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GAY MEN CANNOT ANONYMOUSLY DONATE SPERM?: HOW THE FDA’S EXCLUSION UNCONSTITUTIONALLY RESTRICTS AND DISCRIMINATES AGAINST THE LGBT COMMUNITY.

Taimour Chaudhri*

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I. INTRODUCTION

It comes as no surprise that certain governmental public health policies raise challenges and intense scrutiny from its opponents, as well as, from the public.¹ This has been the case with the Food and Drug Administration's (hereinafter the "FDA") passage of a regulation that excludes gay men from anonymously donating sperm.²

In 2004, the FDA announced its regulation on the transfer of Human Cell and Tissue Based Products ("HCT/P").³ Accompanying the regulation, was a draft guidance document that provided "recommendations for complying with requirements" of the FDA regulation.⁴ Among its recommendations was the exclusion on gay men from anonymously donating sperm, because of the allegedly high risk of communicable diseases among the Lesbian, Gay, Bisexual, and/or Transgendered community (hereinafter "LGBT Community").⁵

Not only does this exclusion place a restriction on what gay men can do, it also perpetuates a stereotype that gay men have a higher rate of communicable diseases than heterosexuals.⁶ In addition, this exclusion is at odds with the FDA's regulation that requires the thorough testing of donated sperm.⁷ Finally, sperm facilities have adopted new techniques that greatly minimize the spread of communicable diseases during insemination.⁸ In light of these factors, there is no

¹ Lawrence O. Gostin, et al., *The Law and Public's Health: A Study of Infectious Disease Law in the United States*, 99 Colum. L. Rev. 59, 94-95 (1999).

² See generally, Eligibility, Determination for Donors of Human Cells, Tissues and Cellular and Tissue Based Products, 69 Fed. Reg. 29,786 (May 25, 2005)(codified as 21 C.F.R. pts. 210, 211, 820, 1271) the rule became effective May 25, 2005 [hereinafter "FDA Regulation"].

³ *Id.*

⁴ See DRAFT GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 1, 16-21 (Aug. 8, 2007), <https://www.fda.gov/Cber/gdlns/tissdonor.pdf> [hereinafter "Draft Guidance Document"].

⁵ *Id.*

⁶ See *Heterosexual Transmission of HIV-29 States, 1999-2002*, 53 Morbidity & Mortality Weekly Rep. 125 (2004) available at <http://www.cdc.gov/mmwr/PDF/wk/mm5306.pdf> (last visited Sept. 12, 2012).

⁷ FDA Regulation, *supra* note 2.

⁸ See V. Savasi, et al., *Safety of Sperm Washing and ART outcome in 741 HIV-1--serodiscordant couples*, 22 Human Reproduction 772 (2006).

reasonable justification to allow this exclusion to remain as an effective barrier against gay men seeking to anonymously donate sperm.

a. The Unique Story of Trent Arsenault

The FDA's justification for excluding gay men from anonymously donating sperm is an example of their overall mission to reduce the risk of communicable diseases in the transfer of HCT/Ps.⁹ However, there are times when their mission detracts them from the actual purpose of donating sperm: to provide couples with a chance to start a family. The unique story of Trent Arsenault is a perfect example of the FDA imposing its regulation on a situation that does not require it.¹⁰

Trent Arsenault is a thirty-four (34) year old virgin, who lives in San Francisco and has made a name for himself as one of the most famous "do it yourself" ("DIY") sperm donors.¹¹ The son of a Pentecostal minister, he grew up in a religious community in Springfield, Missouri.¹² He eventually made his way to the Bay Area, where he took a job with Hewlett-Packard as a computer-security engineer.¹³ During this time, Trent became more interested in becoming a sperm donor and adopted a living regiment that would ensure his health and fertility.¹⁴

Trent began to donate his sperm to interested couples; his first time was to a lesbian couple from his home-town.¹⁵ On December 2006, he met his first donees and established a contract for the donation of his sperm. After the meeting, Trent donated his sperm and two weeks later, he

⁹ See FDA Regulation, *supra* note 2.

¹⁰ See generally, Benjamin Wallace, *The Virgin Father*, NEW YORK MAG., Feb. 5, 2012, available at <http://nymag.com/news/features/trent-arsenault-2012-2>.

¹¹ *Id.* at 1-2.

¹² *Id.*

¹³ *Id.* at 2, 4.

