000 of compensation in the United States.\textsuperscript{102} The U.S. egg business is worth an estimated $4.5 billion, making America "a world centre for egg donation."\textsuperscript{103}

Government regulation has also contributed to the scarcity of UK sperm providers. On April 1, 2005, a new regulation lifted donor anonymity on the grounds that donor-conceived individuals have a right to trace their genetic origins once they reach eighteen years of age.\textsuperscript{104} Thus, sperm providers' identities are no longer shielded by the HFEA as the national government registry will release a provider's identifying information upon the request of anyone conceived with the provider's gametes.\textsuperscript{105} Lack of anonymity

\textsuperscript{99} See Sarah Boseley, Women May Get £1,000 for Their Eggs, THE GUARDIAN, Nov. 12, 2004, http://www.guardian.co.uk/medicine/story/0,11381,1349407,00.html (noting the possibility of increased donor compensation following the passage of new regulations; amounting to approximately $1,973.75, at an exchange rate of $1.00 for £0.506649).

\textsuperscript{100} Thompson & Knight, supra note 96 (noting the drastic upturn in egg prices over the last fifteen years).

\textsuperscript{101} While eggs cannot technically be sold, compensation for "expenses incurred" is not capped and in fact acts as a proxy for the sale of the egg. Simply put, ova providers charge what the market will bear for the time and effort expended in donating eggs—a calculus that includes the quality and conditioning of their genetically linked attributes. For example, a university degree connotes intelligence and diligence.

\textsuperscript{102} See Thompson & Knight, supra note 96 (stating that American "[d]onors with the right physical, personal and intellectual attributes can attract fees of up to $35,000 for their eggs, with some in the industry claiming that as much as $50,000 has changed hands").

\textsuperscript{103} Id.

\textsuperscript{104} Human Fertilisation and Embryology Authority (HFEA), supra note 98 (stating that the information requirements became effective as of an April 1, 2005 change in the law).

\textsuperscript{105} Dr. Kirk Maxey summarizes the view of advocates for ending anonymity:

It's access to the information. . . . [a donor should know that his kids] exist and whether they are healthy or not. And that there is a meeting point, an information exchange point where, if you want to know about each other, you can go there. Becoming connected with your genetic relatives should be facilitated and not blocked.

Martin Bashir, Confessions of a Sperm Donor, ABC NEWS, Aug. 31, 2006,
is a huge disincentive for potential sperm providers because many are concerned about the psychological impact of being contacted by children conceived with their sperm.\textsuperscript{106} This regulation has “decimated the ranks of men once willing to donate . . . .”\textsuperscript{107}—a development to which middleman clinics in countries with surpluses of sperm have responded with semen imports and arrangements for procreative or “fertility tourism.”\textsuperscript{108}

Cryos’ web-based operations have permitted the Danish sperm bank giant to increase its global market power by arranging transactions to meet the disproportionate demand (for access to and use of the genetic material and attached personal information). This disproportionate demand is generated by a combination of the idiosyncratic preferences of consumers and local laws. First, there is generally high market demand for Scandinavian attributes: tall,
blond hair and blue eyes. Secondly, the sexually liberal culture, health care structure and laws protecting anonymity all support a sperm provision regime. Third, while the sperm vault at Cryos stores about 75,000 straws, Denmark is a small country where “only 65,000 children are born each year.” Denmark therefore has a surplus of sperm for export.

Although Denmark may have cornered some markets for frozen sperm, Cryos has by no means ousted American players on either the global scale or domestic turf. Unburdened by anonymity regulations, U.S. sperm banks have thus far been “far more willing than Cryos and other overseas counterparts to reveal information about donors.” Middlemen such as Xytex and Cryobank offer baby and adult photos, Keirsey Personality Test diagnoses, facial feature reports, personal statements, descriptions of love-lives and staff impressions as part of a premium version of the standard provider or “donor” profile. Subscribers to the general database may purchase access to these “add-ons” or extended profiles at carte blanche or upgraded subscription package rates. Some banks even offer audio interviews with the sperm provider.

