

Regulating Relationships: A Challenge to the Constitutional Authority of the FDA Regulation of Private Sperm Donation

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This Note challenges the constitutionality of the FDA's current regulation of private sperm donation under 21 C.F.R. § 1271. The FDA currently regulates private sperm donors donating to known couples in the same way that it regulates anonymous sperm donors donating to a sperm bank. This Note argues that the current FDA regulation does not comply with constitutional guarantees secured by the Due Process Clause of the Fifth and Fourteenth Amendments, specifically their protection of individual rights concerning procreation. The Supreme Court has developed a hands-off approach to family planning over the last ninety years, and the FDA is attempting to bypass almost a century of jurisprudence to ensure that those attempting artificial insemination through sperm donation adhere to the medicalized guidelines currently in place. This Note further argues that the FDA regulation, in addition to overstepping the protections of the Constitution, does not adhere to its stated purpose and creates a regulation that is both arbitrary and capricious in application.

I. INTRODUCTION

Tanya is a woman in her late thirties desperate to become a mother.¹ Financially independent but single, Tanya spent be-

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1. Sunny Antrim & John Meyersohn, *Unusual Online Quest for Motherhood*, ABCNEWS.COM (Jan. 11, 2012), <http://abcnews.go.com/Health/unusual-online-quest-motherhood/story?id=15330915>.

tween \$60,000–\$70,000 on vials of sperm from anonymous sperm donation centers, used by her doctor for artificial insemination.² After multiple attempts to conceive and no success, Tanya turned to online sperm donation, where she found a suitable donor and began having sexual intercourse with the donor in an attempt to become a mother.³

Beth and Richard are a happily married couple who are desperate to become parents, but Richard is unable to impregnate Beth.⁴ The couple spent approximately \$14,000 on unsuccessful artificial insemination through an anonymous sperm donation center.⁵ Frustrated both financially and emotionally, Beth and Richard decided to try free online sperm donation, found a donor they trusted, and after months of calls and chats, decided to go through with the sperm donation.⁶ Using sperm donated just minutes before, Richard used a syringe to inseminate his wife.⁷

Finally, Krista is in a committed partnership and desperately wants to have a child.⁸ Financially secure and independent, Krista and her partner have spent upwards of \$10,000 on artificial insemination procedures using anonymous sperm donation centers.⁹ Krista reached out to Trent Arsenault, a man who has provided sperm free of charge to many couples, resulting in the birth of fourteen children.¹⁰ Using Trent Arsenault's sperm, Krista became pregnant, but tragically miscarried.¹¹

These three stories all ring familiar: individuals who wish to have children but are prevented for lack of partner or depletion of funds after rounds of failed clinical procedures. Interestingly, only one of the three stories is sanctioned by the federal government. The Food and Drug Administration (FDA) regulates all private sperm donation, and requires costly STD tests and tedious procedural requirements to be administered for every at-

2. *Id.*

3. *Id.*

4. Sunny Antrim et al., *From Hotel Rooms to Coffee Shops: New World of Online Sperm Donation*, ABCNEWS.COM (Jan. 13, 2012), <http://abcnews.go.com/Health/sperm-donation-hot-spots-coffee-shops-hotel-rooms/story?id=15343381>.

5. *Id.*

6. *Id.*

7. *Id.*

8. *Id.*

9. *Id.*

10. *Id.*

11. *Id.*

tempted sperm donation.¹² What this means is that Beth and Richard's donor was probably in violation of FDA regulation 21 C.F.R. § 1271 unless he had documentation of the various medical tests with him at the time of donation, labeled cups, and a meticulously kept medical history.¹³ The FDA issued Krista's donor, Trent Arsenault, a Cease Manufacture order, and faces potential jail time and a fine of up to \$100,000 for producing sperm that was used for artificial insemination¹⁴ despite the battery of STD testing he has undergone, documentation of his medical history, and meticulous record of his clean-living lifestyle.¹⁵

The FDA does not impose this type of financial strain or criminal penalty on sperm donors who inseminate via sexual intercourse rather than syringe. In a twist of modern legal arbitrariness, only those donors and recipients who choose reproduction without having sex are plagued by unnecessary and intrusive federal regulations.

This Note discusses the constitutionality of the FDA regulation of private sperm donors in light of the foundational contraception and abortion cases that declare reproduction a fundamental right under the theory of substantive due process.¹⁶ Part II describes in detail what the FDA regulates under 21 C.F.R. § 1271, and points out aspects of the regulatory scheme that may raise constitutional issues. Part III details the history of the fundamental right to procreation and its changes in application through time. Beginning with authority derived from the privacy doctrine and then discussing the shift to the liberty doctrine, Part III traces the law and argues that the FDA's regulation of private sperm donation should be subject to the same legal scrutiny as laws inhibiting access to contraception or abortion. Part IV lays out potential legal challenges to the FDA regulation, and discusses potential defenses to any legal challenges that may present in current legal arena. Part V concludes the Note with a final dis-

12. *Id.* See also 21 C.F.R. § 1271.1 (2013).

13. Antrim et al., *supra* note 4; see also 21 C.F.R. § 1271.55 (2013).

14. Antrim et al., *supra* note 4.

15. See generally Amber D. Abbasi, *The Curious Case of Trent Arsenault: Question FDA Regulatory Authority Over Private Sperm Donation*, 22 ANNALS HEALTH L. 1 (2013); Benjamin Wallace, *The Virgin Father*, N.Y. MAG., Feb. 5, 2012, available at <http://nymag.com/news/features/trent-arsenault-2012-2/>.

16. See, e.g., *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992); *Carey v. Population Servs. Int'l*, 431 U.S. 678 (1977); *Roe v. Wade*, 410 U.S. 113 (1973); *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965).

cussion of the legal rights afforded by the Constitution in the area of family planning, and discusses some of the broader implications of this regulation's enforcement.

II. THE DETAILS OF 21 C.F.R. § 1271

The FDA thoroughly regulates private sperm donation as part of a broader regulation of human cells, tissues, and cellular and tissue-based products.¹⁷ Although it purports to regulate only establishments, something that invokes the image of an anonymous sperm bank, or perhaps a for-profit sperm exchange, it includes within its definition of establishment individuals that “manufacture” any human cells,¹⁸ including semen.¹⁹

A. DO'S AND DON'TS OF DONATING HUMAN TISSUE

Private individual sperm donors must comply with a battery of regulations to donate to someone with whom they are not sexually intimate. Every time the “establishment” (individual) “manufactures” semen, it must be registered and submitted in list form.²⁰ In order to be considered “donor eligible,” a mandatory part of the regulation, one must be tested for communicable diseases.²¹ But before this, one must establish their own written and readily available procedures for the testing, and the donation, and every step of the process, and have those procedures reviewed by a “responsible person” who must then approve them.²² Any departure from the self-made, self-kept procedures must be documented and justified.²³

Once the initial paperwork has been filed and created, would-be donors must be tested to ensure their eligibility.²⁴ This includes testing for HIV, Hepatitis B virus, Hepatitis C virus, Human transmissible spongiform encephalopathy, *Treponema pallidum*, and all communicable disease risks associated with xeno-

17. 21 C.F.R. § 1271.1.

18. *Id.* § 1271.3(b)(1).

19. *Id.* § 1271.3(d)(2).

20. *Id.* § 1271.21(a); § 1271.25(c)(1) (making name and address available for public inspection); § 1271.37.

21. *Id.* § 1271.45(b).

22. *Id.* § 1271.47(a)–(c).

23. *Id.* § 1271.47(d).