¹⁴ "[Trent] took to monitoring his health and having his blood tested for biomarkers, to gauge the effects of his diet on testosterone, metabolic function, liver function, enzymes, cholesterol, and vitamin and hormone levels." Trent's house in Fremont, CA "was far enough from highway exhaust fumes, which could lower sperm count, and sheltered by hills on three sides, blocking out 20 percent of the sky and mitigating his exposure to radiation, another threat to sperm." *Id.* at 4-5.

¹⁵ *Id.* at 6.

received good news that the couple was pregnant.¹⁶ Trent began to get more referrals for his sperm and decided to set up a website where anyone could review his personal information and send their request for his donation.¹⁷ By August 2010, Trent had “made around 340 donations to some 46 recipients,” with multiple success stories.¹⁸

Trent’s activities reached the ears of the FDA and on April 29, 2009, he received an e-mail from the FDA inquiring about his activities published on www.trentdonor.com.¹⁹ After conducting an inspection of Trent’s home, the FDA sent an order to cease manufacturing of HCT/Ps to Trent on November 1, 2010.²⁰ They charged Trent’s “establishment” with violating Title 21, *Code of Federal Regulations*, Part 1271 (21 CFR 1271), because he “[did] not provide adequate protections against the risks of communicable disease transmission.”²¹ As a result, the FDA demanded that Trent ceased his manufacturing of semen, because he did not follow their approved protocol of screening HCT/Ps for communicable diseases.²²

Despite Trent maintaining a healthy, fertile, and celibate lifestyle, the FDA considered his activities to be a risk for the transfer of communicable diseases.²³ In Trent’s case The FDA overextended its regulation and restricted a sperm donor, who was not sexually active and did

¹⁶ *Id.*

¹⁷ *Id.*; TRENT ARSENAULT, <http://www.trentdonor.com>.

¹⁸ Benjamin Wallace, *supra* note 10, at 7.

¹⁹ E-mail from Shelley H. Beausoleil, Investigator, Food and Drug Admin., to Trent Arsenault (Apr. 29, 2009) (on file with recipient) *available at* http://trentdonor.com/v/logos/fda_inspection/correspondence_with_the_fda/FDA-sacramento-request-registration-email-trentdonor-29-apr-2009.jpg.html.

²⁰ Letter from Karen Midthun, M.D., Dir., Ctr. for Biologics Evaluations and Research, Food and Drug Admin., to Trent Arsenault (Nov. 1, 2010) (on file with recipient) *available at* http://trentdonor.com/v/logos/fda_inspection/fda_order_to_cease_manufacturing_01-nov-2010/FDA-order-to-cease-manufacturing-trentdonor-01-Nov-2010-pg-1of5.jpg.html.

²¹In their letter, the FDA charged him with nine (9) counts of violation: 1) “failure to test a donor specimen for relevant communicable diseases;” 2) failure to test specimen for “Human T-cell Lymphotropic Virus types I and II;” 3) failure to test specimens for genitourinary tract diseases; 4) failure to test specimens or donor seven “days before or after recovery of semen;” 5) failure to test specimen for diseases associated with xenotransplantation; 6) failure to screen a donor’s eligibility; 7) failure to attach the medical donor eligibility with the donated specimen; 8) failure to keep records of donations; and 9) failure to have a set of procedures for testing, screening and donating sperm. *Id.* at 1.

²² *Id.*

²³ Benjamin Wallace, *supra* note 10, at 5, 7.

not posed any risk of spreading communicable diseases.²⁴ The FDA's intent to follow its regulation contrasted with Trent's intention for donating sperm and denied donees access to an exemplar donor²⁵

Now imagine if instead of Trent, it is a sperm donor facility that takes anonymous donations from gay men. If the FDA sends them an order to cease manufacturing, they would most likely adhere to it and refrain from accepting those donations. Unfortunately, this scenario is not hard to imagine, because the FDA's exclusion empowers the FDA with the means to deprive model sperm donors the opportunity of helping many couples start a family under pretextual reasons of the risk of communicable diseases.

The purpose of this Note is to illustrate how the exclusion is an ineffective means of reducing communicable diseases and that the exclusion should be stricken from the regulation, and replaced with an alternative, nondiscriminatory. Part I of this Note introduces the FDA regulation and its exclusion of gay men from anonymously donating sperm. Part II examines the data the FDA relies on: (1) the four isolated instances of HIV transmission from sperm donors, none of which address the threat posed by an anonymous gay sperm donor donating under the current testing provisions; and (2) the recommendations of an advisory board, who they, themselves, have questioned the accuracy and effectiveness of the particular exclusion. Part III analyzes a constitutional issue to the exclusion under the Fourteenth Amendment's Equal Protection Clause. Part III also analyzes the prejudice perpetuated against the LGBT community through this exclusion. Finally, Part IV of this note advocates the need to revoke the exclusion and replace it with an alternative nondiscriminatory method.

