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

JANE DOE 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) **PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES** Date: December 21, 2012 Time: 1:30 PM Place: Courtroom 5, 17th Floor 450 Golden Gate Avenue San Francisco, CA 94102 Judge: Hon. Edward M. Chen

Pursuant to Civil L.R. 7-3 and Civil L.R. 7-4, Plaintiff Jane Doe, by and through undersigned counsel, hereby files Plaintiff's Opposition to Defendants' Motion to Dismiss the Complaint ("Opposition").

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STATEMENT OF ISSUES

Whether Doe has Article III and prudential standing to raise the claims asserted in Counts One through Six of her Complaint, and whether those claims are ripe for adjudication.

RELEVANT FACTS

The facts necessary to rule upon this case are adequately described in Doe's Complaint and her supporting Declaration. However, certain important facts are inaccurately represented in or omitted from the Defendants' Motion to Dismiss the Complaint and supporting Memorandum of Points and Authorities ("Mot. to Dismiss"). In describing the enforcement history of Part 1271, Defendants note that the U.S. Food and Drug Administration ("FDA") initiated enforcement action against a private semen donor, Trent Arsenault, for violations of Part 1271. Defendants allege that Arsenault "advertises his semen donation services," but fail to mention that these "services" are provided on a completely uncompensated basis. Contrary to Defendants' contention, Mot. to Dismiss 5, Doe also specifically alleged that her donor "directly violates numerous regulations set forth in 21 C.F.R. pt. 1271." Compl. ¶ 61; Doe Decl. ¶¶ 20, 25.[1]

ARGUMENT

I. Doe's Complaint presents a justiciable dispute over which this Court has subject matter jurisdiction.

Doe has presented a concrete dispute appropriate for judicial resolution. She does not seek an advisory opinion but relief from this Court from the present and looming threat posed by the FDA's prohibition of her freely chosen and private reproductive choices. It is appropriate for this Court to adjudicate her claims for violations of her rights to due process, equal protection,

[1] Moreover, given that there are factual disputes as to nature and extent of Doe's injury that are inextricably linked with the merits of Doe's claims, this Court "should resolve jurisdictional facts that are intertwined with the merits" either at the summary judgment stage or at trial, "not on a Rule 12(b)(1) motion…." *Careau Group v. United Farm Workers*, 940 F.2d 1291, 1293 (9th Cir. 1991); *see also SEC v. Indigenous Global Dev. Corp.*, 2007 U.S. Dist. LEXIS 27783, 11-12 (N.D. Cal. April 2, 2007).

and intimate association, and of the Commerce Clause and Ninth and Tenth Amendments to the U.S. Constitution.

Jurisdictional dismissal is warranted only "'where the alleged claim under the constitution or federal statutes clearly appears to be immaterial and made solely for the purpose of obtaining federal jurisdiction or where such claim is wholly insubstantial and frivolous.'" *Safe Air v. Meyer*, 373 F.3d 1035, 1039 (9th Cir. 2004) (quoting *Bell v. Hood*, 327 U.S. 678, 682-83 (1948)). At the pleading stage, "'general factual allegations of injury resulting from the defendant's conduct may suffice….'" *Oregon v. Legal Servs. Corp.*, 552 F.3d 965, 969 (9th Cir. 2009) (citations omitted), *abrogated on other grounds*. It is "'presume[d] that general allegations [in a plaintiff's complaint] embrace those specific facts that are necessary to support … [her] claim[s].'" *Id*. (citations omitted). Doe's complaint alleges the nature of her injuries in terms sufficient to embrace any additional facts that may be necessary to establish her standing.

A. Doe has established that she has standing in her own right.

Doe has Article III and prudential standing in her own right to bring the claims in her Complaint. "To qualify for standing, a claimant must present an injury that is concrete, particularized, and actual or imminent; fairly traceable to the defendant's challenged behavior; and likely to be redressed by a favorable ruling." *Davis v. FEC*, 554 U.S. 724, 733 (2008) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). Defendants do not argue that there is not a causal connection between the injury Doe alleges and the FDA's prohibition of private semen donation or that a favorable decision in this case would not redress that injury. Defendants instead contend that Doe has not suffered an injury-in-fact sufficient to confer Article III standing. *See* Mot. to Dismiss 6.

