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The Curious Case of Trent Arsenault: Questioning FDA Regulatory Authority Over Private Sperm Donation

Amber D. Abbasi*

Federal government regulation of reproductive medicine is fraught with controversy. In many cases, federal and state laws clash over limiting the extent of an individual's procreative freedom in pursuit of allegedly compelling government interests.¹ Most of these hotly contested regulations target provision of contraception and abortion services.² In relatively few instances has the government prevented two individuals from conceiving a child in the manner they desire.³

Recent action by the Food & Drug Administration (FDA) created an unusual legal situation. In November of 2010, the FDA's Center for Biologics Evaluation and Research (CBER) issued an "Order to Cease Manufacture" to Trent Arsenault, a Fremont, California man who has fathered over a dozen children via artificial insemination (AI). Since 2006, Mr. Arsenault offered semen donations⁴ to women (typically partnered

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1. E.g., *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Planned Parenthood v. Casey*, 505 U.S. 833 (1992); *Stenberg v. Carhart*, 530 U.S. 914 (2000); Steve Eder, Appeals Court Blocks Arizona Abortion Law, *WALL ST. J.*, Aug. 1, 2012, <http://online.wsj.com/article/SB10000872396390443545504577563561817792018.html>; Nathan Koppel, Appellate Ruling Upholds Texas Abortion Law, *WALL ST. J.*, Jan. 12, 2012, <http://online.wsj.com/article/SB10001424052970204124204577152992567818170.html>; Sabrina Tavernise & Erik Eckholm, Ultrasound Abortion Bill Nears Vote in Virginia, *N.Y. TIMES*, Feb. 20, 2012, at A10; Campbell Robertson, Judge Maintains Injunction Against Mississippi Law on Abortion Clinics, *N.Y. TIMES*, July 11, 2012, at A14.

2. See *supra* note 1.

3. *Buck v. Bell*, 274 U.S. 200, 207 (1927) (concluding that society can and must prevent the "feeble-minded" from reproducing through sterilization, effectively endorsing state-sponsored negative eugenics), *Skinner v. Okla.*, 316 U.S. 535, 541 (1942) ("The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects. In evil or reckless hands it can cause races or types, which are inimical to the dominant group to wither and disappear. There is no redemption for the individual whom the law touches.").

4. Although the term "semen donation" is technically accurate here, "sperm donation" is commonly used to describe that activity and the terms are used interchangeably throughout.

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lesbians) on a purely private, uncompensated basis. Typically, the federal government permits women to vet potential fathers without interference, but in this case the FDA announced that a man who provides cups of his fresh semen to women, with the understanding that the artificial insemination will be performed at home, not by a medical professional, must comply with the plethora of regulations applicable to sperm banks and small medical offices that practice reproductive medicine.⁵

The regulation of assisted reproductive technologies (ART) has long been the focus of legal academic study,⁶ and the potential for government regulation of gamete donation and donor eligibility to have discriminatory effects,⁷ or even to trend toward eugenics,⁸ illustrates the necessity of weighing the alleged safety benefits of each such regulation against the burdens imposed on individual rights. In previous instances, these articles have analyzed ART regulation as applied to the fertility clinics, medical practices, and semen banks through which infertile patients typically access reproductive assistance.⁹ The regulation of these commercial enterprises, of course, has indirect effects on individuals' ability to conceive.¹⁰ But because persons conceiving without the assistance of medical personnel or

5. See Center for Biologics Evaluation and Research, Order to Cease Manufacturing of HCT/PS—Trent C. Arsenault, U.S. FOOD AND DRUG ADMIN. (Nov. 1, 2010), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm232852.htm> (last visited July 26, 2012) [hereinafter "Order"] (Ordering Mr. Arsenault to cease dispensation of his sperm to committed couples on an uncompensated basis or risk criminal and financial penalty).

6. E.g., Weldon E. Havins & James J. Dalessio, The Ever-Widening Gap Between the Science of Artificial Reproductive Technology and the Laws Which Govern That Technology, 48 DEPAUL L. REV. 825 (1999); Helen M. Alvare, The Case for Regulating Collaborative Reproduction: A Children's Rights Perspective, 40 HARV. J. ON LEGIS. 1 (2003); Lyria Bennett Moses, Understanding Legal Responses to Technological Change: The Example of In Vitro Fertilization, 6 MINN. J.L. SCI. & TECH. 505 (2005).

7. See Luke A. Boso, The Unjust Exclusion of Gay Sperm Donors: Litigation Strategies to End Discrimination in the Gene Pool, 110 W. VA. L. REV. 843, 844 (2008) (discussing the FDA's explicitly discriminatory donor screening guidance document, which, *inter alia*, excludes semen donors who have engaged in sex with other men at any time within the preceding five years).

8. See Kerry Macintosh, Brave New Eugenics: Regulating Assisted Reproductive Technologies in the Name of Better Babies, 2010 U. ILL. J.L. TECH. & POL'Y 257 (2010). Macintosh notes that not only is infertility itself a disability but that higher rates of health problems among children conceived via ART may be a function of the parents' health status; see *id.* at 296-98. Insofar as increased regulation of ART usage is intended to decrease the number of such births, it functions as a eugenicist bar on reproduction by unhealthy or genetically distinct populations. Cf. Mary Crossley, Dimensions of Equality in Regulating Assisted Reproductive Technologies, 9 J. GENDER RACE & JUST. 273, 285 (2005) (discussing trait selection by users of ART and donated gametes).

9. See, e.g., *supra* note 6.

10. The regulation limits a prospective mother's choice of donors and increases her conception costs.

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institutions have, historically, been permitted to do so without direct regulation by the government,¹¹ such exercises of State power have gone relatively unaddressed by scholars.

The FDA's issuance of a cease-manufacture order to a private individual semen donor presents a unique opportunity for logical extension of the substantive due process doctrines developed by the courts throughout recent decades, which typically addressed sexual and reproductive freedom through a different lens. In many such instances, the challenged law functioned to encourage procreation: bans on contraception,¹² bans and regulatory burdens on abortion,¹³ and criminalization of homosexuality.¹⁴ Conversely, an FDA prohibition on private, uncompensated semen donation prevents the affirmative exercise of procreative liberty.¹⁵

Even as Mr. Arsenault is in the focus of administrative proceedings that challenge the application of these regulations to his particular circumstances,¹⁶ the FDA's announced position affects other private individual sperm donors and women to whom they donate. This article examines the regulations that the FDA seeks to enforce against private

11. See *Griswold v. Connecticut*, 381 U.S. 479, 496-97 (1965) (Goldberg, J., concurring) (noting that the governmental power to ban contraceptives without compelling state interest would implicate the state's ability to circumvent a couple's desire to reproduce, the constitutionality of which he characterized as "silly").

12. E.g., *Id.*; *Eisenstadt v. Baird*, 405 U.S. 438 (1972).

13. E.g., *Roe v. Wade*, 410 U.S. 113, 121 (1973); accord *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 840 (1992); accord *Stenberg v. Carhart*, 530 U.S. 914, 917 (2000); accord *Gonzalez v. Carhart*, 550 U.S. 124, 134 (2007).

14. E.g., *Lawrence v. Texas*, 539 U.S. 558, 564 (2003); accord *Bowers v. Hardwick*, 478 U.S. 186, 189 (1986).

15. See generally *Carey v. Population Servs. Int'l*, 431 U.S. 678, 681 (1977) ("The decision whether or not to beget or bear a child is at the very heart of . . . [a] cluster of constitutionally protected choices . . . [and] holds a particularly important place in the history of the right of privacyFalse"); see also *Paris Adult Theatre I v. Slaton*, 413 U.S. 49, 54 (1973) (The right to privacy "encompasses and protects the personal intimacies of the home, the family, . . . motherhood, [and] procreationFalse" (internal citations and quotation marks omitted)); see generally *Planned Parenthood of Se. Pennsylvania v. Casey*, 505 U.S. 833, 843 (1992) (Concluding that "personal decisions relating to . . . procreation" are among "the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, [that] are central to the liberty protected by the" Constitution); *Planned Parenthood of Se. Pennsylvania v. Casey* at 926-27 (Blackmun, J., concurring in part, concurring in judgment in part, and dissenting in part) ("Throughout this century, this Court . . . has held that the fundamental right of privacy protects citizens against governmental intrusion in such intimate family matters as procreationFalse").

16. See Center for Biologics Evaluation and Research, Order to Cease Manufacturing of HCT/PS—Trent C. Arsenault, U.S. FOOD AND DRUG ADMIN. (Nov. 1, 2010), <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/ucm232852.htm> (last visited July 26, 2012) [hereinafter "Order"] (ordering Mr. Arsenault to cease dispensation of his sperm to committed couples on an uncompensated basis or risk criminal and financial penalty).

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sperm donors, their application in the Arsenault case, and the implications of expanding the government's regulatory authority over individuals' procreative decisions. Part I describes the phenomenon of private sperm donation and how it fits into the landscape of reproductive medicine. Part II discusses federal statutes and regulations that have historically been enforced against medical establishments involved with sperm donation. Part III discusses the Arsenault case and the FDA's unprecedented decision to enforce these regulations against a private sperm donor. Part IV examines whether the regulations and their enabling statute, in fact, cover private sperm donor activity. Part V analyzes the possible consequences of expanded federal regulatory authority over private, individual-to-individual donations of sperm for artificial insemination.

I. SPERM DONATION: AN UNILLUSTRATED PRIMER

For many modern couples that want to start a family, tried and true methods are inadequate. Heterosexual couples increasingly face fertility challenges. But for couples or individuals without a male partner, the obstacle is a lack of a father's genetic contribution, and this requires the assistance of a third party. Perhaps the most established nontraditional route is through sperm banks. These firms, regulated by federal law and staffed by licensed medical professionals,¹⁷ often pay men for donations and then sell the semen to women trying to conceive. Sperm-bank donors' disclosure of information and degree of willingness for future contact with the mother or child varies, but most donors are anonymous, providing data only on medical history and physical traits, and donate on the condition of limited potential for personal contact with resulting offspring.¹⁸ Donors are assessed for infectious disease risk, personal and family health history, sperm count, motility, and resilience to freezing, and are subjected to a physical exam and blood and urine tests for infectious and hereditary diseases.¹⁹ A preservative is added immediately to fresh sperm donations by laboratory personnel,²⁰ and the sample is then frozen and subjected to six months of quarantine.²¹

Customers of sperm banks enter a medicalized and depersonalized space where they exchange cash for the genetic material necessary to create life

17. 21 C.F.R. § 1271.1 (2012); 21 C.F.R. § 1271.170 (2012).

18. LOUISE SLOAN, *KNOCK YOURSELF UP: NO MAN? NO PROBLEM! : A TELL-ALL GUIDE TO BECOMING A SINGLE MOM* (2007).

19. 21 C.F.R. § 1271.50 (2005); 21 C.F.R. § 1271.75 (2005); 21 C.F.R. § 1271.80 (2005); 21 C.F.R. § 1271.85 (2005).

20. SLOAN, *supra* note 18, at 67.

21. 21 C.F.R. § 1271.60 (2012); 21 C.F.R. § 1271.85(d) (2012). Indeed, the six-month quarantine period is mandated by the FDA's regulations governing HCT/P's.

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and have no personal connection to the potential biological father. Vials of frozen semen can be purchased and drop-shipped directly to the recipient's doorstep; the bank staff requires no in-person consultation.²² The most common form of AI, intracervical insemination, closely replicates natural insemination: fresh semen can simply be placed in the woman's vagina using nothing more than a needleless syringe; the procedure can be conducted from the comfort of home without medical personnel assistance.²³

Additionally, significant disadvantages are associated with use of sperm banks. As mentioned above, sperm from banks often come with minimum information about donors and allows for little chance for the woman or child to have contact with them. Would-be purchasers usually go through at least one medical gatekeeper, such as their personal physician.²⁴ The chemicals added to protect sperm from damage in freezing can cause external and internal reactions in some women.²⁵ For women who use intracervical insemination, frozen sperm are less likely than fresh to lead to a pregnancy.²⁶ Costs can also mount quickly: each vial contains only 1

22. Artificial Inseminations, CRYOS INTERNATIONAL, NEW YORK, <http://ny.cryosinternational.com/private-customers/getting-started/artificial-inseminations.aspx> (last visited Aug. 2, 2012); E.g., Instruction Page for Registration in Frozen Donor Program, RAINBOW FLAG HEALTH SERVICES, <http://www.gayspermbank.com/program.htm> (last visited Aug. 2, 2012).

23. SLOAN, *supra* note 18, at 65-91. For women who require more than this to conceive, medical help is necessary. For example, a clinician may perform other insemination methods that place the sperm in closer proximity to the ovum, such as intrauterine, intratubal, or intrauterine-tuboperitoneal insemination. However, fresh semen cannot be used in these procedures, as the sperm must be washed to remove prostaglandin-bearing seminal fluids that cause uterine cramping.

24. Catherine DeLair, Ethical, Moral, Economic and Legal Barriers to Assisted Reproductive Technologies Employed by Gay Men and Lesbian Women, 4 DEPAUL J. HEALTH CARE L. 147, 148 & 152 (2000) (In some states, the gatekeeper is a mandatory role.

Five . . . states have statutory language criminalizing artificial insemination if a licensed physician does not perform it. For example, Georgia's statute provides, in relevant part: "Physicians and surgeons licensed to practice medicine . . . shall be the only persons authorized to administer or perform artificial insemination. . . Any other person or persons . . . shall be guilty of a felonyFalse" This creates a real barrier for gays and lesbians, as well as heterosexuals, wishing to utilize artificial insemination. Many prefer to self-inseminate in the privacy of their own home, thus avoiding medical professionals with perceived or real discriminatory practices. Requiring the involvement of a physician may also create a financial barrier to those who cannot afford the additional medical costs.)

