EXHIBIT 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

REGULATORY HEARING ON THE ORDER TO TRENT ARSENAULT TO CEASE MANUFACTURING

COMMISSIONER'S DECISION

On November 1, 2010, the Center for Biologics Evaluation and Research (CBER) issued an Order to Cease Manufacturing human cells, tissues, and cellular- and tissue-based products (HCT/Ps) to Mr. Trent Arsenault under 21 CFR 1271.440(a)(3). Mr. Arsenault challenged the validity of the Order and requested a hearing under 21 CFR part 16. In response, CBER moved on February 7, 2011 to deny Mr. Arsenault's request for a hearing on the grounds that he failed to raise a genuine and substantial issue of fact as required by 21 CFR 16.26(a).

Based on my review of the parties' submissions, including Mr. Arsenault's November 2010 and November 2011 responses, I find that there is no genuine and substantial issue of fact with regard to whether Mr. Arsenault violated 21 CFR part 1271 and failed to provide adequate protections against the risks of communicable disease transmission. I therefore grant CBER's motion to deny Mr. Arsenault's request for a hearing. I also find that the Cease Manufacturing Order was properly issued and, accordingly, issue this summary decision in favor of CBER.

I. BACKGROUND

The manufacture of HCT/Ps is governed by FDA regulations issued under the authority of Section 361 of the Public Health Service Act (42 U.S.C. 264) and codified at Title 21, Part 1271. HCT/Ps are "articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient[.]" 21 CFR

1271.3(d). Semen is an HCT/P. 21 CFR 1271.3(d). Because semen is a derivative of the human body, it (like all HCT/Ps) poses a risk of transmitting communicable disease. 69 Fed. Reg. 29786, 29787 (May 25, 2004). The purpose of Part 1271 is to prevent the introduction, transmission, and spread of communicable diseases through HCT/Ps. 21 CFR 1271.1(a).

On April 30, 2009, Mr. Arsenault registered his residence, located at 38068 Canyon Heights Drive, Fremont, California 94536-1810, as an HCT/P establishment that recovers and distributes semen. Administrative Record (AR) pages 20-21. Mr. Arsenault maintains a website through which he offers semen from himself, the sole donor, for purposes of artificial insemination. AR 41. Prospective recipients contact him through the website to request a specimen. *Id.* After signing a written agreement stating, among other things, that the semen is being provided "for the purpose of artificial insemination," a recipient may obtain a specimen either through the mail or by picking it up at Mr. Arsenault's establishment. AR 41, 42, 44.

FDA conducted an inspection of Mr. Arsenault's establishment between August 27 and September 16, 2010, and issued its Inspectional Observations to Mr. Arsenault on September 20, 2010. AR 22-26. The observations relate to violations of the donor eligibility screening, testing, and determination requirements in Subpart C of part 1271.

On November 1, 2010, CBER determined that, based on Mr. Arsenault's significant noncompliance with 21 CFR part 1271 and inadequate response to the Form 483,[1] there were reasonable grounds to believe that his operations did not provide adequate protections against the risk of transmitting communicable disease. CBER thus issued Mr. Arsenault an Order to Cease Manufacturing. AR 27-31. Mr. Arsenault requested a hearing and responded to the Order through: (1) a letter to B. Cassens and M. Malarkey dated November 1, 2010 (AR 35-36); (2) a

[1] Mr. Arsenault did not provide a written response specific to the Form 483. His November 1, 2010 letter was described as a "Response to Form 483 and 'Order to Cease Manufacturing.'" AR 35.

letter to Commissioner Hamburg dated November 28, 2010 (AR 37); and (3) a letter to M. Malarkey dated November 28, 2010 (AR 39) (collectively, "2010 response").[2] Approximately one year later, Mr. Arsenault, though his attorney, made another submission in this matter, dated November 7, 2011 ("2011 response"). AR 93-108.

This matter is now before the Commissioner on CBER's Motion under 21 CFR 16.26(a) to deny Mr. Arsenault's request for a hearing and to uphold the validity of CBER's Order to Cease Manufacturing.

II. PROCEDURAL FRAMEWORK

Under 21 CFR 1271.440(a), FDA may order an HCT/P establishment to cease manufacturing if the agency finds that:

> there are reasonable grounds to believe that an HCT/P is a violative HCT/P because it was manufactured in violation of the regulations in this part and, therefore, the conditions of manufacture of the HCT/P do not provide adequate protections against risks of communicable disease transmission; . . . or an establishment is in violation of the regulations in this part and, therefore, does not provide adequate protections against the risks of communicable disease transmission[.]

