DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

IN THE MATTER OF TRENT C. ARSENAULT 38068 Canyon Heights Drive Fremont, California 94536	)	Docket No.

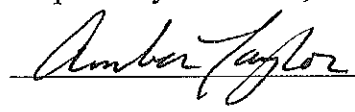
TRENT ARSENAULT'S OPPOSITION TO CBER'S MOTION TO DENY MR. ARSENAULT'S REQUEST FOR A HEARING & FOR ADMINISTRATIVE SUMMARY JUDGMENT AND CROSS-MOTION FOR ADMINISTRATIVE SUMMARY JUDGMENT

Mr. Trent Arsenault, by and through the undersigned counsel, hereby files this opposition to the Center for Biologics Evaluation and Research's motion to deny his request for a hearing and for administrative summary judgment and also cross-moves for administrative summary judgment. In support thereof, he states as follows:

1. On November 1, 2010, the Center for Biologics Evaluation and Research (hereinafter "CBER") delivered an Order to Cease Manufacturing of HCT/Ps (hereinafter "Order").
2. The Order specified that its basis was Mr. Arsenault's lack of "compliance with the regulations in 21 C.F.R. § 1271." Order at 1.
3. Mr. Arsenault wrote a letter on November 1, 2010 to Barbara Cassens and Mary Malarkey of the FDA, requesting a hearing in accordance with 21 C.F.R. § 1271.440(e) and 21 C.F.R. § 16. Mr. Arsenault stated that he could provide documentation by and testimony from women to whom he had donated semen to substantiate the assertion that he was a sexually intimate partner (hereinafter "SIP") of those women, and thereby was exempt from the regulatory requirements applicable to directed donors under 21 C.F.R. § 1271.

4. On February 7, 2011, CBER filed a motion arguing that no genuine and substantial issue of fact exists and therefore Mr. Arsenault's request for a hearing should be denied.
5. However, an evidentiary hearing under Part 16 is required to determine, based on the content and credibility of statements from Mr. Arsenault and the donees, the factual question of whether Mr. Arsenault and his donees were SIPs.
6. Alternatively, Mr. Arsenault moves for administrative summary judgment under 21 C.F.R. § 16.26(a) on the ground that the facts currently on the record support Mr. Arsenault's contention that, because of Mr. Arsenault's status as an SIP, the Order was issued in error.
7. Mr. Arsenault also moves for rescindment of the Order because it constitutes an arbitrary and capricious application of the law, its issuance failed to comport with constitutional requirements for procedural due process, and its effect unconstitutionally burdens Mr. Arsenault's exercise of fundamental rights.

Respectfully submitted,



Amber Taylor
Senior Attorney
Cause of Action

Date: November 7, 2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

IN THE MATTER OF TRENT C. ARSENAULT 38068 Canyon Heights Drive Fremont, California 94536	)	Docket No.

MEMORANDUM IN SUPPORT OF TRENT ARSENAULT'S OPPOSITION TO CBER'S MOTION TO DENY MR. ARSENAULT'S REQUEST FOR A HEARING & FOR ADMINISTRATIVE SUMMARY JUDGMENT AND CROSS-MOTION FOR ADMINISTRATIVE SUMMARY JUDGMENT

Trent Arsenault is a private individual who donates fresh semen,[1] on an uncompensated basis, to women who wish to conceive a child. Mr. Arsenault provides potential donees with substantial information about his personal and medical history, including the current and historical results of tests for communicable diseases or infections. If the donee is satisfied by these disclosures, Mr. Arsenault provides fresh semen to the woman with the hope that this will lead to conception and birth. Should this be successful, Mr. Arsenault and the mother will have a lifelong connection that allows the child to know both the father's identity and health status throughout the child's life.

CBER, however, has attempted to intervene in this process. CBER argues that because Mr. Arsenault delivers the semen in a labeled receptacle for artificial insemination, as opposed to natural insemination,[2] Mr. Arsenault cannot father children using this mutually-agreed-upon method. Instead, Mr. Arsenault must comply with a panoply of federal regulations that would make it impossible for him to provide fresh semen to willing donees because he is a

[1] Many women prefer to use fresh semen instead of previously-frozen semen, believing that doing so maximizes the chance of conception.
[2] Many uncompensated semen donors accomplish insemination via an act of sexual intercourse. This is referred to as "natural insemination."