See generally Recipient Information for Ordering and Use of Donor Specimens, PACIFIC REPRODUCTIVE SERVICES, <https://pacrepro.com/documents/how.pdf> (outlining an example of the procedures).

25. Artificial Insemination Information, NW CRYOBANK, <https://www.nwcryobank.com/artificial-insemination> (last visited June 13, 2012).

26. LL Subak, GD Adamson, NL Boltz, Therapeutic Donor Insemination: A Prospective

milliliter (mL) of semen (versus the average ejaculatory output in natural insemination of 2-4 mL), costs hundreds of dollars, and many women use more than one vial per attempt.²⁷

Women who are discouraged by the bank's conditions or priced out of the frozen-semen market may seek out a more unconventional, old-fashioned path: to conceive a child using genetic material from a private individual, unmediated by doctors, sperm banks, or anonymity requirements.²⁸ Although in decades past a woman seeking impregnation without legal ties might have little choice but to roll the dice through sexual contact with strangers, the immense power of connectivity created by the Internet has allowed otherwise isolated individuals to find each other: women seeking a non-standard sperm donor and men willing to provide sperm on the woman's terms.²⁹

Private sperm donation is not a new phenomenon, but it is a growing one. Donors may advertise their availability on a centralized forum, such as FreeSpermDonorRegistry.com, or on other Internet venues such as Yahoo or Google Groups.³⁰ Still others have individual websites collecting a wide range of frequently requested information.³¹ Because the donors provide the information, a certain amount of trust is involved. Many women are comfortable with the prospect of assessing the honesty of men seeking to impregnate them.

The contrast between the meticulously mediated sperm-bank experience and the direct donor/donee interaction available with private donors is remarkable. Women can initiate contact with donors, talk with donors, even meet them. Women can also seek out donors who have certain physical or personality traits and question them personally. And because private donors are more diverse than bank donors and vary as to the scope of services they provide, a wider set of preferences can be catered to.

While sperm banks enforce sameness, the possibilities with private donation are theoretically limitless. Many sperm banks only accept donations from men in a certain age range, and some favor donations from taller or slimmer men, but (as we see in many families) not all women

Randomized Trial of Fresh Versus Frozen Sperm. NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION, available at <http://www.ncbi.nlm.nih.gov/pubmed/1615966>.

27. SEATTLE SPERM BANK, Information for Directed Donors and their Recipients, http://www.seattlespermbank.com/directed_donors.asp (last visited June 13, 2012); see generally DeLair, *supra* note 24, at 160-61 (discussing economic barriers to use of ART).

28. Tony Dokoupil, You Got Your Sperm Where?, THE DAILY BEAST (Oct. 2, 2011), <http://www.thedailybeast.com/newsweek/2011/10/02/free-sperm-donors-and-the-women-who-want-them.html>.

29. *Id.*

30. *Id.*

31. See, e.g., TRENTDONOR, <http://www.trentdonor.org> (last visited June 13, 2012).

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prioritize youth, height, or svelteness in determining the suitability of a potential father. Private donors may make different commitments to present and future information disclosures and contact than do donors at banks, providing recipients with more information about their continuing lifestyle and health and more flexible terms for disclosing donor identity to offspring.

Selecting a private sperm donor is, by its very nature, a personal and individualized decision. Just as in choosing a conventional sexual partner, the woman can exercise as much or as little care as she desires—some donors are asked for and provide questionnaires, interviews, reference checks, and requests for medical test results.³² Screening for sexually transmitted infections (STIs) and other health problems, including genetic disorders, may occur if the donor-recipient agreement calls for it, but the accuracy of the results must be taken at face value, without the added layer of objectivity that testing by a bank could provide. After donor and recipient reach an accord, they may formalize the arrangement by signing contracts that outline their understanding and seek to limit the legal responsibilities of the donor.³³ All that remains is the actual process of insemination.

Some private donors provide natural insemination services. Natural insemination involves sexual intercourse between the donor and recipient. This form of sperm donation is distinguishable from conventional sexual relationships only by the intentions of the parties and involves significant disease risk to both. Obviously, barrier methods cannot be used; diseases can be spread not just via male-to-female transmission of bodily fluids, but female-to-male, as well as via skin-to-skin contact between the donor and recipient. Additionally, disease risk is present if the donor or recipient is sexually active. Although ideally the donor and recipient (like any pair engaging in unprotected sex) would provide current STI and other medical test results to ensure that neither party is exposed to contagion, the risks of a sexual encounter are unavoidably greater with natural insemination than with artificial insemination.

As practiced by private donors, though, artificial insemination is not risk free. Fluid-based infections could still be transmitted to the recipient. Nevertheless, these risks are much less than those of natural insemination,

32. Dokoupil, *supra* note 28.

33. A married or partnered recipient may have to take additional legal action to ensure that her spouse or partner is a registered second parent on the birth certificate of any offspring. CAL. FAM. CODE § 7613(b) (Deering 2012). Although state laws vary, many states do not treat private sperm donors similarly to donors to sperm banks. For example, California only limits legal and financial liability for sperm donors whose gametes were channeled through a bank or other medical physician or surgeon.

and even lower than those presented by singles-bar hookups or no-strings-attached casual encounters in which many engage. Absent access to sperm banks or private donors, women seeking impregnation outside a relationship may turn toward such options.³⁴ However, when offered a choice, many take advantage of willing donors to create new lives on their own terms.

If a recipient elects to use privately donated sperm for artificial insemination, she can perform the insemination (using the intracervical method) at a clinic, at home, or even in her car.³⁵ She can coordinate these donations with her ovulation cycle to maximize the chance of fresh sperm encountering a released ovum. And, like women who conceive via intercourse with a partner, she needs not work with or through a medical professional, whose services may not be covered by insurance³⁶ and who may act as a gatekeeper, discouraging single women and lesbians from

34. See Katheryn D. Katz, *The Clonal Child: Procreative Liberty and Asexual Reproduction*, 8 ALB. L.J. SCI. & TECH. 1, 33-34 (1997) (discussing single or lesbian women's diminished access to ART due to the historically entrenched gatekeeper role of physicians and the resulting use of private donors in private settings).

35. Joanna L. Grossman, *Men Who Give It Away: The Potential Perils of Free and Non-Anonymous Sperm Donation*, VERDICT JUSTIA (Jan. 24, 2012), <http://verdict.justia.com/2012/01/24/men-who-give-it-away> (last visited Aug. 3, 2012).

36. Michelle Andrews, *Health Insurance Rules May Decide Whether Infertility Treatment is Essential*, WASH. POST, (Jan. 24, 2011), <http://www.washingtonpost.com/wp-dyn/content/article/2011/01/24/AR2011012405363.html> (last accessed Jun. 13, 2012). "Even if a plan covers IVF, it may cover only a certain number of cycles, or attempts, or cap the dollar amount it will pay for services." Of note also is the plethora of state laws regulating the provision of insurance coverage for infertility treatment. NAT'L CONF. OF ST. LEGISLATION, *State Laws Related to Insurance Coverage for Infertility Treatment*, <http://www.ncsl.org/issues-research/health/insurance-coverage-for-infertility-laws.aspx> (last accessed June 13, 2012). However, it is uncertain whether lesbian couples, like those to whom Arsenault donates, can reap the benefits of these laws:

[M]ost insurance companies and all nine states, provide benefits for assisted reproductive technology, only for "medically necessary" treatments related to the diagnosis of "infertility." For example, Connecticut's statute requires insurance companies to offer insurance providing "medically necessary expenses for the diagnosis or treatment of infertility." Infertility is defined as the inability to conceive after one year of intercourse without contraception. Treatment that is medically necessary is typically defined as treatments that require a physician's order, are recognized as the appropriate treatment for the illness, and are not experimental in nature. By definition, gays and lesbians are not medically infertile, rather, they are constructively infertile because they do not have sexual intercourse with members of the opposite sex. Therefore, assisted reproductive technologies would not be considered medically necessary for a homosexual who could "technically" reproduce by lesser intrusive means. Thus, it is unlikely that the inability to procreate secondary to homosexuality will be recognized as an illness requiring "appropriate treatment."

DeLair, *supra* note 24, at 175-76.

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obtaining fertility care.³⁷ The private nature of the relationship between donor and recipient provides a unique option to women seeking to conceive and does not function as a perfect substitute for sperm bank donations.

II. THE REGULATED STATUS QUO OF SPERM BANK DONATION

Private sperm donation, with its close correspondence to familiar models of mate selection, contrasts dramatically with the sperm bank industry. Sperm banks are subject to federal (and, often, state)³⁸ regulations that attempt to ensure safety of users of these businesses. However, the complexity of the federal regulatory scheme alone creates compliance burdens that are significant for a profit-oriented medical enterprise and practically impossible for an individual.

First, a sperm bank is subject to a panoply of regulations promulgated pursuant to Section 361 of the Public Health Service Act (PHSA).³⁹ These regulations are intended to set up a “unified registration and listing system for establishments that manufacture human cells, tissues, and cellular and tissue-based products (HCT/P’s) and to establish donor-eligibility, current

37. Mary Crossley, *Dimensions of Equality in Regulating Assisted Reproductive Technologies*, 9 J. GENDER RACE & JUST. 273 (2005) (discussing discriminatory provision of access to ART); see also Interview by David Masci with Ira “Chip” Lupu, F. Elwood and Eleanor Davis Professor of Law, The George Washington University Law School, & Robert W. Tuttle, David R. and Sherry Kirschner Berz Research Professor of Law and Religion, The George Washington University Law School (June 3, 2010), <http://www.pewforum.org/Church-State-Law/Tensions-Between-Rights-of-Conscience-and-Civil-Rights.aspx>; *N. Coast Women’s Care Med. Group v. Superior Court*, 44 Cal. 4th 1145 (2008) (Although the Supreme Court of California held that physicians’ free exercise rights did not allow them to decline to serve a lesbian couple seeking fertility treatment, it is unclear whether such a result would also be reached in other jurisdictions, given the role of State law antidiscrimination protections in that case and recent developments in federal First Amendment jurisprudence.).

38. See, e.g., CRYOGAM COLORADO, <http://www.cryogam.com/CG-Licensure.html> (last visited Sept. 28, 2012); N.Y. PUB. HEALTH LAW §§ 573, 575 (Mckinney 1993); CAL. HEALTH & SAFETY CODE § 1639.1 (West 1991); MD. CODE ANN., HEALTH OCC. § 17.301 (West 2012). New York, California, and Maryland require licensure of sperm banks.

39. See Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, 69 Fed. Reg. 29, 786-7, 29 (May 25, 2004) (codified at 21 C.F.R. §§ 210-1, 820, 1271 (2012)):

We are issuing these new regulations under the authority of section 361 of the Public Health Services (PHS) Act, 42 U.S.C. 264 (2012). Under that section, by delegation from the Surgeon General and the Secretary of Health and Human Services, the FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or from foreign countries into the States. Intrastate transactions affecting communicable disease transmission may also be regulated under section 361 of the PHS Act.

See also Public Health Service Act, Pub. L. No. 78-410, 58 Stat. 682, 703, § 361 (1944) (codified as amended at 42 U.S.C. § 264 (2012)).

good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's."⁴⁰ Although additional regulations apply to institutions trafficking in HCT/P's that are, due to extensive manipulation or the addition of adulterating agents, considered "drugs, devices or biological products,"⁴¹ sperm banks must comply with those regulations set out in 21 C.F.R. Part 1271, Subparts A, B, C, and F, and a portion of Subpart D.⁴² The requirements apply "whether or not the HCT/P enters into interstate commerce."⁴³ Violation of the FDA's HCT/P regulations is a strict-liability federal crime that is punishable by imprisonment for up to one year and a substantial fine.⁴⁴

The FDA's role in ensuring compliance with these regulations is of comparatively recent vintage. Although other human cells and tissues were regulated under C.F.R. Part 1270 since 1993,⁴⁵ the regulations in Part 1271

40. 21 C.F.R. § 1271.1(a) (2012). 21 C.F.R. § 1271.3(d) defines HCT/P's as "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples of HCT/P's include, but are not limited to . . . semen or other reproductive tissue."

41. 42 U.S.C. § 262(i)(1) (2010). E.g. "[B]lood, blood component[s] or derivative[s] . . . applicable to the prevention, treatment or cure of a disease or condition of human beings."

42. 21 C.F.R. § 1271.10 (2012); see also U.S. FOOD AND DRUG ADMIN., Guidance for Industry Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) - Small Entity Compliance Guide, at 5, <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm062592.pdf> (last visited Aug. 3, 2012). "Subparts A through C apply to all 361 HCT/Ps. Subpart D applies only to nonreproductive 361 HCT/Ps, with the exception of 21 C.F.R. 1271.150(c) and 1271.155, which apply to all 361 HCT/Ps. Subpart E applies only to nonreproductive 361 HCT/Ps. Subpart F applies to all 361 HCT/P's."

43. 21 C.F.R. § 1271.1(b) (2012).