²⁴ *Id.* at 7.

²⁵ "Trent states that his reason for donating his sperm is to help people, "I think I'm doing a good thing," "[h]elping people. It's compassion, which is a tenet of religion. The official Assemblies of God view on it is that the seed of a man is between a man and a woman, and if God wants you to have a child, you will, and otherwise you don't have a child. And if you believe that, it shuts out quite a large group of people wanting to have children. What do you think Jesus would do?" *Id.* at 9-10.

Although this Note emphasizes that the development of the exclusion derives from the FDA's actions, it becomes difficult to ascribe an intention upon the exclusion. Even assuming the absence of discriminatory intent, the exclusion is the product of flawed research findings, and misguided efforts to pander to social conservative legislators, who disregard the significance of constitutional protections. Moreover, since its promulgation, proven scientific techniques have emerged to assure the fitness of all sperm donations, irrespective of their origin. Hence, the exclusion of gay men from anonymously donating sperm must be abrogated.

II. THE FDA REGULATION AND ITS EXCLUSION ON ANONYMOUS GAY SPERM DONATION

The FDA regulation was first proposed on September 30, 1999; it was introduced as a rule relating to donor suitability regarding the transfer of HCT/P.²⁶ After a protracted period, in which the FDA entertained various comments, the final rule was issued on May 25, 2004, and went into effect on May 25, 2005.²⁷ In conjunction with the final rule, the FDA issued an industry guidance document that provided a list of recommendations to sperm donor facilities on how to screen potential donors.²⁸ The guidance document instructed sperm-donor officials interviewing potential donors to review their medical records, and “ask questions about the donor’s medical history and relevant social behavior, including risk factors for relevant communicable disease agents....”²⁹ It listed the relevant risk factors for communicable diseases, which included as number one: “[m]en who have had sex with another man in the proceeding five (5) years”

²⁶ John G. Culhane, *Sexual Orientation: Law & Policy: Bad Science, Worse Policy: The Exclusion of Gay Males from Donor Pools*, 24 St. Louis U. Pub. L. Rev. 129, 137 (2005).

²⁷ FDA Regulation, *supra* note 2.

²⁸ Draft Guidance Document, *supra* note 4, at 16-21.

²⁹ *Id.* at 14.

(“MSM”).³⁰ If these risk factors were revealed during the interview, then it was recommended that the interviewer consider the potential donor ineligible to donate sperm.³¹

Although the FDA received much criticism about this exclusion, it justified its decision by stating that no new data existed that would warrant a revision of the risk factor.³² In support of its position the FDA responded to criticism by stated that:

In response to the comments suggesting that the FDA should allow establishments to rely on HIV test results alone, or on quarantine and retesting without screening risk factors, [the] FDA rejects that approach at this time. Although it is reasonable to expect that more sensitive nucleic acid amplification testing (“NAT”) will be available soon for reproductive tissue donors, even that testing may fail to detect early stage HIV and other infections, particularly because the level of viremia may be extremely low in the early stages of infection. Moreover, even the best test may fail to provide an accurate test result due to human error in running the test or in linking the test result to the correct donor. Accordingly, FDA believes that based on the current state of testing and current knowledge about disease transmission, it is necessary to screen for risk factors as well as to test for diseases such as HIV.³³

In its refusal to amend the regulation and remove the exclusion, the FDA believed it was in line with its mission statement, which was to protect and advance the public health.³⁴

As a means to further honor its commitment to the public, the FDA implements a strict policy of testing all anonymous sperm donors.³⁵ Under its regulation, the sperm banks must test a donor’s blood seven (7) days in advance of the donation.³⁶ The FDA requires a quarantine period of six (6) months, in which the donation is frozen, and after 6 months the donor’s blood is retested for any infection.³⁷ The FDA’s 6-month quarantine on all anonymous donations ensures that if a recently-infected donor does not test positive at the time of donation, the virus and

³⁰ *Id.*

³¹ *Id.*

³² FDA Regulation, *supra* note 2.

³³ *Id.*

³⁴ See FDA’s Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Sept. 8, 2012).

³⁵ 21 C.F.R. §§ 1271.80, 1271.85(d) (West 2007).