"manufacturer of human cells, tissues, and cellular and tissue-based products."[3] Based on this contention, CBER issued an Order on November 10, 2010 which instructed Mr. Arsenault to cease donating.

These regulations would not apply to Mr. Arsenault's donations were he a "sexually intimate partner" of the donee.[4] Pursuant to the procedure outlined in the Order, Mr. Arsenault requested an evidentiary hearing so he and the donees could present statements showing that they held a sincere belief their actions constituted a sexually intimate partnership. CBER then moved for the hearing request to be denied and the Commissioner issue administrative summary judgment as a matter of law on the question of whether the Order was properly issued to Mr. Arsenault.

The Commissioner should reject CBER's motion and grant Mr. Arsenault an evidentiary hearing to provide him with the opportunity to present testimony on the factual question of whether the interactions between the donees and him created an SIP relationship.

If the Commissioner determines that the facts already on the record suffice to decide the legal question of whether Mr. Arsenault donated semen as an SIP, then administrative summary judgment should be issued recognizing Mr. Arsenault's activities as falling within the SIP exception to the regulatory requirements of 21 C.F.R. § 1271 and rescinding the cease Order. As an SIP of the donees, the regulations cited as support for the Order do not apply to Mr. Arsenault and it is thus without basis in law.

However, even if the FDA's definition of SIP does not encompass Mr. Arsenault in his capacity as a private semen donor, the Order should be rescinded. The process by which the Order was issued and is being reviewed fails to comply with procedural due process

[3] ORDER TO CEASE MANUFACTURING of HCT/Ps, November 1, 2010 (henceforth the "Order").
[4] Are there exceptions from the requirement of determining donor eligibility, and what labeling requirements apply?, 21 C.F.R. § 1271.90(a) (2) (2011).

requirements applicable to the exercise of fundamental constitutional rights to procreation and sexual intimacy. Additionally, CBER's interpretation of the cited regulations is arbitrary and capricious and violates Mr. Arsenault's substantive due process rights under the U.S. Constitution.

ARGUMENT

I. Mr. Arsenault's Request for an Evidentiary Hearing Should Be Granted.

The Commissioner should grant an evidentiary hearing in this matter to assess Mr. Arsenault's proffered evidence. This evidence will show that the facts support Mr. Arsenault's contention that he is an SIP of the donees.

A. Mr. Arsenault's request meets the burden to obtain an evidentiary hearing prescribed by 53 Fed. Reg. 4613, 4614.

A party seeking a hearing is required to meet a "threshold burden of tendering evidence suggesting the need for a hearing."[5] In his letter of November 10, 2010 responding to the Order, Mr. Arsenault described evidence he wishes to offer in a manner sufficient to justify granting his request for a hearing.

The purpose of an evidentiary hearing is to resolve factual questions. These hearings serve as an opportunity to gain additional information to resolve genuine and substantial issues of fact.[6] This requires additional facts, beyond what the agency already has before it.[7] Mr. Arsenault's evidence consists of written statements and oral testimony from women to whom he had donated semen prior to and during the FDA's investigation. Further, it also includes such

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[5] Costle v. Pacific Legal Foundation, 445 U.S. 198, 214-215 (1980), reh'g. denied, 446 U.S. 947 (1980), citing Weinberger v. Hynson, Westcott & Dunning, Inc., 412 U.S. 609, 620-621 (1973)).

[6] See Regulatory Hearing Before the Food and Drug Administration, 53 Fed. Reg. 4613 (February 17, 1988) (codified at 21 C.F.R. part 16), ("The procedures in this part apply when: (a) The Commissioner is considering any regulatory action, including a refusal to act, and concludes, as a matter of discretion, on the Commissioner's initiative or at the suggestion of any person, to offer an opportunity for a regulatory hearing to obtain additional information before making a decision or taking action.").

[7] Id.

statements and testimony from women to whom he donated semen after that investigation had ended.[8] Thus, by definition Mr. Arsenault's evidence includes facts that cannot be known through reference to those already provided to the FDA and which are not part of the record in this matter.