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109 See Alvarez, supra note 85 (noting that Cryos’ above average pregnancy rate of 12-31% is also a factor).

110 Male Danes receive a thorough sexual education at primary school, and are given the “option of having their sperm tested” during a mandatory health check required by the national conscription scheme. Sexual health awareness coupled with a pro-donation attitude in blood makes sperm donation a natural choice for many Danes. Pavia, supra note 107.

111 Id.


114 For example:

For $81, a consumer could... [purchase] a package that would provide them with a photograph of the donor as an infant, a profile of more than 20 pages of information, an audio interview with the donor, a 10-page report based on a Keirsey Temperament evaluation, sketches of the donor’s features, an essay written by the donor, and a document entitled Staff Impressions in which members of the facility’s staff offer their opinions on the donor’s personality.

Barney, supra note 11, at 212 (citation omitted).

115 See, e.g., Sperm Banking with Fairfax Cryobank, Sperm Donor Information, http://www.fairfaxcryobank.com/donorinfo.aspx?menu=4&turn=on (last visited Nov. 15, 2007) (“Also available on a majority of our donors, audio interviews provide insightful information into the donor’s childhood, aspirations, accomplishments, values, family life, and personal interests in his own words.”).
While Cryos, since opening its New York office, has fleshed out its donor profiles to include personal information on favorite animals, colors, food and childhood memory, there are limits to the amount of identifying information that the company can provide. For instance, it is unlikely that a childhood photo or facial feature sketch, let alone a current photo, will ever be permitted under Denmark's anonymity laws.

The availability of upgraded access for purchase reflects consumer thirst for information that helps them "establish 'an emotional connection' to the donor 'to understand what he's like as a person'" and "divine the magical alchemy of genetics and personality." It also underlines that the valuable and profitable service that sperm (and ova) banks provide is access to that information.

3.3. Middlemen and the Regulatory Landscape in the United States over their Practices and Procedures

3.3.1. Information Privacy Issues

There are two topical information privacy concerns in the sperm and ova bank industry. The first one revolves around the entrustment of a sperm or ova provider of his/her sensitive personal information to a middleman bank. Since the information stored involves medical, genetic and personal information linked to an individual, it is unsurprising that entrustment of personal information is a general concern of tissue banking. The 2003 bankruptcy of Options National Fertility Registry, which left in limbo eleven large storage cabinets filled with "potentially explosive" highly sensitive files on providers and recipients, illustrates the danger of relying on un-regulated middlemen to safeguard the information. That is, it illustrates the danger of what happens when a middleman bank changes its policy on protecting the information, sells the business or, as in the case of bankruptcy, is unable to


continue protecting the information. Since sperm and ova banks are not physicians, they do not have any "medical or legal obligation to maintain these records," which means that middlemen are not subject to scrutiny for failure to protect the data privacy of their providers. In sum:

[t]he concern is that, while such potentially sensitive information is becoming increasingly easier to obtain, adequate safeguards and procedures for handling this information are not yet in place. Therefore, the current system for protecting tissue donors, which has worked well in the past, is becoming and will continue to become increasingly obsolete.

Secondly, the global nature of sperm (and increasingly ova) markets due to franchising or foreign affiliate partnerships amongst the major middleman banks, and the operation of web store fronts translates into cross-border information flows. Gamete provider profiles contain substantial personal information, including attributes that in the aggregate establish a link to the identity of the provider. This information may be accessed by the public upon remittance of a subscription fee or a pay-per-view charge.

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118 Change of stewardship over the information can compromise the data privacy of providers. Suppose the "highly sensitive records" are sold on eBay to insurance companies or identity theft rings? Id. (reporting that a founder of an online database of potential egg donors feels "obligated to contact . . . post-2004 clients at their last known address to inform them of the pending sale [of the business] . . . [and give them] the choice of paying a service to hold the information, or the information would most probably be destroyed.").

