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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

JANE DOE Oakland, CA 94619 Plaintiff, v. MARGARET A. HAMBURG, M.D., in her official capacity as Commissioner, U.S. Food and Drug Administration and KATHLEEN SEBELIUS, in her official capacity as Secretary, U.S. Dep't of Health and Human Services, Defendants.	Case No. C 12-03412 (EMC)

FIRST AMENDED COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. This is an action brought to prevent the Food and Drug Administration (FDA) from violating the constitutional privacy and liberty rights of women who wish to conceive children and start families, including the pseudonymously named Plaintiff.

2. The Plaintiff is trying to conceive a child but she does not engage in heterosexual intercourse. She wishes to become pregnant via artificial insemination with semen donated on an uncompensated basis by a private individual, without a medical intermediary such as a semen bank or medical professional.

3. Additionally, the Plaintiff wishes to provide the identity, health status, and access to a personal relationship with the male biological parent to her future child or children. In order to provide these details to her future child or children, the Plaintiff has elected to use gametes from an individual known to her.

4. However, the FDA prohibits private individuals from donating semen for artificial insemination on an uncompensated basis unless these individuals comply with a panoply of costly and burdensome regulatory requirements. These requirements apply even if a man donates semen directly to a woman he considers to be his intimate partner. The FDA has thus interpreted its regulations to give it the power to proscribe private, noncommercial acts of conception between consenting adults accomplished through artificial insemination in the privacy of the home—in violation of their constitutional rights.

5. These FDA regulations are unconstitutional, facially and as applied to Ms. Doe, to the extent that they operate to regulate noncommercial, sexually intimate choices and activity protected by the rights to privacy, bodily integrity and autonomy, liberty, life, due process, and equal protection guaranteed by the First, Fifth, Ninth, and Tenth Amendments to the United States Constitution.

Jurisdiction

6. This case, arising under the Constitution and laws of the United States, presents a federal question. This Court has jurisdiction under 28 U.S.C. § 1331.

7. Plaintiff's right to judicial review of the actions complained of is secured by the First, Fifth, Ninth, and Tenth Amendments to the U.S. Constitution; Article I, Section 8 of the U.S. Constitution; and the Administrative Procedure Act (APA), 5 U.S.C. §§ 702 and 704.

8. Plaintiff's claims for declaratory and injunctive relief are authorized by 28 U.S.C. §§ 2201 and 2202, by Rules 57 and 65 of the Federal Rules of Civil Procedure, and by the general legal and equitable powers of this Court.

Venue

9. Venue is proper under 28 U.S.C. § 1391(e) because the Defendants are officers or employees of the United States, Plaintiff Jane Doe resides in this district, and no real property is involved in this action.

Intradistrict Assignment

10. This action is assigned to the San Francisco Division.

Parties

11. JANE DOE is a woman residing in the City of Oakland, Alameda County, California. She wishes to become pregnant via artificial insemination with semen donated on an uncompensated basis by a private individual, without a medical intermediary such as a semen bank or medical professional. Ms. Doe has attempted to become pregnant through this means in the past and intends to do so in the future. FDA regulations applying to uncompensated donations of semen by private individuals directly to other private individuals deprive Ms. Doe of access to the reproductive method of her choice and burden her procreative liberty.

12. MARGARET A. HAMBURG, M.D., is the Commissioner of the FDA and is charged with supervising the activities of the FDA. Defendant HAMBURG is being sued in her official capacity. FDA is an agency within the U.S. Department of Health and Human Services and is thus an "agency" within the meaning of the APA.

13. KATHLEEN SEBELIUS is Secretary of the U.S. Department of Health and Human Services (DHHS), an agency of the federal government and an "agency" within the meaning of the APA. Defendant SEBELIUS is being sued in her official capacity.

Statement of Facts

The Plaintiff

14. Plaintiff Jane Doe is a woman in a committed, long-term, monogamous relationship with her female partner. Ms. Doe does not have sexual intercourse with male partners.

15. Ms. Doe wants to, and is trying to, conceive a child.

16. Ms. Doe prefers to conceive via intracervical insemination of fresh donor sperm, as it is her understanding that she is more likely to become pregnant if she uses fresh donor sperm.