24. *Id.* § 1271.75(a)(1).

transplantation.²⁵ And then, because the donation is of reproductive tissue, there is an added requirement of reviewing all relevant medical records of the donor and being screened for chlamydia and gonorrhea.²⁶ All of these tests must be performed using an FDA-licensed donor screening test, which may or may not be available information when testing.²⁷

Should any of these tests come back positive the donor is “ineligible.” This means that the donor, be it a donor who is HIV-positive, or has gonorrhea, is still able to donate the reproductive tissue.²⁸ The donation cup merely must be labeled with a sticker saying “For Nonclinical Use Only” and have a biohazard label.²⁹ This is the only extra limitation distinguishing ineligible and eligible sperm donors — a label and a sticker.

Concisely stated: procedures must be established and complied with (or departures documented), the donation must be tested (regardless of the outcome of the test), and the donation must be labeled correctly, then it can be used for artificial insemination. This type of tedious and arbitrary intrusion into the realm of the family decision making is forbidden by the Supreme Court’s recognized fundamental right to family.

III. THE FUNDAMENTAL RIGHT TO FAMILY

This Part offers a brief overview of the Supreme Court’s reproductive freedom doctrine. Part III.A begins with a history of substantive due process under the Fourteenth Amendment as it emerged under the privacy doctrine in cases concerning access to contraception and abortion. Part III.B discusses the shift from the privacy doctrine to a broader doctrine of liberty that encompasses the prior rulings under the privacy doctrine.

A. SUBSTANTIVE DUE PROCESS AND PRIVACY

The legal treatment of procreation rights by the Supreme Court has been elaborated in the framework of substantive due

25. *Id.* § 1271.75(a)(1)(i)–(v)(2).

26. *Id.* § 1271.75(c).

27. *Id.* § 1271.80(c).

28. *Id.* § 1271.65(b)(ii) (regulation does not apply to anonymous sperm donors who are deemed “ineligible”).

29. *Id.* § 1271.65(3)(c)(1)–(2).

process and the recognition of a fundamental right to privacy. The area of law concerning procreation developed out of the doctrine of substantive due process concerning a fundamental right to privacy.³⁰ This area of the law first defined what fundamental rights the due process clause established,³¹ and then defined a standard that must be met in order to infringe upon any fundamental right.³²

The following subsections develop and explain the development of a fundamental right to privacy under the doctrine of substantive due process.

1. *The Beginning of Substantive Due Process and Protection of Family*

Substantive due process refers to rights arising from the Due Process Clause of the Fourteenth³³ and Fifth Amendments.³⁴ Because the FDA is a federal agency, its regulations would be challenged under the Fifth Amendment; however, the overall doctrine of substantive due process is not limited by whether the Fourteenth or Fifth Amendment is controlling.³⁵

30. See, e.g., *Eisenstadt v. Baird*, 405 U.S. 438 (1972); *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965).

31. See *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923) (“While this court has not attempted to define with exactness the liberty thus guaranteed, the term has received much consideration and some of the included things have been definitely stated. Without doubt, it denotes not merely freedom from bodily restraint but also the right of the individual to contract, to engage in any of the common occupations of life, to acquire useful knowledge, to marry, establish a home and bring up children, to worship God according to the dictates of his own conscience, and generally to enjoy those privileges long recognized at common law as essential to the orderly pursuit of happiness by free men.”).

32. See *Roe v. Wade*, 410 U.S. 113, 155 (1973) (“Where certain ‘fundamental rights’ are involved, the Court has held that regulation limiting these rights may be justified only by a ‘compelling state interest,’ and that legislative enactments must be narrowly drawn to express only the legitimate state interests at stake.”) (internal citations omitted).

33. U.S. CONST. amend. XIV, § 1 (“nor shall any State deprive any person of life, liberty, or property, without due process of law.”).

34. U.S. CONST. amend. V (“No person shall . . . be deprived of life, liberty, or property, without due process of law . . .”).

35. See generally Ryan C. Williams, *The One and Only Substantive Due Process Clause*, 120 YALE L.J. 408 (2010) (discussing why the divergent interpretation of a substantive due process clause meaning one thing in the Fifth Amendment and another in the Fourteenth has been rejected). See also *Adamson v. California*, 332 U.S. 42, 66 (1947) (Frankfurter, J., concurring) (“The Due Process Clause of the Fourteenth Amendment has an independent potency, precisely as does the Due Process Clause of the Fifth Amendment in relation to the Federal Government. It ought not to require argument to reject the

In the 1920s, *Meyer v. Nebraska*³⁶ and *Pierce v. Society of the Sisters*³⁷ limited the government's ability to regulate or standardize family.³⁸ In *Meyer*, the Court found that the Constitution guaranteed a right to "establish a home and bring up children" under the due process clause, and found that guaranteed rights could not be interfered with by arbitrary legislation.³⁹ *Meyer* may not seem relevant in that it dealt with a law prohibiting the teaching of any language other than English to children who had not completed the eighth grade.⁴⁰ However, this case is and remains significant because in striking down that law, the Court recognized a right to protection under the Due Process Clause of the Fourteenth Amendment, and enumerated accepted individual rights protected by the Clause.⁴¹ Also, *Meyer* informs the issue of whether private sperm donation is constitutionally protected in that it set up protections for family, home, and children to be free from arbitrary governmental legislation.⁴² *Pierce* expanded *Meyer* to include the right to educate children as one sees fit as a fundamental right, declaring that children were not "the mere creature[s] of the State."⁴³ Again, a case overturning a law requiring children attend public school⁴⁴ may not seem particularly relevant, but what *Pierce* strengthens and validates the doctrine of substantive due process *Meyer* announced by using extending it to protect the right of the family from government intrusion.⁴⁵

In addition to expanding the doctrine of substantive due process, the Court announced in *Meyer*,⁴⁶ and upheld in *Pierce*,⁴⁷ that

notion that due process of law meant one thing in the Fifth Amendment and another in the Fourteenth.").

36. 262 U.S. 390 (1923).

37. *Pierce v. Society of the Sisters of the Holy Names of Jesus and Mary*, 268 U.S. 510 (1925).

38. Commentators such as Jed Rubenfeld have referenced *Meyer* and *Pierce* as the "true parents" of the privacy doctrine. See Jed Rubenfeld, *The Right of Privacy*, 102 HARV. L. REV. 737, 743 (1989).

39. *Meyer*, 262 U.S. at 399–400.

40. *Id.* at 397.

41. *Id.* at 399.

42. *Id.* at 399–400.

43. *Pierce*, 268 U.S. at 534–35.

44. *Id.* at 530.

45. *Id.* at 534–35.

46. *Meyer*, 262 U.S. at 399–400 ("The established doctrine is that this liberty may not be interfered with, under the guise of protecting the public interest, by legislative action which is arbitrary or without reasonable relation to some purpose within the competency of the state to effect.").

legislation intruding on a fundamental right must have some reasonable relation to a purpose within the purview of the state and must not be arbitrary.⁴⁸ This legal standard developed into the modern rule, which requires regulations to be narrowly tailored to serve a compelling state interest when fundamental rights are at issue.⁴⁹

These cases are foundational because they were the first to establish that the Due Process Clause protects the realm of family.⁵⁰ By including family into the early protections of the Due Process Clause, the Court laid the groundwork for later holding that procreation and family planning are similarly protected. These two cases also established the notion that laws may not be arbitrary where they impede a fundamental right. From there, the Court has expanded into the area of procreation as protected by the substantive due process doctrine.⁵¹

2. *Privacy Emerging as a Spatial Protection*

The emergence of the privacy doctrine in reproductive cases can be traced to Justice Douglas in *Griswold v. Connecticut*.⁵² In *Griswold*, the court struck down a Connecticut law prohibiting access to contraception.⁵³ The Court announced that their decision was mandated by the privacy doctrine, specifically citing to “zones of privacy” created by multiple constitutional provisions.⁵⁴

47. *Pierce*, 268 U.S. at 535.