The recipient of a cease manufacturing order may request a hearing in accordance with part 16 of the regulations. 21 CFR 1271.440(e). Part 16 authorizes the Commissioner of Food and Drugs or the Commissioner's designee to deny a hearing request if "no genuine and substantial issue of fact has been raised by the material submitted." 21 CFR 16.26(a). If the Commissioner or the Commissioner's designee determines that there is no genuine and substantial issue of fact and thus that "a hearing is not justified, written notice of the determination will be given to the parties explaining the reason for the denial. *Id.*

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[2] Mr. Arsenault stated via telephone that he intended his November 1, 2010 letter to be a hearing request. AR 33. The regulations required Mr. Arsenault to submit his hearing request "within 5 working days of receipt" of the Cease Manufacturing Order, which was sent to him on November 1, 2010. 21 CFR 1271.440(e). CBER accepted Mr. Arsenault's hearing request as timely.

Part 16 further authorizes a presiding officer to "issue a summary decision on any issue... if the presiding officer determines from the material submitted...or from matters officially noticed, that there is no genuine and substantial issue of fact respecting that issue." 21 CFR 16.26(b). This standard mirrors the standard for summary judgment in federal court. *See John D. Copanos and Sons, Inc. v. Food and Drug Admin.*, 854 F.2d 510, 522 (D.C. Cir. 1988) (comparing the "no genuine and substantial issue of fact" standard for denying a hearing and granting summary decision under 21 CFR 314.200(g), the language of which is similar to 21 CFR 16.26, to the standard for summary judgment in federal court); 53 Fed. Reg. 4613 (Feb. 17, 1988). Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment is proper when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. The party moving for summary judgment bears the burden of showing that a rational trier of fact could not find for the nonmoving party and that there is no "genuine issue for trial." *Matsushita Electrical Indus. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986).

However, "[t]he mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986) (emphasis in original). As is the case for summary judgment under Rule 56, the key criterion for determining whether summary decision is appropriate under 21 CFR 16.26 is whether there are disputed facts that might affect the outcome of the proceeding. The opposing party may not rest on mere allegations or denials of the moving party's evidence, and bears the burden of producing "information…to show that there exists a genuine and substantial issue of fact." 53 Fed. Reg. 4613, 4614 (Feb. 17, 1988).

III. HCT/P REGULATORY FRAMEWORK

FDA regulations generally prohibit the transfer of HCT/Ps, including semen, until the donor has been determined to be eligible to donate. 21 CFR 1271.45(c). A donor is determined to be eligible only if: (1) screening indicates that the donor is free from risk factors for, and clinical evidence of, infection due to relevant communicable diseases[3]; and (2) testing for these communicable disease agents is negative or nonreactive. 21 CFR 1271.50(b).

Screening must include a review of the donor's relevant medical records for risk factors for and clinical evidence of certain communicable diseases, including documentation of a current medical history interview and a physical examination of the donor. 21 CFR 1271.75 and 1271.3(s). Communicable disease testing requires the laboratory analysis of a specimen, typically a blood sample, from the donor. 21 CFR 1271.80. The specimen must be collected at the time of HCT/P donation, or within 7 days before or after donation. 21 CFR 1271.80(b). The regulations further require that testing be conducted by a qualified laboratory using appropriate FDA-licensed, approved, or cleared tests. 21 CFR 1271.80(c). The results of screening, testing, and the conclusion that a donor is eligible (or ineligible) to donate (i.e., the "eligibility determination") based on the results of screening and testing must be documented in writing or electronically. 21 CFR 1271.75, 1271.80, and 1271.85.

There are some variations in these requirements.

- ***Anonymous Repeat Semen Donor***. For an anonymous semen donor who makes repeat donations, blood testing is not required at each donation, and the use of an abbreviated screening process is permitted, provided that complete donor screening and testing is

[3] Relevant communicable diseases for a sperm donor include HIV, Hepatitis B and C, human transmissible spongiform encephalopathy, syphilis, gonorrhea, *Chlamydia trachomatis*, and cytomegalovirus (CMV). Screening and testing may also be required for a disease not explicitly listed in the regulations under certain circumstances. *See* 21 CFR 1271.3(r).

performed at least once every six months. 21 CFR 1271.75(e) and 1271.85(d). The recovered semen also must be quarantined for six months, at which time the donor must be retested. 21 CFR 1271.85(d). Mr. Arsenault is not an anonymous donor and he does not quarantine his recovered semen, however. AR 42.