44. See 42 U.S.C. § 271(a) (2012). "Penalties for persons violating quarantine laws. Any person who violates any regulation prescribed under sections 361, 362, or 363 [42 U.S.C.S. §§ 264, 265, or 266], or any provision of section 366 [42 U.S.C.S. § 269] or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than \$1,000 or by imprisonment for not more than one year, or both."; see also Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. 68, 612, 68, 614 (Nov. 24, 2004) (codified at 21 C.F.R. pts. 16, 1270, 1271). "[U]nder section 368(a) of the PHS Act (42 U.S.C. 271), any person who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Individuals may also be punished for violating such a regulation by a fine of up to \$100,000 if death has not resulted from the violation or up to \$250,000 if death has resulted." The FDA's decision to interpret its regulations to criminalize certain private procreative decisions stands in tension with a long line of Supreme Court cases striking down state statutes that criminalized private procreation-related choices; see, e.g., *Griswold v. Connecticut*, 381 U.S. 479 (1965); *Planned Parenthood Ass'n v. Fitzpatrick*, 401 F. Supp. 554 (1975); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992).

45. U. S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: SCREENING AND TESTING OF DONORS OF HUMAN TISSUE INTENDED FOR TRANSPLANTATION 2 (July 1997),

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applicable to reproductive tissues are less than a decade old:⁴⁶ registration and listing requirements were established in 2001,⁴⁷ and the subparts specifying donor-eligibility requirements and current good tissue practice, inspection, and enforcement were not created until 2004.⁴⁸ However, the short history of these regulations is in sharp contrast to their requirements.

A. Registration

A sperm bank must first register and list its HCT/P's with the FDA's Center for Biologics Evaluation and Research.⁴⁹ This registration, which must be sent within five days of beginning operations and updated every December,⁵⁰ must include the establishment's name, location, the name, address, title of the reporting official, and a list of all HCT/P's that the establishment recovers, processes, stores, labels, packages, distributes, or upon which it performs donor screening or testing.⁵¹ These registrations are then available for public inspection.⁵²

B. Determining and Recording Donor Eligibility

Sperm banks must conduct donor-eligibility determinations, which require donor screening and testing for relevant communicable disease agents and diseases.⁵³ Donated semen must not be transferred to a recipient until after the donor-eligibility determination is complete⁵⁴ and must be quarantined in the interim.⁵⁵ The determinations must be conducted according to established procedures that have been defined, documented, reviewed by a responsible party prior to implementation, and revised as

<http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/UCM188251.pdf>.

46. U.S. FOOD & DRUG ADMIN. GUIDANCE FOR INDUSTRY REGULATION OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) - SMALL ENTITY COMPLIANCE GUIDE (Aug. 2007), <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm062592.pdf>.

47. Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing, 69 Fed. Reg. 3823-24 (Jan. 27, 2004) (to be codified at 21 C.F.R. § 1271).

48. Current Good Tissue Practice for Human Cell, Tissue and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. 68612 (November 24, 2004) (to be codified at 21 C.F.R. § 1270-71).

49. *Id.*

50. 21 C.F.R. § 1271.21 (2012).

51. 21 C.F.R. § 1271.25 (2012).

52. 21 C.F.R. § 1271.37 (2012).

53. 21 C.F.R. § 1271.45(b) (2012). A limited exception exists for donations from sexually intimate partners of the recipient, as will be discussed at length *infra*.

54. 21 C.F.R. § 1271.45(c) (2012).

55. 21 C.F.R. § 1271.60(a) (2012).

necessary in response to continuing review.⁵⁶

The determination procedure includes both screening and testing components. Donor screening establishes that the donor “[i]s free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases [and] communicable disease risks associated with xenotransplantation”; donor testing confirms that the donor is not positive for “relevant communicable disease agents.”⁵⁷

The donor must provide available laboratory test results and other records, medical or otherwise, which pertain to risk factors for relevant communicable disease agents or diseases (RCDADs).⁵⁸ This process also requires a “current donor medical history interview” (conducted in person or by telephone, and verifies answers to any self-administered medical questionnaire)⁵⁹ and physical examination of the donor.⁶⁰ The “current medical history interview” is not, strictly speaking, “medical”; rather, it is a “documented dialog about,” among other things, the donor’s “relevant social behavior.”⁶¹

Although it can affect whether a prospective donor is eligible to help a woman start a family, FDA regulations do not specify what constitutes a “relevant social behavior.”⁶² 21 C.F.R. Part 1271.3’s definition of “[d]onor medical history interview” indicates “relevant social behavior” includes, but

56. 21 C.F.R. § 1271.47 (2012).

57. 21 C.F.R. § 1271.50 (2012).

58. *Id.* This includes “[r]ecords or other information received from any source pertaining to risk factors for relevant communicable disease (e.g. social behavior, clinical signs and symptoms of relevant communicable disease, and treatments related to medical conditions suggestive of risk for relevant communicable disease).” For repeat donors, a bank may perform an abbreviated screening if it has been six months or less since he completed a full screening. An abbreviated screening requires only review and documentation of “any changes in the donor’s medical history since the previous donation that would make the donor ineligible, including relevant social behavior.” 21 C.F.R. § 1271.75(e) (2012).

59. See 21 C.F.R. § 1271.75(a)(1) (stating “if you are the establishment that performs donor screening, you must screen a donor of cells or tissue by reviewing the donor’s relevant medical records for . . . [r]isk factors for, and clinical evidence of, relevant communicable disease agents and diseases” (emphasis added)); see 21 C.F.R. § 1271.3(s) (“Relevant medical records means a collection of documents that includes a current donor medical history interview” (emphasis added)).

60. 21 C.F.R. § 1271.75; Guidance for Industry: Eligible Determination for Doctors of Human Cells, Tissues, and Cellular and Tissue-Based Products, U.S. FOOD & DRUG ADMIN. (Apr. 19, 2012), <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm#DONORSCREENING1271.75>.

61. 21 C.F.R. § 1271.3(n) (“Donor medical history interview means a documented dialog about the donor’s medical history and relevant social behavior, including activities, behaviors, and descriptions considered to increase the donor’s relevant communicable disease risk.”).

62. See 21 C.F.R. § 1271.3 (How does FDA define important terms in this part?); 21 C.F.R. § 1271.75 (How do I screen a donor?).

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is not limited to, “activities, behaviors, and descriptions considered to increase the donor’s relevant communicable disease risk.”⁶³

As the FDA acknowledged in the preamble to its final rule establishing the requirement to screen for “relevant social behaviors,” commenters on the proposed rule “asserted that the regulations would abridge the reproductive, civil, or constitutional rights of both donor and recipient” and “[m]any comments argued that the proposed regulations were discriminatory.”⁶⁴ In response to those comments, which urged the FDA to limit screening to actual medical tests, instead of screening for “relevant social behaviors” that are “risk factors,” the FDA noted simply that the “FDA rejects that approach at this time.”⁶⁵ The FDA explained that specific “risk factors” will be outlined in a subsequent guidance document.⁶⁶

As promised, the FDA fleshed out the requirement to screen for “risk factors” in a 2007 guidance document, which indicated that the donor-screening process requires exclusion of potential donors who manifest one or more of a long list of “relevant” behaviors or characteristics.⁶⁷ This list encompasses not just intravenous drug users, prostitutes, and individuals with hemophilia who have received human-blood-derived clotting treatments, but also men who have engaged in homosexual sex and persons who have had sex with any individual in the aforementioned categories.⁶⁸ Additionally, the regulations bar donation by, inter alia, xenotransplantation product recipients and their intimate contacts;⁶⁹ the recently tattooed;⁷⁰ anyone who has had his ears or body pierced in the past year without

63. 21 C.F.R. § 1271.3(n).

64. Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products, Final Rule, 69 Fed. Reg. 29, 786, 29, 805 (May 25, 2004) (to be codified at 21 C.F.R. §§ 210-1, 820, 1271).

65. *Id.* at 29, 806.

66. *Id.* “[T]his final rule does not specify risk factors. Risk factors and other information about screening are contained in the donor-eligibility draft guidance announced elsewhere in this Federal Register.”

67. *Id.* at 1; U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) pt. IV(E), at 14-20 (2007) [hereinafter ELIGIBILITY GUIDANCE], <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm073964.htm> (listing “potential donor[s]” that a covered entity “should determine to be ineligible” because they “exhibit[] one or more . . . conditions or behaviors” (emphasis added)). The FDA claims that this guidance document merely prescribes “nonbinding recommendations.”

68. *Id.* pt. IV(E)(1)-(5), at 14-15 (excluding various categories of men from the donor pool, the regulations effectively prevent some women from conceiving a child with the type of man, or even specific man, of their choice).

69. *Id.* pt. IV(E)(29), at 20-21.

70. *Id.* pt. IV(E)(10), at 16.

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observing FDA-approved protocol;⁷¹ persons who have resided in the United Kingdom, Europe, or specified African countries for certain proscribed periods (and persons whose “sexual partners” were born in certain African countries);⁷² U.S. military personnel and “civilian military employees” and their dependents, if they resided at certain U.S. military bases during the 1980s;⁷³ persons who have shared a house or apartment with someone who has certain forms of hepatitis within the past year;⁷⁴ prospective donors who have been diagnosed with certain forms of mental illness;⁷⁵ and anyone who was detained in “juvenile detention, lock up, jail or prison” for more than 72 hours in the past year (irrespective of the person’s guilt or innocence and regardless of whether he was charged with a crime).⁷⁶ The foregoing list of “relevant social behaviors” is illustrative, not exhaustive. The FDA’s proffered reason for recommending that anyone who engaged in this type of “relevant [i.e., undesirable] social behavior” from the donor pool is, of course, that the foregoing are “risk factors for relevant communicable disease agents and diseases.”⁷⁷

The FDA also has specific requirements to screen for communicable diseases. Semen donor-eligibility determinations must include screening and testing for human immunodeficiency virus (HIV), types 1 and 2; hepatitis B virus; hepatitis C virus; human transmissible spongiform encephalopathy diseases, including Creutzfeldt-Jakob disease (the human form of “mad cow disease”); *treponema pallidum*, a spirochete that can cause syphilis or other infectious diseases; types I and II of human T-lymphotropic virus, a human RNA retrovirus that causes certain cancers; cytomegalovirus; *chlamydia trachomatis*; and *neisseria gonorrhoea*.⁷⁸ Additionally, the FDA has noted that certain other diseases pose sufficient disease risk to justify screening including West Nile virus, sepsis, and vaccinia (the virus used in smallpox vaccinations).⁷⁹ Moreover, semen banks must use FDA licensed, approved, or cleared donor screening tests and be certified to perform such testing on human specimens either under the Clinical Laboratory Improvement Amendments (CLIA) or equivalent requirements as determined by the Centers for Medicare and Medicaid

71. *Id.*

72. *Id.* pt. IV(E)(23), (25), (27), at 19.

73. *Id.* pt. IV(E)(24).

74. *Id.* pt. IV(E)(9), at 15.

75. *Id.* pt. IV(E)(20), at 18.

76. *Id.* pt. IV(E)(8), at 15.

77. *Id.* pt. IV(E), at 14.

78. 21 C.F.R § 1271.75(a)-(c) (2012).

79. ELIGIBILITY GUIDANCE, *supra* note 67, pt. III(D), at 5-7.

Services.⁸⁰

After a semen bank performs the testing and screening described above, it must retain records and interpretation of the tests, the name and address of the testing laboratory, and the resulting donor eligibility determination, including the name of the responsible person who made the donor eligibility determination, and the date of the determination.⁸¹ These records must be maintained for least ten years.⁸² The donated semen itself must be kept in a container labeled with a distinct identification code, the results of the donor eligibility determination, and a summary of the records used to make the determination.⁸³ These records must also accompany the sample if it is distributed or transported.⁸⁴

Even donors who are initially deemed “eligible” to assist women who want to conceive children via AI, can subsequently be excluded from the donor pool based on changes in their “relevant social behavior.” Indeed, 21 C.F.R. Part 1271.75(e), which allows for an “abbreviated donor screening procedure on repeat donations,” explicitly instructs “establishments that perform[] donor screening” to “determine and document” any changes in the repeat donor’s “relevant social behavior” that could “make the donor ineligible.”⁸⁵

As one can see, sperm banks are subject to a comprehensive set of regulatory obligations applicable to gamete donation. They must conduct extensive reviews of donors’ medical records and “relevant social behaviors” and test donors for a wide variety of diseases within a week of the donation itself using government-approved tests in labs meeting government-approved standards. The expense of performing these screening and testing procedures, as well as the cost of maintaining records of the results for at least a decade, highlights the necessity of professionalization, economies of scale, and perhaps most importantly, monetary compensation for institutions performing these functions. However, not every donation triggers the full slate of precautions.

C. Donations Exempt from Part 1271’s Requirements

Perhaps the most important exception to the Part 1271 requirements is

80. 21 C.F.R § 1271.80(c) (2012); ELIGIBILITY GUIDANCE, supra note 67, pt. V(2), at 25. Where the establishment accepting the donation contracts with another entity to perform testing, the establishment is responsible for ensuring that the testing facility complies with current good tissue practice requirements. 21 C.F.R § 1271.150(c) (2012).

81. 21 C.F.R § 1271.55(d)(1) (2012).

82. 21 C.F.R § 1271.55(d)(4) (2012).

83. 21 C.F.R § 1271.55(a) (2012).

84. Id.

85. 21 C.F.R § 1271.75(e) (2012).

the exception for donations that will be immediately transferred into a sexually intimate partner (SIP) of the semen donor. An establishment that “only recovers reproductive cells or tissue and immediately transfers them into a sexually intimate partner of the cell or tissue donor” is not required to register or list its HCT/Ps with CBER.⁸⁶ Similarly, “[r]eproductive cells or tissue donated by a sexually intimate partner of the recipient for reproductive use” are exempt from Part 1271’s requirements to screen, test, and conduct donor eligibility determinations.⁸⁷ Thus, many of the burdensome and costly FDA regulations do not apply if a donation comes from the recipient’s sexually intimate partner, and the definition of that term becomes vital to individuals who seek to give or receive donated semen in a purely private, non-clinical context.