B. The request contains information to show there is a genuine and substantial issue of fact.

The new evidence Mr. Arsenault seeks to introduce will resolve a genuine and substantial issue of fact before the Commissioner, namely whether Mr. Arsenault and the donees have engaged in conduct that qualifies them as SIPs. Mr. Arsenault contends that the testimony described above is necessary to justify resolution of this factual issue.[9]

C. Mr. Arsenault has a right to have a fact finder assess the weight and credibility of his evidence on this question.

Although CBER argues that no hearing is justified because the issues Mr. Arsenault raises are legally insufficient even if true,[10] the Commissioner cannot determine whether Mr. Arsenault's relationships were legally insufficient to qualify as SIPs until content of his and the donees' testimony is assessed. Absent such vital evidence, the essential facts in dispute have not been established. Moreover, there is no suggestion that FDA has obtained such testimony from the donees regarding their course of conduct during their SIPs with Mr. Arsenault or regarding the basis for Mr. Arsenault's sincerely held belief that he has entered into SIPs with the donees.[11] This is made clear by the fact that the Order was issued before Mr. Arsenault proffered this evidence.

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[8] Letter from Trent Arsenault to Barbara Cassens and Mary Malarkey, Directors, FDA (Nov. 1, 2010) (available at http://trentdonor.org/sites/g2sites/trentdonor/d/21459-4/trentdonor-fda-form-483-response-doc-01-nov-2010.pdf).
[9] See Regulatory Hearing Before the Food and Drug Administration, 53 Fed. Reg. 4613 (Feb. 17, 1988) (codified at 21 C.F.R. pt. 16).
[10] See Pineapple Grower's Ass'n of Hawaii v. FDA, 673 F.2d .1083, 1085 (9th Cir. 1982).
[11] Cf. Georgia Pacific Corp. v. U.S. Environmental Protection Agency, 671 F.2d 1235, 1241 (9th Cir. 1982) (hearing not necessary if essential facts are undisputed).

The true nature of Mr. Arsenault's relationships with the donees cannot be established if the parties to the relationships have not been permitted to testify as to the relationship's character. An evidentiary hearing on this issue is needed.

II. If No Evidentiary Hearing Is Necessary, Administrative Summary Judgment Should Be Issued Recognizing That Mr. Arsenault Qualifies For the SIP Exception.

Although Mr. Arsenault contends that the proffered testimony is essential to the question of whether he is an SIP of each donee and thus exempted from the regulatory requirements applicable to designated donors in 21 C.F.R. § 1271, if the Commissioner determines that only a legal question remains,[12] Mr. Arsenault requests that this question be resolved by recognizing that his relationships with the donees fall within the legal definition of sexually intimate partnerships. Doing so would require that the Order be rescinded in recognition of Mr. Arsenault's status.

Neither the Code of Federal Regulations nor the preamble to the relevant Final Rule define SIPs for purposes of 21 C.F.R. § 1271. CBER asserts that "the plain meaning of the words ... do not require further explanation."[13] But this bluff and condescending statement ignores the reality that the meaning of those words to officials in Washington may not reflect the meaning they have to individuals attempting to start a family through methods which are, if uncommon, still freighted with intimacy.

By leaving SIP undefined, the FDA perhaps recognized that a federal agency is not institutionally competent to create one definition of SIP applicable to more than 300 million Americans. Indeed, it is inevitable that every individual will define this term for him- or herself.

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[12] See Food Additives Permitted for Direct Addition to Food for Human Consumption; Bacteriophage Preparation, 76 Fed. Reg. 16285 (August 18, 2006)(codified at 21 C.F.R. 172)(In judicial proceedings, a court is authorized to issue summary judgment without an evidentiary hearing whenever it finds that there are no genuine issues of material fact in dispute and a party is entitled to judgment as a matter of law).

[13] Order at 10.

Just as individual persons ultimately arrive at their own sincerely held religious beliefs, sincerely held beliefs about sex, intimacy, and relationships will differ based on subjective experience. Mr. Arsenault and the donees have the right, in the absence of any legal definition of SIP, to define that term for themselves.

Abjuring a one-size-fits-all definition is not inconsistent with the preamble language cited by CBER. Although that language notes that routine exposure to an SIP's body fluids is "likely," it does not assume that such exposure is universal, nor does it make exposure a necessary condition for SIP status.[14] In the view of Mr. Arsenault and the donees, privately agreeing to conceive a child together is a sexually intimate decision that creates a lifelong relationship. The FDA should defer to the judgment of the parties to the conception and refrain from erasing or redefining their experiences.