1. Doe has suffered and continues to suffer injury from the FDA's prohibition of her chosen reproductive method.

Doe has a fundamental right to procreate that is protected by the U.S. Constitution. This right is well established in both Supreme Court and Ninth Circuit case law. *See, e.g., Carey v. Population Servs. Int'l*, 431 U.S. 678, 695-96 (1977) (characterizing procreation as a

"fundamental right"); *Gerber v. Hickman*, 291 F.3d 617 (9th Cir. 2002) (en banc), *cert. denied* 2002 U.S. LEXIS 8634 (2002). Doe has chosen to exercise that right by inseminating herself with sperm obtained from a private donor who does not comply with the federal regulations outlined in Part 1271. She selected this donor herself, and their relationship was not mediated in any way by medical personnel and has no commercial element. Compl. ¶ 61; Doe Decl. ¶ 10-12. If she cannot conceive by this preferred method, the alternatives are either to purchase semen for artificial insemination from a Part-1271-compliant sperm bank for hundreds of dollars, or evade Part 1271 by engaging in sexual intercourse with her donor—counter to her sexual orientation. The crux of this case is whether requiring Doe's uncompensated donor of semen for artificial insemination to comply with the manifold regulations in Part 1271 infringes the exercise of her fundamental right to procreate. The FDA has "thwarted" her exercise of that right, *see Roe v. Wade*, 410 U.S. 113, 124 (1971), by legally prohibiting the wholly private and noncommercial actions of Doe and her donor. *Id*. at 124 (holding that a "'logical nexus between the status asserted and the claim sought to be adjudicated,' … and the necessary degree of contentiousness, are both present"). The FDA cannot evade a challenge to its burdening of reproductive rights by asserting that a law that bars a man from consensually conceiving a child with a willing woman somehow does not relate to her or infringe her rights.

Defendants incorrectly assert that Doe has fielded only "generalized and speculative allegations" about a statute that "may or may not ever be applied to" her. Mot. to Dismiss 7. On the contrary, Doe's injury is real, immediate, and direct. Although FDA states that "Part 1271 applies to manufacturers and distributors of HCT/Ps, rather than individual recipients like Doe," for a man to donate such that Part 1271 applies requires a recipient; her role is reciprocal and necessary. Her ongoing attempts to conceive are directly affected by enforcement of Part 1271 on donors because the regulatory requirements imposed, *see* Compl. ¶¶ 34-40, are financially and logistically impracticable for a private individual to comply with and bar the exact kind of arrangement Doe and her donor created to conceive a child. As noted in her Declaration, Doe currently seeks to become pregnant, which requires her to obtain gametes from a third party, and

to the extent medically advisable wishes to utilize ICI with semen from a private individual donor procured outside the FDA's regulated processes. Doe Decl. ¶¶ 4-9. The time and date of her future conduct are subject to the medical necessity of attempting fertilization at a time and in a manner most likely to lead to pregnancy,[2] but her desire to start a family in the manner of her choice is not a mere "'some day' intention," *Lujan*, 504 U.S. at 564; *compare McCormack v. Hiedeman*, 2012 U.S. Dist. LEXIS 10226, at *8 (9th Cir. September 11, 2012) (no standing for nonpregnant woman to challenge abortion-related statute because it was "inherently unknowable when (if ever) [Plaintiff] will become pregnant"), but an ongoing effort that is concretely and imminently endangered by the FDA's decision to enforce Part 1271 against private individual donors. *See San Diego County Gun Rights Comm. v. Reno*, 98 F.3d 1121, 1126 (9th Cir. 1996) (possibility of further harm, not just past injury, required for declaratory and injunctive relief).[3] If the FDA "coerced [Doe's donor] to comply with" Part 1271 by banning noncompliant donations, Doe would be unable to try to conceive with her chosen partner by her preferred method. *San Luis & Delta-Mendota Water Auth. v. Salazar,* 638 F.3d 1163, 1169-70 (9th Cir. 2011). Like the plaintiffs in *Jackson v. San Francisco*, Doe's constitutional rights are being burdened "*now*." 829 F. Supp. 2d 867, 872 (N.D. Cal. 2011) (gun owners alleged immediate and concrete injury from ban on keeping guns unlocked, even if the time they would use those guns for self-defense was

[2] Doe's Declaration provides specific dates of one of her previous attempts to conceive via semen from her private donor, ¶¶ 12-14. Part 1271 was effective during this time.

[3] An injury-in-fact may be suffered due to the anticipated operation of the challenged statute upon a person other than the plaintiff. For example, in *Davis v. FEC*, the Supreme Court evaluated the constitutionality of a statute granting favorable fundraising terms to the plaintiff's electoral opponent if the plaintiff spent more than a specified amount of personal funds on his campaign. 554 U.S. 724 (2008). The challenged provision operated on the plaintiff only indirectly, but he would suffer a disadvantage if he exercised his constitutionally-protected right. *See id.* The Court held that because Davis had declared his intention to make expenditures sufficient to trigger the law and no evidence existed to indicate that his opponent would forego the advantage, operation of the statute presented "a realistic and impending threat of direct injury" to Davis's rights and concluded that he had standing to challenge the law. *Id.* at 734-35 (citation omitted). Doe has declared her intention to attempt conception with her chosen donor in a manner violative of Part 1271, the FDA has not foregone its option to enforce Part 1271 against private semen donors, and enforcement of Part 1271 on private, uncompensated sperm donors poses just such a threat.

unknown). Moreover, as articulated in *Jackson*, the *Gun Rights Committee* plaintiffs alleged "that they 'wish and intend' to engaged in unspecified conduct prohibited by the Act." *Jackson v. San Francisco*, 829 F. Supp. 2d 867 at 871 (citing *Gun Rights Comm.,* 98 F.3d at 1124, 1127). Here, Doe has specified her planned course of action—which encompasses conduct prohibited by the FDA.