The FDA distinguishes sexually intimate partners from so-called “directed donors.” A directed reproductive donor is defined in 21 C.F.R. Part 1271.3(l) as “a donor of reproductive cells or tissue (including semen, oocytes, and embryos to which the donor contributed the spermatozoa or oocyte) to a specific recipient, and who knows and is known by the recipient before donation.”⁸⁸ Importantly, the term directed reproductive donor “does not include a sexually intimate partner.”⁸⁹ Under FDA regulations, a donor eligibility determination is mandatory for directed donations of reproductive tissue, as are screening and tests for disease.⁹⁰ Thus, if a donor is “known” but is not an SIP, the regulatory burden is much greater, and the FDA imposes the aforementioned screening, testing, labeling, and records requirements, most of which are impracticable for private individuals to follow.

By implication, then, the FDA’s HCT/P regulations distinguish between sexually intimate heterosexual couples and others: heterosexual sexually intimate couples need not adhere to the same regulatory strictures as married women whose husbands happen to be infertile, single women,

86. 21 C.F.R. § 1271.15(e) (2012).

87. 21 C.F.R. § 1271.90(a)(2) (2012).

88. 21 C.F.R. § 1271.3(l) (2012).

89. *Id.* See also 69 F.R. § 29,786, 29793. “We have also clarified the definition by noting that directed reproductive donors do not include sexually intimate donors, who are excepted from screening and testing requirements under § 1271.90. This change is intended to make clear that, for the purpose of this rule, there are three categories of reproductive donors, subject to three different sets of requirements listed as follows: (1) The anonymous donor, to whom all the donor-eligibility requirements apply; (2) the directed reproductive donor, whose reproductive cells and tissue may be used even if the donor is determined ineligible; and (3) the sexually intimate partner, for whom testing and screening are not required (discussed in section III.D.11 of this document).”

90. 21 C.F.R. § 1271.50 (2012); U.S. FOOD & DRUG ADMIN., VACCINES, BLOOD, AND BIOLOGICS (Apr. 19, 2012), <http://www.fda.gov/biologicsbloodvaccines/guidance/compliance/regulatoryinformation/guidances/tissue/ucm073964>.

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women who are in same-sex relationships; and men who, for any reason, wish to exercise their fundamental right to procreate outside of a sexually intimate relationship. This suspect classification seems to not only suggest an institutionalized bias against certain nontraditional methods of conception but also reflects a normative judgment that more traditional family structures—i.e., one in which a child is raised by his or her biological parents—are somehow more valid than less conventional family structures in which a biological parent is absent.

III. MAKING AN EXAMPLE: THE ARSENAULT CASE⁹¹

The difficulty of applying these regulatory requirements to private individuals outside the bounds of a medical facility is well illustrated by the recent case of Trent Arsenault, the first-ever individual semen donor to be issued a cease-manufacture order by the FDA. Although the conduct Arsenault engaged in bears some resemblance to the conventional donation process, the challenges of holding individuals to the same standards as clinics raise serious questions as to the proper scope of regulating artificial insemination.

Trent Arsenault is a computer-security professional who lives in the San Francisco Bay Area. Since 2006, Arsenault has donated semen to women wishing to conceive. What distinguishes Arsenault from most other donors is that he does so without the involvement of a medical facility or semen bank.⁹²

Most of Arsenault's recipients find him through the Internet. Arsenault's website, trentdonor.org, is an encyclopedic repository of information about him and his donation activities. It includes photographs of Arsenault at a wide range of ages, from infancy to the present.⁹³ He publicly posts his physical appearance, including age, weight,⁹⁴ an IQ test result,⁹⁵ educational history including areas of study and university attended,⁹⁶ field of employment and earnings history,⁹⁷ ethnic heritage,⁹⁸ musical abilities,

91. The author, through her employer organization, provided pro bono legal services to Mr. Arsenault and filed a brief on his behalf in support of his request for a hearing before the FDA. See *supra* note *.

92. Benjamin Wallace, *The Virgin Father*, N. Y. MAGAZINE (Feb. 5, 2012), available at <http://nymag.com/news/features/trent-arsenault-2012-2/index3.html>.

93. Trent Arsenault, *Gallery*, <http://trentdonor.org/index.php?q=gallery> (last visited June 13, 2012).

94. Trent Arsenault, *Trent's Profile*, <http://trentdonor.org/trent> (last visited June 13, 2012).

95. Trent Arsenault, *Psychological and IQ*, <http://trentdonor.org/iq> (last visited June 13, 2012).

96. Arsenault, *supra* note 94.

97. Trent Arsenault, *About Trent - Background Check Information*, <http://trentdonor.org/>

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hobbies, personality traits,⁹⁹ and even the results of his criminal background check.¹⁰⁰ He includes a lengthy set of health records,¹⁰¹ including genetic analysis and family medical history,¹⁰² the results of regular tests for communicable diseases,¹⁰³ responses to the FDA-recommended screening questions,¹⁰⁴ and a description of his exercise and dietary regimen.¹⁰⁵ Arsenault also is open about his abstinent lifestyle, which reduces his risk of communicable disease.¹⁰⁶ Arsenault currently donates only to couples, including both male/female and female/female partnerships.

Arsenault details the history of his donation activities, with the ratio of donations to successful pregnancies tracked.¹⁰⁷ The site explains that semen donations themselves are packaged in sterile specimen cups and offered for in-person pickup on a date selected by the recipient (shipping is not available).¹⁰⁸ The semen is not frozen or quarantined, and Arsenault provides links to studies suggesting a greater likelihood of pregnancy from the use of fresh semen.¹⁰⁹

Arsenault posts a blank version of the donor agreement that he uses as well.¹¹⁰ The agreement states that Arsenault disclaims any interest in custody, visitation, or guardianship of resulting children and that the recipient agrees to absolve Arsenault of financial liability. The terms provide that any decision to inform a child of his or her biological origin

background (last visited June 13, 2012).

98. Trent Arsenault, Family History, Ancestry, <http://trentdonor.org/family> (last visited June 13, 2012).

99. Arsenault, *supra* note 94.

100. Arsenault, *supra* note 97.

101. Trent Arsenault, Medical History, <http://trentdonor.org/medical> (last visited June 13, 2012).

102. Trent Arsenault, Genetics, Tay-Sachs, Cystic Fibrosis, Canavan Disease, 23andme, DNA Analysis, Telomere Length, <http://trentdonor.org/genetics> (last visited June 13, 2012).

103. Trent Arsenault, Sexually Transmitted Diseases (STD) Tests Copies, <http://trentdonor.org/std> (last visited June 13, 2012).

104. Trent Arsenault, Lifestyle Questionnaire, <http://trentdonor.org/screening> (last visited June 13, 2012).

105. Trent Arsenault, Fertility Diet, Increase Sperm Count, Limit DNA Damage, Calorie Restriction, and Telomere Length <http://trentdonor.org/diet> (last visited June 13, 2012).

106. Trent Arsenault, Abstinence and Sperm Donation, Sex, Health and Longevity, <http://trentdonor.org/abstinence> (last visited June 13, 2012); Wallace, *supra* at note 92.

107. Trent Arsenault, Statistics Data, <http://trentdonor.org/statistics> (last visited June 13, 2012).

108. Trent Arsenault, Local Recipients, <http://trentdonor.org/local> (last accessed June 13, 2012); Arsenault formerly was willing to ship to recipients if they purchased a professionally-created overnight shipping kit from Northwest Andrology and Cryobank.

109. Trent Arsenault, Fresh Raw Semen vs. Frozen (cryopreserved) Semen, <http://trentdonor.org/fresh> (last visited June 13, 2012).

110. Trent Arsenault, Donor Agreement, <http://trentdonor.org/contract> (last visited June 13, 2012).

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rests entirely upon the recipient and that any contact or communications between Arsenault and such children are also at the sole discretion of the recipient. Although agreements between biological parents cannot trump the legal rights of an actual child (and Arsenault posts links directing readers to the relevant California Family Code provisions,¹¹¹ which do not protect him from liability), the agreement's terms clearly establish that Arsenault sees his role as that of a gamete donor, not a parent.¹¹² However, Arsenault's commitment to provide information about his life and health, as well as his openness to establishing contact with children on the recipient's terms, differentiate him from many other donors accessible through semen banks.

Other unusual circumstances also distinguish these donations from the assistance conventionally offered by banks or fertility clinics. First, no money changes hands. Arsenault is not compensated for his donations in any way, nor is he reimbursed for any of the many costs associated with the donations, such as his regular medical tests, purchases of sterile packaging, or even travel to the drop-off location. Second, no medical intermediary is involved. Fresh semen can be used for artificial insemination intracervically by the recipient or her partner with no more than a syringe, allowing for conception to take place privately and without the presence of a medical professional. Third, Arsenault offers only his own semen. Fourth, the contact between donor and recipient is direct. If a woman seeking donated semen discovers Arsenault's website, she can review the full slate of information and then contact him directly. Only after an in-person meeting, a contract signed by both parties, and a meeting of the minds can a recipient receive Arsenault's semen. Compared with the common practice of requesting a physician's approval, selecting an anonymous donor from a brief catalog description, and receiving a drop-shipped sample of frozen sperm via Federal Express, donations from Trent Arsenault are significantly more private and personal.

111. Trent Arsenault, California Family Law, <http://trentdonor.org/law> (last visited June 13, 2012); CAL. FAM. CODE § 7613 (2012).

112. Under California law, legal parentage is determined by examining the intent of the parties; "the legal parents are those who intended to bring about the birth of the child." Emily Zapotocny, *My Two Moms: California's Supreme Court Decision in K.M. v. E.G. and Why Gay Marriage Offers the Best Protection for Same-Sex Families*, 21 WIS. WOMEN L.J. 111, 117-18 (2006) (discussing the California Supreme Court's ruling in *Johnson v. Calvert*, in which a gestational surrogate was ruled not to be the legal mother of a child produced using the egg and sperm of a married couple, where the egg-donor wife intended to create the child, and a California appellate court's ruling in *Buzzanca v. Buzzanca*, which held that a then-married couple's intent to create a child using third-party gametes of both types trumped the divorcing husband's lack of genetic connection to the resulting offspring. *Calvert* has since been superseded by statute, as stated in *Chatterjee v. King*, 2012 NMSC 19, 21 (NMSC 2012)).

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Despite these many dissimilarities, in 2009 the FDA elected to apply 21 C.F.R. Part 1271 to Arsenault's donations. Although it is unclear how the FDA was alerted to Arsenault's activities, in April of 2009 an investigator from the FDA's Sacramento office initiated contact with Arsenault.¹¹³ After conversations with the investigator and without the advice of legal counsel, Arsenault filed a form in November registering himself as a "directed donor" of HCT/P's, but asserting that his activities were exempt from the regulatory requirements of 21 C.F.R. Part 1271.¹¹⁴ Shortly afterwards, FDA agents began a series of four on-site inspections of Arsenault's "business." (Because the site of manufacture and packaging was Arsenault's home, this meant that the FDA conducted four separate inspections of his personal residence.) At the time of the first inspection, on August 27, 2010, Arsenault attempted to explain to three FDA agents in his home that he believed that his activities were exempt, but the federal investigators disagreed. They conducted three additional inspections, on September 2, 2010; September 9, 2010; and September 16, 2010. At the September 9th inspection, Arsenault provided to the FDA copies of forty-one donor agreements, a calendar with the names of recipients and donation dates, and lists naming individuals who signed donor agreements, even those who did not later receive a donation.¹¹⁵ The FDA also took copies of Arsenault's health records, including the results of communicable disease testing.

On September 20, 2010, FDA investigators issued Arsenault with an inspection observations report describing the various ways in which his conduct failed to meet 21 C.F.R. Part 1271's regulatory requirements. The FDA asserted that Arsenault was "not determined to be eligible based on the results of donor screening and testing."¹¹⁶ He "did not adequately screen [himself] for risk factors related to relevant communicable diseases . . . every six months," and the FDA specifically faulted him for

113. E-mail from Shelley H. Beausoleil, Investigator, Sacramento Office, Food and Drug Administration, to Trent Arsenault (Apr. 29, 2009, 14:57 PST) available at <http://trentdonor.org/sites/g2sites/trentdonor/d/21570-1/FDA-sacramento-request-registration-email-trentdonor-29-apr-2009.pdf>.

114. Interview with Trent Arsenault (Oct. 6, 2011); Trent Arsenault, 2010 FDA Directed Donor Registration, http://trentdonor.org/v/logos/fda_human_cell_and_tissue_establishment_registration/FDA3356_FEI3007575901A2009-portrait_p2.jpg.html (last visited June 13, 2012).

115. Trent Arsenault, Form FDA 463a Signed Affidavit – 16-Sep-2010, <http://trentdonor.org/sites/g2sites/trentdonor/d/21523-1/FDA-463a-signed-affadavit-16-Sep-2010-4-Pages.pdf> (last visited June 13, 2012).

116. U.S. FOOD & DRUG ADMIN., FDA Form 483 Inspection-Observation 20-Sep-2010, <http://trentdonor.org/trentdonor/d/21520-2/FDA-Form-483-Inspection-Observations-TrentDonor-20-Sep-2010-5-Pages.pdf> (last visited Aug. 3, 2012) [hereinafter FDA Inspection Form 483].