48. *See Meyer*, 262 U.S. at 399 (1923).

49. *See Roe v. Wade*, 410 U.S. 113, 155 (1973).

50. Some authors have cited to *Meyer* and *Pierce* as the parents of the privacy doctrine because they encompass so many of the rights surrounding procreation. *See Rubinfeld*, *supra* note 38, at 743.

51. Note, both *Meyer* and *Pierce* announce this doctrine as one protecting liberty and not privacy. What these two cases can really be seen as is the beginning of the Court setting boundaries to the State’s ability to pass illegitimate impositions that interfere with individual choices seen as protected. This general theory is the basis for what becomes the privacy doctrine as announced in the contraception and abortion cases. For more discussion on *Meyer* and *Pierce* as the foundation to the privacy doctrine, see Rubinfeld, *supra* note 38, at 783–88.

52. 381 U.S. 479 (1965).

53. *Id.*

54. *Id.* at 484–85. Specifically, the court finds authority in the following amendments. The First Amendment is said to have penumbras that extend from the enumerated guaranteed freedoms specifically listed. The penumbras of the First Amendment include a penumbra of privacy, extending from the right of association, upon which the government cannot intrude. The rationale behind this penumbral extension of rights is that the First Amendment would not be truly meaningful without a rich development of

The term “zones of privacy” suggests a physical or spatial barrier blocking the government out. This notion is confirmed by Justice Douglas’ dicta, “[w]ould we allow the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives? The very idea is repulsive to the notions of privacy.”⁵⁵ This form of privacy protection is tangible and spatial: it focuses on keeping the government out of certain areas, particularly areas controlled by matters of family, such as the bedroom.

While it would be easy to dismiss *Griswold* as protecting only those acts taking place within the marital bedroom, the ruling of *Griswold* has stood more generally for a protection against intrusion by the government into the most personal of spaces.⁵⁶ This essential holding of *Griswold* was upheld and expanded beyond the marital bedroom in *Eisenstadt v. Baird*.⁵⁷ Although *Eisenstadt* was decided under the Equal Protection Clause,⁵⁸ it broadens *Griswold*’s protection of fundamental rights under the Due Process Clause.⁵⁹ Both of these cases stand for protection against governmental interference with the right not to procreate, but they can be read broadly as steps towards protecting individuals from the overregulation of private actions by the government.⁶⁰

its enumerated rights. *Id.* at 483. The Third Amendment against the quartering of soldiers is also cited as proof that the Constitution valued a right of physical, spatial privacy belonging to citizens that the Government could not enter. *Id.* at 484. The Fourth Amendment’s protection from unreasonable searches and seizures, much like the Third Amendment, stands for a spatial protection against government intrusion. *Id.* The Fifth Amendment protecting against self-incrimination is a more abstract zone of privacy, but the theory is the same, that the government cannot intrude into a certain zone of privacy by forcing a citizen to speak. *Id.* The Ninth Amendment is used to justify this type of reasoning, as it states that enumerated rights in the Constitution do not exclude or disparage against other rights. *Id.* Without the Ninth Amendment, it would be difficult to argue with a textual interpretation that there are no rights extending beyond those specifically enumerated in the Constitution. Finally, the Fourteenth Amendment specifically cites to due process, including and protecting liberty from deprivation by the State. U.S. CONST. amend. XIV, § 1.

55. *Griswold*, 381 U.S. at 485–86.

56. See Glenn Cohen, *The Constitution and the Right Not to Procreate*, 60 STAN. L. REV. 1135, 1149–50 (2008).

57. 405 U.S. 438 (1972).

58. The holding of the case expanded the scope of the doctrine established in *Griswold* by applying it to non-married couples. *Eisenstadt*, 405 U.S. at 453–54.

59. *Id.* at 448–49.

60. This can be thought of as an extension of Justice Brandeis’ “right to be let alone” which he considered “the most comprehensive of rights and the right most valued by civilized men.” *Griswold*, 381 U.S. at 494 (Goldberg, J., concurring) (quoting *Olmstead v. United States*, 227 U.S. 438, 478 (1928) (Brandeis, J., dissenting)). This “right to be let alone” encompasses the type of spatial privacy *Griswold* emphasizes as a protection from

The language used by the Court to protect a couple's right not to procreate is not narrow; instead, it sets up a spatial barrier around the area of procreation that the government may not cross.⁶¹

The idea of protection against intrusion by the government is dramatized by the case of Trent Arsenault, where the government actually raided his home looking for signs of sperm production.⁶² If Justice Douglas' words are taken as a physical legal barrier to governmental intrusion wherever a fundamental right is at stake, then the FDA could only regulate sperm donation if it was found that the regulation did not "sweep unnecessarily broadly and thereby invade the area of protected freedoms."⁶³

Based on the way this regulation has been applied, it does sweep into the private, consensual actions of adults determining when and how to conceive.⁶⁴ The initial problem with FDA regulation of private sperm donation is that sperm donation is a *private* act necessary for the creation of a family. Courts have carved out a protection for individuals that is highly respectful of "spatial" privacy and that covers intimate acts involved in family planning. The FDA regulations run afoul of this body of law by creating an intrusive, comprehensive regulatory regime for sexually intimate partners donating sperm.⁶⁵

For the purposes of this Note, it is assumed that the act of donating sperm is intimate; however this is not always *sexually* intimate according to the FDA.⁶⁶ It may be argued that not all private sperm donation is intimate, and that the courts do not pro-

actual intrusion upon decisions and spaces alike. It is akin to a type of autonomy which is heavily intertwined with the privacy doctrine. For more, see Thomas P. Crocker, *From Privacy to Liberty: The Fourth Amendment After Lawrence*, 57 U.C.L.A. L. REV. 1, 23–24 (2009).

61. For example, Justice Brennan could have announced a narrow expansion of *Griswold's* holding to include unmarried as well as married individuals. Instead, he describes the right guaranteed by substantive due process' right to privacy as a "right of the individual . . . to be free from unwarranted governmental intrusion. . ." *Eisenstadt*, 405 U.S. at 453. The notion of freedom from intrusion is a very physical idea that goes beyond what is necessary to simply announce that state laws denying access to contraception are banned.

62. See Abbasi, *supra* note 15.

63. *Griswold*, 381 U.S. at 485 (quoting *NAACP v. Alabama*, 377 U.S. 288, 307 (1964)).

64. See *supra* Part I.

65. 21 C.F.R. § 1271.15(e) (2013).

66. Based on the fact that the FDA is currently bringing action against a private sperm donor rather than classifying all private sperm donors as sexually intimate partners. See Abbasi, *supra* note 15, at 11.

tect regulation of business-like transactions. While this argument holds some weight, it ultimately fails for two reasons. First, an argument by the FDA turning on what is considered “intimate” is beyond the scope of the government. The Court has not allowed the government to control personal relationships between consenting adults through the use of criminal punishment “absent injury to a person or abuse of an institution the law protects.”⁶⁷ Second, in regards to procreation and family planning, the Court to date has not made any known exception in their protection for transactions that are too business-like or arms length. If a couple first conducts extensive negotiations as to whether to use contraception, their right to access contraception absent criminal punishment is not affected. Regardless of whether the hypothetical couple plans to ever even have sexual relations, the court has drawn a barrier between the government and individuals that the government cannot look behind and control. While intimacy is often presumed, it is not a prerequisite to obtaining the guaranteed protection of substantive due process.