III. The Order Should Be Rescinded Because It Is Based On An Arbitrary And Capricious Interpretation Of the Law.

The difference between the deference normally granted to persons seeking to conceive a child with a new or current sexual partner and the government intervention in this case highlights the arbitrary and capricious nature of CBER's application of 21 C.F.R. § 1271 to Mr. Arsenault. An agency action must be "rational, based on consideration of the relevant factors, and within the scope of the authority delegated to the agency by the statute."[15] But CBER's actions here are irrational and do not consider important factors.

CBER's targeting of Mr. Arsenault highlights the irrationality of its regulatory approach. CBER asserts that it can order Mr. Arsenault to cease donating semen to consenting adult donees because he does not follow a plethora of regulatory standards which purportedly protect donees

[14] Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52696, 52707 (September 30, 1999) (to be codified at 21 C.F.R. parts 210, 211, 820, 1271) (Preamble to the Proposed Rule).
[15] Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 42 (1983); see also FCC v. Fox TV Stations, Inc., 556 U.S. 502 (2009).

from disease. However, CBER's ability to stand between a woman and the man she wishes to father her child seems to hinge completely on the use of a semen receptacle. If Mr. Arsenault (like some other uncompensated donors) provided natural insemination, CBER's position may be that it could not intervene—even though such activity is riskier than the procedures followed by Mr. Arsenault.[16]

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

IV. The Order Should Be Rescinded Because The FDA Failed To Provide Procedural Due Process As Required By The Constitution.

The Order is procedurally as well as substantively flawed. Although it effectively declares that Mr. Arsenault must cease fathering children with consenting adult donees—a

[16] Although CBER has not asserted that it has authority to regulate sexual acts between two previously unacquainted persons if the male partner has offered himself for the sole purpose of impregnating the female, such a conclusion follows logically from many of the arguments in its brief. Such an expansion of scope *would* exceed the FDA's statutory grant of authority due to the limitations of the Commerce Clause under United States v. Morrison, 529 U.S. 598 (2000), and Gonzales v. Raich, 545 U.S. 1 (2005), and bring individual-rights concerns to the fore with additional urgency. See *infra* Section V.

serious infringement of a core liberty[17]—its issuance was the result of an administrative process lacking in safeguards required to protect such rights. It should therefore be rescinded.

In Mathews v. Eldridge, the Court described the balancing test that should be used to determine the amount of process that must be provided before the government may deprive an individual of their rights:

> First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used... and finally, the Government's interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail.[18]

The effective consequence of this balancing test is that the amount of process due is directly proportional to the right being deprived.[19] With respect to the right to reproduce, the Court has determined the right is fundamental, requiring the utmost procedural due process.[20] While the Court does not generally provide detailed guidance on procedure, in this instance it has explicitly held that "[t]he opportunity to present reasons, either in person or in writing, why proposed action should not be taken is a fundamental due process requirement."[21] The decision to issue an order to Mr. Arsenault before granting even a simple hearing to present his evidence clearly falls short of what the constitution requires.

Additionally, CBER's contention that the burden of proof rests on Mr. Arsenault to prove that he is not a directed donor is simply false. The Court made it clear in Stanley v. Illinois that in matters regarding fundamental rights the individual must be provided a hearing before action is taken, not after.[22] The FDA cannot simply determine that Mr. Arsenault is a directed donor,

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[17] See Carey v. Population Services International, 431 U.S. 678, 685 (1977).
[18] 424 U.S. 319, 335 (1976).
[19] Clark v. Jeter, 486 U.S. 456, 461 (1988).
[20] Skinner v. Oklahoma, 316 U.S. 535 (1942).
[21] Cleveland Bd. of Educ. v. Loudermill, 470 U.S. 532, 546 (1985)
[22] 405 U.S. 645, 649 (1972).

and then require him to prove that he is not. The burden of proof is on the state to prove the matter asserted.[23]

By failing to provide a hearing prior to issuance of an Order that infringes on a fundamental constitutional right and by placing the burden on Mr. Arsenault to prove to the government why he should be allowed to father additional children, the FDA has comprehensively failed in its due process obligations to Mr. Arsenault. The Order issued as a result of these inadequate procedures should be rescinded immediately.