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failing to adequately screen “for disease risks associated with xenotransplantation and Creutzfeldt-Jakob disease.”¹¹⁷ Despite Arsenault being tested seven times in less than four years, the FDA asserted that the “testing of communicable disease agents were not collected at the appropriate time.”¹¹⁸ When the donations were handed over to recipients, the “HCT/P’s were not accompanied with the summary of the records used to make the donor-eligibility determination.”¹¹⁹ The FDA also told Arsenault that his “firm has not developed written procedures related to testing, screening, and determining donor eligibility of semen.”¹²⁰

After being informed that his “firm” had failed to comply with 21 C.F.R. Part 1271’s various obligations, Arsenault requested a time extension to respond.¹²¹ The FDA informed him that he was welcome to respond to the observations report if he did so within fifteen working days of its issuance, but that the FDA could proceed with an enforcement action without considering any responses received after that deadline.¹²² Arsenault, still lacking legal counsel, was unable to respond in time.

On November 1, 2010, the FDA’s Center for Biologics Evaluation and Research (CBER) issued an “Order to Cease Manufacture” to Trent Arsenault:

Your firm, Trent Arsenault (or Establishment), located at 38068 Canyon Heights Drive, Fremont, California, recovers and distributes semen and therefore is a manufacturer of human cells, tissues, and cellular and tissue-based products (HCT/Ps). The Food and Drug Administration (FDA or agency) conducted an inspection of your Establishment between August 27 and September 16, 2010, and at the conclusion of the inspection, the FDA investigator issued you a Form FDA- 483, Inspectional Observations. Our review of the information and records examined and collected during the inspection revealed significant violations of Title 21, Code [of Federal Regulations, Part 1271 (21 C.F.R. Part 1271) issued under the authority of Section 361 of the Public Health Service Act (PHS Act) [42 United States Code (U.S.C.)

117. Id. at 2.

118. Id.

119. Id. at 4.

120. Id.

121. Trent Arsenault, Letter from Trent Arsenault to FDA (Oct. 1, 2010), available at <http://trentdonor.org/sites/g2sites/trentdonor/d/21526-1/extension-request-to-FDA-SF-office-trentdonor-01-oct-2010-1-page.pdf> (requesting more time to reply).

122. Trent Arsenault, Letter from FDA to Trent Arsenault (Oct. 7, 2010), available at <http://trentdonor.org/sites/g2sites/trentdonor/d/21529-1/FDA-SF-office-reply-to-extension-trentdonor-07-oct-2010-1-page.pdf> (encouraging a partial response from Mr. Arsenault as soon as possible).

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264 (2012)]. The agency has determined that because your Establishment is in violation of 21 CFR Part 1271, your Establishment does not provide adequate protections against the risks of communicable disease transmission through the use of these HCT/P's. This Order to Cease Manufacturing relates to conduct occurring on or after May 25, 2005, the effective date of the applicable regulations. FDA retains the authority to pursue other actions and remedies.

Because of your failure to provide adequate protections against the risks of communicable disease transmission, pursuant to 21 C.F.R. Part 1271.440(a)(3), you must cease manufacturing until compliance with the regulations in 21 C.F.R. Part 1271 has been achieved and you have been provided written authorization from FDA to resume operations. Under 21 C.F.R. Part 1271.3(e), manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any HCT/P, and the screening or testing of the HCT/P donor.

The Order was to be effective either five working days from its issuance or after a hearing and determination, if such was requested by Arsenault.¹²³ Arsenault immediately responded with a letter addressed to FDA Directors Barbara Cassens and Mary Malarkey, requesting a hearing and describing his relationships with the recipients.¹²⁴ Apparently for the first time, Arsenault informed the FDA in writing that he considered himself exempt from the 21 C.F.R. Part 1271 directed donor requirements because he fell within the “sexually intimate partner” exception. On November 11, 2010, Arsenault confirmed that his November 1, 2010 response had been intended to invoke the Part 16 hearing process under 21 C.F.R. Part 1271.440(e).¹²⁵ The next day, the FDA formally acknowledged the request, informing him that “the Order to Cease Manufacturing will be effective after a decision in,

123. Given that the Order was not effective immediately, there is reason to believe that CBER did not conclude that there were reasonable grounds to believe that Arsenault's conduct as a threat to public health. See 21 C.F.R. § 1271.440(a)(3) (“When FDA determines there are reasonable grounds to believe there is a danger to health, such order will be effective immediately. In other situations, such order will be effective after one of the following events, whichever is later: (i) Passage of 5 working days from the establishment's receipt of the order False”).

124. Trent Arsenault, Letter from Trent Arsenault to FDA (Nov. 1, 2010), available at <http://trentdonor.org/sites/g2sites/trentdonor/d/21459-4/trentdonor-fda-form-483-response-doc-01-nov-2010.pdf> (replying to the FDA's Cease Manufacturing order, making a hearing request, and reply to Form 483).

125. Stephany Wesley, Order for Cessation, CBER, (Nov. 12, 2010), <http://trentdonor.org/sites/g2sites/trentdonor/d/21535-1/FDA-CBER-email-effective-date-cease-order-12-nov-trentdonor-2010.pdf> (confirming the Cease Manufacturing order would be effective after a Part 16 hearing).

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and in accordance with, the Part 16 proceedings.”¹²⁶

Although the Order was not effective due to the pending hearing request, many potential recipients, including families who had previously had children with Arsenault’s assistance and wanted to conceive genetically related siblings, were thrown into a state of uncertainty by the FDA’s actions.¹²⁷ Arsenault kept in communication with the FDA’s hearing coordinator and stated, in accordance with Part 16.24 (g), that he intended to present and rely upon written information at the hearing: specifically, “written statements signed by myself and the females who met with me declaring that we are sexually intimate partners.”¹²⁸ However, months passed with no response to his hearing request.

The Part 16 hearing process lacks many of the elements of due process available in courts—or even in formal administrative proceedings. The rules of evidence do not apply¹²⁹ and there is no right to counsel. There is no formal deadline for the agency to respond to a hearing request. Although the requestor and the government both may file papers in support or opposition, there are no strictures on the length, timing, or format of such filings. The request itself is technically before the FDA Commissioner, Margaret Hamburg, but Hamburg’s designee for these purposes is, as of this writing and at the time of Arsenault’s request, Dr. Jesse Goodman, Chief Scientist and Deputy Commissioner for Science and Public Health of the FDA. Perhaps ominously, Dr. Goodman was, until only weeks before the Arsenault investigation began, the Director of CBER—the very entity whose order Arsenault sought to overturn.¹³⁰ A Part 16 hearing decision could encompass only the grant or denial of a hearing, or also include the substantive legal question of whether the Order was properly issued. A decision could be made at any time, with or without further information from the requestor.

Finally, on February 11, 2011, something happened: CBER filed a motion opposing Arsenault’s request. CBER’s motion asked that its former director deny the request for an evidentiary hearing and grant administrative summary judgment on the question of whether 21 C.F.R. Part 1271 legally applies to Arsenault’s conduct.

The government’s chief argument was that no genuine or substantial

126. *Id.*

127. Trent Arsenault, Order from CBER to Cease Manufacturing of Semen and Hearing Request <http://trentdonor.org/sites/g2sites/trentdonor/d/21508-2/letter-to-FDA-Commissioner-Hamburg-trentdonor-2010-1128.pdf> (Nov. 28, 2010) (pleading for consideration).

128. Pls.’ Mot. Opp. CBER’s Mot. Summ. J. 1, Nov. 7, 2011.

129. 21 C.F.R. § 16.60 2(c) (2012).

130. Pls.’ Mem. Supp. Mot. Opp. CBER’s Mot. Summ. J. 2, Nov. 7, 2011.

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issues of fact existed to justify the use of FDA resources conducting a hearing. Citing the section's preamble, CBER noted that "the primary purpose of a Part 16 hearing is to resolve factual issues."¹³¹ Under § 16.26(a), "the person requesting the hearing" bears the burden of producing "information . . . to show that there exists a genuine and substantial issue of fact." 53 Fed. Reg. 4,613, 4,614 (Feb. 17, 1988). In this case, Arsenault has offered to produce, at a hearing, written and oral testimony by himself and some of the recipients describing their relationship. These statements would be offered to resolve the factual question of what type of relationship existed between the donor and recipient—a necessary precondition to determining whether the sexually intimate partner exception could apply. CBER argued that Arsenault's new evidence constituted "mere allegations"¹³² that "disputed FDA's application of its own regulations,"¹³³ and did not raise a genuine or substantial issue of fact. CBER stressed that these statements were inconsistent with documentation produced to FDA inspectors during their investigation: numerous statements by Arsenault, such as those in donor agreements, his FDA registration form, and his website, described him as a "directed donor."¹³⁴ CBER also recapped the various regulations under 21 C.F.R. Part 1271 with which Arsenault failed to comply before asking the Commissioner to reject the hearing request, stating that:

[Arsenault's] explanation, that he is the sexually intimate partner with those to whom he donates, is nothing more than an attempt to skirt the law and is offered without a shred of evidence. FDA cannot accept an expanded definition of the term 'sexually intimate partner'. To do so, would create a hurdle for the very individuals Mr. Arsenault claims to be helping. It would create a hurdle to the protections offered by the donor eligibility requirements.¹³⁵

CBER's attempt to short-circuit the hearing process and affirm the issuance of the Order did not produce results. Months passed with no action from the Commissioner on either Arsenault's request or CBER's filing. However, the provision permitting Arsenault to donate during the pendency of the hearing request functioned to increase the stakes, as Arsenault's decision to continue responding to potential recipients resulted in even more donations—and pregnancies.

131. 53 Fed. Reg. 4614 (Feb. 17, 1988).

132. CBER's Mem. Supp. Mot. To Deny Hearing Req. & Summ. J. 8, Feb. 7, 2011.

133. *Id.* at 10.

134. *Id.* at 9.

135. *Id.* at 15.

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News coverage of private sperm donation drew widespread attention to the issue. After his legal troubles were discussed in a Newsweek cover story, Arsenault obtained pro bono counsel from a nonprofit that focused on federal regulatory overreach.¹³⁶ This enabled him to file a response in November of 2011 to CBER's motion, arguing that his evidence merited a hearing, and alternatively that the Order was not lawfully issued.¹³⁷ Over a year later, Dr. Jesse Goodman issued a Commissioner's Decision that denied Arsenault's hearing request and deemed "the Cease Manufacture Order properly issued."¹³⁸ The Order was thus made effective as of December 7, 2012; Arsenault is barred from donating semen to consenting women unless he complies with Part 1271's regulations and he receives written authorization from the FDA.

IV. ISSUES RAISED BY APPLICATION OF 21 C.F.R. PART 1271 TO PRIVATE, UNCOMPENSATED SEMEN DONATION

By interpreting its regulations to apply to Arsenault, and potentially others engaging in similar conduct, the FDA has extended its authority in a new and troubling manner. The regulations themselves do not appear to apply to private individuals who give semen directly to recipients for artificial insemination.¹³⁹ Reading them to do so purportedly protects recipients, but upon examination it may incent riskier, not safer, conceptions. Barring a man from fathering children with consenting women by administrative order also raises the question of whether fundamental rights are being burdened without due process of law. Even if the FDA had afforded Arsenault more procedural safeguards before issuing the Order, there remains the substantive question of whether the federal government has the authority to infringe on the right to procreate in this manner (which cabins not only Arsenault's procreative liberty, but that of

136. The author, on behalf of her employer organization Cause of Action, represented Arsenault for the purpose of filing a brief in opposition to CBER's motion. See Pls.' Mot. Opp. CBER's Mot. Summ. J. 2, Nov. 7, 2011.

137. See Food Additives Permitted for Direct Addition to Food for Human Consumption; Bacteriophage Preparation, 76 Fed. Reg. 16285 (March 23, 2011) (to be codified at 21 C.F.R. § 172), ("In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law").

138. Trent Arsenault, Comm'r Decision 12-13 (Food & Drug Admin. Dec. 7, 2012) ("Mr. Arsenault therefore appears to assert that he has a Constitutional right to transfer his sperm to others for artificial insemination without adhering to protections against communicable disease transmission to the recipients. I disagree that he has a right to violate the applicable FDA regulations.").

139. See generally 21 C.F.R. § 1271.3. C.F.R. § 1271.3 does not include "sexually intimate partner" in its defined terms.

women who wish to conceive via AI and a private donor).

A. Extending the Textual Boundaries of 21 C.F.R. Part 1271

The FDA's decision to apply existing regulations to private donors like Arsenault does not naturally follow from their text. Although the regulations themselves do not explicitly recognize or account for private donations taking place entirely through negotiations between individuals, the preamble to the final rule cited by CBER speaks specifically of reducing the risk posed by artificial insemination in "small medical practice[s]."¹⁴⁰ The distinction between conceptions that involve interventions by the personnel of such practices and those that involve only the biological parents presents a potential bright-line rule that would carve out space for Arsenault and other private donors by grouping them with the vast majority of biological fathers who conceive through intercourse. However, the FDA's refusal of such a rule highlights the potential scope of a loose interpretation of 21 C.F.R. Part 1271 and the implications thereof.¹⁴¹

Even if one concedes that 21 C.F.R. Part 1271 applies to Arsenault and other private donors, the regulations themselves create an exception to many of the regulatory requirements for donations by sexually intimate partners (SIPs).¹⁴² But neither the Code of Federal Regulations nor the preamble to the relevant Final Rule define SIPs for purposes of 21 C.F.R. Part 1271. In its objection to Arsenault's hearing request, CBER asserted that "the plain meaning of the words . . . do not require further explanation," citing the preamble to the proposed rule to support its contention that the "FDA exempted sexually intimate partners because

140. CBER, *supra* 132, at 9. The cited regulation provides in relevant Part III A: "[T]he compliance expectations for a small medical practice that provides artificial insemination are commensurate with the communicable disease risks associated with its activities." 69 Fed. Reg. 29, 786, 29, 790 (May 25, 2004) (to be codified at 21 C.F.R. 1271).