119 Id. (noting that bioethicist Arthur Caplan believes that gamete banks and brokers should be accountable for all the records and that regulations "mandating minimal requirements for egg banks and brokers, including bankruptcy and disaster/catastrophe plans" should be implemented).


121 For instance, the Cryos International Sperm Bank Ltd. is the franchisor of Cryos International – Denmark (offices in Aarhus, Copenhagen and Odense) and Cryos New York (previously Scandinavian Cryobank). See Cryos International, Cryos’ Franchise Concept, http://www.cryosinternational.com/franchise/cryos-franchise-concept.aspx (last visited Dec. 7, 2007) ("Cryos International franchise concept focuses on the establishment of sperm banks worldwide. Our goal is to provide an extensive selection of high quality donor semen to patients and clinics all over the world through our network of sperm banks.").

122 Like any online database, the database of donor profiles, even if encrypted, is susceptible to security breaches by careless employees or malicious...
Genetic information, encapsulated in frozen reproductive cells, is also physically sent to consumers (or their medical providers) who are often in foreign countries. The concern over the flow of such cross-border information stems from the varying data protection standards of different countries. Information transferred abroad is only protected so far as provided by contractual terms, and to the extent that these terms will be enforced by regulatory and enforcement authorities in the destination country. Thus, when a potential customer in a country with weaker information protection laws purchases access to the gamete provider profile, and then purchases the provider's actual genetic information by way of the gamete, there are concerns that the provider's information may be abused. The protection over the gamete provider's information privacy may be diluted as the information is transmitted to a weaker information protection regime.

It is in the middleman's commercial interest to protect the data privacy of the sperm and ova providers—that is, the information suppliers—because the providers will only contract with banks that they trust. Xytex's statement on its donor website highlights the sensitivity of this relationship:

Reproduction is a very personal matter and we respect your desire for privacy. The information you share with us is held in strictest confidence, unavailable to anyone other than your health care professionals without your express

 hackers. See Privacy Rights Clearinghouse, A Chronology of Data Breaches, http://www.privacyrights.org/ar/ChronDataBreaches.htm (last visited Dec. 7, 2007) (tracking incidents of electronic data breaches since 2005 ranging from university files to health records). Middle-men databases of the providers contain an even greater wealth of sensitive personal information—medical information, physical attributes, personality information, and sometimes even the names and contact details of providers "open" to disclosing their identities. There is certainly an incentive for hackers to breach the electronic database and make a windfall by selling data packages on the providers.

Abuse occurs when someone other than the designated recipient gains access to the provider's information. For instance, if sperm provider Z contracts with the sperm bank to supply his personal information for the sole purpose of facilitating the transaction of his genetic material for conception, and researchers for a biotech company somehow gain database access to Z's information, Z's information privacy—his ability to control who has access to and use of his personal information—has been violated.

Sperm banks do, however, traditionally destroy records of the provider after his samples are sold, in order to preserve anonymity. Kotler, supra note 91 (noting that California Cryobank reacted to media reports of children trying to track their biological fathers by removing information from donor profiles).
permission. Your information will not be shared or sold to any other company or institution. Likewise, Xytex respects donor privacy and releases information about the donors only with the donor’s permission. Encryption of your financial information is provided . . . .125

However, while some banks and gamete providers enter into contracts with confidentiality and privacy clauses, the lack of comprehensive and general information privacy laws in the U.S. means that the standards of information protection and terms of liability will fluctuate from middleman to middleman.126

3.3.2. Formal Regulations in the United States Affecting Sperm and Ova Banks – HIPAA and FDA

The Health Insurance Portability and Accountability Act ("HIPAA")127 Privacy Rule128 expressly covers personal health information and access to medical records. HIPAA "requires disclosures only to the individual . . . and to the Secretary of Health and Human Services for the purpose of enforcement"129 and mandates that "covered entities" appoint a Privacy Officer in charge of responding to complaints, notifying individuals of uses of their personal health information, track disclosures, and document privacy policies and procedures.130 HIPAA’s protection131 of the privacy of

125 Xytex Patient Page, supra note 77.

126 In the contract for provision of personal information and gametes, the banks are the sophisticated parties. Sperm and ova providers sign boilerplate information release forms so that any arms-length negotiation that occurs tends to revolve around the value of special or highly desirable traits of the provider. Kotler, supra note 91 (reporting that Northwest Andrology has requested at least one provider to remove his information from a sibling donor registry site as part of his contract).