If the privacy doctrine articulated in *Griswold* and *Eisenstadt* was the only standing authority, it would be obvious that procreation and family planning is protected as an announced fundamental right, and actions involving something as intimate and private as sperm donation would be beyond governmental regulatory authority. However, the doctrine of privacy where the fundamental right of conception is concerned has developed over time, first into a protection of decisions, and later into a subsection of the guaranteed protection of liberty. The evolving doctrine applicable to acts of conception has expanded and changed the way courts have interpreted a right to privacy, and what is off limits from government regulation. However, this evolution has not weakened the ultimate conclusion that an act such as sperm donation is beyond the legislative and regulatory authority of the government.

3. *Privacy Emerging as a Decisional Protection*

The privacy doctrine’s protection of procreation morphed from one protecting spatial “zones” of privacy to one protecting the de-

67. *Lawrence v. Texas*, 539 U.S. 558, 567 (2003). For further discussion see *infra* Part III.B.

cision surrounding procreation. One of the earliest indications of this switch came in *Eisenstadt v. Baird*,⁶⁸ an equal protection case extending the holding of *Griswold* to non-married individuals. In *Eisenstadt*, the Court announced that “[i]f the right to 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 a person as the decision whether to bear or beget a child.”⁶⁹ This declaration transformed the fundamental right to privacy from one simply setting up a barrier around zones the government could not cross, into a recognized right to make personal decisions privately without the government interfering.⁷⁰

This right to private decision-making laid the groundwork for the abortion cases, which further extended the protection of decisional privacy. The year after *Eisenstadt*, *Roe v. Wade*⁷¹ marked a peak for the expansion of privacy.⁷² The Court announced that the fundamental right to privacy was “broad enough to encompass a woman’s decision whether or not to terminate her pregnancy.”⁷³ The Court also held that the government needed a “compelling state interest” to justify a regulation where “‘fundamental rights’ are involved,” and that the regulation needs to be “narrowly drawn to express only the legitimate state interests at stake.”⁷⁴

The decisional privacy doctrine was further developed, and arguably broadened, in *Carey v. Population Services, International*, where the Court announced a broad application of the fundamental right to decisional privacy.⁷⁵ The Court leaves many of the specifics of what is covered under the right to privacy unclear, but says it is clear that it includes procreation, as well as “decisions whether to accomplish or to prevent conception.”⁷⁶ Again, the Court imposes the burden of justifying a regulation that imposes

68. 405 U.S. 438 (1972).

69. *Id.* at 453–54.

70. See Cohen, *supra* note 56, at 1149–50.

71. 410 U.S. 113 (1973).

72. Some argue that *Roe* was the last case where the fundamental right to privacy did any work. See, e.g., Jamal Greene, *The So-Called Right to Privacy*, 43 U.C. DAVIS L. REV. 715, 724 (2010).

73. *Roe*, 410 U.S. at 153.

74. *Id.* at 155.

75. 431 U.S. 678 (1977).

76. *Id.* at 684–85.

a burden on the decision of procreation on the government, who must show “compelling state interests . . . narrowly drawn to express only those interests.”⁷⁷

4. *The FDA and the Fundamental Right to Privacy*

The FDA circumvents the Court’s plain holdings with 21 C.F.R. § 1271. In order to justify the restrictive burdens of expensive medical testing and tedious and painstaking record keeping, the FDA, as a governmental agency, must demonstrate that it has not acted arbitrarily or capriciously.⁷⁸ The FDA must also show that it is not acting “contrary to constitutional right, power, privilege, or immunity.”⁷⁹ The FDA has regulated an area the Court has deemed constitutionally protected as a fundamental right — procreation — which is thoroughly protected by both the decisional privacy and zonal privacy announced in the Court’s contraception and abortion cases.

Based on the rulings of the Court, the FDA’s regulation violates a constitutionally protected right to privacy. Given that procreation is an area broadly protected by the right to privacy,⁸⁰ burdening this decision with unnecessary governmental intervention goes against the Court’s holdings in *Griswold*, *Eisenstadt*, *Roe*, and *Carey*.⁸¹ However, any challenge based on substantive due process must be framed in terms aligned with the previous constitutional protection.

In order for any claimed right to be viewed as a protected “fundamental” right, the Court must find that the alleged right fits within their previous holding, or if alleging a new right fits within a vague two-part framework announced in *Washington v. Glucksberg*.⁸² Since having children is commonly referenced as a

77. *Id.* at 686.

78. 5 U.S.C. § 706(2)(A) (2012) (“To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious . . .”). The arbitrary nature of the FDA regulation is discussed in Part IV.B.

79. 5 U.S.C. § 706(2)(B) (2012).

80. *Carey*, 431 U.S. at 684–85.

81. *See supra* Parts II.A.1–2.

82. 521 U.S. 702 (1997). First, it must be “objectively, ‘deeply rooted in this Nation’s history and tradition.’” *Id.* at 720–21 (citations omitted) (quoting *Moore v. City of East Cleveland*, 431 U.S. 494, 503 (1977)). Second, there must be a “‘careful description’ of the

fundamental right, it may seem unnecessary to focus on the importance of framing.⁸³ However, it is possible for a court to interpret narrowly any right that is being asserted.⁸⁴ For example, in the challenge at hand, it is possible that the court may interpret this as seeking protection for a “fundamental right to donate sperm.”

In the event that a court chooses to narrowly frame the issue concerning what the FDA is regulating, there is still a strong argument that sperm donation falls in line with the precedent established by the cases discussed previously. The contraception and abortion cases are written so broadly that even a fundamental right to sperm donation could fall within the already announced right to procreation,⁸⁵ to have children,⁸⁶ to accomplish or to prevent conception,⁸⁷ or to decide whether to beget a child.⁸⁸ Since sperm donation is necessary for all of these protected rights, it is not a stretch to assume it is necessarily protected as well within both the decision and the physical act of procreation, or accomplishing conception.

What may not be necessarily protected under a doctrine of privacy is a fundamental right to sperm donation *absent sexual intercourse*. The Court in the privacy cases consistently implies sexual intimacy. *Griswold*, for example, emphasized the intimacy of marriage, calling it “sacred.”⁸⁹ It seems logical to assume that a case about abortion involved some preceding sexual intercourse,

asserted fundamental liberty interest.” *Id.* at 721 (citing earlier due process cases). Note, that even *Glucksberg* assumes that having children is a fundamental right protected by the Due Process Clause of the Constitution, and in fact uses it as a reference point for noting the fundamental rights the Court has recognized and accepted in the past. *Id.* at 720.

83. *Id.* at 720.

84. One very clear example of this is the difference between the holdings in *Bowers v. Hardwick* and *Lawrence v. Texas*, both dealing with state laws against sodomy. In *Bowers*, the Court interpreted the challenge as asserting a fundamental right for homosexuals to engage in sodomy. *Bowers v. Hardwick*, 478 U.S. 186, 190 (1986). *Lawrence* took up a similar law and found that the law challenged “the most private human conduct, sexual behavior, and in the most private of places, the home.” *Lawrence v. Texas*, 539 U.S. 558, 567 (2003). Obviously, the way the Court chose to frame what the harm was and what the parties were seeking to challenge affected what authority was drawn from precedent, and ultimately what the outcome of the case was.

85. See, e.g., *Roe v. Wade*, 410 U.S. 113, 726 (1973).

86. See, e.g., *Glucksberg*, 521 U.S. at 720.

87. *Carey v. Population Servs. Int'l*, 431 U.S. 678, 684–85 (1977).