- ***Directed Reproductive Donor***. The transfer of semen from a "directed donor" who is determined to be ineligible to donate based on the results of screening and testing, is permitted. 21 CFR 1271.65(b)(1)(ii). A directed donor is one who provides reproductive cells or tissues "to a specific recipient, and who knows and is known by the recipient before donation." 21 CFR 1271.3(n). However, directed donors are *not exempt* from the screening, communicable disease testing, and eligibility determination requirements. A specimen from a directed donor also must be accompanied by certain records, and the recipient must be given specified warnings regarding disease risk and other information. 21 CFR 1271.65(b)(2).
- ***Sexually Intimate Partners***. Donor screening, testing, and eligibility determination are not required when a donor and recipient are "sexually intimate partners" and the donated semen is intended for reproductive use. 21 CFR 1271.90(a)(2). The rationale for this exception is that, for sexually intimate partners, "the recipient will likely have been routinely exposed to the donor's semen or other bodily fluids," and that appropriate screening and testing will be the responsibility of the "attending physician and the donor and recipient." 64 Fed. Reg. 52696, 52707 (Sept. 20, 1999).

IV. CBER FINDINGS

CBER found that Mr. Arsenault failed to adhere to the donor screening, testing, and eligibility requirements that apply to him as a directed donor for semen donations that were

recovered and distributed to approximately 46 different recipients between December 2006 and September 2010. AR 28. CBER also found that Mr. Arsenault failed to adhere to related recordkeeping requirements. AR 29. For example:[4]

- ***Testing***: Mr. Arsenault failed to conduct the required testing for relevant communicable diseases. When testing was conducted, it did not include all of the relevant communicable diseases, and there was inadequate or no evidence that the testing was conducted using an FDA-licensed, approved, or cleared screening test. For example, based on Mr. Arsenault's records, he failed to consistently conduct the required testing for Human Immunodeficiency Virus (HIV), syphilis, Gonorrhea, Chlamydia, cytomegalovirus, and Hepatitis B and C. Mr. Arsenault also failed to properly collect the blood specimens that were used for testing. Only 19 of the approximately 328 donations had blood samples collected at the time of, or up to 7 days before or after donation, as required by the regulations.
- ***Screening***: There was no evidence that Mr. Arsenault had received a physical examination for purposes of HCT/P donor screening, or that he was screened for potential exposure to human transmissible spongiform encephalopathy, including Creutzfeldt-Jakob disease, a fatal brain disorder.
- ***Eligibility Determination***: Mr. Arsenault failed to determine his eligibility[5] to donate semen for any of the approximately 328 donations cited.
- ***Recordkeeping***: Mr. Arsenault did not have documentation of the results and interpretation of communicable disease screening, testing, and eligibility determinations for each HCT/P

[4] For a complete description of the charges, *see* AR 8-18 and 21-26.

[5] As noted above, FDA regulations generally prohibit the transfer of HCT/Ps, including semen, until the donor has been determined to be eligible to donate. 21 CFR 1271.45(c). A donor is determined to be eligible only if: (1) screening indicates that the donor is free from risk factors for, and clinical evidence of, infection due to relevant communicable diseases; and (2) testing for these communicable disease agents is negative or nonreactive. 21 CFR 1271.50(b). The results of screening, testing, and eligibility determination also must be appropriately documented in writing or electronically. 21 CFR 1271.75, 1271.80, and 1271.85.

donation, as required by the regulations. For example, Mr. Arsenault admitted that none of the approximately 328 semen distributions covered by the inspection were accompanied by a summary of records that were used to make the donor eligibility determination, as required under 21 CFR 1271.55(a)(3). AR 25. Mr. Arsenault also did not have written procedures for donor eligibility determinations or the timeframes for collecting blood samples for communicable disease testing.

V. ANALYSIS

A. 2010 Response

In his November 2010 response to the Cease Manufacturing Order, Mr. Arsenault does not dispute his failure to meet these requirements. Rather, he argues that the requirements do not apply because he and the "females" who received his sperm were "sexually intimate partners."[6] AR 35; 21 CFR 1271.90(a)(2). Mr. Arsenault asserts that there are written statements from the recipients attesting that the recipients and Mr. Arsenault were sexually intimate partners. AR 35. However, despite repeated requests from the agency, he has not provided copies of the statements, or any other documentation or evidence to support this contention.