2. The justiciability of Doe's claims is properly evaluated under *Abbott*'s ripeness test, not the *Thomas* pre-enforcement analysis.

If, for the sake of argument, one accepts the position advanced in the Malarkey Declaration and Defendants' Motion to Dismiss, *see* Mot. to Dismiss 7 (citing *Thomas v. Anchorage Equal Rights Comm'n,* 220 F.3d 1134, 1138 (9th Cir. 2000) (*en banc*))—that Doe is not a potential target of prosecution—then the familiar pre-enforcement analysis articulated in *Thomas* should not apply. The Ninth Circuit recently held in *San Luis & Delta-Mendota Water Auth. v. Salazar*, that a plaintiff that was not an enforcement target of the challenged statute and that would actually benefit if the statute was violated by a third party was properly subject to the general ripeness criteria articulated in *Abbott*, not the *Thomas* test. 638 F.3d at 1173 (citing *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967)). Like the plaintiff in *San Luis*, Doe desires that the challenged law be violated; an enforcement action against Doe's donor for violations of Part 1271 means that she will have benefited—not been injured—because her chosen conception attempt will have occurred. *See id.* at 1173 (discussing how plaintiffs would benefit if water was released in violation of the law). Doe's circumstances differ sufficiently from those of the typical plaintiff in a pre-enforcement challenge such that her claims should be evaluated under the *Abbott* ripeness standard, which analyzes "the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Abbott Labs.,* 387 U.S. at 149. As discussed at greater length in section I.B below, Doe's claims are ripe.

3. Doe is in realistic danger of sustaining direct injury because the FDA poses a genuine threat of imminent prosecution.

However, even if the pre-enforcement analysis advanced by Defendants applies, Doe meets the criteria for standing. Doe must merely "demonstrat[e] a realistic danger of sustaining a direct injury as a result of the statute's operation or enforcement" by "alleg[ing] an intention to engage in a course of conduct arguably affected with a constitutional interest, but proscribed by a statute, and ... a credible threat of prosecution thereunder." *Lopez v. Candaele*, 630 F.3d 775, 785 (9th Cir. 2010) (quoting *Babbitt v. United Farm Workers Nat'l Union*, 442 U.S. 289, 298 (1979)). Doe meets each of these requirements. The FDA's recent position—that Part 1271 bars Doe's chosen male partner from giving a noncomplying donation, upon pain of civil or criminal sanctions—directly prevents Doe from receiving the donation she needs to conceive a child how and with whom she chooses.

As explained above, Doe has articulated a concrete plan to violate Part 1271. She has in the past and will in the future (at a time and in a manner medically appropriate to maximize chances of conception) obtain semen donated on an uncompensated basis by a private individual who does not comply with the regulations in Part 1271. Although Defendants imply that Doe's claims are not justiciable because "'it is impossible to know whether a party will ever be found to have violated a statute,'" Mot. to Dismiss 10 (quoting *Alaska Airlines v. City of Long Beach*, 951 F.2d 977, 986 (9th Cir. 1992)), they admit that the FDA "obtained" records from Trent Arsenault through a government inspection which contained the identities of some women to whom he has donated. Mot. to Dismiss 9, n.7. If the FDA continues to enforce Part 1271 against Arsenault and other private donors, it may be able to obtain additional records showing that Doe—or other women—have received semen donated without full compliance with Part 1271's regulatory requirements.

Where a genuine threat of government enforcement is present, the Supreme Court has stated that "we do not require a plaintiff to expose himself to liability before bringing suit to challenge the basis for the threat—for example, the constitutionality of a law threatened to be enforced." *Medimmune v. Genentech,* 549 U.S. 118, 128-29 (2007). Thus, Doe may vindicate her

rights in this Court even if she has not demonstrated that her donor is under an effective cease-manufacture order issued by the FDA.[4] Although the FDA asserts that it "intends to pursue only those violations that FDA deems to present the greatest risk to public health," *See* Declaration of Mary A. Malarkey In Support Of Defendants' Motion to Dismiss (hereinafter, "Malarkey Decl.") ¶ 5, it has not articulated any criteria that it will use in exercising this discretion.[5] All that is known is that Trent Arsenault, an uncompensated private donor who engages in systematic and frequent health testing (albeit testing that does not meet Part 1271's requirements) has apparently met these unvoiced FDA criteria. The threat of future FDA action against Doe's donor is a realistic and impending threat because Doe's donor does not comply with Part 1271. Doe Decl. ¶¶ 18-20, 24; *see Lopez v. Candaele*, 630 F.3d at 786-87 (history of past enforcement against similarly situated parties favors conclusion that a threat is specific and credible) (citing *Adult Video Ass'n v. Barr*, 960 F.2d 781, 785 (9th Cir. 1992)). The FDA's position is that a private, uncompensated man who donates semen may be subject to the requirements of Part 1271 just as is a fertility clinic or small medical practice.