³⁶ *Id.*

³⁷ *Id.*

antibodies would appear at the end of the six months and would be revealed through the second test.³⁸ In order to achieve accurate results, the FDA explicitly recommends that sperm banks and fertility clinics implement new forms of testing that provide earlier detection of HIV and HCV, usually within days or weeks of infection.³⁹

Not only does the FDA issue a guidance document to its regulation, it also implements a safety mechanism in requiring all anonymous sperm donation to be tested twice.⁴⁰ According to the FDA, all of these measures are necessary to protect the public from the risk of communicable diseases.⁴¹

III. THE ABSENCE OF RELIABLE SOURCES TO JUSTIFY THE FDA'S EXCLUSION OF MSMS.

The FDA is the regulating body of the Department of Health and Human Services; it is established by the Federal Food and Drugs Act of 1906 and is "responsible for regulating food, drugs, cosmetics, animal feed, biologics, and many other similar products."⁴² The FDA's primary mission is to protect the public from the potential dangers associated with many of these products, which it attempts to accomplish through its regulations.⁴³ Before finalizing its proposals, the FDA seeks the advice of officials and experts in their respected fields in order to create a comprehensive regulation that addresses all the issues concerning the public's welfare.

³⁸ Luke A. Boso, *The Unjust Exclusion of Gay Sperm Donors: Litigation Strategies to End Discrimination in the Gene Pool*, 110 W. Va. L. Rev. 843, 848 (2008) (citing Suitability Determination for Donors of Human and Cellular and Tissue-Based Products, 64 Fed. Reg. 52,696, 52,706 (proposed Sept. 30, 1999) (to be codified as 21 C.F.R. pts. 210, 211, 820, 1271)).

³⁹ Letter from John Givner, Staff Attorney, Lambda Legal to Div. of Dockets Mgmt. Food and Drug Admin. 1, 3-4. 4 n. 4 (Aug. 23, 2004), available at <http://www.fda.gov/OHRMS/DOCKETS/dailys/04/aug04/083004/04d-0193-c00017-voll.pdf>.

⁴⁰ FDA Regulation, *supra* note 2; see also Draft Guidance Document, *supra* note 4, at 16-21.

⁴¹ FDA Regulation, *supra* note 2; see also Draft Guidance Document, *supra* note 4, at 16-21.

⁴² Luke A. Boso, *supra* note 38, at 845.

⁴³ FDA Mission Statement, *supra* note 34.

The FDA relies on a variety of sources when compiling its regulation for the transfer of HCT/Ps.⁴⁴

The FDA excludes MSMs in the hopes of reducing the risk of HIV and AIDS transmissions.⁴⁵ This belief is primarily based upon its reliance on two sources: the first source is an eighteen year old “Recommendation and Report” issued by the Center for Disease Control and Prevention (“CDC”) entitled “Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs” (hereinafter “CDC Report”).⁴⁶ In this report, four instances of HIV transmission from semen donors is recorded; however, neither one of the instances demonstrates the threat posed by an anonymous donation from an MSM under the FDA’s strict testing provision.⁴⁷ The second source is a transcript of a meeting of the “FDA Blood Products Advisory Committee” (hereinafter “Advisory Committee Meeting”) held in December 2001, where a group of medical professionals debated on the validity of excluding MSMs from anonymous sperm donations.⁴⁸ Although the majority of the committee has agreed that the provided data does not accurately portray the threat of HIV transmission posed by MSMs, the committee has still voted on the limited information available to them at the meeting.⁴⁹ These two sources constitute the primary information the FDA relies on to justify its exclusion of MSMs from anonymously donating sperm.

a. The CDC Report

⁴⁴ FDA Regulation, *supra* note 2.

⁴⁵ *Id.*

⁴⁶ Ctr. for Disease Control & Prevention, Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissues and Organs, 43 Morbidity & Mortality Weekly Rep. 1 (1994), *available at* <http://www.cdc.gov/mmwrhtml/0031670.htm> (last visited Sept. 13, 2012) [hereinafter CDC Report].

⁴⁷ *Id.* at 1; FDA Regulation, *supra* note 2.

⁴⁸ *See generally* Food & Drug Admin., Dep’t of Health & Human Servs., Blood Products Advisory Committee 70 [su’th] Meeting (Dec. 14, 2001), *available at* <http://www.fda.gov/ohrms/dockets/ac/01/transcripts/3817t2.html> (last visited Sept. 13, 2012) [hereinafter Advisory Committee Meeting].