88. See, e.g., *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972).

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

although it should be obvious from this Note that sexual intercourse is not always necessary. And there seems to be some question about the ability of a court to allow those trying to achieve the benefits of sexual intimacy without actually partaking in the act of sex.⁹⁰ Unfortunately, there is no clear precedent or court discussion on a right to reproduce *in a certain manner*, and as the doctrine of substantive due process in this area develops more fully, it only becomes murkier.

B. SUBSTANTIVE DUE PROCESS AND LIBERTY

Griswold and *Eisenstadt* laid the foundation for a protected right to family planning under substantive due process, while *Roe v. Wade*⁹¹ further extended the right to make decisions regarding procreation under a fundamental right to privacy by extending it to abortion.⁹² *Roe v. Wade* may mark the peak of recognizing a fundamental right to privacy, be it spatial or decisional.⁹³ From there, the Court made a shift towards recognizing fundamental rights under a liberty-based doctrine of substantive due process.⁹⁴ The development and shift from privacy to liberty actually further strengthens the argument that the government breaches an individual's constitutionally protected rights when it tries to dictate rules on procreation.

90. Compare *Williams v. Pryor*, 240 F.3d 944, 949 (11th Cir. 2001) (recognizing as a legitimate state interest Alabama's interest in "discouraging prurient interests in autonomous sex" by allowing a statewide ban on sex toys), with *Reliable Consultants, Inc. v. Earle*, 517 F.3d 738, 744 (5th Cir. 2008) (striking down a Texas ban on sex toys, finding that it violated a "right to be free from governmental intrusion regarding 'the most private human contact, sexual behavior.'"). The biggest, and most important, distinguishing factor here is that achieving orgasm is only tangentially covered under any fundamental rights, while, again, procreation necessarily involving sperm has been protected over and over again.

91. 410 U.S. 113 (1973).

92. *Id.* ("This right of privacy, whether it be founded in the Fourteenth Amendment's concept of personal liberty and restrictions upon state action, as we feel it is, or, as the District Court determined, in the Ninth Amendment's reservation of rights to the people, is broad enough to encompass a woman's decision whether or not to terminate her pregnancy.").

93. See Greene, *supra* note 72, at 724.

94. See generally Sonu Bedi, *Repudiating Morals Legislation: Rendering the Constitutional Right to Privacy Obsolete*, 53 CLEV. ST. L. REV. 447 (2005–2006); Greene, *supra* note 72; Helen J. Knowles, *From a Value to a Right: The Supreme Court's Oh-So-Conscious Move From "Privacy" to "Liberty"*, 33 OHIO N. U. L. REV. 595 (2007).

One of the starkest examples of this is in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, where the opinion opens by framing *Roe* as a case about liberty.⁹⁵ *Casey* goes on to reframe the controversy of abortion in a liberty context. Justices O'Connor, Kennedy, and Souter reject an "all-encompassing 'right of privacy,'" though do so in a portion of their opinion that is concurring and not controlling.⁹⁶ In the controlling opinion, the Court seems to broaden rather than limit what is protected by a fundamental right to liberty, stating "[a]t 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."⁹⁷ Given this language in *Casey*, it could be argued that any legislation defining for every individual what it means to reproduce strikes directly through the "heart of liberty" because it eliminates the individual's ability to define the concepts of the human life. However, in determining whether the government may regulate the ability to procreate, it is enough to recognize that the Supreme Court's concept of liberty, as announced in *Casey*, prevents such meaningful authority from resting in the hands of our government by reaffirming an individual's right to a decisional autonomy much like that discussed in the earlier privacy cases.⁹⁸

Casey's shift to liberty was further strengthened by the holding in *Lawrence v. Texas*. Justice Kennedy's opinion in *Lawrence* is a full consumption of the right to privacy by a recognized right to liberty and even opens with "[l]iberty protects the person from unwarranted government intrusions into a dwelling or other private places."⁹⁹ This sounds eerily similar to the spatial privacy from *Griswold* folded into notions of liberty. However, Justice Kennedy quickly notes that the liberty he references in his opinion encompasses the spatial as well as the "more transcendent

95. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 844 (1992) ("Liberty finds no refuge in a jurisprudence of doubt. Yet 19 years after our holding that the Constitution protects a woman's right to terminate her pregnancy in its early stages, that definition of liberty is still questioned." (internal citations omitted)).

96. *Id.* at 951. That portion of the opinion goes on to narrow the fundamental right to abortion under the privacy context as too broad. *Id.* at 951–52.

97. *Id.* at 851.

98. "These matters, involving the most intimate and personal choices a person may make in a lifetime, choices central to personal dignity and autonomy, are central to the liberty protected by the Fourteenth Amendment." *Id.* at 851.

99. *Lawrence v. Texas*, 539 U.S. 558, 562 (2003).

dimensions.”¹⁰⁰ Just what those “transcendent dimensions” encompass is unclear.

It has been suggested that Justice Kennedy’s opinion on liberty pares down the broad language of *Casey* and in a sense domesticates the doctrine by again moving the recognition of fundamental rights to a specific location — the home.¹⁰¹ Even if *Lawrence* does confine protected liberty to the home, or institute a type of spatially protected liberty, it would still apply to the issue at hand. The act of sperm donation, though not necessarily performed within the home, is a domestic issue much like that discussed in *Lawrence* in that it occurs privately between consenting adults. Ultimately, one need not wrestle with Kennedy’s language of transcendence to reach the conclusion that something as fundamental to procreation as sperm donation is protected from government interference, regardless of whether the sperm is donated naturally or artificially. The crucial issue is whether sperm donation falls within the protection of a right to liberty. Based on Kennedy’s spatial protection of the home “and other private places,” combined with the already announced protection of the right to procreate,¹⁰² it would require arguing that private sperm donation is neither performed in the type of “private places” Justice Kennedy referenced, nor fundamental to the act of procreation to remove it from the protection of liberty.¹⁰³

1. *Applying Lawrence to the FDA*

The Court’s articulation of the Constitution’s protection of individual liberty poses a greater threat to the FDA regulations at issue here than the strand of cases protecting individual privacy. For the challenge to the FDA, having a fundamental right to liberty brings a better challenge than even a fundamental right to privacy because it allows for the protection of certain decisions and actions inclusive of, and expanded beyond what was originally protected by the right to privacy.¹⁰⁴ Regardless of whether the

100. *Id.* at 562.

101. See Katherine Franke, *The Domesticated Liberty of Lawrence v. Texas*, 104 COLUM. L. REV. 1399 (2004).

102. See *supra* Parts II.A.1–2.

103. *Lawrence*, 539 U.S. at 562.

104. For example, *Lawrence* protects the right to sexual intimacy which was not enumerated in any previous right to privacy cases.

right to liberty is inclusive of the home and the “transcendent,” or if it is merely a more abstract way to encompass and expand privacy, the way in which the doctrine of liberty has been applied suggests an inclusive, expansive reading of substantive due process. Based on this interpretation of *Lawrence*, the Court has rejected the narrow framing of fundamental rights protected by liberty.

Lawrence overturned the holding of *Bowers v. Hardwick*,¹⁰⁵ and dismissed the previous narrow framing of the issue.¹⁰⁶ Justice Kennedy takes issue with the way in which the Court in *Bowers* framed the inquiry as one of whether the Constitution directly conferred a fundamental right to engage in homosexual sodomy and instead broadly reframes the issue.¹⁰⁷ Using this move to think about how a court might view the framing of the issue of private sperm donation, a court should understand that prohibiting adults from choosing their own methods of reproduction without financial penalty is neither a simple nor a harmless regulation. The FDA regulation is effectively the government substituting their will for the will of the individual, and it touches “upon the most private human conduct,” something Justice Kennedy specifically admonished the anti-sodomy laws for doing.¹⁰⁸ While the law did allow for sexually intimate partners to engage in private sperm donation,¹⁰⁹ the FDA still infringed on the protected rights of those that are not “sexually intimate” with their sperm donors.¹¹⁰

Consider an essential holding of *Lawrence*:

105. *Lawrence*, 539 U.S. at 578 (“*Bowers* was not correct when it was decided, and it is not correct today. It ought not to remain binding precedent. *Bowers v. Hardwick* should be and now is overruled.”).