The FDA's previous record of civil enforcement would weigh in favor of justiciability, even in the absence of a criminal enforcement record. *See Conant v. McCaffrey*, 2000 U.S. Dist. LEXIS 13024, 20-30 & n.3 (N.D. Cal. Sept. 7, 2000). The agency's record shows that FDA enforcement of Part 1271 is well-established beyond the cease-manufacture order issued to

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[4] Defendants challenge the factual basis for subject-matter jurisdiction in part on the ground that "FDA has not taken enforcement action and has not rendered a regulatory interpretation with respect to the circumstances of Doe or her intended donor." Mot. to Dismiss 10. However, this as a factual assertion is without basis, as Doe has not identified her donor.

[5] *Cf.* U.S. Food and Drug Admin., Guidance for Industry: Regulation of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps): Small Entity Compliance Guide 12, n.9 (2007) ("FDA may pursue prosecution for gross, flagrant or intentional violations, fraud, danger to health, or a continued or repeated course of violative conduct."); ("Sections 3559 and 3571(c) of Title 18, U.S.C., and section 368 of the PHS Act (42 U.S.C. 271) are the applicable statutes when pursuing prosecution for violating regulations promulgated under section 361 of the PHS Act. Under section 368(a) of the PHS Act, any individual who violates a regulation prescribed under section 361 of the PHS Act may be punished by imprisonment for up to 1 year. Additionally, individuals may be punished by a fine of up to $100,000 if death has not resulted from a violation of the regulations or up to $250,000 if death has resulted." *Id*.

Arsenault, with at least five additional cease-manufacture orders[6] and twenty-four warning letters[7] issued since 2001. If Arsenault—or Doe's donor—is sufficiently similar to the commercial enterprises against which Part 1271 has been repeatedly enforced to justify its application to his circumstances, then the enforcement record against these allegedly similar establishments should demonstrate the agency's commitment to vigorous policing of HCT/P donation.

In this case, the Complaint described a history of enforcement by showing that FDA has already begun to enforce Part 1271 against uncompensated semen donors. *See* Compl. ¶¶ 44-53. Doe has alleged that her donor violates FDA regulations in all of the ways for which the agency has targeted an uncompensated donor in a recent enforcement action, *compare* Compl. ¶¶ 18-26, 30, *with* Compl. ¶¶ 44-53, so according to FDA standards he would be as much a "clear public health risk" as the donor in FDA's previous enforcement action. *See* Mot. to Dismiss 2. The FDA's history of enforcement establishes a credible threat of enforcement.

First, FDA enforcement of Part 1271 against uncompensated sperm donors exposes Doe to a credible threat that she will be prosecuted for exercising her right to conceive a child with whom and how she chooses, despite the declaration presented by Defendants. *See* Malarkey Decl. The only indications that the FDA intends to limit its enforcement and target only donors are its own assurances,[8] in the form of a declaration prepared for this litigation.

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[6] *See Tissue Safety & Availability: Orders and Public Notifications*, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/TissueSafety/default.htm (last accessed Nov. 1, 2012).

[7] *FDA's Electronic Reading Room - Warning Letters*, U.S. FOOD AND DRUG ADMIN., http://www.accessdata.fda.gov/scripts/warningletters/wlSearchResult.cfm?webSearch=true&qryStr=21+CFR+1271 (last accessed Nov. 1, 2012).

[8] Although Defendants alludes once in passing to a vague assertion that FDA does not intend to pursue "minor violations," Mot. to Dismiss 4, this is inapposite as it specifically addressed a Commenter's concern over consumer alarm if FDA issued a recall or a destroy order. Current Good Tissue Practice for Human Cell, Tissue, and Cellular and Tissue-Based Product Establishments; Inspection and Enforcement, 69 Fed. Reg. 68612, 6864 (Nov. 24, 2004).

Ms. Malarkey's declaration on behalf of the FDA stating that the agency does not intend to take action against a recipient of a semen donation is not sufficient to allow the FDA to eliminate Doe's standing.[9] *See* Malarkey Decl. ¶¶ 6-7. Doe's belief that the FDA will undertake an enforcement action against her is reasonable in light of the facts that the FDA actually took an enforcement action with respect to Trent Arsenault, that enforcement options include civil and criminal liability, and that Doe could be deemed an accomplice to her donor's violation of Part 1271.[10] The FDA has articulated a policy of limiting their enforcement to exclude donees only once: in materials prepared for the litigation of this case. *Compare* Compl. (filed July 2, 2012), *with* Malarkey Decl. (executed September 28, 2012). Even where it is possible to disavow an interpretation of a statute that would make it applicable to the facts of the case, the Ninth Circuit has specified that a disavowal must not be a "mere litigation position." *Lopez v. Candaele,* 630 F.3d at 788. This Court should reject FDA's self-serving disavowal, made only after Doe brought suit.[11]