17. Ms. Doe does not want to pay money to a traditional semen bank, medical personnel, a sperm donor, or any other commercial establishment as a condition of conception. Ms. Doe also wishes to avoid using a traditional semen bank because of limitations on donor selection and because such semen donations are often anonymous and very expensive.

18. Instead, Ms. Doe wishes to conceive a child in the privacy of her own home using semen donated by someone she knows, who wants to be the biological father of her child. Ms. Doe wants to conceive a child and start a family on her own terms without government involvement.

19. Ms. Doe decided to become pregnant using fresh semen provided by an individual known to her, Mr. Trent C. Arsenault (hereinafter "Mr. Arsenault"). Mr. Arsenault has also donated semen privately and without compensation to other women who wanted to become pregnant via artificial insemination.

20. On or about August 10, 2010, Ms. Doe contacted Mr. Arsenault about donating his semen without compensation for the purpose of artificial insemination. She extensively reviewed substantial information about Mr. Arsenault and his personal and medical history, including the current and past results of tests for communicable diseases or infections.

21. Mr. Arsenault is a self-described virgin who does not have sexual intercourse and procreates only through artificial insemination.

22. Mr. Arsenault agreed that he would provide Ms. Doe with updates about his future health information and a potential line of contact in case her child desired more information about his or her biological male parent. It was important to both of them that Ms. Doe should be able to stay in contact with Mr. Arsenault to allow any child they were fortunate enough to bring into this world to form a long-term relationship with Mr. Arsenault if he or she wanted to do so.

23. Mr. Arsenault agreed that he would provide Ms. Doe with fresh semen to use for the purpose of artificial insemination, which he did, uncompensated, on a mutually agreed-upon date in a mutually agreed-upon manner.

24. Prior to their first act of conception, Mr. Arsenault and Ms. Doe formed an intimate bond and close friendship over the course of numerous conversations. Mr. Arsenault revealed many intimate, personal details of his life to Ms. Doe and discussed with Ms. Doe his medical history, his health, and his views on the role of a father who helps a woman in a same-sex relationship conceive a child and start a family with her partner.

25. The fresh semen that Mr. Arsenault donated to Ms. Doe enabled Ms. Doe to inseminate herself without engaging in sexual intercourse with him or any other male partner.

26. Ms. Doe inseminated herself with Mr. Arsenault's donated fresh semen in the privacy of her own home, without using medical devices and without assistance from a medical establishment or other commercial business, at a time and in a manner of her choosing. Ms. Doe consequently became pregnant.

27. Unfortunately, Ms. Doe's pregnancy was not carried to term.

28. However, barring doctor's orders to the contrary, Ms. Doe intends to attempt artificial insemination again with fresh semen from Mr. Arsenault.

29. Ms. Doe does not want to engage in sexual intercourse outside of her committed relationship. Ms. Doe does not want to be forced to engage in sexual intercourse with a male partner to conceive a child, even though such a male partner would not be subject to FDA-required screening and testing and other FDA-mandated donor-eligibility requirements.

30. Ms. Doe, after thoughtful screening, consideration, and agreement, has selected a male biological parent with whom she wishes to conceive a child and a method by which to conceive that child.

31. Ms. Doe's choices of conception partner and method of conception are directly barred by FDA regulations respecting artificial insemination and semen donation.

The Basics of Artificial Insemination

How Does Artificial Insemination Work?

32. For women seeking to conceive, purchasing vials of donated semen and/or artificial insemination services from a semen bank or medical practice incurs significant financial costs. Many donors to semen banks donate on an anonymous basis, or under conditions limiting access to information regarding their personal history or future contact with the mother or child.

33. Because of screening practices by semen banks, some combinations of personal traits present in the population are underrepresented or unavailable in the donor pool.

34. Ms. Doe prefers to obtain semen donations from men without a medical or institutional intermediary because semen banks and fertility clinics are prohibitively expensive and because of subjective preferences regarding donors' identity, personal information and characteristics, and specific commitments regarding continued contact or communication. These individual donors are not financially compensated for donating. These donors also do not comply with all 21 C.F.R. pt. 1271 regulations, including those concerning personal or genetic traits which may automatically exclude them from customary semen donation.