130 Id. at 1068.

131 The Privacy Rule sports civil penalties for noncompliance and criminal penalties for malicious misappropriation and misuse of health information, which are enforced by the Department of Health and Human Services' Office for Civil Rights and the Department of Justice, respectively. Id. at 1068. The Privacy Rule
medical information does not apply beyond the "covered entities." 132

While middleman banks do electronically transmit health information in connection with certain transactions, it is not fully clear whether middleman banks constitute "health care providers" 133 or "health care clearinghouses" within the definition of "covered entities." 134 Middleman banks differ from such institutional and non-institutional providers of medical services as hospitals and dentists respectively. 135 Sperm and ova banks are only health care providers if the services they offer—access to and use of genetic information from human sources of particular attributes—constitute "furnishing health care." Alternately, while middleman banks do receive and process non-standard information from the gamete providers, their business does not resemble the traditional "health care clearinghouses" which offer "billing services, repricing companies, community health management information systems, and value-added networks and switches if these entities perform clearinghouse functions." 136 Even if gamete banks were "covered entities" and subject to the HIPAA Privacy Rule, the scope of protection would be inadequate. The HIPAA Privacy Rule does not cover non-medical or non-health information. 137

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133 But see Johnson v. Cal. Cryobank, 124 Cal. Rptr. 2d 650, 655 (Cal. Ct. App. 2002) (holding that a sperm bank constitutes a 'health care provider' under the State Code of Civil Procedure section 425.13(a)). This case adheres to the state's civil procedure definition of 'health care provider' and thus may be discounted in relevance to the HIPAA definition.

134 HIPAA Covered Entity, supra note 132.

135 29 C.F.R. § 825.118 (2007) defines the following as health care providers: medical or osteopathic doctors, podiatrists, dentists, nurse practitioners, clinical psychologists, and "any health care provider from whom an employer or the employer's group health plan's benefits manager will accept certification of the existence of a serious health condition to substantiate a claim for benefits..." Since the banks merely provide brokering services—transactions in information—and do not perform the clinical procedures themselves, they are arguably not "health care providers" under the purview of 29 CFR § 825.118.


which leaves much of the remaining identifying information in the gamete provider profile unprotected.

Since 2005, the procedures and practices of sperm and ova banks have been governed by the Food and Drug Administration's ("FDA") general regulations on tissue banking. The regulations were intended to address concerns over ineffective screening procedures that either gave rise to recipients infected by the diseased sperm or their children conceived with genetic defects due to the diseased sperm.\textsuperscript{138} The rule\textsuperscript{139} focuses on "donor screening, quality processing, and record keeping, [with the] ... goal [of] keep[ing] infectious tissue out of circulation."\textsuperscript{140}

21 C.F.R. § 1271,\textsuperscript{141} which applies to human cells, tissues, and cellular and tissue-based products, in effect creates a mandatory tissue bank registry that includes sperm and ova banks, prescribes a uniform and authoritative standard for donor screening, and grants the FDA inspection and enforcement rights over the screening and testing processes and standard operating procedures used by middlemen.\textsuperscript{142} However, the regulations are unlikely to translate into strict FDA oversight of the specific commercial activities of sperm and ova banks beyond egregious practices that disregard

\textsuperscript{138} One prominent case involved Cryobank. After conceiving a child with autosomal dominant polycystic kidney disease using sperm from Cryobank, recipient couple sued Cryobank for professional negligence, fraud and breach of contract. Alleging that Cryobank knew of donor's family history of kidney disease, recipients claimed that Cryobank had failed to ascertain whether the donor "was a potential carrier of the ADPKD gene, failed to property investigate [his] family history of kidney disease, and falsely represented to the [recipient couple] that the sperm they were purchasing had been tested and screened for infectious and 'reasonably detectable genetically transferred' diseases...." \textit{Johnson}, 124 Cal. Rptr. 2d at 654.