Further, there is ample evidence in the record, including admissions from Mr. Arsenault, that he was a directed reproductive donor. Mr. Arsenault represented his establishment as that of a directed donor when he registered with FDA. AR 20. He also represented himself as a directed reproductive donor in an affidavit given to the FDA employee who inspected the

[6] Mr. Arsenault implies that the Part 1271 requirements also do not apply because the semen he recovers "is not washed or processed in any way." AR 42. However, neither Subpart D specifically nor Part 1271 generally is limited to HCT/P processing; both apply more broadly to the "manufacture" of HCT/Ps. 21 CFR 1271.150(a); 21 CFR 1271.1(b)(2). Manufacture means, but is not limited to, "any or all steps in the *recovery*, processing, storage, labeling, packaging, or *distribution* of any human cell or tissue, and the screening or testing of the cell or tissue donor." 21 CFR 1271.3(e) (emphases added). Mr. Arsenault admits that he is recovering semen. AR 40. The record shows that he is also distributing semen for transfer to other individuals. *See, e.g.*, AR 41, 42, 44. As such, Mr. Arsenault is engaged in the "manufacture" of HCT/Ps as defined in Part 1271.

establishment, in written agreements with recipients of his semen, and on his website. AR 40, 43, 57, 61. A sexually intimate partner is not considered a directed reproductive donor under FDA regulations. 21 CFR 1271.3(l). As such, Mr. Arsenault has repeatedly admitted that he and the recipients of his HCT/Ps were not sexually intimate partners.

Absent an "honest discrepancy" or newly discovered evidence, a party cannot create an issue of fact and avoid summary judgment by making a conclusory allegation that contradicts a clear earlier statement. *Bank of Illinois v. Allied Signal Safety Restraint Sys.*, 75 F.3d 1162, 1170 (7th Cir. 1996). Otherwise, "the very purpose of the summary judgment motion -- to weed out unfounded claims, specious denials, and sham defenses -- would be severely undercut." *Babrocky v. Jewel Food Co. & Retail Meatcutters Union*, 773 F.2d 857, 861 (7th Cir. 1985) (internal citation omitted). This principle applies "with equal force" in an administrative proceeding. *Copanos & Sons*, 854 F.2d at 523. I therefore conclude that, based on Mr. Arsenault's 2010 response, there is no genuine and substantial issue of fact regarding his status as a directed reproductive donor, or his failure to comply with the applicable requirements cited above.

Mr. Arsenault notes that FDA regulations do not define "sexually intimate partners," and seems to suggest that the lack of a regulatory definition means that he and the recipients of his HCT/Ps qualify as such if he says so. AR 35. Mr. Arsenault also argues that this proceeding has the effect of treating nontraditional families like "second-class citizens." AR 37. However, to the extent Mr. Arsenault challenges CBER's interpretation of the term sexually intimate partners in 21 CFR 1271.90 or questions the legal impact of that interpretation in this proceeding, he raises questions of law, not fact. As such, those questions are not appropriate for consideration in an oral evidentiary hearing under Part 16. With respect to those questions, I find that:

(1) There is no need for an express regulatory definition of the term "sexually intimate partners." FDA regulations exempt sexually intimate partners from donor eligibility requirements based on the agency's reasonable and common sense understanding that such persons would *already* have been exposed to communicable disease risks.

(2) There is no evidence in the record to support Mr. Arsenault's contention that this proceeding has a discriminatory effect against him or nontraditional families. The purpose of this proceeding and Part 1271 generally is simply to protect all recipients of HCT/Ps, regardless of their family configuration or status, from communicable disease.

B. 2011 Response

As noted above, Mr. Arsenault provided an additional response to the Cease Manufacturing Order in November 2011. It is not clear whether the Commissioner is obligated to consider this submission in reaching a decision in this matter.[7] However, we have considered it carefully and provide our analysis below.

Mr. Arsenault's 2011 response repeats and expands on some of the same arguments he made a year earlier. For example, Mr. Arsenault again promises that there are written statements and oral testimony from women who have received his semen that address the nature of the relationships between these women and Mr. Arsenault, but again does not actually provide them. AR 93-94, 97. Mr. Arsenault admits that these statements are "not part of the record in this

[7] Section 16.26(b) states that a summary decision can be based on "material submitted in connection with the [Part 16] hearing." However, Part 16 does not specify a temporal deadline for the submission of that material, except to state that the administrative record remains open until the "close of a hearing" unless the Presiding Officer allows for additional time. 21 CFR 16.80(b).

matter," but asserts that the Presiding Officer must grant an oral evidentiary hearing because of their absence. AR 98- 99.

These arguments are contrary to common sense and the law. As stated earlier, a party opposing summary judgment "may not rely on allegations or denials" of the moving party's evidence, but must present evidence of its own that establishes a genuine issue of fact.[8] Mr. Arsenault has again failed to provide such evidence. Therefore, his 2011 response does not alter my determination that there is no genuine and substantial issue of fact regarding the applicability of Part 1271 requirements to Mr. Arsenault's activities as a directed donor of HCT/Ps, or his failure to comply with those requirements.