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[9] As another court in this circuit has recognized, a party may not avoid a declaratory judgment simply by declaring an intention not to bring suit when it could do so. *Photothera, Inc. v. Oron*, 2009 U.S. Dist. LEXIS 22709 *14-15 (S.D. Cal. Mar. 19, 2009); *see also SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007). In *Photothera*, a patent-holder directly assured the plaintiff that it would not bring suit, yet the plaintiff had standing and a ripe claim because "the requirements for declaratory judgment jurisdiction may be satisfied when a patent holder has made no indications that it will file suit but has taken positions or made demands such that a declaratory judgment plaintiff justifiably believes that the defendant patent holder might take such action in the future." *Id.*

[10] *See, e.g., Womens Servs., P.C. v. Thone*, 483 F. Supp. 1022, 1030 (D. Neb. 1979) (holding that, in challenge to abortion statute criminalizing doctors' conduct, a plaintiff that provided support services to doctors had standing on theory that "[a]ccomplice liability . . . [can] give[] rise to standing"), *aff'd* 636 F.2d 206 (8th Cir. 1980), *vacated on other grounds by* 452 U.S. 911 (1981); *cf. American-Arab Anti-Discrimination Comm. v. Thornburgh*, 970 F.2d 501, 508 (9th Cir. 1992) (governmental refusal to disavow future prosecutions was only "an attitudinal factor" and did not suffice to confer or deny standing).

[11] *San Luis & Delta-Mendota Water Auth. v. Salazar*, 638 F.3d 1163, 1170-1171 (9th Cir. Cal. 2011) (noting the "powerful coercive and determinative effect" of the agency's power to enforce regulations (internal quotation marks omitted)); *see also Thornburgh*, 970 F.2d at 508 (citing *Dombrowski v. Pfister*, 380 U.S. 479, 494 (1965)) ("So long as the statute remains available to the State the threat of prosecutions … is a real and substantial one).

Second, FDA's enforcement of Part 1271 against uncompensated sperm donors poses an imminent threat to Doe's rights. Her reproductive rights are infringed by the prospect of enforcement against her donor. *See Bennett v. Spear*, 520 U.S. 154, 169 (1997) ("[I]t does not suffice if the injury complained of is the result of the independent action of some third party … [but] that does not exclude injury produced by determinative or coercive effect upon the action of someone else." (internal quotation marks and citation omitted)); *San Luis,* 638 F.3d at 1170-171 (where the plaintiff's injury was caused by a potential enforcement target's compliance with a government mandate, "injury [was] produced by determinative or coercive effect upon the action of someone else."). An imminent threat to enforce the regulation that prevents her donor from giving a noncomplying donation simultaneously prevents Doe from receiving it and exercising her right to conceive a child how and with whom she chooses. These circumstances closely mirror those in such landmark cases as *Roe v. Wade*, 410 U.S. at 124-125, and *Doe v. Bolton*, 410 U.S. 179, 187-88 (1971) in which the burden to reproductive rights posed by looming legal sanctions against a third party whose participation was necessary to the exercise of those rights was recognized as sufficient to confer standing. *See infra* section I.D.

B. Doe has satisfied her burden of establishing prudential standing and ripeness.

Doe's claims of direct injury are ripe and prudential concerns do not preclude this Court's adjudication of her claims. She has demonstrated that (1) no further factual development is necessary to decide this case accurately, (2) it would not be an inappropriate interference with administrative action for this Court to decide whether FDA has abridged her constitutional rights, and (3) she would continue to suffer hardship from delayed review. *See Ohio Forestry Ass'n v. Sierra Club,* 523 U.S. 726, 733 (1998).

1. Doe's circumstances present a concrete factual situation, not an abstract disagreement.

No further factual development is needed to make this case justiciable. The issues for this Court are primarily legal and do not require extensive factual development. *See Gun Rights Comm.*, 98 F.3d at 1132 ("Pure legal questions that require little factual development are more

likely to be ripe."); *see also Abbott Labs.*, 387 U.S. at 149. The question of whether the FDA may constitutionally regulate the private reproductive behavior of two consenting individuals who wish to conceive a child without the involvement of medical professionals or commercial interests and in the privacy of the home is a question of law. Defendants confirmed that they believe that the FDA can regulate the manner in which private acts of conception can occur, Mot. to Dismiss 9; Doe contends that such regulation of noncommercial procreative conduct is unconstitutional.

Even if these issues were not primarily legal, the facts are fully developed, and a "concrete factual situation" has been presented to the Court for adjudication. *See Gun Rights Comm.,* 98 F.3d at 1132. In *Gun Rights Committee*, which the Defendants cite, the situation was not sufficiently "concrete" and more facts were needed because the plaintiffs never actually took any action, they only contemplated doing so. 98 F.3d at 1121.[12] Defendants also cite *Thomas*, but the plaintiffs in that case asserted their rights "contingent upon the occurrence of unforeseeable events"; they could not identify a couple to whom they would refuse to rent in violation of the statute, and such a couple might never appear. *Thomas*, 220 F.3d at 1141.