35. Insemination using gametes from a private, individual donor can be achieved through natural insemination, i.e., sexual intercourse between the donor and recipient, or through intracervical insemination (ICI), an artificial insemination method in which semen from a specimen cup is transferred to the recipient via a syringe. ICI can be accomplished by the recipient herself without medical assistance and is the method of choice for Ms. Doe. This is because natural insemination would require Ms. Doe to engage in heterosexual intercourse, which would be unconscionable for Ms. Doe on the grounds that she is a lesbian who only

engages in sexual intercourse with women. Furthermore, Ms. Doe is in a committed, monogamous relationship and does not wish to engage in sexual intercourse outside of that relationship.

36. Moreover, because natural insemination carries the potential risk of disease transmission from recipient to donor via both bodily fluids and skin-to-skin contact, in addition to the theoretical risk of transmission from donor to recipient present in ICI, private semen donation for artificial insemination poses less risk of communicable disease than private semen donation via natural insemination.

Regulatory and Statutory Requirements for Sperm Banks

37. Congress adopted the Public Health Service Act (PHSA) in 1944 to enable the creation and enforcement of regulations "necessary to prevent the introduction, transmission, or spread of communicable diseases" into or among the United States. 42 U.S.C. § 264.

38. Pursuant to the PHSA's authorization, the FDA created a number of regulations applicable to human cells, tissues, and tissue-based products (HCT/P's). Semen banks and other "establishments" that manufacture HCT/P's must comply with those regulations set out in 21 C.F.R. Part 1271, Subparts A, B, C, and F as well as a portion of Subpart D. *See* 21 C.F.R. §§ 1271.1, 1271.3. Part 1271 does not distinguish between commercial "establishments" that manufacture HCT/P's and those that are noncommercial in nature.

39. 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 fine of up to $1,000. *See* 42 U.S.C. § 271.

40. 21. C.F.R. pt. 1271 requires that each establishment register and list its HCT/P's with the Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER). The registrations must be frequently updated and made available for public inspection. 21 C.F.R. §§ 1271.21, 1271.25, 1271.37.

41. 21 C.F.R. pt. 1271 also requires establishments to create and use screening and testing procedures and apply them to prospective donors, as described in the FDA regulations and protocols. This requires that a donor provide extensive medical and lifestyle information and

be tested for a large number of genetic and communicable diseases. Donors must be tested using FDA-approved tests and on an FDA-approved schedule. The donated semen is typically cryogenically quarantined for a six-month period. *See* 21 C.F.R. §§ 1271.45(b)-(c), 1271.60, 1271.47, 1271.50.

42. After a semen bank or other establishment performs the testing and screening described above, it must retain records and interpretation of the test results, 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 that determination. These records must be maintained for at least ten years. 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. These records must accompany the sample if it is distributed or transported. 21 C.F.R § 1271.55(d)(1), (4); 21 C.F.R. § 1271.55(a).

Regulatory and Statutory Requirements for Known Donors

43. If the prospective donor is "known" to a particular prospective recipient (i.e., not anonymous), he cannot be disqualified by an establishment even if he would otherwise fail the screening process. For example, the FDA recommends exclusion of men who have had sexual relations with another man within the five years preceding the donation.

44. The testing, quarantine, registration, and recordkeeping requirements apply to donations from known donors to the same extent as donations from anonymous or other donors.

45. 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/P's with CBER. 21 C.F.R. § 1271.15(e). 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. 21 C.F.R. § 1271.90(a)(2).

46. Thus, many of the burdensome and costly FDA regulations do not apply if a donation comes from the recipient's sexually intimate partner (SIP).

47. There is no definition of SIP in 21 C.F.R. pt. 1271, its enabling statute, or the FDA's guidance statements.

The Sudden Enforcement of 21 C.F.R. pt. 1271 Against Private, Uncompensated Semen Donors

48. On November 1, 2010, CBER issued an Order to Cease Manufacturing ("Order") to a California man, Trent C. Arsenault. A true and correct copy of the Order is attached to Plaintiff's First Amended Complaint as Exhibit 1.

49. Mr. Arsenault is regularly tested for communicable diseases and posts the results of these tests, along with substantial information regarding his personal health and history, on a publicly-viewable website, trentdonor.org.

50. Mr. Arsenault is personally known to all women to whom he donates semen, including Ms. Doe, and has entered into agreements with them regarding mutually agreed-upon obligations regarding continued provision of personal and health information.

51. Mr. Arsenault does not meet all 21 C.F.R. pt. 1271 requirements for screening, testing, and recordkeeping applicable to establishments such as semen banks or small medical practices and to donations by individuals who are not SIPs of the recipient.

