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JANE DOE

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA

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. _____ Date: Time: Court:

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. In doing so, it violates the rights of the Plaintiff, other similarly situated women, and men from whom they seek freely donated gametes.

5. These FDA regulations are unconstitutional 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. This Court may award costs and attorneys' fees pursuant to 28 U.S.C. § 2412.

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. Intradistrict assignment to the Oakland Division is proper pursuant to N.D. Cal. Civ. Local Rule 3-2 because a substantial part of the events that give rise to the claims asserted here occurred in Alameda County, California.

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.

17. Because she feels that it is important for her child to be able to know the identity and health status of his or her male biological parent and develop a relationship with that person if he or she wishes to do so, Ms. DOE has decided to become pregnant using fresh semen provided by an individual known to her.

18. Ms. DOE contacted a male individual about donating his semen without compensation for the purpose of artificial insemination. She extensively reviewed substantial information about this individual and his personal and medical history, including the current and past results of tests for communicable diseases or infections. This individual 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.

19. This individual 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.

20. The donation enabled Ms. DOE to inseminate herself without engaging in sexual intercourse with this individual or any other male partner.

21. Ms. DOE did in fact inseminate herself with this individual's donated fresh semen and became pregnant.

22. Unfortunately, the pregnancy was not carried to term.

23. However, barring doctor's orders to the contrary, Ms. DOE intends to attempt artificial insemination again with fresh semen from an individual known to her who donates on this basis.

24. 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.

25. Ms. DOE does not want to be forced to use a medical intermediary, such as a medical professional or a semen bank, due to its limitations on donor selection and because such semen donations are often anonymous and very expensive.

26. Ms. DOE, after thoughtful screening, consideration, and agreement, has selected a male biological parent for her child and a method by which to conceive that child.

27. Even though she wishes to conceive a child without the involvement of a medical intermediary or through a semen bank, 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?

28. 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.

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

30. Ms. DOE and women similarly situated to herself prefer 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.

31. 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 and other similarly situated women 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.

32. 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

33. 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.

34. 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 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.

35. 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.

36. 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.

37. 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.

38. 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

39. 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.

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

41. 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).

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

43. 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

44. On November 1, 2010, CBER issued an Order to Cease Manufacturing ("Order") to a California man, Trent C. Arsenault, an individual who donated semen privately and without compensation to women seeking to become pregnant via ICI.

45. 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.

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

47. 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.

48. In the Order, CBER stated 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)."

49. The Order further stated 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.

50. 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."

51. Arsenault contends that he falls within the SIP exception to 21 C.F.R. pt. 1271's regulatory requirements.

52. After Arsenault requested a hearing to challenge the Order, CBER filed a brief in opposition, which explicitly stated that the "FDA cannot accept an expanded definition of the term 'sexually intimate partner'" and rejected Arsenault's characterization of his relationship with each recipient as a sexually intimate partnership.

53. In that brief, CBER also declared that by applying 21 C.F.R. pt. 1271 to Arsenault's private, uncompensated individual semen donation for artificial insemination, the FDA "is protecting [non-traditional] 'families' from communicable diseases."

54. CBER's brief further cites the preamble to the proposed rule on HCT/P's as support for the proposition that prior exposure to the donating partner's bodily fluids is the *sine qua non* of sexually intimate partnerships.

55. 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

56. 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."

57. The right to procreate is a fundamental right. *Gerber v. Hickman,* 291 F.3d 617, 621 (9th Cir. 2002). Infringements on fundamental liberties call for strict scrutiny of the means by which the federal government exercises its enumerated powers. 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.

58. Ms. DOE is entitled to heightened protection against Defendants' interference with Ms. DOE's 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.

59. Ms. DOE seeks protection for conduct that has no effect whatsoever on interstate commerce; indeed, Ms. DOE's reproductive conduct is not commercial at all. Wholly intrastate, noncommercial 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 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

60. The reproductive rights of individual men 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 a child with them.

61. 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 who she has selected, in a manner that directly violates numerous regulations set forth in 21 C.F.R. pt. 1271.

62. 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, constitutes a sexually intimate partnership between herself and the individual she has selected as the biological father of her desired children.

63. 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.

64. 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, may prevent her from becoming pregnant with the individual and in the manner she has chosen.

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

66. 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, without paying a semen bank or medical practice for semen or ICI procedures.

67. 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 to criminal liability, due to the consequential restriction of her ability to conceive in the manner mutually agreeable to the intended biological father and herself.

68. Ms. DOE is injured by FDA regulations set forth in 21 C.F.R. pt. 1271 because those regulations directly prohibit her chosen method of procreation.

69. Ms. DOE is further injured because she can be charged with a federal crime and exposed to criminal penalties if she aids, abets, encourages, facilitates, or assists a private, uncompensated semen donor in violating any regulation in 21 C.F.R. pt. 1271.

70. Ms. DOE is irreparably harmed and continues to be irreparably harmed by an objectively reasonable fear that the FDA will enforce 21 C.F.R. pt. 1271 against private, uncompensated individual semen donors in a manner that prevents her from procreating with the partner and in the manner of her choice.

CLAIMS FOR RELIEF

Count One: Due Process

71. Plaintiff hereby incorporates by reference paragraphs 1 through 70 above.

72. 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.

73. 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.

74. 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, other similarly situated women, and male donors with whom they seek to conceive children.

75. 21 C.F.R. pt. 1271 unconstitutionally infringes Ms. DOE's, other similarly situated women's, and individual male donors' rights to privacy, bodily integrity and autonomy, procreative liberty, and due process in violation of the Due Process Clause of the Fifth Amendment.

Count Two: Equal Protection

76. Plaintiff hereby incorporates by reference paragraphs 1 through 75 above.

77. 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 in all relevant respects alike. Separating private individual semen donors on this basis is not reasonably related to any legitimate government interest and has no rational basis.

78. 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 less risk of communicable disease but not against similarly situated individuals whose behavior poses a greater risk.

79. 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 and those women who choose to attempt to conceive a child with them.

80. 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.

81. 21 C.F.R. pt. 1271 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

82. Plaintiff hereby incorporates by reference paragraphs 1 through 81 above.

83. 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, other

similarly situated women, and willing male donors with whom they have chosen to conceive children via artificial insemination.

84. 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 Fifth Amendment-based substantive due process right to intimate association, which extends to child bearing and rearing.

Count Four: Commerce Clause

85. Plaintiff hereby incorporates by reference paragraphs 1 through 84 above.

86. 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 . . . . "

87. 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.

88. 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.

Count Five: Ninth Amendment

89. Plaintiff hereby incorporates by reference paragraphs 1 through 88 above.

90. 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."

91. 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.

Count Six: Tenth Amendment

92. Plaintiff hereby incorporates by reference paragraphs 1 through 91 above.

93. 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."

94. 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.

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 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. Award Plaintiff her reasonable attorneys' fees and costs.

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

Dated:

Respectfully submitted,

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