In contrast, Doe's donor has already supplied her with semen without complying with Part 1271, in violation of the FDA regulations; Doe has already attempted to become pregnant

[12] It is unclear if, in light of the Supreme Court's decision in *Medimmune v. Genentech*, *Gun Rights Comm.* remains good law. *Jackson v. San Francisco*, 829 F. Supp. 2d 867, 871 (N.D. Cal. 2011). The *Medimmune* Court held that, in actions for declaratory relief, subject matter jurisdiction is present if "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. 118, 127 (2007) (citations and internal quotation marks omitted). As Doe's Declaration and Complaint explained, her right to procreate is being burdened now by the FDA's decision to apply Part 1271 to conduct like her donor's. *See Jackson*, 829 F. Supp. 2d at 871-72 ("[E]ven to the extent that at least some aspects of *Gun Rights Committee* remain good law, it simply is distinguishable [where] Plaintiffs have not merely alleged that they "wish and intend" to violate the ordinances in some vague and unspecified way."). Even if the FDA elects not to take enforcement action against Doe or women like her, Doe's right to procreate is inextricably bound to that of the donor she chose to conceive with, and not only does the FDA reserve the right to initiate further enforcement action against donors, it does not articulate any substantive criteria that donors and recipients could use to determine whether they were potential enforcement targets.

using that semen; Doe and her donor have formed a concrete plan to continue to violate the regulation; the FDA has already enforced this regulation in a similar situation; and thus the FDA's threat of enforcement burdens Doe's constitutional rights. Compl. at ¶¶ 15-27, 30, 44-55, 71-94. This Court needs no further facts to decide the case.

2. A decision by this Court would not interfere with administrative action in any inappropriate way.

Adjudication of Doe's constitutional claims is ripe because it will not interfere inappropriately with FDA administrative action. This case differs in certain crucial respects from *American-Arab Anti-Discrimination Comm. v. Thornburgh*, in which the agency had not had an opportunity to interpret the challenged provisions and it was factually unclear whether any of the Committee's members were also actually members of another organization that advocated communism in violation of the challenged act. 970 F.2d 501, 511 (9th Cir. 1992).

Here, the agency has already implemented the regulation in question. Doe has alleged all of the facts necessary to allay any uncertainty over whether and how her rights are abridged by the FDA's implementation of the regulation in question. It is not an inappropriate interference with administrative action for the court to review the constitutionality of a regulation that has harmed Doe.[13]

3. Doe will suffer hardship in the absence of review.

Because Doe's quest to become pregnant and start a family is ongoing, she will be substantially burdened by delayed review. Doe's challenge is unlike those deemed unripe in *Gun Rights Committee* and *Thomas*. In the former case, the court relied heavily on the fact that the plaintiffs had never committed an affirmative act in violation of the law. *See* 98 F.3d 1121. The

[13] Although administrative proceedings are ongoing with respect to Trent Arsenault's challenge to the November 1, 2010 cease-manufacture order, the agency has not yet ruled on his request for a hearing, even though the last brief was filed on November 7, 2011. This apparently endless gestation, coupled with the unsuitability of constitutional questions for agency resolution, *see Barron v. Ashcroft*, 358 F.3d 674, 678 (9th Cir. 2004); *cf. Morgan v. Gonzales*, 495 F.3d 1084, 1089 (9th Cir. 2007), indicates that this Court is the proper forum to assess the constitutionality of applying Part 1271 to private, noncommercial semen donation.

Ninth Circuit's rationale in *Thomas* was that no "threat of enforcement" existed because the landlords could not identify an unmarried couple against whom they had actually discriminated; they had committed no act of a kind prohibited by the challenged law. *Thomas*, 220 F.3d at 1141-42. And, as the Ninth Circuit subsequently held, "[o]ur ruling in Thomas did not purport to overrule years of Ninth Circuit and Supreme Court precedent recognizing the validity of pre-enforcement challenges to statutes infringing upon constitutional rights." *Cal. Pro-Life Council, Inc. v. Getman*, 328 F.3d 1088, 1094 (9th Cir. 2003).

Here, Doe has obtained from her chosen donor semen that did not undergo the extensive and burdensome testing and screening requirements in Part 1271, attempted to become pregnant using that semen, and articulated a concrete and specific intent to do so again when medically appropriate for conception. This conduct has been the direct target of FDA enforcement as evidenced by the Arsenault order. If this Court does not act and the FDA continues to ban private semen donation that does not comply with the burdensome requirements of Part 1271, Doe suffers hardship to the extent that her access to the private reproductive choice she and her donor have agreed to use is limited or eliminated.