52. In the Order, CBER states that "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)."

53. The Order states that the FDA "inspection and record review … noted significant noncompliance with the federal regulations in numerous areas" of Mr. Arsenault's efforts to conceive children through artificial insemination and help women become pregnant and start families.

54. The Order accuses Mr. Arsenault of "significant violations of … Part 1271 issued under the Authority of Section 361 of the" PHSA and states that FDA has "the authority to pursue other actions and remedies."

55. The Order further states that:

> The agency has determined that because your Establishment is in violation of 21 C.F.R. Part 1271, your Establishment does not provide adequate protections against the risks of communicable disease transmission through the use of these HCT/Ps. 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. 1271.440(a)(3), you must cease manufacturing until compliance with the regulations in 21 C.F.R. 1271 has been achieved and you have been provided written authorization from FDA to resume operations. Under 21 C.F.R. 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.

56. The Order operates to prohibit Mr. Arsenault from conceiving children via artificial insemination with women who are not his "sexually intimate partners" (as that term is interpreted by the FDA) until he has achieved full compliance with 21 C.F.R. Part 1271 and has "been provided written authorization from FDA to resume operations."

57. The FDA posted the Order prominently on its website and has publicly stated that "FDA regulatory requirements do not vary based on whether a sperm donation is free of charge. FDA regulates any establishment that performs any of these manufacturing steps: recovery, processing, storage, labeling, packaging, distribution, or screening of sperm."

58. Mr. Arsenault contends that he falls within the SIP exception to 21 C.F.R. pt. 1271's regulatory requirements. On November 1, 2010, he requested an administrative hearing from the FDA to challenge the Order.

59. After Mr. Arsenault requested a hearing, CBER filed a brief in opposition, which explicitly stated that the "FDA cannot accept an expanded definition of the term 'sexually intimate partner.'" Instead, CBER took the position that prior exposure to the donating partner's bodily fluids is the *sine qua non* of a sexually intimate partnership.

60. On December 7, 2012, two years after Mr. Arsenault first requested a hearing to challenge the Order, Mr. Jesse Goodman, "[p]ursuant to the authority delegated to [him] by the Commissioner" and acting in his official capacity as "Chief Scientist," issued the Commissioner's Decision: Regulatory Hearing on the Order to Trent Arsenault to Cease Manufacturing (hereinafter "Commissioner's Decision"). A true and correct copy of the Commissioner's Decision is attached to Plaintiff's First Amended Complaint as Exhibit 2.

61. The Commissioner's Decision "grant[ed] CBER's motion to deny Mr. Arsenault's request for a hearing" and "issued … [a] summary decision in favor of CBER."

62. The Commissioner's Decision asserts that Mr. Arsenault had "failed to determine" whether he was "eligibl[e]" to conceive children with consenting adult women by freely donating his semen on a noncommercial basis.

63. The Commissioner's Decision states that Mr. Arsenault did not maintain a proper "summary of records that were used to make the donor eligibility determination, as required" by FDA regulations.

64. The Commissioner's Decision explained that "FDA regulations exempt sexually intimate partners from donor eligibility requirements" because of the FDA's "reasonable and common sense understanding" that individuals the FDA in its discretion deems as "sexually intimate partners" do not need to be protected from "communicable disease risks" to which they "*already* have been exposed" and thus an express regulatory definition of the term "sexually intimate partners" is not required.

65. The Commissioner's Decision states that the rationale for the SIP exception from FDA donor-eligibility requirements is that the mother "'will likely have been routinely exposed to the donor's semen or other bodily fluids….'"

66. The Commissioner's Decision concluded that Mr. Arsenault was a "directed reproductive donor," instead of a "sexually intimate partner," to women like Ms. Doe, explaining that this was because he helped women he "knows and is known by" to become pregnant without having a "sexually intimate partner[ship]" with them that was consistent with the FDA's

understanding of that undefined term.

67. The Commissioner's Decision flatly rejected the notion that Mr. Arsenault has a fundamental constitutional right to conceive children and help women to start families through an act of conception that violates FDA regulations:

> Mr. Arsenault contends that the Cease Manufacturing Order violates his due process rights … [and] infring[es] … his fundamental Constitutional rights to reproduce and to define his own intimate relationships as he sees fit…. Mr. Arsenault therefore appears to assert that he has a Constitutional right to transfer his sperm to others for artificial insemination without adhering to … [FDA regulations]. I disagree that he has a right to violate the applicable FDA regulations ….