Mr. Arsenault's 2011 submission includes new legal arguments. Again, however, questions of law are not grounds for, or appropriate for consideration in, an oral evidentiary hearing under Part 16. Moreover, for the reasons summarized below, I find that these legal challenges are without merit.

1. *Administrative Procedure Act*

Mr. Arsenault argues that the agency's regulations are irrational (and therefore arbitrary and capricious and in violation of the Administrative Procedure Act) because they require communicable disease screening for men who donate semen for purposes of artificial insemination, but not for men who transfer semen through sexual intercourse (referred to as "natural insemination" by Mr. Arsenault). This claim is meritless. FDA protects the public health, in part, through regulations designed to prevent the transmission of communicable diseases that could be spread through activity such as that in which Mr. Arsenault engages. The fact that FDA regulations do not require donor screening, testing, or eligibility determination

[8] *See* page 4, *supra*.

when a sperm donor and recipient are sexually intimate partners in no way undermines the regulatory framework that applies to Mr. Arsenault.[9] The agency must always consider its public health priorities, statutory authority, and common-sense, practical constraints when adopting regulations or making a regulatory decision -- and it has reasonably done so here. Again, the purpose of this proceeding and Part 1271 generally is simply to protect all recipients of HCT/Ps, regardless of their family configuration or status, from communicable disease.

Mr. Arsenault also claims that FDA regulations requiring communicable disease screening for semen donors are irrational because they *increase* communicable disease risk by increasing "the likelihood that a donee who lacks funds to purchase semen from a bank will engage in sexual intercourse with donors." AR 101. These arguments are entirely unconvincing. Further, no evidence is provided to support them.

2. *Due Process*

Mr. Arsenault contends that the Cease Manufacturing Order violates his due process rights because it "effectively declares that [he] must cease fathering children," thus infringing on his fundamental Constitutional rights to reproduce and to define his own intimate human relationships as he sees fit. AR 101-09. However, the effect of FDA regulations and the Cease Manufacturing Order is not nearly so sweeping. The regulations and Cease Manufacturing Order require only that, if Mr. Arsenault chooses to operate as a directed sperm donor, other than with individuals with whom he is sexually intimate, he adhere to the communicable disease screening requirements that apply to all directed donors and that protect recipients against infectious diseases. Mr. Arsenault's therefore appears to assert that he has a Constitutional right to transfer his sperm to others for artificial insemination without adhering to protections against

[9] FDA has not "targeted" Mr. Arsenault, as stated in his November 2011 submission. *See* AR 100. Mr. Arsenault registered his residence as an establishment engaged in the manufacture of HCT/Ps. AR 20-21.

communicable disease transmission to the recipients. I disagree that he has a right to violate the applicable FDA regulations, and note that nowhere has Mr. Arsenault acknowledged the public health interest in protecting the *recipients* of his semen from communicable disease.

Mr. Arsenault also avers that the Cease Manufacturing Order violates his procedural due process rights because no hearing was held prior to its issuance. AR 102. Balanced against Mr. Arsenault's more accurately defined and therefore significantly narrower interest (in disseminating HCT/Ps without adhering to communicable disease prevention requirements), however, the process afforded him is more than adequate. Mr. Arsenault has had ample opportunity to respond to the charges against him and has in fact provided four written submissions describing his position in this matter. The Constitution does not obligate FDA to hold an oral evidentiary hearing under such circumstances, and Mr. Arsenault has not raised a genuine and substantial issue of fact such that a hearing would be justified under agency regulations. Moreover, the Cease Manufacturing Order did not become effective until the date of this decision. 21 CFR 1271.440(a)(3)(ii).

VI. CONCLUSION

Pursuant to the authority delegated to me by the Commissioner, I am issuing the decision in this matter. Based on the evidence in the record, I find that there is no genuine and substantial issue of fact with regard to whether Mr. Arsenault violated 21 CFR part 1271 and, therefore, failed to provide adequate protections against the risks of communicable disease transmission. For the reasons articulated herein, I therefore: (1) deny Mr. Arsenault's request for a hearing; and (2) find that the Cease Manufacturing Order was properly issued. **The Cease Manufacturing Order is therefore effective as of the date of this decision, in accordance with 21 CFR**

1271.440(a)(3)(ii). Should Mr. Arsenault wish to resume operations, he may do so only after obtaining written authorization from FDA under 21 CFR 1271.440(d).

Signed:

Jesse Goodman, M.D., M.P.H.
Chief Scientist

December 7, 2012
Date