C. Doe also has third-party standing based on the rights of semen donors who violate Part 1271.

Defendants erroneously contend that Doe lacks standing to assert claims based on the constitutional rights of her donor. The relevant test is that discussed in *McCollum v. Cal. Dep't of Corrs. and Rehab*., which requires that Doe "show [her] own injury, a close relationship between [her]self and the parties whose rights [s]he asserts, and the inability of the parties to assert their own rights." 647 F.3d 870, 879 (9th Cir. 2011) (citation omitted).

Doe meets all three criteria. First, as discussed previously, she is injured by the burden to her freedom imposed by Part 1271's prohibition of her chosen method of reproduction. Second, Doe and her donor, by virtue of the process by which they identified one another and came to a mutual agreement regarding scope and quality of their donor-recipient relationship, have a "close relationship" as required by the Supreme Court. *See id*. at 879 (citing *Powers v. Ohio*, 499 U.S.

400, 409-10 (1991)). Doe's status as a recipient is dependent upon donation by her chosen partner in this endeavor, and his role as donor is similarly dependent upon her desire to conceive. *Cf. San Luis*, 638 F.3d at 1170 ("Article III standing cannot be supported by the '*independent* action of some third party not before the court, but that does not exclude injury produced by determinative or coercive effect upon the action of someone else.'" (quoting *Bennett*, 520 U.S. at 169) (internal quotation marks omitted and emphasis added)).

Defendants argue that Doe cannot "advocate for a male donor's rights as effectively as he would." Mot. to Dismiss 12. However, they themselves acknowledge that perfect alignment of interests is not required for third-party standing. *See* Mot. to Dismiss 12 (quoting *Singleton v. Wulff*, 428 U.S. 106, 115 (1976) (third party standing merited if plaintiff is "very nearly[] as effective a proponent of the right as [the third party would be].") Third-party standing has been recognized for decades in reproductive-rights cases despite the imperfect alignment of interests between patients and doctors or clinics. *See, e.g., Singleton*, 428 U.S. at 118 (1976); *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992); *Planned Parenthood of Idaho v. Wasden*, 376 F.3d 908, 917 (9th Cir. 2004); *see generally, Stenberg v. Carhart*, 530 U.S. 914, 922, 932 (2000); *Gonzales v. Carhart*, 550 U.S. 124 (2007). Even a mere buyer-seller relationship has been "found an adequate 'relation' between litigants alleging third-party standing and those whose rights they seek to assert." *Kowalski v. Tesmer*, 543 U.S. 125, 139 (2004) (citing *Carey v. Population Servs. Int'l*, 431 U.S. 678, 683 (1977); *Craig v. Boren*, 429 U.S. 190, 195 (1976)).

Doe's alignment of interests is based upon the intimate and private relationship she has created with her donor. Nearly forty years ago, the Supreme Court explained that "[i]f the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child." *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972); *see also Carey* 431 U.S. at 684-85 ("[I]t is clear that among the decisions that an individual may make without unjustified government interference are personal decisions relating to marriage, procreation, contraception, family relationships, and child rearing and education." (internal

citations omitted)). Decisions about accomplishing conception are "among the most private and sensitive" and the partnership between two persons creating a child "by definition concerns the most intimate of human activities and relationships." *Carey*, 431 U.S. at 684-85.

Given the abundance of case law describing the protected and private nature of procreative relationships between individuals, Defendants' contention that Doe and her donor do not have a relationship with closely aligned interests is yet another manifestation of the FDA's paternalistic and overbearing attitude toward Doe and her reproductive choices. Doe and her donor have an intimate and continuing connection that revolves around such deeply personal matters as her fertility, procreative choices, and expectations on disclosure of medical information. This relationship was created entirely on a private basis and contains no commercial elements or monetary interests (in sharp contrast with the vendor-vendee relationships in *Carey* and *Craig*). As two partners in a procreative endeavor, they have elected to align their interests in a manner that involves a potential for life-long connection.

Part 1271's burden on the rights of Doe's donor is at least as clear, if not more so, than its burden on hers. As the Malarkey Declaration makes clear, the FDA's position is that the regulations in Part 1271 apply to anyone who donates semen for artificial insemination—whether an enforcement action is ultimately pursued or not. The FDA has thus avowed that the purely private and noncommercial reproductive decision of Doe's donor to attempt to conceive a child is conditioned on that donor's compliance with a complex federal regulatory regime. Further, the FDA has expressed an intent to enforce that regime against donors who engage in behaviors like those of Doe's donor. *See* Mot. to Dismiss 2; Compl. ¶¶ 18-26, 30, 44-53. The burden on his reproductive rights is clear: if he does not comply with an onerous and inappropriate regulatory regime, the law forbids him from conceiving a child with a willing partner in the manner of their choice. *Cf. Gerber v. Hickman*, 291 F.3d at 623.