V. The Order Should Be Rescinded Because It Unlawfully Violates Fundamental Constitutional Rights Protected By Substantive Due Process.

Even if the Commissioner determines that the Order was properly issued and Mr. Arsenault is not, under its regulations, an SIP of the donees, the Order should be rescinded. To do otherwise would be to uphold action by CBER that violates Mr. Arsenault's constitutional rights to substantive due process.

Mr. Arsenault's private and uncompensated provision of semen to a consenting individual recipient for the purpose of conceiving a child implicates fundamental constitutional rights recognized by the U.S. Supreme Court. The Order seeks to prevent Mr. Arsenault from the exercise of his rights, in contravention of decades of precedent.

A. Personal decisions about procreation are guaranteed constitutional protection.

The decision to attempt to conceive a child falls within the constitutional right to make individual decisions about procreation free of unwarranted government intrusion. This right has been repeatedly recognized as a fundamental right arising out of an individual's right to privacy. For example, nearly forty years ago, the Court held 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

[23] Loudermill, 470 U.S. at 658.

intrusion into matters so fundamentally affecting a person as the decision whether to bear or beget a child."[24]

The language CBER cites recognizes potential parents' autonomy when it explicitly defers to the attending physician, donor, and recipient in the context of determining the scope of appropriate screening and testing for SIP donations.[25] In the absence of an attending physician (or any medical intermediary) the FDA should defer to the judgment of the two parents-to-be and accept the mutually agreeable arrangement to which Mr. Arsenault is a party—just as the FDA does with millions upon millions of independent judgments by partners attempting to conceive a child through simple acts of intercourse.

Decisions about accomplishing conception are "among the most private and sensitive."[26] The protected, personal, and intimate nature of this choice is not eliminated if the recipient or her partner makes use of a cup and syringe to maximize the chance of pregnancy.

B. The right to enter into and self-define intimate relationships is also protected under the Constitution.

Likewise, Mr. Arsenault and the donees have a right to create sexually intimate partnerships in a manner of their choosing without erasure by a government agency. The Court has recognized that the partnership between two persons creating a child "by definition concerns the most intimate of human activities and relationships."[27] Mr. Arsenault and the donees have entered into such a relationship here.

The definition of a sexually intimate partnership does not require physical touching. As noted above, the explanatory language CBER itself cites as bearing on the definition of SIP does

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[24] Eisenstadt v. Baird, 405 U.S. 438, 453 (1972). See also Carey v. Population Services International, 431 U.S. 678, 685 (1977) ("Our law affords constitutional protection to personal decisions relating to marriage, procreation, contraception, family relationships, child rearing, and education.").
[25] Eisenstadt, 405 U.S. at 453.
[26] Carey, 431 U.S. at 685.
[27] Id.

not presume that an SIP will always have had previous exposure to his or her partner's body fluids.[28] Such sexual contact is "but one element in a personal bond."[29]

The relationship between private, non-anonymous, individual semen donors and their recipients is an intimate exchange and an expression of personal trust different from, but no less important than, an act of sexual intercourse. Mr. Arsenault's contribution and connection to these mothers is permanent and indelible. There is no intermediary, no medical personnel. There is a meeting, face-to-face, between two individuals: one who wants to have a baby and one who has offered assistance. From this union, with luck, a child will be born. And notwithstanding the unusual nature of the partnership, that living connection belies CBER's contention that Mr. Arsenault and a donee are not SIPs.

Mr. Arsenault and donees have a protected liberty interest in defining their relationships as they see fit. The Supreme Court has repeatedly recognized the importance of allowing for individuals to make judgments about their sexual and procreative relations without unnecessary governmental interference.[30] Most recently, the Court in Lawrence noted that the "general rule[] should counsel against attempts by the State, or a court, to define the meaning of the relationship or to set its boundaries absent injury to a person or abuse of an institution the law protects."[31] As in Lawrence, the relationships at issue here fall outside the historical norm. But that in no way should impair the ability of Mr. Arsenault and a donee, as free, consenting adults, to create an intimate connection with each other.

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[28] Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52696, 52707 (September 30, 1999) (to be codified at 21 C.F.R. parts 210, 211, 820, 1271) (Preamble to the Proposed Rule).
[29] Lawrence v. Texas, 539 U.S. 558, 567 (2003).
[30] Planned Parenthood of Southeastern Pa. v. Casey, 505 U.S. 833, 851 (1992) ("At the heart of liberty is the right to define one's own concept of existence, of meaning, of the universe, and of the mystery of human life.").
[31] Lawrence, 539 U.S. at 567.