106. *Id.* at 567 (“To say that the issue in *Bowers* was simply the right to engage in certain sexual conduct demeans the claim the individual put forward, just as it would demean a married couple were it to be said marriage is simply about the right to have sexual intercourse. The laws involved in *Bowers* and here are, to be sure, statutes that purport to do no more than prohibit a particular sexual act. Their penalties and purposes, though, have more far-reaching consequences, touching upon the most private human conduct, sexual behavior, and in the most private of places, the home.”).

107. *Id.* at 566–68.

108. *Id.*

109. 21 C.F.R. § 1271.15(e) (2013).

110. The FDA has refused to define “sexually intimate,” and likely does not have the authority to do so. It does not include “sexually intimate partner” in its list of definitions. *See id.* § 1271.3.

The present case does not involve minors. It does not involve persons who might be injured or coerced or who are situated in relationships where consent might not easily be refused. It does not involve public conduct or prostitution . . . The petitioners are entitled to respect for their private lives. The State cannot demean their existence or control their destiny by making their private sexual conduct a crime. Their right to liberty under the Due Process Clause gives them the full right to engage in their conduct without intervention of the government. “It is a promise of the Constitution that there is a realm of personal liberty which the government may not enter.”¹¹¹

This statement could easily be the opening to a challenge against the FDA regulating the ways in which certain people may or may not reproduce. For example, in the case of Trent Arsenault, neither he nor the women to whom he donated his sperm were minors, they were neither injured nor coerced into giving consent, and the entire process involved two, and sometimes three, adults who, with “full and mutual consent from each other”¹¹² engaged in conduct not uncommon to reproduction. By virtue of the holding in *Lawrence*, these individuals should be entitled to “respect for their private lives,” and are protected constitutionally from the government entering the “realm of personal liberty.”¹¹³

That the FDA can threaten jail time for committing the “crime” of procreation by artificial insemination instead of natural insemination is an attempt by the FDA to define what is an appropriate reproductive relationship. Justice Kennedy stated that the holding of *Lawrence* should “counsel against” the government attempting to “define the meaning of [a] relationship or to set its boundaries” and reiterates that “adults may choose to enter upon this relationship in the confines of their homes and their own private lives and still retain their dignity as free persons.”¹¹⁴ While he is referencing homosexual relationships, Ken-

111. *Lawrence*, 39 U.S. at 578 (quoting *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 847 (1992)).

112. *Id.*

113. *Id.*

114. *Id.* at 567.

nedey's warning applies to the current challenge as individuals choose to enter private, consensual relationships in their own private lives in an attempt to procreate.

By regulating consensual, individual, adult relationship based upon a belief that only "sexually intimate partners" are able to reproduce without a need for governmental interference, the FDA is defining what types of relationships individuals may enter legally without paying high fees.¹¹⁵ This is in direct opposition to the holdings of cases supporting a fundamental right to liberty. By defining liberty as that which protects individuals from governmental intrusion into our private lives, the Court has erected a boundary that the government cannot cross.¹¹⁶ Further, by including within the right to liberty a presumption of autonomy that includes "intimate conduct" and freedom to make decisions, the Court has upheld the protection of rights including procreation through both artificial and natural insemination.¹¹⁷ Artificial insemination may not involve sexual intercourse, but it is certainly intimate conduct, and the FDA cannot regulate relationships based upon assumptions of sexual intimacy in contradiction to the holding of the Supreme Court.

IV. FUNDAMENTAL PROBLEMS WITH THE FDA REGULATION

A legal challenge to the current FDA regulation of private sperm donation would depend heavily on the constitutional issues discussed so far.¹¹⁸ But beyond the constitutional issue, the FDA regulation has problems inherent in its formulation. Below is a discussion of problems with 21 C.F.R. § 1271 beyond a legal challenge brought on constitutional grounds. Part IV.A discusses the stated purpose of the FDA regulation, and how the effect of the

115. See 21 C.F.R. § 1271 (2013).

116. *Lawrence*, 539 U.S. at 562.

117. *Id.*

118. There is currently an administrative challenge to the FDA regulation of private sperm donation on behalf of Trent Arsenault, although the FDA denied Mr. Arsenault. See Memorandum in Support of Trent Arsenault's Opposition to CBER's Motion to Deny Mr. Arsenault's Request for Hearing and for Administrative Summary Judgment and Cross-Motion for Administrative Summary Judgment, *In re Arsenault* (Nov. 7, 2011) (FDA HCT/P regulatory adjudication), available at http://trentdonor.org/sites/g2sites/trentdonor/d/222281/7_Nov_2011_Opposition_to_CBER_motion_to_deny_hearing_and_for_ASJ_with_supporting_memo-trentdonor.pdf.

regulation diverges from that stated purpose. Part IV.B discusses the arbitrary and capricious nature of the FDA regulation.

A. COMPLIANCE WITH THE STATED PURPOSE OF THE FDA

The stated purpose of the FDA in having this testing and labeling requirement is

to create 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 good tissue practice, and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/P's.¹¹⁹

This stated purpose is not furthered by compliance with the FDA regulations.

The FDA's current regulation is both over- and under-inclusive, and ultimately ineffective in its goal of diminishing the spread of communicable diseases. To establish guidelines truly effective in mitigating the spread of communicable diseases, the FDA would have to cast their scope must wider. Requiring such drastic measures for the "protection" of so few people amounts more to harassment of the few than protection of many.

Furthermore, after complying with the costly testing procedures, and keeping records, an ineligible donor, one that fails perhaps every test, is still able to donate sperm for artificial insemination.¹²⁰ While the FDA may hope that uncovering a history of disease would dissuade a recipient from continuing artificial insemination with the infected donor, the actual regulation does nothing to prevent this from happening. Idealism by the FDA is not preventing any communicable diseases from spreading. Instead, the FDA is mandating an extreme, regimented form of forced communication between donors who are choosing to procreate through artificial insemination from private donors, as opposed to natural insemination from either known or unknown donors. Additionally, if the donor and the recipient are not in a financial situation to comply with the costly FDA testing, the

119. 21 C.F.R. § 1271.1(a) (2013).

120. *Id.* § 1271.65(b)(ii).

FDA is providing a monetary incentive for relative strangers to have unprotected sex with or without first communicating about medical histories.¹²¹

By including the exemption for sexually intimate partners, the FDA saves itself from other constitutional infringements, as the government may not insert itself into the sexual relationships of individuals. However, because *Lawrence* forbids the government from defining what it means to be in an intimate relationship, the FDA cannot define what it means to be a sexually intimate partner.¹²² This leaves only the FDA's insistence that sperm donations from friends do not count under the sexually intimate partner exemption,¹²³ and what appears to be the FDA advocating for unprotected sex ("natural insemination") as the only viable means of procreation without a hefty price tag.

Advocating for unprotected sex as opposed to artificial insemination actually defeats the stated purpose of the FDA rather than furthers compliance with it. There are a multitude of communicable diseases that are transferred by skin-to-skin contact, the risk of which would dramatically decrease by artificial insemination practices.¹²⁴ Also, from a practical standpoint, if a recipient has a communicable disease, the sperm donor is in no danger of contracting it. This is not the case if the two engage in unprotected sex in an attempt to procreate. In addition to this gaping hole in the logic of the FDA's stated purpose, many women who

121. This is based off the inclusion of the sexually intimate partner exemption to the rule, whereby all procedures and testing are no longer required so long as the two individuals engage in sexual intercourse. See 21 C.F.R. § 1271.15(e) (2013).