Doe has also previously described why a donor like hers might be inhibited from asserting his rights in court. In Doe's Motion to Proceed Anonymously, this Court reviewed the many reasons why public litigation of these very private and personal decisions poses serious

problems.[14] The abundant press coverage of Mr. Arsenault and the FDA's cease-manufacture order illustrates why a donor might be discouraged from filing suit.[15] *See Singleton v. Wulff,* 428 U.S. at 117 (permitting third-party standing of doctor in abortion context because a patient "may be chilled from such assertion by a desire to protect the very privacy of her decision from the publicity of a court suit."); *see also Pa. Psychiatric Soc'y v. Green Spring Health Servs.*, 280 F.3d 278, 290 (3d Cir. 2002) (citing *Singleton* for the proposition that a patient's desire to protect her privacy and avoid stigma could discourage her from bringing suit and constituted a sufficient impediment to justify third-party standing). Additionally, the FDA's refusal to articulate its criteria for enforcement in the Malarkey Declaration affirms Doe's assertion that her donor would, in any such complaint, be admitting illegal conduct. Compl. at ¶¶ 64; *see United States v. Dotterweich*, 320 U.S. 277 (1943); *United States v. Good*, 257 F. Supp. 2d 1306, 1319 (D. Colo. 2003) ("Moreover, the cases are overwhelming that the government is not required to pursue administrative proceedings before bringing enforcement actions in federal court."); *Kent v. Benson*, 945 F.2d 372, 373-74 (11th Cir. 1991). Doe is an appropriate party to vindicate not just her own rights in this case, but also those of her donor.

D. Doe has standing to raise her Commerce Clause, Tenth Amendment, and Ninth Amendment claims.

Because 21 C.F.R. Part 1271, facially and as applied and enforced by Defendants, has caused Doe to suffer an injury-in-fact that this Court may redress, Doe has prudential standing to raise her Commerce Clause and Tenth Amendment claims under *Bond v. United States*, 131 S. Ct. 2355, 2366-67 (2011) (holding that plaintiff who meets Article III standing requirements has standing to raise a Tenth Amendment claim), and *Gonzales v. Raich*, 545 U.S. 1 (2005) (California residents suffering from serious medical conditions have standing to seek injunctive and declaratory relief prohibiting enforcement of the federal Controlled Substances Act on the

[14] Memorandum in Support of Plaintiff's Motion for Leave to Proceed Anonymously Using a Pseudonym at 4-12.

[15] *See, e.g.*, Benjamin Wallace, *The Virgin Father*, NEW YORK MAGAZINE (Feb. 5, 2012), available at http://nymag.com/news/features/trent-arsenault-2012-2/ (last visited June 13, 2012).

ground that it violated the Commerce Clause). Likewise, Doe has standing to raise her Ninth Amendment claim under well-established Supreme Court precedent. *See, e.g., Roe v. Wade*, 410 U.S. at 120, 153) (plaintiff had standing to raise Ninth Amendment claim challenging law that criminalized conduct of abortion providers, even though the challenged statute did not criminalize the conduct she wanted to engage in, where she alleged "that she wished to terminate her pregnancy by an abortion 'performed by a competent, licensed physician, under safe, clinical conditions'"; was injured by her inability to get a "'legal' abortion in Texas"; and was unable to "afford to travel to another jurisdiction in order to secure a legal abortion under safe conditions"); *Doe v. Bolton*, 410 U.S. at 210-11 (Douglas, J., concurring) (reaching merits of plaintiff's Ninth Amendment claim regarding statute that criminalized the conduct of abortion-providers, even though the challenged law did not directly criminalize Doe's actions and the record did not address whether any of the doctors had been prosecuted—or even threatened with—prosecution under the challenged statute).

II. The request to dismiss Doe's complaint with prejudice is inappropriate.

Defendants request that this Court dismiss Doe's Complaint with prejudice. Mot. to Dismiss 2. It is well established that dismissal for lack of standing is dismissal without prejudice. *Fleck & Assocs. v. City of Phoenix*, 471 F.3d 1100, 1106 (9th Cir. 2006) (citing *Steel Co. v. Citizens for a Better Env't.*, 523 U.S. 83, 94 (1998), and *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 235 (1990), for the proposition that if a court lacks jurisdiction it is powerless to reach the merits and a dismissal for want of standing must be without prejudice.) Further, it is improper to dismiss without leave to amend "unless the district court determines that the pleading could not possibly be cured by the allegation of other facts." *Nevius v. Read-Rite Corp.*, 335 F.3d 843, 845 (9th Cir. 2003) (citations omitted). If additional facts regarding Doe's past or future conduct are necessary for this Court to conclude that it has subject-matter jurisdiction to adjudicate this case, they could be provided via an amended complaint or supplementary affidavits, and as such, dismissal with prejudice would be inappropriate.

CONCLUSION

For the aforementioned reasons, Plaintiff Jane Doe respectfully requests that Defendants' Motion to Dismiss be DENIED.

Dated: November 5, 2012

Respectfully submitted,

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on this 5th day of November, 2012, Plaintiff's Opposition to Defendant's Motion to Dismiss the Complaint; Memorandum of Points and Authorities was filed in the U.S. District Court for the Northern District of California, and that a true and exact copy was delivered, via ECF, to:

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