C. The Order is based on a perilous and unconstitutional rationale that endangers fundamental rights to privacy.

By rejecting Mr. Arsenault's characterization of his connections with the donees, CBER implicitly affirms its own supremacy in the area of defining personal relationships and its ability to intervene in non-standard procreative arrangements where a new risk of disease is present. Both of these principles unconstitutionally infringe on the rights of Mr. Arsenault, the donees, and potentially other citizens.

By construing its regulations to cover interactions between private individuals, where no medical personnel are involved and no medical procedure is performed, CBER has dramatically widened the scope of its supposed mandate to protect. It asserted that it has the right to stop Mr. Arsenault from providing semen to consenting adult recipients because doing so "protects [families] from communicable diseases."[32] However, the preamble to the final rule cited by CBER speaks specifically of reducing the risk posed by artificial insemination in "small medical practice[s]."[33] If CBER's purview is not limited to the regulation of medical practices or professionals, and instead includes the ability to regulate reproductive decisions made by two private individuals in a non-commercial context, the consequences for individual autonomy and privacy are dire.

To put it plainly, if CBER's regulatory sphere encompasses private, uncompensated donations of semen in receptacles due to the disease risk posed by transmission of body fluids from a new partner, then its basis for regulation could easily and logically extend to cover exchanges of body fluids in which no receptacle is involved and instead insemination is

[32] Order at 10.
[33] Order at 9.

accomplished via physical contact between the donor and recipient: i.e. sexual intercourse.[34] This would bring Mr. Arsenault as well as donors who give via natural insemination within CBER's purview—along with millions of other sexually active persons. Surely CBER would not agree that it could regulate such conduct—but the arguments fielded in support of the Order lead to just that conclusion.

Moreover, CBER's interpretation of the regulations requires it (as was the case with Mr. Arsenault) to send investigators into the sites of manufacture of private semen donation, even when that means inspecting an individual's bedroom.[35] The outrageous nature of such actions has been cited by the Supreme Court for rhetorical effect in Griswold v. Connecticut, in which the majority noted that "the very idea" of "allow[ing] the police to search the sacred precincts of marital bedrooms for telltale signs of the use of contraceptives ... is repulsive to the notions of privacy."[36] Here, just as the Supreme Court feared, FDA agents went marching into Mr. Arsenault's bedroom—but instead on the hunt for telltale signs of unauthorized attempts to conceive.

CBER claims that its intervention is justified because of safety concerns. But, ironically, by expanding its scope of regulatory authority, CBER may decrease both reproductive autonomy and safety. As noted above, CBER has created a loophole in regulatory enforcement for donors who have unprotected sexual intercourse with donees—even if their intentions are identical to Mr. Arsenault's.

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[34] Any such extension of regulatory authority over uncompensated private sexual or procreational activities would be unconstitutional under Gonzales v. Raich, 545 U.S. 1 (2005) (the Commerce Clause does not extend to regulation of noneconomic activity).

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

[36] Griswold v. Connecticut, 381 U.S. 479, 485-86 (1965).

In the final analysis, CBER's overbroad interpretation cannot stand "in light of the familiar principle, so often applied by the Court, that a 'governmental purpose to control or prevent activities constitutionally subject to state regulation may not be achieved by means which sweep unnecessarily broadly and thereby invade the area of protected freedoms.'"[37]

CONCLUSION

Given CBER's articulated bases for issuing the Order to Cease Manufacture and the importance of the rights endangered by its operation, the Commissioner should, at minimum, grant Mr. Arsenault's request for an evidentiary hearing so he can present testimony demonstrating that the facts do not support the Order. However, Mr. Arsenault also respectfully requests that the Commissioner consider the legal issues raised by CBER's interpretation of 21 C.F.R. § 1271 and grant administrative summary judgment in his favor. As a matter of law, the Commissioner should hold that the regulatory burden normally placed on medical practices does not lawfully or constitutionally apply to Mr. Arsenault, a private individual who enters into mutually agreeable arrangements with consenting adults to father children.

Respectfully submitted,

Amber Taylor

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Cause of Action

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