\textsuperscript{139} 21 C.F.R. § 1271.1 (2007) requires manufacturers of human cellular and tissue-based products to screen and test cell and tissue donors, in a way that "prevents the introduction, transmission, or spread of communicable diseases...." available at http://www.fda.gov/cber/rules/frtisreg011901.pdf

\textsuperscript{140} Jeffrey Prottas, \textit{Ethics of Allocation: Lessons from Organ Procurement History, in Transplanting Human Tissue} 120, 130 (Stuart J. Youngner et al., eds., Oxford University Press 2004).

\textsuperscript{141} 21 C.F.R. § 1271.

\textsuperscript{142} If the agency determines a bank is violating the rule, it may undertake such enforcement actions as confiscating and destroying the violative tissue/cells, ordering the bank to cease all operations, and engage in prosecution or fines. \textit{See} Martha A. Wells, Ctr. for Biologics Evaluation & Research, Presentation at the AATB Annual Meeting, FDA Update: Regulation of Reproductive Establishments (Sept. 2006), available at http://www.fda.gov/cber/tissue/aatb090906mw.pdf.
health and safety factors. Information protection provisions are conspicuously absent in the agency-promulgated standards for donor screening.

3.3.3. Self-regulation

Some middleman banks, including Cryobank, have opted to join professional organizations such as the American Association of Tissue Banks ("AATB"). The ATTB confers accreditation for retrieval, processing, storage, and distribution of tissues to members who submit to a "rigorous inspection of their operations" for compliance to the AATB's Standards for Tissue Banking. However, much like the FDA regulations, the AATB Standards' singular focus is on good technical practices, as well as disease detection, prevention, and control. Information privacy protection is not addressed.

4. AN INFORMATION PRIVACY REGULATORY APPROACH—REGULATE THE MIDDLEMAN IN THE GAMETES MARKET

Existing concerns over unauthorized access and use of sensitive personal information of gamete providers would be mitigated by an international standard mandating that sperm and ova banks and brokers undertake certain safeguards in collecting, using and disposing the information. The standard would also ideally hold gamete banks and brokers legally accountable to the provider in the event of a data privacy breach. It is extremely unlikely, however, that an international standard of any form will be promulgated, because to do so would force member states (of the international body promulgating the standard) to recognize the gametes

143 Barney, supra note 11, at 211.


145 See id. at 2 ("[T]he AATB inspection is not meant to be, nor is it, a surrogate inspection for an FDA inspection. The accreditation program is meant to ascertain if good faith efforts are being made by the bank to comply with AATB Standards and that the bank has a self-assessment mechanism and corrective and preventive action procedures in place that will enable the bank to correct deficiencies.").