122. *Lawrence*, 539 U.S. at 558.

123. The definition of a "directed reproductive donor" is "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. The term directed reproductive donor does not include a sexually intimate partner." 21 C.F.R. § 1271.3(l) (2013). By making such a broad definition of who must comply with these regulations, the FDA is leaving little room for the argument that sperm donation and receipt is such an intimate act that is by its nature sexual, therefore all acts of sperm donation that are not anonymous are sexually intimate. This means that they are carving out a specific, but undefined, exemption, for which someone like Trent Arsenault would not apply, despite his continued relationship with the parents of the children his sperm has created, or his initial friendships with many of the women to whom he has donated sperm. See generally Wallace, *supra* note 15.

124. For example, herpes and human papillomavirus are transmitted by skin-to-skin contact. See *Genital Herpes Fact Sheet*, CENTER FOR DISEASE CONTROL, <http://www.cdc.gov/std/herpes/herpes-fact-sheet-sept-2012.pdf> (last visited Dec. 10, 2013) and *Genital HPV Infection Fact Sheet*, CENTER FOR DISEASE CONTROL, <http://www.cdc.gov/std/HPV/HPV-Factsheet-March-2013.pdf> (last visited Dec. 10, 2013).

wish to get pregnant are left with only one viable option for becoming pregnant — sexual intercourse. This encourages risky behavior and eliminates potentially safe donors that would otherwise donate but fear FDA penalties, fines, or potential jail time. For example, the case of Trent Arsenault, currently working its way through the courts, exemplifies the type of donor that would not be available to women seeking a partner for sexual intercourse because Mr. Arsenault is a virgin and wishes to remain one.¹²⁵ The FDA has eliminated a viable and willing donor who is open and forthcoming with his medical records because he chooses not to engage in sexual intercourse. This measure also forces a number of safety conscious women who desire a sperm donation but do not wish to have the type of vulnerable exposure that sexual intercourse requires to either have unprotected sex or abandon their hope of having a child.¹²⁶

These are examples of approved FDA insemination methods that lead to more danger and an increased risk of spreading communicable diseases. The stated purpose of the FDA to prevent the introduction and transmission of communicable diseases is not furthered by these regulations. This leaves only the stated purpose of creating a unified registration and listing system.¹²⁷ A desire for unification in listing and registration does not outweigh the infringement upon an individual's ability to determine the manner and timing of reproduction.

B. CHALLENGES TO 21 C.F.R. § 1271

When evaluating whether a governmental agency has exceeded the scope of its authority one must determine whether the regulation is arbitrary and/or capricious. This standard of review is required by Administrative Procedures Act, as codified in the United States Code, which states,

To the extent necessary to decide and when presented, the reviewing court shall decide all relevant questions of law,

125. See, e.g., Wallace, *supra* note 15.

126. This is in addition to the women that would choose not to have sexual intercourse even despite the vulnerability that it brings, perhaps because they are married and do not wish to engage in what they would consider adultery, or because they are homosexual and do not choose to engage in sexual intercourse with men.

127. 21 C.F.R. § 1271.1(a) (2013).

interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be . . . arbitrary, capricious”¹²⁸

The FDA regulations may serve the rational purpose of providing administrative guidance and constraints for entities that are storing and transferring large amounts of anonymously donated semen, and it is logical to require some sort of procedure for keeping up with all of the various anonymous donations.¹²⁹ It is not contested that regulating businesses dealing in the sale of sperm is a useful function, as many people likely rely on a policing system for anonymous sperm donation centers. It is only with the inclusion of the “directed reproductive donor” that the FDA exceeds its authority by stepping into the private interactions of individuals in an arbitrary and unconstitutional manner.

The arbitrariness of this regulation has already been touched on by noting that the specifics of the regulation as applied to individuals bear no relation to achieving the stated purpose of the FDA’s regulation.¹³⁰ But the FDA is also arbitrary in where it chooses to draw the line determining who is bound by the restrictions, and who is able to procreate free from all governmental involvement.¹³¹ The FDA has no objection to the spread of com-

128. 5 U.S.C. § 706(2)(A) (2012).

129. This is based on the extent to which the FDA requires established procedures and the detailed way in which they explain how and what to register, what must be labeled, the assigning of a registration number by the FDA. *See generally* 21 C.F.R. § 1271 (2013). These all point towards regulation of a business operating in facilitating donated sperm to the public, which would require some sort of governmental policing to ensure they were not consistently duping innocent women into believing they were receiving the sperm of one individual and in reality receiving contaminate sperm of some other individual.

130. *See supra* Part III.B.

131. Obviously, the Court has restricted all government access to marital bedrooms, so the FDA makes a sexually intimate partner exemption. 21 C.F.R. § 1271(l) (2013). But in this exemption the FDA allows for random sexual encounters between two individuals that have never previously met, do not know each other, and are both riddled with disease. The FDA exempts paying a man to naturally inseminate a woman. While prostitution laws may interfere with certain transactions, the FDA is silent on a woman paying money for a man to attempt to impregnate her through sexual intercourse, having had no conversation about medial diseases. The FDA is comfortable with relative strangers who are meeting to inject a man’s sperm into a woman, with or without a view towards pregnancy, so long as this is an act of sexual intimacy and not of a neutral, non-sexual persuasion. Finally, The FDA does not attempt to stop artificial insemination of a woman with a man’s sperm that is riddled with disease so long as the man has not strayed from his

municable disease in order to procreate, it only requires that procreation by artificial insemination where the sperm is not donated by a sexually intimate partner be more tedious and costly than all other forms of procreation. This is what makes the FDA regulation entirely arbitrary — it does nothing to serve its state purpose and instead adds meaningless restrictions and punishments on individuals.

The Courts have not suffered arbitrary laws.¹³² Liberty cannot be achieved when individuals are prosecuted and penalized for arbitrary laws furthering no real purpose.¹³³ That the United States Code requires a court to find agency actions unlawful when arbitrary¹³⁴ can be thought of as an extension of a ban on arbitrary law dating back even to *Meyer v. Nebraska*, which stated that “liberty may not be interfered with, under the guise of protecting the public interest, by legislative action which is arbitrary or without reasonable relation to some purpose within the competency of the state to effect.”¹³⁵

Even if the FDA were able to show that the regulation was not arbitrary, they will have to show that the infringement is narrowly tailored to serve a compelling state interest because their regulation infringes on a constitutionally protected right.¹³⁶ There are several possible, and compelling, interests that the FDA could argue they are serving with their regulation. Regulations to slow the transmission of communicable diseases are within the purview of the FDA in the interest of public health. The issue is that

written procedures for obtaining it, and the cup carries a biohazard sticker, and his records are in perfect order. 21 C.F.R. § 1271.65(c)(1)–(2) (2013).

132. See, e.g., *Poe v. Ullman*, 367 U.S. 497, 542 (1961) (Harlan, J., dissenting) (“[L]iberty’ is not a series of isolated points pricked out in terms of taking property; the freedom of speech, press, and religion; the right to keep and bear arms; the freedom from unreasonable searches and seizures; and so on. It is a rational continuum which, broadly speaking, includes a freedom from all substantial arbitrary impositions and purposeless restraints.”); *Skinner v. Oklahoma*, 316 U.S. 535, 544 (1942) (Stone, J., concurring) (“There are limits to the extent to which the presumption of constitutionality can be pressed . . . where the presumption is resorted to only to dispense with a procedure which the ordinary dictates of prudence would seem to demand for the protection of the individual from arbitrary action.” (internal citations omitted)).