68. The Commissioner's Decision states that "[t]he Constitution does not obligate FDA to hold an oral evidentiary hearing" before prohibiting Mr. Arsenault from procreating via a method of artificial insemination that the FDA determines violates its regulations.

69. The Commissioner's Decision reaffirms the FDA's position that it has the power, consistent with the United States Constitution, to promulgate regulations that proscribe private, consensual, noncommercial procreative conduct and enforce those regulations, concluding that "the Cease Manufacturing Order was properly issued."

70. The Commissioner's Decision states that "[s]hould Mr. Arsenault wish to" help women he has a preexisting relationship with who are not his "sexually intimate partners" (as that term is interpreted by the FDA) consensually conceive children via artificial insemination, "he may do so only after obtaining written authorization from FDA," as required by FDA regulations, and after achieving full compliance with FDA's screening, testing, recordkeeping, and other requirements.

71. The Commissioner's Decision states that "the purpose of this proceeding and Part 1271 generally is simply to protect" women who want to conceive children with Mr. Arsenault via artificial insemination without having sexual intercourse with him "from communicable disease" and invoked "the public health interest in protecting *recipients* of his semen from communicable disease."

72. The Commissioner's Decision states that "[t]he Cease Manufacturing Order is … effective as of … [December 7, 2012], in accordance with 21 CFR 1271.440(a)(3)(ii)."

73. The Commissioner's Decision is a final agency action under 5 U.S.C. § 704. All of Mr. Arsenault's administrative remedies regarding the Order have been exhausted.

74. In her September 28, 2012, declaration (hereinafter "Malarkey Declaration"), Ms. Mary A. Malarkey, Director of the Office of Compliance and Biologics Quality (OCBQ) for the FDA's CBER, stated that "[i]n the context of semen donations made by individual donors that may violate 21 C.F.R. Part 1271, FDA intends to pursue only those violations that FDA deems to present the greatest risk to public health."

75. The FDA explained in promulgating Part 1271 that "under section 368(a) of the PHS Act (42 U.S.C. 271), any person who violates [21 C.F.R. Part 1271] . . . may be punished by imprisonment for up to 1 year." 68 Fed. Reg. 68,612, 68,614 (Nov 24, 2004).

76. The FDA's Compliance Program Guidance Manual, Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) 7341.002, Part V—Regulatory/Administrative Strategy states that "[i]t is Agency policy to consider prosecution of individuals [for violations of Part 1271] when there is documented evidence of … gross violations, a hazard to health and/or continuing significant violations."

77. An August 2007 FDA guidance document, "Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) Small Entity Compliance Guide," states that "FDA may pursue prosecution for gross, flagrant or intentional violations, … danger to health, or a continued or repeated course of violative conduct."

78. Upon information and belief, because the FDA has determined that Mr. Arsenault is a clear threat to public health who has committed gross and flagrant violations of their regulations and because violation of the Order could reasonably be considered a continued or repeated course of violative conduct, there is a substantial risk that Mr. Arsenault would be referred by FDA for criminal prosecution if he were to attempt to conceive a child with Mr. Doe using their chosen method of procreation.

79. A Memorandum of Points and Authorities in support of a Motion to Dismiss Complaint that was filed in this action on behalf of the FDA on October 1, 2012, and subsequently withdrawn, states that the enforcement action against Mr. Arsenault was "on facts that presented a clear public health risk…."

80. Even though Ms. Doe wants to have children with Mr. Arsenault using their chosen method of procreation, Mr. Arsenault, her chosen donor, has been prohibited from conceiving a child with her in the manner of their choosing because the FDA has determined that doing so is illegal under its regulations, violation of which is a federal crime.

81. Upon information and belief, the FDA has not applied 21 C.F.R. pt. 1271 to private, individual semen donors who help women to become pregnant via natural insemination.

Ms. Doe Has a Fundamental Right to Procreative Choice

82. The Due Process Clause of the Fifth Amendment protects unenumerated, substantive rights and liberties against federal-government intrusion. The Ninth Amendment also provides protection under its express injunction that "[t]he enumeration in the Constitution of certain rights shall not be construed to deny or disparage others retained by the people." U.S. CONST. amend. IX. To receive constitutional protection, an unenumerated right must have roots in "our Nation's history, legal traditions, and practices."