⁴⁹ *Id.*

The FDA relied on the CDC report to justify the exclusion of MSMs. The CDC report explained whether there was a need for increased federal oversight of transplantation of HCT/P.⁵⁰ It was created after a 1991 investigation revealed several instances of HIV transmission in recipients that had received an organ or tissue donation.⁵¹ Despite the important need to reduce the risk of HIV transmission, the CDC report was only able to identify four instances of HIV transmissions, none of which pertained to MSM donations.⁵²

The first case of HIV transmission showed a human error to be the cause of the transmission, where a required confirmatory test for HIV was never administered.⁵³ In the second case, the facility allowed a period of eight months to elapse between the time the donor was tested for HIV and the time he donated.⁵⁴ The third case resulted from an emergency condition, which heightened the risk of HIV transmission, because no precautionary testing could be taken.⁵⁵ Finally, the fourth case involved an issue regarding the risk of HIV transmission within the window phase or period of “seroconversion.”⁵⁶

In addition to citing instances of HIV transmission in HCT/P recipients, the CDC report cited several studies of HIV transmission that were conducted in the 1980s.⁵⁷ Through these studies,

⁵⁰ CDC Report, *supra* note 46, at 1.

⁵¹ *Id.*

⁵² *Id.* at 2.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Seroconversion is defined as: “the production of antibodies in response to an antigen,” *Seroconversion Definition*, MERRIAM-WEBSTER DICTIONARY, available at <http://www.merriam-webster.com/medical/seroconversion>; or “The change from HIV-negative to HIV-positive status during blood testing. Persons who are HIV-positive are called seroconverters.” *Seroconversion Definition*, THE FREE-DICTIONARY, available at <http://medical-dictionary.thefreedictionary.com/seroconversion>.

⁵⁷ CDC Report, *supra* note 46, at 15; see also John G. Culhane, *supra* note 26, at 140 (citing Ctrs. for Disease Control & Prevention, Current Trends Prevention of Acquired Immune Deficiency Syndrome (AIDS); Report of Inter-Agency Recommendations, 32 Morbidity & Mortality Weekly Rep. 101-3 (1983), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/0001257.htm> (last visited Sept. 12, 2012); Ctrs. for Disease Control & Prevention, Provisional Public Health Service Inter-Agency Recommendations for Screening Donated Blood and Plasma for Antibody to the Virus Causing Acquired Immunodeficiency Syndrome, 34 Morbidity & Mortality Weekly Rep. 1-5 (1985), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/0033029.htm> (last visited Sept. 12, 2012); Ctrs. for Disease Control & Prevention, Epidemiologic Notes and Reports Testing Donors of Organs, Tissues, and Semen for

the CDC fortified its recommendation to exclude MSMs.⁵⁸ In addition to these early reports, the CDC report cited their 1988 report that focused on blood and sperm donations.⁵⁹ The FDA based its regulation on the recommendations of the CDC report, which itself relied on isolated instances of HIV transmission in donor recipients, and CDC reports from the early to late 1980s.⁶⁰

b. The FDA Advisory Blood Products Committee Meeting and the Young Men's Survey

The second source the FDA based its decision on was the transcript from the Advisory Committee Meeting held in December 2001.⁶¹ After the FDA drafted the proposed rule in 1999, it invited the Blood Products Advisory Committee to review various comments and concerns regarding the proposed regulation.⁶² Among other issues, the Committee focused on the issue of whether MSMs constituted a risk factor for communicable diseases.⁶³ In analyzing this question, the Committee reviewed the data assembled by Dr. Linda Valleroy, an epidemiologist for the CDC's Division of HIV-AIDS Prevention.⁶⁴

Dr. Valleroy assembled her data in the Young Men's Survey ("YMS").⁶⁵ The study was conducted in seven U.S. cities beginning in 1993.⁶⁶ Based on the results of the survey, Dr. Valleroy stated that "[c]ompared to the general population the incidence rates among men who have sex with men [were] [eighty-seven] 87 to [one hundred ninety three] 193 times higher for

Antibody to Human T-Lymphotropic Virus Typ III/Lymphadenopathy-Associated Virus, 34 *Morbidity & Mortality Weekly Rep.* (1985), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00000547.htm> (last visited Sept. 12, 2012)).

⁵⁸ CDC Report, *supra* note 46, at 15.

⁵⁹ John G. Culhane, *supra* note 4, at 141 (citing Ctrs. for Disease Control & Prevention, Perspectives in Disease Prevention and Health Promotion, Semen Banking, Organ and Tissue Transplantation, and HIV Antibody Testing, 37 *Morbidity & Mortality Weekly Rep.* 57-58, 63 (1988), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001037.htm> (last visited Sept. 12, 2012)).