141. The Supreme Court has held that courts should afford substantial deference to an agency's interpretation of regulations that it has issued. *Auer v. Robbins*, 519 U.S. 452, 462 (1997) (applying *Bowles v. Seminole Rock & Sand Co.*, 325 U.S. 410, 414 (1945) ("[T]he ultimate criterion is the administrative interpretation, which becomes of controlling weight unless it is plainly erroneous or inconsistent with the regulation")). However, this deferential standard has been criticized by scholars. See, e.g., John F. Manning, *Constitutional Structure and Judicial Deference to Agency Interpretations of Agency Rules*, 96 COLUM. L. REV. 612 (1996); Robert A. Anthony, *The Supreme Court and the APA: Sometimes They Just Don't Get It*, 10 ADMIN. L. J. AM. U. 1 (1996). *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), articulates an alternative in stating that respect afforded to an agency's interpretive position depends upon the thoroughness of its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all other persuasive factors. Moreover, this deference arises out of the agency's position as the recipient of delegated statutory authority from Congress, and statutory provisions violative of the U.S. Constitution are, of course, illegitimate. See *Id.* at 137-38.

142. See 21 C.F.R. §§ 1271.3(l), .15(e), .90(a)(2), .420.

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insemination with the semen from a sexually intimate partner entails minimal risks.”¹⁴³ However, this bluff and condescending statement ignores the reality that the meaning of those words to officials in Washington may not reflect the meaning they have to individuals attempting to start a family through methods that are, if uncommon, still freighted with intimacy.

Of course, the hazard posed by insemination with a SIP’s semen varies based on the degree to which the attempt to conceive would expose the recipient to new disease risk. The FDA’s logic applies where the partnership in question is a monogamous couple that regularly engage in sexual intercourse and do not take part in individual activities that could lead to asymmetrical exposure. Not only does that describe only a subset of sexually intimate relationships, but it privileges this subset under a federal regulatory regime.

By leaving SIP undefined, the FDA perhaps recognized that a federal agency is not institutionally competent to create one definition of SIP applicable to more than 300 million Americans. Indeed, it is inevitable that every individual will define this term for him- or herself. Just as individual persons ultimately arrive at their own sincerely held religious beliefs, sincerely held beliefs about sex, intimacy, and relationships will differ based on subjective experience.

Of course, a less generous interpretation of the government’s actions is supported by CBER’s actions in the Arsenault matter. By leaving SIP undefined, the FDA can avoid a potential controversy,¹⁴⁴ but raise a legalistic eyebrow whenever an individual steps out of line and tries something that transgresses against the unwritten, heterosexually-monogamous definition. For example, in the Arsenault matter, CBER explicitly claimed that the SIP exemption was created “with the understanding that such partners would not need to be follow donor eligibility requirements.”¹⁴⁵ To base a regulation on some unspoken and undefined understanding about sexually intimate partnerships is, at minimum, problematic.

Moreover, the FDA’s “understanding” that SIPs are those between monogamous, sexually active heterosexual couples does not necessarily flow from the regulations themselves. A broader understanding is consistent with the preamble language CBER cited in the Arsenault matter.

143. CBER, *supra* note 132, at 9-10.

144. Lauren Bruce, What Makes a Woman a Woman?, *FEMINISTE*, (Apr. 4, 2005) <http://www.feministe.us/blog/archives/2005/04/24/what-makes-a-woman-a-woman/> (discussing the controversy of the proposed Unborn Child Pain Awareness Act of 2005, which defines a woman as solely a female human being capable of becoming pregnant).

145. CBER, *supra* note 132, at 10 (emphasis added).

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Although that language notes that routine exposure to an SIP's body fluids is "likely," it does not assume that such exposure is universal, nor does it make exposure a necessary condition for SIP status.¹⁴⁶

Sexual relationships in modern American society are more diverse than ever. This poses a challenge to regulatory agencies whose enforcement actions affect the composition of or rights afforded to these families. In some instances, as here, the government has a choice between interpreting a regulation to paternalistically redefine an individual's intimate partnerships (with the direct effect of making it more difficult for the individual to exercise his or her reproductive rights), or reading the law in a manner that respects differences and personal choices about the meaning of intimate connections. By imposing its particular set of beliefs about the true meaning of a procreative partnership, the FDA has made a deliberate decision to apply 21 C.F.R. Part 1271 in a manner that results in serious harms to individual autonomy.

B. Risk Reduction and 21 C.F.R. Part 1271

The government's decision would be understandable if narrowly defining the SIP exception actually resulted in a reduction in health risk. However, the Arsenault case highlighted the irrationality of this interpretation in practice. CBER asserted that it could order Arsenault to cease donating semen to consenting adult recipients because he did not follow a plethora of regulatory standards, which purportedly protect recipients from disease. However, CBER's ability to stand between a woman and the man she wished to father her child appeared to hinge completely on the use of a semen receptacle. If Arsenault (like some other uncompensated donors) provided natural insemination, CBER's position is apparently that it could not intervene—even though such activity is riskier than the procedures followed by Arsenault.¹⁴⁷

146. Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52, 696, 52, 707 (September 30, 1999) (to be codified at 21 C.F.R. §§ 210, 211, 820, 1271) (Preamble to the Proposed Rule). See also *Perry v. Schwarzenegger*, 704 F. Supp. 2d 921, 956 (N.D. Cal. 2010), (quoting *In re Marriage Cases*, "This contention [that marriage is limited to opposite-sex couples because only a man and a woman can produce children biologically related to both] is fundamentally flawed.") (internal citations omitted); *Id.* at 956-57, (quoting *Lawrence v. Texas*, (Scalia, J., dissenting) "What justification could there possibly be for denying the benefits of marriage to homosexual couples exercising 'the liberty protected by the Constitution'? Surely not the encouragement of procreation, since the sterile and the elderly are allowed to marry.") (internal citations omitted).

147. Although CBER has not asserted that it has the authority to regulate sexual acts between two previously unacquainted persons if the male partner has offered himself for the sole purpose of impregnating the female, such a conclusion follows logically from many of the arguments in its brief. Such an expansion of scope would appear to exceed

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The irrationality of CBER's actions is further illustrated by their consequences: to avoid disease risk, CBER inadvertently encourages conduct that poses a greater hazard. If CBER can shut down private, individual donors providing semen for artificial insemination but cannot regulate those providing natural insemination, the latter may become the only free option for women seeking donated semen. CBER's interpretation of the regulations thus increases the likelihood that a donee lacking funds to purchase semen from a bank will engage in sexual intercourse with donors, even if this would mean that she had to engage in an adulterous sexual act or violate her sexual orientation. Natural insemination carries a greater risk to both partners: each is exposed to the other's bodily fluids, as well as potential contagion spread via skin-to-skin contact. To create a regulatory regime that increases the very type of risk that it seeks to minimize is irrational on its face.

Issuance of a cease-manufacture order, like any action by an administrative agency, must be "rational, based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute."¹⁴⁸ However, CBER's extension of 21 C.F.R. Part 1271 to donor like Arsenault is irrational and failed to consider important factors bearing on disease risk, as noted above. Moreover, individuals seeking to conceive a child together have a protected constitutional interest in procreative liberty, but this important factor received little or no attention from CBER in its analysis of 21 C.F.R. Part 1271. The government's brief described Arsenault as "attempting to circumvent the protections afforded [non-traditional] 'families,'"¹⁴⁹ yet ignoring the individual interests of the recipients and assumed that the government's proper role is to step in and

constitutionally grounded limitations on federal regulatory authority under the Commerce Clause, U.S. CONST. art I, § 8, cl. 3, even as interpreted broadly by cases such as *Gonzales v. Raich*, 545 U.S. 1, 16-17 (2005). Under our system of federalism, the federal government's regulatory authority is not untrammelled but rather is constitutionally limited; purely intrastate noneconomic activity is outside of the purview of federal regulation. See *U. S. v. Morrison*, 529 U.S. 598, 602, 611 (2000) (characterizing family law, marriage, divorce, and childrearing as "areas of traditional state regulation" that are outside of the ambit of federal regulatory authority and outlining constitutional limits on the federal government's regulatory authority under the Commerce Clause). Moreover, such a broad assertion of federal power to regulate private procreative choices would bring individual-rights concerns to the fore with additional urgency. See also *infra* Part V.

148. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 27, 37 (1983); see also *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 532 (2009).

149. CBER Brief, *supra* note 132, at 10. Of note is the government's repeated use of quotation marks around "families" when it refers to the non-traditional partnerships (predominantly lesbian couples) to which Arsenault donates. The implication is that the FDA has an "understanding" about what constitutes a family—and a childless same-sex couple does not qualify.

protect families from the risk of disease.¹⁵⁰

Contrast this with the deference normally granted to persons seeking to conceive a child with a new or current sexual partner. The courts have affirmed the importance of individual autonomy in this sphere time and again and invariably find that the government's ability to interfere in consensual adults' attempts at conception is extremely limited.¹⁵¹ The inconsistency with decades of case law accentuates the arbitrary and capricious nature of CBER's application of 21 C.F.R. Part 1271 to private semen donation.

V. PROTECTING PROCREATIVE RIGHTS THROUGH PROCESS

Even if 21 C.F.R. Part 1271 was intended to encompass private, uncompensated semen donation, the Supreme Court's decisions over the last century have established certain procedural protections that must be afforded before the government may deprive an individual of a substantive right. The FDA failed to meet those requirements before issuing a cease-manufacturing order to Arsenault.¹⁵² Although the order effectively declared that Arsenault must cease fathering children with consenting adult

150. CBER Brief, *supra* note 132, at 10.

150. It is unclear whether CBER's references to "families" include children who could be created through use of ART via a private donor. To the extent that a failure to comply with 21 C.F.R. 1271's regulatory regime risks harms to presently nonexistent children, it poses an alternative case of the

"the non-identity problem" famously identified by Derek Parfit. . . . Because the children in question would not exist unless they were brought into the world, . . . they are not harmed simply because they have been born into what some have claimed to be less than optimal circumstances. Indeed, tort law has long recognized this point in its refusal to grant children damages for "wrongful life" for being born in disadvantaged or diminished states of well-being when there was no alternative way for them to have been born. Protecting those children by denying them existence altogether would thus not provide rational grounds for denying gays and lesbians the right to marry or to procreate with ARTs.

John A Robertson, *Gay and Lesbian Access to Assisted Reproductive Technology*, 55 *CASE W. RES. L. REV.* 323, 341-42 (2004).

151. See, e.g., *Skinner v. Okla.*, 316 U.S. 535, 538, 541 (1942) (holding that state law requiring forced sterilization of repeat criminals is unconstitutional because it deprives those persons of their fundamental right to procreate). But cf. *Gerber v. Hickman*, 291 F.3d 617, 623 (9th Cir. 2002) (holding that an inmate "has no constitutional right to procreate while in prison").

152. 21 C.F.R. § 1271. The standard of proof that must be met before a cease-manufacturing order may issue is considerably lower than even the preponderance-of-the-evidence standard; cf. per 21 C.F.R. § 1271.440(a), (A cease-manufacturer may issue "[u]pon an agency finding that there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in" [this section]).

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recipients—a serious infringement of a core liberty¹⁵³—its issuance was the result of an administrative process lacking in safeguards required to protect such rights.

Prior to taking an action that deprives an individual of his rights, the government must conduct a searching inquiry on how such a deprivation can be accomplished. In *Mathews v. Eldridge*, the Supreme Court described the balancing test that should be used to determine the amount of process that must be provided before the government may deprive an individual of their rights:

First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used. . . and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.¹⁵⁴

The effective consequence of this balancing test is that the amount of process due is directly proportional to the right being deprived.¹⁵⁵ With respect to the right to reproduce, the Court has determined the right is fundamental, which requires the utmost procedural due process.¹⁵⁶ While the Court does not generally provide detailed guidance on procedure, in this instance it has explicitly held that “[t]he opportunity to present reasons, either in person or in writing, why proposed action should not be taken is a fundamental due process requirement.”¹⁵⁷

The decision to issue an order to Mr. Arsenault before granting even a simple hearing to present his evidence clearly falls short of what the Constitution requires. Arsenault was not afforded a hearing prior to issuance of the order, and the existing regulatory framework, as the FDA itself affirmed, permits the agency to decline his request for one if it determines that no questions of fact remain.¹⁵⁸

The FDA also incorrectly imposed the burden of proof on Arsenault when he attempted to challenge the cease-manufacturing order. According to CBER, the burden of proof rested on Arsenault to prove that a genuine

153. See *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977).

154. *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

155. *Clark v. Jeter*, 486 U.S. 456, 461 (1988).

156. *Skinner*, 316 U.S. at 538.

157. *Cleveland Bd. of Educ. v. Loudermill*, 470 U.S. 532, 546 (1985).

158. Motion to Deny Trent Arsenault's Request for a Hearing at 4, Center for Biologics Evaluation and Research (CBER), (Feb. 7, 2011), available at <http://trentdonor.org/sites/g2sites/trentdonor/d/21703-2/trentdonor-fda-motion-to-deny-hearing-07feb2010.pdf> (last visited Aug. 3, 2012).