83. The right to privacy is a fundamental right, anchored in the First, Fourth, Fifth, and Ninth Amendments. *Griswold v. Connecticut*, 381 U.S. 479, 485-486 (1965).

84. The right to procreate is a fundamental right frequently described as arising out of the right to privacy. *Gerber v. Hickman*, 291 F.3d 617, 621 (9th Cir. 2002). The right to procreate includes the right to procreate via artificial insemination. Infringements on fundamental rights call for strict scrutiny of the means by which the federal government exercises its enumerated powers.

85. Unless doing so is necessary to achieve a compelling government purpose, the government cannot, consistent with the Constitution, abridge the procreative rights of Ms. Doe.

86. Ms. Doe is entitled to heightened protection against Defendants' interference with her exercise of her fundamental rights and liberty interests. The Constitution does not allow Congress to authorize Defendants to deny, or disparage the activities for which Ms. Doe seeks protection herein.

87. Ms. Doe seeks protection for noncommercial, wholly-intrastate reproductive conduct and, *inter alia*, does not want to be forced to choose between engaging in commercial activity and violating her sexuality as a condition of conceiving a child with the person of her choice. Noncommercial, wholly-intrastate activity is beyond the power of Congress "to regulate Commerce . . . among the several States." U.S. CONST. Art. I, sec. 8; *see* The Federalist 42 (J. Madison) (referring to the power "to regulate between State and State"). To the extent that Section 361 of the PHSA purports to grant Defendants the authority to conduct the activities complained of herein, such Act exceeds the authority granted to Congress under the Commerce Clause.

Injury to Ms. Doe

88. The reproductive rights of individual men, like Mr. Arsenault, who donate semen for artificial insemination on an uncompensated and private basis are inextricably entwined with the reproductive rights of women, such as Ms. Doe, who intend to conceive children with them.

89. Ms. Doe intends to conceive a child via ICI artificial insemination performed without a medical intermediary, using semen donated directly to her for that purpose by an uncompensated individual whom she has selected, Mr. Arsenault, in a manner that directly violates numerous regulations set forth in 21 C.F.R. pt. 1271.

90. Ms. Doe harbors a good-faith belief that the identification of a private, individual donor; the in-person meetings between the donor and recipient; the creation of a mutually-reached agreement regarding the donor's and recipient's obligations; and the conception process, which may involve coordination of fertility cycles with donations and artificial insemination attempts, constitute a sexually intimate partnership between herself and the individual donor.

91. Ms. Doe further harbors a good-faith belief that the process of screening,

considering, selecting, and agreeing with an uncompensated donor on a sperm donation with the intent of conceiving a child, and the subsequent conception process, constitutes an intimate association between herself and the individual she has selected as the biological father of her desired children, Mr. Arsenault.

92. Ms. Doe reasonably fears that the application of 21 C.F.R. pt. 1271 to private, uncompensated semen donation, with the potential for criminal penalties for violators, will prevent her from conceiving with Mr. Arsenault in the manner she has chosen.

93. This fear is not imaginary or speculative, because the FDA has already issued an Order requiring Mr. Arsenault, the uncompensated private semen donor chosen by Ms. Doe, to comply with 21 C.F.R. pt. 1271 and carrying criminal penalties for its violation.

94. The FDA's application of 21 C.F.R. pt. 1271 to private, uncompensated individual semen donation causes irreparable economic and noneconomic harms to women, like Ms. Doe, attempting to conceive who choose to do so via an uncompensated private donor, like Mr. Arsenault, without paying a semen bank or medical practice for semen or ICI procedures.

95. Ms. Doe has suffered and continues to suffer an injury-in-fact from FDA regulations, codified at 21 C.F.R. pt. 1271, requiring private, uncompensated, individual semen donors to comply with a panoply of expensive and burdensome requirements and limitations and exposing noncompliant individual semen donors, like Mr. Arsenault, to criminal liability, because this prevents her from lawfully conceiving a child using the method of procreation she has chosen.

96. Ms. Doe is injured by FDA regulations set forth in 21 C.F.R. pt. 1271, facially and as applied and enforced by the Order, because they directly prohibit her and Mr. Arsenault from conceiving a child together using their chosen method of procreation.