146 The World Trade Organization is one international authority that can address the issue of gamete transactions. See Alice J. Carson, Trade in Reproductive Human Biota: Our Quest for Babies, TED CASE STUDY TEMPLATE, Fall 2003, http://www.american.edu/TED/reproductive-trade.htm (explaining that within the WTO framework, the TRIPS agreement addressing public health, the
market as a legitimate one.\footnote{Countries prohibiting commercial and/or non-commercial gamete transactions for various cultural, religious and historic reasons will refuse to recognize or endorse such a standard even if their own laws make it a practical insignificance. See \textit{Buying Babies}, supra note 39 (explaining that governments want to regulate the reproductive industry because the “manufacturing of anything which is regarded as God-given—or at least natural—touches a moral nerve” and that such regulations vary in conjunction with attitudes to the family). Even the United States, as one of the largest markets, is unlikely to subscribe to such a standard if it means formally acknowledging that a gametes market exists, because “[s]trictly speaking, paying for donated eggs is illegal in America too, since it counts as buying a body part.” \textit{Id.} at 118. In other words, the gamete trade is conceptually acceptable to legislators only if consideration is construed as compensation for donor time and effort rather than the gamete itself.} Even if gamete middleman suppliers are narrowly construed as merely selling brokering services, the discomfort of countries such as Germany towards any type of gamete exchange makes it unlikely that they will support a standard regulating even the intermediaries that facilitate such exchanges.\footnote{Germany has a flat-out ban on any form of egg transfers because it is “still haunted by the memory of Nazi experiments.” Caballero, \textit{supra} note 14.} Given the poor prospects for an international regulatory standard safeguarding the personal information of gamete providers from any country, we should at least strive to protect the data privacy of those gamete providers from the United States. A binding national standard is necessary to ensure that sperm and ova banks maintain practices that vigorously protect the information privacy of their suppliers on a global scale. The FDA, as the sole authority with enforcement capabilities in the human tissue banking industry, is the appropriate agency to promulgate a new mandatory standard for middlemen in the reproductive tissue business. This new standard should comprise of data protection principles that fully vest the gatekeeping powers in the hands of the individual gamete provider. As the first internationally derived set of information protection principles “intended to offer
harmonized protection of individual privacy rights while being flexible enough to apply across a variety of social, legal, and economic circumstances," the Organization for Economic Cooperation and Development Privacy Guidelines ("OECD Privacy Guidelines") encapsulates eight such data protection principles.

In the sperm and ova banking context, the gamete providers are the "data subjects" and the middleman clinics are the "data controllers." Principles 2 through 5 function to protect against misuse or abuse of the control the gamete provider contractually yields to the middleman. Principle 7 recognizes that the gamete

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150 OECD Privacy Guidelines consist of:

1) Collection Limitation: there should be limits to the collection of personal data, and any such data collected ought to be obtained with the consent of the data subject and in a lawful manner;

2) Data Quality: collected data should be relevant to a specific purpose, and be accurate, complete, and up-to-date;

3) Purpose Specification: the purpose for collecting the data should be communicated at the outset so that only new purposes that are compatible with the original ones can be introduced, and data that no longer serves a purpose should be destroyed or anonymized;

4) Use Limitation: data acquired for one purpose should only be used for the specified purposes unless otherwise legally required or the data subject's consent is obtained;

5) Security Safeguards: data must be collected and stored so that it is reasonably guarded from loss or unauthorized access, destruction, use, modification or disclosure;

6) Openness: there should be general policy of transparency vis-à-vis developments, practices and policies with respect to the data, and data subjects should have the means to confirm the existence and status of their information, as well as the contact information of the data controller;

7) Individual Participation: data subjects should have the right to access, confirm and demand correction of their personal information, and;

8) Accountability: the data controller assumes responsibility for complying with the aforementioned principles.

provider ultimately retains full power of his gatekeeping role (with respect to granting others access to his personal information) despite contractually delegating aspects of that role to the bank. Principle 1, in conjunction with Principle 6, sets the foundation for gamete providers to enter into arms-length negotiations with the middleman as to the nature and scope of the information (and access thereto) to be transacted in. Principle 8 supports the imposition of liability on the sperm and ova banks should they fail to adequately protect against un-consented access or use of the gamete provider’s information in the normal course of their operations.