133. See Donald H.J. Hermann, *Pulling the Fig Leaf Off the Right of Privacy: Sex and the Constitution*, 54 DEPAUL L. REV. 909, 914 n.23 (2005).

134. 5 U.S.C. § 706(2)(A) (2012).

135. 262 U.S. 390, 399 (1923).

136. See, e.g., *Lawrence v. Texas* 539 U.S. 558, 593 (2003); *Washington v. Glucksberg*, 521 U.S. 702, 721 (1997); *Roe v. Wade*, 410 U.S. 113, 155 (1973).

the FDA must demonstrate that the regulation is both narrowly tailored, and that it serves a compelling state interest.¹³⁷

It is possible for the FDA to argue that even though the regulation is not ideal or particularly effective in preventing the transmission of communicable diseases, it still does serve the interest of public health because it prevents, even if a minuscule percentage, some communicable diseases from being transferred. This argument is insufficient for two reasons.

First, the regulation does allow for using sperm containing communicable diseases for the purpose of reproduction, so it really only serves as a financial penalty for those choosing to reproduce by artificial insemination. This makes the regulation a monetized, mandatory disclosure mechanism more than a ban or bar on the transmission of communicable diseases.¹³⁸

Second, the Court has not been favorable to sweeping legislation with only a *potential* effect on a compelling interest. *Eisenstadt*, for example, stated that a classification “must be reasonable, not arbitrary, and must rest upon some ground of difference having a fair and substantial relation to the object of the legislation.”¹³⁹ The Court, though inconsistent in its definition of what is necessary to serve a compelling state interest, has preferred to look at the means used to accomplish the governmental goal.¹⁴⁰ Where a fundamental interest is at stake, as it is here, then the

137. See *supra* Part III.A.

138. Note that for an establishment such as an anonymous donor bank, ineligible donors are not allowed to have their donations used. The regulation states that the only times in which an ineligible donor's donation may still be used is if it is made by a first or second-degree blood relative for allogenic use; if it is reproductive tissue from a directed reproductive donor; or if there is a documented urgent medical necessity. 21 C.F.R. § 1271.65 (b)(i)–(iii) (2013).

139. *Eisenstadt v. Baird*, 405 U.S. 438, 447 (1972) (quoting *Reed v. Reed*, 404 U.S. 71, 75–76 (1971)). Although *Eisenstadt* is an equal protection case, it is applicable because the FDA regulation makes a sweeping allowance for sexually intimate partners and regulates only those that choose artificial insemination, presumably with the intent to stop the transmission of communicable disease. The argument for the applicability of *Eisenstadt* is that it provides a model for assessing classifications that are not suspect (i.e. race, sex, national origin), but nonetheless serve to restrict actions of one group but not the other with only arbitrary reasons for doing so. The FDA has as yet offered no reason for why they have chosen to regulate known private sperm donors for artificial insemination, but not for natural insemination. See generally TRENT ARSENAULT, <http://www.trentdonor.org> (last accessed Mar. 22, 2013), for more information on what the FDA has offered in defense of its authority.

140. See Ashutosh Bhagwat, *Purpose Scrutiny in Constitutional Analysis*, 85 CAL. L. REV. 297, 306 (1997).

Court applies strict scrutiny,¹⁴¹ which makes the limited effectiveness of the FDA's regulation especially difficult to overcome.¹⁴²

The FDA may argue that, under *Casey*, if a regulation increases the waiting time and cost of an abortion and is not automatically considered an undue burden,¹⁴³ then a regulation that merely increases the cost of artificial insemination is not an undue burden. While it is not clear whether the undue burden test would be used in a challenge to the right to reproduce, it is indicative of the court's willingness to allow "particularly burdensome" regulations where the compelling governmental interest is "especially strong."¹⁴⁴ However, this would require furthering a compelling governmental interest that is especially strong, and as demonstrated above the FDA's regulation does not actually further their stated purpose, or any state interest. The undue burden test used in abortion cases may actually work in the favor of a challenge to the FDA regulation because the compelling state interest cited by the Supreme Court is an interest in childbirth even if it does not further an interest in health.¹⁴⁵ Even if there is no similarity found in the state interest in childbirth and an interest in procreation, *Casey's* narrow definition of what constitutes an undue burden is still limited to cases of abortion and it is unlikely that a court would need to adopt an undue burden to procreation test because procreation and family planning is already so firmly protected within the realm of substantive due process.¹⁴⁶

141. *See id.*

142. Strict scrutiny, though not "fatal in fact" does require a much stronger justification for the law in place than say rational basis review, which requires only the existence of a potential rational reason for the law. *See* Adam Winkler, *Fatal in Theory and Strict in Fact: An Empirical Analysis of Strict Scrutiny in the Federal Courts*, 59 VAND. L. REV. 793, 863 (2006) (detailing that strict scrutiny analysis to challenges of substantive due process rights survived only 22% of the time.).

143. *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833, 886 (1992).

144. *Id.* at 886–87.

145. *Id.* at 886. This is in reference to a 24-hour waiting period for abortions that may not be in the best interest of the health of the woman seeking an abortion. The Supreme Court found that the state has an interest in childbirth over abortion. While not wholly applicable to the issue at hand, it is interesting that the FDA is attempting to interfere with procreation, and thus childbirth.

146. *See supra* Part II.

V. CONCLUSION

Though the Court has never determinatively settled the question, the act of sperm donation must be treated as among the “intimate” activities protected from undue government interference by the Supreme Court’s richly developed doctrine of substantive due process. In the last century, the Court has consistently held that the freedom to make basic choices about individual procreation is a constitutionally protected and fundamental right.¹⁴⁷ The FDA, in choosing to aim regulations best suited for business establishments dealing in the business of selling sperm at the private individuals, has grossly overstepped its authority. In doing so, the FDA has breached the fundamental rights of the individual.

The Court has established recognition of procreation and reproduction belonging solely to the individual. This recognition of the individual right to determine the timing and manner of reproduction makes the FDA regulation one that reaches beyond the most intimate of constitutionally protected fundamental rights. The agency’s regulations are also arbitrary and capricious, and should be struck down as administrative deficient.

Though one man, Trent Arsenault, is attempting to bring a case against the FDA, the FDA has yet to mount a full defense of its authority to regulate private individual’s decision to use a sperm donor for artificial insemination.¹⁴⁸ Should the FDA be allowed to continue to regulate private interactions between individuals regarding something as intimate and protected as procreation, it would have huge implications for the continued protection of procreation as a fundamental right. Allowing the government to impose unnecessary, arbitrary regulations allows the government to determine for society which reproductive methods are socially acceptable, and which must be laden with costly expenditures of time and money. The Constitution and the Courts

147. See *Lawrence v. Texas* 539 U.S. 558, 575 (2003); *Carey v. Population Servs. Int’l*, 431 U.S. 678, 685 (1977); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *Poe v. Ullman*, 367 U.S. 497, 517 (1961); *Skinner v. Oklahoma*, 316 U.S. 535, 541 (1942); *Meyer v. Nebraska*, 262 U.S. 390, 399 (1923).

148. Memorandum in Support of Trent Arsenault’s Opposition, *supra* note 118. At time of publication, no court hearing or ruling had been issued for any case challenging private sperm donation. It remains to be seen whether any challenge to the FDA regulation will receive judicial review.

that interpret its scope protect individual citizens from this type of interference by the government, and will hopefully recognize the abhorrent infringement that exists on the books at this moment.