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question of fact existed: namely, whether he was a directed donor subject to 21 C.F.R. Part 1271 or an exempt SIP.¹⁵⁹ Arsenault was only able to present his legal arguments on why the order should not be issued after he received the order. The Court made it clear in *Stanley v. Illinois* that in matters regarding fundamental rights the individual must be provided a hearing before action is taken, not after.¹⁶⁰ The FDA cannot simply determine that Arsenault, or any donor, is subject to their regulatory regime and then require him to prove that he is not. The burden of proof is on the State to prove the matter asserted.¹⁶¹

The FDA's investigatory procedures and process for issuing cease-manufacture orders are not legally sufficient where, as in the Arsenault matter, an individual's fundamental rights are at stake. Although they might be adequate where a regulated commercial enterprise is the target, a corporation's right to do business in the health care industry, or even an individual medical professional's right to practice his or her occupation, differs in kind from an individual's right to make intimate decisions about procreation. As discussed below, a long line of cases recognize this right as fundamental.¹⁶² By failing to provide a hearing prior to issuance of an order that infringes a fundamental constitutional right and by placing the burden on Arsenault to prove to the government why he should be allowed to father additional children, the FDA comprehensively failed in its due process obligations to Mr. Arsenault.

VI. APPLYING 21 C.F.R. PART 1271 TO THE EXERCISE OF FUNDAMENTAL RIGHTS PROTECTED BY SUBSTANTIVE DUE PROCESS VIOLATES THE CONSTITUTION

Perhaps the most troubling aspect of the FDA's targeting of private, uncompensated semen donation and Trent Arsenault is the implication that two adults may be prevented from conceiving a child together if the government disapproves.¹⁶³ CBER's cease-manufacture order and the related Commissioner's Decision signify that if your sexual relationship does not fall within certain privileged categories, or if you wish to conceive without medical intervention but also without sexual intercourse between

159. *Id.* at 4-5.

160. *Stanley v. Illinois*, 405 U.S. 645, 649 (1972).

161. *Loudermill*, 470 U.S. at 658.

162. See *infra* notes 165-70 and accompanying text.

163. The FDA's decision to interpret its regulations to constrain and potentially criminalize certain private procreative decisions stands in tension with a long line of Supreme Court cases striking down state criminal statutes that criminalized both contraception and conception-related procreative choices. See *supra* note 151 and accompanying text.

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the biological parents, the FDA may regulate your reproductive conduct. American history is pockmarked with a shameful series of attempts by government to regulate reproductive freedom and to legally bar certain individuals from reproducing how and with whom they choose—or at all.¹⁶⁴ The U.S. Supreme Court has held, however, that federal and state governments must respect procreative liberty under the doctrine of substantive due process. Private and uncompensated provision of semen to a consenting individual recipient for the purpose of conceiving a child implicates these fundamental constitutional rights. By asserting the right to regulate Arsenault, the FDA flew in the face of decades of precedent.

The decision to attempt to conceive a child falls within the constitutional right to make individual decisions about procreation free from unwarranted government intrusion. This right has been repeatedly recognized as a fundamental one arising out of an individual's right to privacy. The first case doing so, *Skinner v. State of Oklahoma*, struck down a state law permitting the sterilization of habitual criminals. The *Skinner* Court

described procreation as a basic liberty that is fundamental to our existence and recognized that the statute deprived certain individuals of a right which is basic to the perpetuation of a race - the right to have offspring. Although the Court arrived at its holding through an equal protection analysis, *Skinner* is generally identified as the seminal case for establishing the right to procreate.¹⁶⁵

Moreover, nearly forty years ago, the Court further elaborated on the right to procreate in the context of a law barring unmarried persons from possessing contraception, holding that “[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting

164. E.g., *Pace v. Alabama*, 106 U.S. 583 (1883) (upholding an Alabama ruling upholding the state's anti-miscegenation law that prevented the “evil tendency of [fornication]” from being made greater by the “amalgamation of the two races, producing a mongrel population and a degraded civilization. . .” *Pace & Cox v. State*, 69 Ala 231, 233 (1882)); *Buck v. Bell*, 274 U.S. 200, 207 (1927) (concluding that society can and must prevent the “feeble-minded” from reproducing through sterilization, effectively endorsing state-sponsored negative eugenics), but see *Skinner v. Okla.*, 316 U.S. 535, 541 (1942) (“The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects. In evil or reckless hands it can cause races or types, which are inimical to the dominant group to wither and disappear. There is no redemption for the individual whom the law touches.”).

165. Allison Lampert, Note: An Andy Warhol Society – First Coca-Cola, Now Humans: An Examination of Whether a Ban on Human Cloning Violates Procreative Liberty, 16 *ST. JOHN'S J.LEGAL COMM.* 245, 253-54 (Winter 2002). See also Sarah L. Dunn, Note: The “ART” of Procreation: Why Assisted Reproduction Technology Allows for the Preservation of Female Prisoners’ Right to Procreate, 70 *FORDHAM L. REV.* 2561, 2565-67 (2002).

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a person as the decision whether to bear or beget a child.”¹⁶⁶

The courts have, if anything, continued to respect and, indeed, broaden privacy rights’ umbrella of protection over procreative liberty. The well-known case of *Roe v. Wade* established that the right of privacy included the right of a woman to choose whether to have an abortion prior to fetal viability.¹⁶⁷ In another contraception case, *Carey v. Population Services International*,¹⁶⁸ the Court stated that “access to contraceptives is essential to exercise of the constitutionally protected right of deciding matters of childbearing that is the underlying foundation of the holdings in *Griswold*, *Eisenstadt*, and *Roe*.”¹⁶⁹ Even as the scope of abortion rights was qualified by subsequent cases, the Court was careful to note that “subsequent constitutional developments have neither disturbed, nor do they threaten to diminish, the scope of recognized protection accorded to the liberty relating to intimate relationships, the family, and decisions about whether or not to beget or bear a child.”¹⁷⁰

Substantive due process, via the rights to privacy and individual autonomy, extends to protect those important decisions even when they involve traditionally non-procreative relationships or nontraditional procreative acts.¹⁷¹ As one scholar noted during the early days of ART,

A court interpreting the procreative rights of married persons as extending to noncoital or collaborative reproduction cannot reasonably be accused of reading its own values into the due process clause; it is merely recognizing the logical extension of a

166. *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (protecting the right of unmarried persons to possess contraceptives). Of course, CBER’s position is that governmental intrusion is warranted where the biological father seeks only to donate his gametes for the purpose of facilitating the reproductive aspirations of a couple incapable of conceiving otherwise, and where those gametes are not conveyed via natural insemination.

167. *Roe v. Wade*, 410 U.S. 113, 163-64 (1973).

168. *Carey v. Population Servs. Int’l*, 431 U.S. 678 (1977).

169. Lampert, *supra* note 165, at 256 (citing *Carey*, 431 U.S. at 685). See also *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 851 (1992) (citing *Carey*, 431 U.S. at 685) (“Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education.”).

170. *Casey*, 505 U.S. 833, 857 (1992).

171. See John Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J. L. AND MED. 439, 446-50 (2003). (“[T]here may be intense debate about whether something is central or material to reproduction and thus properly regarded as part of, or an aspect of, procreative liberty, just as there is sharp debate about the seriousness and risk of resulting harms. . . . All such arguments, it seems, relate to how essential or material those activities are to the values that underlay the importance to individuals of their decision to avoid or engage in reproduction. While people may disagree over the precise limits, the argument, if properly focused, should be about the closeness of the activity in question to the values that support freedom in reproductive decision-making and whether the effects on others of exercising that freedom justify limiting it.”) *Id.* at 449.

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right already firmly established. If the sin of basing a right on substantive due process is being committed, the sinners are the justices who have, over several decades, established the principles that form the basis of the right of a married couple to conceive, bear, and rear children.¹⁷²

The appropriate degree of scrutiny for regulations impairing the exercise of this right has generally been described as strict scrutiny: the government must demonstrate that the regulation will advance a compelling interest and there is no less restrictive alternative.¹⁷³

These vital interests were even recognized by CBER in its opposition to Arsenault's hearing request, if only obliquely. In discussing the preamble to the proposed rule, CBER cited the FDA's explicit deference to the attending physician, donor, and recipient in the context of determining the scope of appropriate screening and testing for SIP donations—a decision that respects the autonomy of the potential parents and their assessment of risk.¹⁷⁴ Although CBER asserted that the basis for this decision was the FDA's belief that “insemination with the semen from a sexually intimate partner entails minimal risks,”¹⁷⁵ it is perhaps more literally true that the preamble recognizes simply that the parties to a sexually intimate partnership are in the best position to know if insemination entails minimal risks or not. The donor and recipient base this upon their first-hand knowledge of each other's medical¹⁷⁶ and sexual histories, as well as of

172. John A. Robertson, *Procreative Liberty and the Control of Conception, Pregnancy, and Childbirth*, 69 VA. L. REV. 405, 429 (1982) (footnote omitted). But see Gail H. Javitt, *Annotated Bibliography, SYMPOSIUM: “AT THE CROSSROADS—PUBLIC/PRIVATE PRIORITIES CONCERNING ACCESS TO GENETIC INFORMATION”*: ANNOTATED BIBLIOGRAPHY: *Reproductive Genetics 1991-2002: A Selected Annotated Legal Bibliography of Genetic Testing, Gene Transfer and Reproductive Cloning*, 6 J. HEALTH CARE L. & POL'Y 317, 352 (2003) (discussing Clarke D. Forsythe, *Human Cloning and the Constitution*, 32 VAL. U. L. REV. 469 (1998), which argues that

substantive due process decisions relating to family law and reproduction do not encompass using technology for asexual reproduction, and in particular, for cloning. These cases recognize limited privacy interests in marital coital reproduction, in protecting traditional family relationships and protecting “negative” liberties such as the right to refuse medical treatment. These cases recognize rights that are “deeply rooted in the common law.” Furthermore, the reproduction-related cases are premised on coital reproduction, and cannot be extended to extracorporeal reproduction. . . . The author construes *Roe v. Wade* as protecting only a “negative” right to terminate pregnancy free of governmental intrusion, and not a broader “positive” reproductive liberty.

173. Robertson, *supra* note 172, at 433.

174. CBER, *supra* note 132, at 9 (citing *Suitability Determination for Donors of Human Cellular and Tissue-Based Products*, 64 Fed. Reg. 52696 (September 30, 1999)). See also *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

175. CBER, *supra* note 132, at 9.

176. Of course, HIPAA regulations such as 45 C.F.R. §§ 164.532, 160.103, and other

their partner's likelihood of engaging in activities that risk disease exposure.¹⁷⁷ Where the partners are personally acquainted, as are the vast majority of the biological parents of children conceived in the U.S., these assessments are typically performed without government second-guessing. Absent any personal knowledge or communication between a donor and recipient, as with anonymous donors to semen banks, screening seems wise and necessary. However, Arsenault and many other private donors differentiate themselves from the anonymous status quo by providing interpersonal connection: in-person meetings, email correspondence, and commitments to continued contact and disclosure.

Another crucial difference between private semen donors and the typical fertility clinic or semen bank regulated by the FDA is the absence of a medical intermediary. As previously noted, where the donor and recipient are not intimately acquainted, it may be helpful to have a third-party conduct screening and testing for disease. But when two individuals enter into a relationship they believe to be sexually intimate and plan to conceive a child without the participation of a medical professional, the government does not typically intervene.

This is because the government's interest in regulating gamete donation is part and parcel of its broader interest in ensuring that medical practices conduct themselves safely and in accordance with professional norms. This is implicit in the various regulations in 21 C.F.R. Part 1271. The regulations are targeted at "establishments": "place[s] of business under one management, at one general physical location, that engage [. . .] in the manufacture of human cells, tissues, and cellular and tissue-based products."¹⁷⁸ Customers of a semen bank, fertility clinic, or small medical practice rely upon a matrix of state and federal regulations to ensure that the opaque and complex services they purchase are provided safely. Such regulation of commerce and of licensed professionals is common in the health care field as well as in many other elements of the economy.¹⁷⁹ Pecuniary incentives pervade provision of commercially provided health care services; the many and costly requirements of 21 C.F.R. Part 1271

laws protecting individual privacy in medical records mean that many couples have only indirect knowledge of their partner's STI test results and must take the partner's representation on faith, just as is the case with Arsenault's recipients, who have access to online summaries of test results but not original records or third-party testing.

177. Screening might be appropriate in monogamous heterosexual sexual relationships if, for example, one or both partners were exposed to infectious disease through a job in a hospital or prison, or via intravenous drug use. An open or non-dyadic relationship would also pose a more complex challenge and potentially merit screening.

178. 21 C.F.R. 1271.3 (b) (2012) (emphasis added).

179. Nat'l Fed'n of Indep. Bus. v. Sebelius, 132 S. Ct. 2566, 2586 (2012) ("[t]he power to regulate commerce presupposes the existence of commercial activity to be regulated.").

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attempt to ensure that establishments offering fertility assistance do not cut costs in a manner that increases disease risk for their customers.

But how are regulations aimed at businesses' bottom lines relevant to uncompensated private individuals? And what use are the standards of care applicable to regulated medical professions if the only parties to a conception are the donor and recipient? A private semen donor may have an interest in minimizing his outlay on health screening and testing—but so does any individual looking for sexual partners. As previously noted, women are accustomed to assessing the veracity of their partners' statements about disease risk and defining the scope of sexual activity accordingly. They may elect to require less screening than a medical professional would apply to an anonymous human tissue donation, but those standards prevent doctors from imposing risk on patients; in a donor/recipient partnership without medical involvement, the risk is assessed by and taken on by the partners themselves.