In more concrete terms, the FDA should promulgate a standard with the following information protection rules:

1) Sperm and ova banks shall collect no more non-essential information (i.e., non-medical) than what the gamete provider is willing to provide; however the “purchase price” (compensation value) may reflect the amount of personally identifiable information the provider wishes to reveal;

2) Should the gamete provider wish to update her profile with non-trivial developments such as pregnancy, or a recent change in a family member’s medical condition (i.e., grandparent recently diagnosed with Alzheimer’s), the sperm and ova banks shall accordingly adjust the provider’s profile in a timely fashion;

3) Sperm and ova banks that market to or conduct business with citizens in foreign countries will undertake measures to ensure that access to and/or use of the provider’s personal and genetic information remains strongly protected,

Banks should observe the following guidelines:

1) Give notice to the gamete providers each time a foreign recipient-customer expresses interest in accessing and using their particular information (genetic information and any additional personal information such as audio interview), and;

2) Inform the gamete providers of the procedures that will be undertaken to guarantee that their information privacy will not be compromised during
or as a result of the cross-border transfer of the information.
3) Information in electronic databases should be encrypted and the access protected from unauthorized access (i.e., non-subscribers) with up-to-date authentication technology;
4) Sperm and ova banks will be legally and financially liable for misuse, misappropriation, or abuse of provider information (intrusions into the provider's information privacy) if reasonable steps were not taken to prevent the circumvention of protective measures.
5) Sperm and ova banks may not contract out of their liability for failing to undertake reasonable steps to protect the information privacy of their providers.

The FDA should initiate an official accreditation process vis-à-vis compliance with the above standard, and closely monitor the operations as well as the information contracts that providers enter into with banks. Banks that fail periodic inspections by the agency will lose their accreditation and be subject to fines and orders to cease operation. This solution places a premium on protecting information privacy without chilling the comparative advantage middlemen in the United States currently enjoy: the freedom to contract for access to various levels of personally identifiable information. If a gamete provider wishes to provide less information, he will contract for more anonymity.151 It is possible that one market effect of this regulation may be a decrease in the number of U.S.-based anonymous gamete providers as the middlemen focus on contracting for the more valuable access “packages.” However, any negative effect is likely to be negligible for the U.S. gamete market because the primary appeal of U.S. banks and brokers is the greater access to information about the source (the data subject or

151 While anonymity does preserve family privacy — by protecting the identity of the provider and recipient, and "shield[s] the donor from parental obligations, inheritance claims and unwanted contact with his progeny" — it is distinguishable from information privacy. EMILY JACKSON, REGULATING REPRODUCTION: LAW, TECHNOLOGY AND AUTONOMY 212 (2001). Anonymity prevents middlemen banks and brokers from disclosing the provider's identity and contact information to the recipient and ensuing progeny but does not prevent the disclosure of any other personal information about the provider.
gamete provider) of the genetic information itself. Without imposing a heavy burden on commerce, this form of regulatory approach both preserves the increased access to the individual supplier's being and structures the process so that it is the gamete provider who retains gatekeeping control over others' access to him or herself.

5. **Extrapolating the Information Privacy Regulatory Approach to a Potential Organs Market**

Can the information privacy approach successfully be extrapolated from gamete banking to regulate the middlemen in a hypothetical but legal organs market? The gametes market and the illegal organ market share certain similarities, including the global scope of the commercial activity facilitated by international middlemen. Local regulations, usually in the form of prohibitions, often create scarcity in the non-cadaveric supply of organs and thereby spurs medical procedure tourism.\(^{152}\) Regarding potential organ sources as data subjects skirts some of the traditional property-based justifications for prohibiting sales of kidneys and other specialized groups of tissue that perform specific functions. For instance, one property-based argument distinguishes between the sale of gametes (and blood) and organs on the grounds that the former is regenerative while in the latter case, every living human body possesses just one spare part: the kidney.\(^{153}\) In other words, the argument is that the scarcity of body part per human producer determines whether something should be commoditized. Yet this argument is easily rebutted when "we narrow organ markets to the

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\(^{152}\) See Bill Berkowitz, *Health: Poor Countries Raided to Traffic Human Organs*, INTER PRESS SERVICE, Apr. 27, 2006 ("The rise in illegal transplant tourism . . . was developed to meet an insatiable demand for organ transplants that rises exponentially against a flat supply of organs donated through traditional and regulated means . . . [P]oor people are recruited or entrapped into donating their body parts to satisfy the demand from rich patients who can afford to travel abroad and . . . to break national laws and international medical regulations to get the organs and medical procedures they need.") (internal quotations omitted).