97. But for the FDA's position that Ms. Doe's chosen method of conception with her choice of a father for her child, Mr. Arsenault, is unlawful, Ms. Doe specifically intends to procreate with Mr. Arsenault in the same manner that the FDA has concluded is a violation of Part 1271 and a potential federal crime. If it is lawful to do so, Ms. Doe will ask Mr. Arsenault to

provide her with fresh semen on an uncompensated basis and attempt to conceive a child using that semen in the privacy of her home.

CLAIMS FOR RELIEF

Count One: Due Process

98. Plaintiff hereby incorporates by reference paragraphs 1 through 97 above.

99. Under the Due Process Clause of the Fifth Amendment, Ms. Doe has a fundamental, substantive, privacy-based right to procreate with the person of her choice using the method of her choice, free from governmental intrusion and regulation.

100. The government cannot prescribe regulations that burden Ms. Doe's fundamental right to procreate unless doing so is necessary to achieve an overriding government purpose.

101. By prohibiting or severely restricting individual donors from freely donating semen for artificial insemination to consenting adult women even though doing so is not necessary to achieve a compelling government purpose, 21 C.F.R. pt. 1271 impermissibly burdens the procreative liberty of Ms. Doe and Mr. Arsenault.

102. 21 C.F.R. pt. 1271, facially and as applied, unconstitutionally infringes Ms. Doe's and Mr. Arsenault's rights to privacy, bodily integrity and autonomy, procreative liberty, and due process in violation of the Due Process Clause of the Fifth Amendment.

103. The Order and Commissioner's Decision violate Ms. Doe's and Mr. Arsenault's fundamental rights to privacy, bodily integrity and autonomy, procreative liberty, and procedural and substantive due process in violation of the Due Process Clause of the Fifth Amendment.

Count Two: Equal Protection

104. Plaintiff hereby incorporates by reference paragraphs 1 through 103 above.

105. Private, individual semen donors who help women to become pregnant using artificial insemination and those who help women to become pregnant using natural insemination are alike in all relevant respects. Separating private, individual semen donors on this basis is not reasonably related to any legitimate government interest and has no rational basis.

106. By applying 21 C.F.R. pt. 1271 to private, individual donors who provide semen

for artificial insemination but not to private, individual donors who distribute semen via natural insemination, the FDA acts arbitrarily, capriciously, and irrationally by enforcing the regulations against individuals who engage in conduct that by definition poses a lesser risk of communicable disease but not against similarly-situated individuals whose behavior poses a greater risk.

107. By forcing private, individual, uncompensated donors of semen for artificial insemination to comply with the registration, screening, testing, and record-keeping requirements of 21 C.F.R. pt. 1271 for no legitimate, substantial, or compelling purpose, the FDA violates the right of these donors, like Mr. Arsenault, and those women who choose to attempt to conceive a child with them, like Ms. Doe.

108. By imposing a costly and extensive set of regulatory requirements on men who seek to donate their semen without compensation for artificial insemination to women with whom they enter into a direct and private agreement, the FDA burdens the procreative liberty of Ms. Doe, thus violating her rights to privacy and liberty.

109. 21 C.F.R. pt. 1271, facially and as implemented and enforced by the Order and Commissioner's Decision and applied to Ms. Doe and Mr. Arsenault, thus arbitrarily and irrationally interferes with their rights to privacy, bodily integrity and autonomy, liberty, due process, and equal protection guaranteed by the Fifth Amendment to the United States Constitution.

Count Three: Intimate Association

110. Plaintiff hereby incorporates by reference paragraphs 1 through 109 above.

111. By refusing to accept an expanded definition of sexually intimate partnership, the FDA has violated the First Amendment rights of intimate association of Ms. Doe and Mr. Arsenault.

112. By prohibiting or severely restricting individual donors from freely donating semen for artificial insemination to consenting adult women, the FDA has violated Ms. Doe's and Mr. Arsenault's Fifth Amendment-based substantive due process right to intimate association, which extends to child bearing and rearing.

Count Four: Commerce Clause

113. Plaintiff hereby incorporates by reference paragraphs 1 through 112 above.

114. The Commerce Clause, Article I, Section 8, of the U.S. Constitution provides that "Congress shall have Power … To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes…."