The absence of a representative of the medical establishment in private semen donation activities highlights their similarity to the countless conception attempts over which the FDA has not asserted regulatory authority. Private donation, in these circumstances, resembles the millions upon millions of independent judgments by partners attempting to conceive a child through simple acts of intercourse; and personal decisions to conceive via private sperm donation should be afforded the same degree of freedom from government interference as those judgments. As the Court has recognized, decisions about accomplishing conception are “among the most private and sensitive.”¹⁸⁰ The protected, personal, and intimate nature of this choice is not eliminated if the recipient or her partner makes use of a cup and syringe to maximize the chance of pregnancy.

VII. GOVERNMENT OR INDIVIDUALS: WHO DEFINES SEXUAL INTIMACY?

The nature of the intimate partnership between individual private semen donors and recipients itself raises questions. The FDA's attempt to apply 21 C.F.R. Part 1271 to Arsenault could founder on the government's failure to define the exception under which Arsenault seeks shelter. If a private semen donor and a recipient with whom he agrees to conceive children have created a sexually intimate partnership, the cease-manufacture order to Arsenault would be void, as none of the various infractions for which he was cited would apply to an SIP.¹⁸¹ This term, undefined in the regulations or statute, is the fulcrum on which the future of unregulated private semen donation may rest.

180. *Carey v. Population Servs. Int'l*, 431 U.S. 678, 685 (1977).

181. See *supra* note 142.

Despite CBER's bald assertion that its interpretation of SIP (which excludes Arsenault and his recipient partners) "is in sync with the plain meaning of the words, which do not require further explanation,"¹⁸² it is far from clear that the meaning of sexually intimate partnership is—or can be—delimited by a government agency. The right to intimate association is implicated where the government seeks to define a procreative relationship out of existence and impose burdensome regulations upon individuals who fall outside the norm.¹⁸³

The Supreme Court has recognized that the partnership between two persons creating a child "by definition concerns the most intimate of human activities and relationships."¹⁸⁴ Furthermore, sexually intimate relationships can involve a broad range of physical and emotional intimacies, only some of which are contained within the SIP definition advanced by the FDA. On one end of the spectrum are partners who procreate together, sharing a romantic connection and a variety of bodily fluids. Genuine sexual intimacy is a fundamentally subjective experience, and in other contexts could be present even when a couple engaged in sexually gratifying conduct that involved no physical contact.¹⁸⁵ Moreover, the regulations' definition of a sexually intimate partnership does not require touching.¹⁸⁶ As noted above, the explanatory language CBER itself cited as bearing on the definition of SIP does not presume that an SIP will always have had previous exposure to his or her partner's body fluids.¹⁸⁷ And the

182. CBER, *supra* note 132, at 10.

183. Challenges to the extension of constitutional jurisprudence to protect certain intimate choices must account for changing social mores and the government's interest in protecting discrete and insular minorities from majoritarian tyranny and oppression. But see David M. Smolin, *Fourteenth Amendment Unenumerated Rights Jurisprudence: An Essay in Response to Stenberg v. Carhart*, 24 HARV. J.L. & PUB. POL'Y 815, 838 (2001) (attributing the constitutional instability of substantive due process as arising from "an amoral jurisprudence of unenumerated rights disconnected from the historical narrative of emancipation," with particular instability present where the courts "embrac[e] as a fundamental right an act regarded as ethically aberrant by the broader society.")

184. *Id.*

185. See *Perry v. Schwarzenegger*, 704 F. Supp. 2d 921, 956-57 (N.D. Cal. 2010) (quoting *In re Marriage Cases*, "This contention [that marriage is limited to opposite-sex couples because only a man and a woman can produce children biologically related to both] is fundamentally flawed.") (internal citations omitted); *id.* (quoting *Lawrence v. Texas*, (Scalia, J., dissenting) "What justification could there possibly be for denying the benefits of marriage to homosexual couples exercising 'the liberty protected by the Constitution'? Surely not the encouragement of procreation, since the sterile and the elderly are allowed to marry.") (internal citations omitted).

186. *Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 347 (1936) (Brandeis, J., concurring) ("The Court will not pass upon a constitutional question although properly presented by the record, if there is also some other ground upon which the case may be disposed of.")

187. Suitability Determination for Donors of Human Cellular and Tissue-Based

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relationship between private, non-anonymous semen donors and their recipients is an intimate exchange and an expression of personal trust different from, but no less important than, an act of sexual intercourse.

For people whose concept of intimacy differs from the “plain meaning” the FDA might grasp (and perhaps from the majority of Americans), the prospect that the federal government could define their relationship out of existence is a real and ongoing threat.¹⁸⁸ Supreme Court precedent supports the rights of donors and recipients to self-define. *Lawrence* reflected a significant commitment by the Supreme Court to the protection of individually defined and chosen intimate relationships.¹⁸⁹ Sexual contact is, per Justice Kennedy’s opinion for the Court, “but one element in a personal bond.”¹⁹⁰ And the Court has repeatedly recognized the importance of allowing individuals to make judgments about their sexual and procreative relations without unnecessary governmental interference.¹⁹¹ Most recently, the Court noted that the “general rule should counsel against attempts by the State, or a court, to define the meaning of the relationship or to set its boundaries absent injury to a person or abuse of an institution the law protects.”¹⁹² Although the FDA claims an interest in preventing disease, permitting a federal agency to ban medically unassisted, non-commercial reproductive activity has serious implications for individual liberty.

VIII. CUPS, SYRINGES, AND SLIPPERY SLOPES

By rejecting Arsenault’s characterization of his connections with the recipients, CBER implicitly affirmed its own supremacy in the area of defining personal relationships and its ability to intervene in non-standard procreative arrangements where a new risk of disease is present. Both of

Products, 64 Fed. Reg. 52,696, 52,707 (September 30, 1999) (to be codified at 21 C.F.R. §§ 210, 211, 820, 1271) (Preamble to the Proposed Rule).

188. Cf. Ellen Waldman & Marybeth Herald, *Eyes Wide Shut: Erasing Women’s Experiences from the Clinic to the Courtroom*, 28 HARV. J.L. & GENDER 285 (2005) (discussing the dangers of limiting substantive due process rights of intimacy and privacy rights to historical, androcentric, or consanguineous definitions).

189. Kathryn D. Katz, *Lawrence v. Texas: A Case for Cautious Optimism Regarding Procreative Liberty*, 25 WOMEN’S RIGHTS L. REP. 249, 252 (Fall 2004) (comparing the trend in pre-*Lawrence* cases extending substantive due process protection “to only the most traditional family arrangements” with *Lawrence*’s recognition of the dignity of same-sex relationships). Katz further notes that the majority opinion in *Lawrence* “gives reason to hope and a basis to argue that reproductive choices using ARTS are also entitled to recognition and protection.” *Id.* at 253.

190. *Lawrence v. Texas*, 539 U.S. 558, 567 (2003).

191. *Planned Parenthood of Southeastern Pa. v. Casey*, 505 U.S. 833, 851 (1992) (“At the heart of liberty is the right to define one’s own concept of existence, of meaning, of the universe, and of the mystery of human life.”)

192. *Lawrence*, 539 U.S. at 567.

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these principles unconstitutionally infringe on the rights of Arsenault, the recipients, and potentially other citizens.

By construing its regulations to cover interactions between private individuals, where no medical personnel are involved and no medical procedure is performed, CBER has dramatically widened the scope of its supposed mandate to protect. It asserted that it had the right to stop Arsenault from providing semen to consenting adult recipients because doing so “protects [families] from communicable diseases.”¹⁹³ However, the preamble to the final rule cited by CBER speaks specifically to reducing the risk posed by artificial insemination in “small medical practice[s].”¹⁹⁴ If CBER’s purview is not limited to the regulation of medical practices or professionals, and instead includes the ability to regulate reproductive decisions made by two private individuals in a non-commercial context, the consequences for individual autonomy and privacy are dire.

To put it plainly, if CBER’s regulatory sphere encompasses private, uncompensated donations of semen in receptacles due to the disease risk posed by transmission of body fluids from a new partner, then its basis for regulation could easily and logically extend to cover exchanges of body fluids in which no receptacle is involved and instead insemination is accomplished via physical contact between the donor and recipient: i.e., sexual intercourse.¹⁹⁵ This would bring Arsenault as well as donors who give via natural insemination within CBER’s purview—along with millions of other sexually active persons. Surely CBER would not agree that it could regulate such conduct—but the arguments fielded in support of the order lead to just that conclusion. Even if private donors were subject to regulation, unlike other biological fathers, due to their stated intent, CBER would be forced to investigate the subjective intentions of male sexual partners—an intrusive emotional inquiry.¹⁹⁶

193. CBER, *supra* note 132, at 10

194. See *supra* note 137 and accompanying text.

195. Any such extension of regulatory authority over uncompensated private sexual or procreational activities would be unconstitutional even under *Gonzales v. Raich*, 545 U.S. 1 (2005) (the Commerce Clause does not extend to regulation of noneconomic activity unless it has a substantial impact on interstate commerce). Cf. Anne Lawton, *The Frankenstein Controversy: The Constitutionality of a Federal Ban on Cloning*, 87 KY. L.J. 277 (1998-99) (arguing that the Commerce Clause does not preclude a federal ban on cloning because it may be used in conjunction with in vitro fertilization, a significant business enterprise; research facilities conducting cloning employ scientists, who share information interstate; and patients will probably cross state lines to access cloning, just as they do for existing ART services).

196. The law, recognizing the burdensome nature of such investigations, has arrived at several solutions for determining paternity absent knowledge of the biological father’s intent. A general description of these can be found in Richard F. Storrow, *Parenthood By Pure Intention: Assisted Reproduction and the Functional Approach to Parentage*, 53 HASTINGS

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Moreover, CBER's interpretation of the regulations requires it (as was the case with Arsenault) to send investigators into the sites of manufacture of private semen donation, even when that means inspecting an individual's bedroom.¹⁹⁷ The outrageous nature of such actions was cited by the Supreme Court for rhetorical effect in *Griswold v. Connecticut*, in which the majority noted that "the very idea" of "allow[ing] the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives . . . is repulsive to the notions of privacy."¹⁹⁸ Just as the Supreme Court feared, FDA agents went marching into Mr. Arsenault's bedroom—but this time on the hunt for telltale signs of unauthorized attempts to conceive.

CBER claimed that its intervention is justified because of safety concerns. However, ironically, by expanding its scope of regulatory authority, CBER may decrease both reproductive autonomy and safety. As noted above, CBER has created a loophole in regulatory enforcement for donors who have unprotected sexual intercourse with recipients—even if their intentions are identical to Arsenault's. In the final analysis, CBER's overbroad interpretation cannot stand "in light of the familiar principle, so often applied by the Court, that a 'governmental purpose to control or prevent activities constitutionally subject to state regulation may not be achieved by means which sweep unnecessarily broadly and thereby invade the area of protected freedoms.'"¹⁹⁹

L.J. 597, 623-24 (March 2002).

Under all statutes that define the paternity ramifications of artificial insemination by donor, the husband of an artificially inseminated woman is the father of the resulting child if he consented to the insemination. . . . The typical method of demonstrating consent is through a signed writing, but consent can also be established orally. Where a husband gives no written or oral consent, even in states with no governing statute, he may nonetheless be liable for support under contract theories or equitable principles.

Storrow is careful to note that the law sometimes applies different presumptions to anonymous versus known sperm donors, however, and that a presumption of legal parental status for husbands can function to discriminate against single women and lesbian couples. See *id.* at 628 (citing Catherine DeLair, *Ethical, Moral, Economic and Legal Barriers to Assisted Reproductive Technologies Employed by Gay Men and Lesbian Women*, 4 *DEPAUL J. HEALTH CARE L.* 147, 150-51 (2000)).

197. See DEP'T. OF HEALTH AND HUMAN SERVS., FOOD AND DRUG ADMIN., *INSPECTIONAL OBSERVATIONS OF TRENT ARSENAULT*, (2010), available at <http://trentdonor.org/trentdonor/d/21520-2/FDA-Form-483-Inspection-Observations-TrentDonor-20-Sep-2010-5-Pages.pdf>.

198. *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965).

199. *Griswold*, 381 U.S. at 485-86 (citing *NAACP v. Alabama*, 377 U.S. 288, 307 (1964)).

IX. CONCLUSION

Although the number of individuals directly affected by the FDA's cease-manufacture order to Trent Arsenault was relatively small, that exercise of new authority by the agency justifies careful examination. First, is it consistent with the cited regulations and the enabling statute? Second, is it a legitimate exercise of government authority as limited by recent constitutional jurisprudence? Third, is regulation of private, noncommercial use of artificial insemination wise public policy?

The prevailing norms in the reproductive medicine industry, along with existing application of federal and state regulations, create a safe and widely acceptable option for many couples struggling with infertility. However, individuals who are underserved by the medical profession's attempts to industrialize conception have sought new alternatives that provide different and distinctive benefits, such as specific knowledge about the donor's past and future actions and well being. These private arrangements, carefully tailored to respect the needs and desires of individual couples, have come under attack by the federal government, under the guise of promoting safety. Doing so required the FDA to blur the boundaries between commercial and non-commercial conduct in a manner that raises constitutional questions and erodes individual privacy. It rested on an artificial and unstable distinction between semen donations via natural versus artificial insemination and it functions to prevent loving couples from conceiving much-desired children in the manner and with the partner of their choice. Although the courts have often heard cases on reproductive rights dealing with the rights to contraception or abortion, they may soon be posed before a funhouse mirror of substantive due process rarely confronted since the days when "[t]hree generations of imbeciles [were] enough".²⁰⁰ Under what circumstances can the government tell you not to conceive with another person?

200. *Buck v. Bell*, 274 U.S. 200, 207 (1927) (concluding that society can and must prevent the "feeble-minded" from reproducing through sterilization, effectively endorsing state-sponsored negative eugenics).