\(^{153}\) See Bernier & Grégoire, *supra* note 90, at 531 (distinguishing human embryos and body parts from sperm and "other human cells that can regenerate and divide infinitely," on the grounds that donation of the latter does not risk the donor's health thus making the grant of property rights for gametes a "logical and equitable solution, . . . [that] could ensure a better respect for individual autonomy, . . . resolve important shortages and dismantle unsafe underground markets").
deceased—dead kidney suppliers have no use for multiple kidneys, and no physical risk of harm exists...."154

One construction that sidesteps the issues surrounding property-based arguments is to view the act of supplying replenishable bodily material as a service. While the National Organ Transplant Act ("NOTA")155 makes the sale of specified organs a felonious act, there are no state and federal statutes prohibiting one from offering consideration in exchange for blood or reproductive tissue. The potential of procuring a fairly continuous flow of body material such as blood, stamps the monetary exchanges for these body parts as "compensation for services" rather than consideration for property, as construed by common law and state statutes such as the Uniform Anatomical Gift Act and Uniform Commercial Code.156

From an information privacy view, arguments based on regenerativity align closer to the concept of having "access to a continuous source or supply" than the concept based on whether something is alienable from the self. However, an information privacy regulatory approach over middlemen is unlikely to succeed in the organ trade because of the greatly increased complexity of tissue processing.

In tissue banking, therefore, the nature and behavior of tissue processors becomes an issue of importance with regard to tissue use. There is no equivalent in organ transplantation. Tissue processing is a highly specialized, technical activity. It requires substantial capital investment and therefore a large amount of tissue to operate economically. Many of the processors are for-profit firms. The complex mix of generally nonprofit tissue procuring banks, for-profit processors, unregulated pricing, and multiple and conflicting final tissue "products" is a major cause of the concerns

154 Michele Goodwin, supra note 3, at 161.
156 Armand Karow, Implications of Tissue Banking for Human Reproductive Medicine, in REPRODUCTIVE TISSUE BANKING: SCIENTIFIC PRINCIPLES 451 (Armand M. Karow & John K Critser eds., 1997) ("The primary legal reason for characterizing these transactions as involving services rather than commodities is to avoid the specific performance provisions of the Uniform Commercial Code and to avoid liability for transmission of infectious diseases.").
about ethics in tissue banking and a major impediment to resolving concerns.\textsuperscript{157}

Moreover, the inherent perception of information privacy in the gametes market stems from the genetic information itself. Genetic information, as the "building blocks or instructions for life" connotes a stronger sense of access and control over information that defines our identities. One could argue that organs are comprised of tissue which in turn is comprised of cells containing genetic data (DNA). However, the absence of a direct link between the organ’s function and our sense of identity vis-à-vis genetic makeup makes the transfer of organs an interruption of spatial privacy rather than information privacy.

6. CONCLUSION

Information privacy concerns the control one has over others’ access to self and his identity-defining information. An analysis of the gametes industry from the information privacy perspective, as opposed to the traditional property lens, reveals that the market shifts to alternately meet the \textit{niche} demands and idiosyncratic preferences of consumers and the \textit{general} demand for increased access to the gamete provider’s personal information. The U.S. market also responds to artificial scarcity imposed by local laws restricting the extent to which gamete provider information is disclosed or by those outright prohibiting transfer in the first place. The middleman sperm and ova banks enable gamete transfer by engaging in cross-border information transactions between the providers and recipients. Varying cultural and religious conceptions of gamete exchanges around the world makes it unlikely that an international standard addressing the information privacy of providers will be promulgated. Thus, federal regulation based on the OECD Privacy Guidelines and administered by the FDA—the existing authority over tissue banks—is necessary to ensure that the information privacy of providers from the United States are not compromised during the process. Lastly, this information privacy paradigm is unique to the gametes market because of the nature of the middleman’s operations and the innate association of reproductive cells to our sense of being.