115. Application of 21 C.F.R. pt. 1271 to persons who donate semen for artificial insemination directly to other individuals on a private, uncompensated basis exceeds Congress's powers under Article I of the Constitution of the United States, and cannot be upheld under the Commerce Clause, U.S. CONST. art. I, § 8, or any other provision of the Constitution.

116. Defendants' actions to investigate, prosecute, punish, or seek civil or administrative sanctions against persons who donate semen for artificial insemination directly to other individuals on a private, uncompensated basis would violate the Commerce Clause as applied to Ms. Doe and Mr. Arsenault.

Count Five: Ninth Amendment

117. Plaintiff hereby incorporates by reference paragraphs 1 through 116 above.

118. The Ninth Amendment to the U.S. Constitution provides that "[t]he enumeration in the Constitution, of certain rights, shall not be construed to deny or disparage others retained by the people."

119. Defendants' actions to investigate, prosecute, punish, or seek civil or administrative sanctions against persons who donate semen for artificial insemination directly to other individuals on a private, uncompensated basis would violate the Ninth Amendment as applied to Ms. Doe and Mr. Arsenault.

Count Six: Tenth Amendment

120. Plaintiff hereby incorporates by reference paragraphs 1 through 119 above.

121. The Tenth Amendment to the U.S. Constitution provides that "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

122. Defendants' actions to investigate, prosecute, punish, or seek civil or administrative sanctions against persons who donate semen for artificial insemination directly to other individuals on a private, uncompensated basis would violate the Tenth Amendment as applied to Ms. Doe and Mr. Arsenault.

Count Seven: Administrative Procedure Act and the PHSA

123. Plaintiff hereby incorporates by reference paragraphs 1 through 122 above.

124. Because the PHSA does not give Defendants the authority to regulate or proscribe private, noncommercial acts of conception accomplished by consenting adults through artificial insemination in the privacy of their homes, 21 C.F.R. pt. 1271's regulation of those acts is in excess of Defendants' statutory jurisdiction, authority, and limitations and short of statutory right under the PHSA in violation of 5 U.S.C. § 706(2) and contrary to its plain language.

125. In violation of 5 U.S.C. § 706(2), 21 C.F.R. pt. 1271's regulation of private, noncommercial acts of conception accomplished by consenting adults through artificial insemination in the privacy of their homes is contrary to constitutional right, power, privilege, or immunity; and it is arbitrary, capricious, an abuse of discretion, and otherwise not in accordance with law.

Count Eight: Administrative Procedure Act

126. Plaintiff hereby incorporates by reference paragraphs 1 through 125 above.

127. The Order and Commissioner's Decision violate 5 U.S.C. § 706(2) because they are arbitrary and capricious; in excess of statutory authority, jurisdiction, and limitations and short of statutory right; an abuse of discretion; without observance of procedure required by law; otherwise not in accordance with law; and contrary to constitutional right, power, privilege, or immunity.

WHEREFORE, Ms. Doe respectfully requests that this Court grant the following relief:

A. Issue a preliminary injunction during the pendency of this action and a permanent injunction enjoining Defendants and their successors and all persons and entities in active concert or participation with Defendants and their successors from enforcing 21 C.F.R.

pt. 1271 to prevent individuals from donating semen for artificial insemination directly to other individuals on a private, uncompensated basis.

B. Declare that 21 C.F.R. pt. 1271 is unconstitutional to the extent it purports to prevent individuals from donating semen for artificial insemination directly to other individuals on a private, uncompensated basis.

C. Declare that 21 C.F.R. pt. 1271 is in excess of the FDA's statutory authority under the PHSA and violates the APA to the extent it purports to prevent individuals from donating semen for artificial insemination directly to other individuals on a private, uncompensated basis.

D. Declare that the Order and Commissioner's Decision are unconstitutional under the Fifth Amendment; arbitrary and capricious, an abuse of discretion, or otherwise not in accordance with law in violation of the APA; contrary to constitutional right, power, privilege, or immunity in violation of the APA; and in excess of statutory jurisdiction, authority, or limitations, or short of statutory right in violation of the APA.

E. Vacate, set aside, and hold unlawful the Order and Commissioner's Decision.

F. Grant Plaintiff such other and further relief as the Court deems just and proper.

Dated: January 11, 2013

Respectfully submitted,

/s/ Amber D. Abbasi
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