⁶⁰ See generally CDC Report, *supra* note 46.

⁶¹ See generally Advisory Committee Meeting, *supra* note 48.

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.* (citing Linda Valleroy, et al., *The Young Men's Survey: Methods of Estimating HIV Seroprevalence and Risk Factors among Young Men Who Have Sex with Men*, 111 *Pub. Health Rep.* 138 (1996)).

⁶⁶ Advisory Committee Meeting, *supra* note 48.

HIV.”⁶⁷ She based her results on the process by which she and her team obtained the relevant data, which was conducted by taking samplings of young men between the ages of 15 and 22 who admitted to having sex with men from the periods of 1994 to 1998.⁶⁸ The survey was conducted in Baltimore, Dallas, Los Angeles, Miami, New York City, San Francisco and Seattle.⁶⁹ Dr. Valleroy located her subgroup of young men by going to specific venues that were known to attract young promiscuous men.⁷⁰ These venues “were [anything] from parks, beaches, street locations, restaurants, coffee shops, dance clubs, bars, gyms, [or] any place that young men who [have] sex with men would go.”⁷¹

In order to conduct each sampling, a four-person survey team would park a van modified to hold two simultaneous interviews near the venues.⁷² The team would then target young men between the ages of 15-22 and asks a series of questions, followed by drawing their blood and testing it for HIV, Hepatitis B, and Syphilis.⁷³ At each sampling, the team collected the following data: “(a) the total number of young men who visited the venue; (b) of those counted, the number of young men intercepted and briefly interviewed; (c) the age, race, and county residence of young men intercepted; (d) of those intercepted, the number of young men who were determined eligible for the first time; and (e) the number of young men who enrolled in YMS.”⁷⁴

Dr. Valleroy’s team enrolled three thousand four hundred ninety two (3,492) young men, which was approximately five hundred (500) young men in each city.⁷⁵ The enrollment rate was around sixty-two percent (62%), which provided the desired data regarding HIV transmission

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² Linda Valleroy, et al., *supra* note 65, at 140.

⁷³ Advisory Committee Meeting, *supra* note 48.

⁷⁴ Linda Valleroy, *supra* note 65, at 141.

⁷⁵ Advisory Committee Meeting, *supra* note 48.

among young men who had sex with men.⁷⁶ The data from the survey showed an HIV prevalence of 7.2%, and a hepatitis B prevalence of 10.7%, which was categorized as a very high prevalence of communicable diseases in a subgroup.⁷⁷ Dr. Valleroy provided this data to the Advisory Committee as a sampling and an illustration of the high rates of communicable diseases within the entire MSM subgroup.⁷⁸

Upon the conclusion of the meeting, the committee casted a vote concerning whether MSMs should be considered a risk factor in the proposed FDA regulation.⁷⁹ The question the committee asked was “[were] there existing data that identif[ied] subsets of men who [had] sex with other men, in which the incidence and prevalence rates of HIV, HBV, and HCV of the subsets [were] similar to the population at large?”⁸⁰ Many of the members expressed concerns over the wording of the question, and observed that because the only data available was the YMS study, the answer to the question was a resounding “no.”⁸¹ The committee decided to posit a recommendation to the FDA to request data about the identity of a subgroup of men who have sex with men, in which the prevalence of communicable diseases was similar to the rate in the public at large.⁸² Despite the recommendation, the FDA in its final rule did not request a study to be conducted to answer this question; instead, the FDA took as authoritative the answer the committee gave to the initially proposed question.⁸³

⁷⁶ *Id.*

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ *Id.*

⁸¹ The committee attempted to replace the question with another more accurate question, but failed to reach a consensus. One Committee member, Dr. Stroncek came close to a more accurate question stating that the question should ask if “[e]xisting screening questions, laboratory tests and quarantine procedures can be used to identify a subset of men who had sex with other men in which the prevalence rates of HIV, HBV, and HCV of the subjects is similar to that of the public at large.” *Id.*

⁸² *Id.*

⁸³ FDA Regulation, *supra* note 2.

The FDA's reliance on the CDC report and the Advisory Committee Meeting to justify their exclusion is misplaced. The CDC report based its information on four, isolated instances of HIV transmission and reports that are over twenty-five years old. In turn, the FDA based its decision and rulings on the YMS study, which over-generalizes the MSM subgroup by applying a study that focuses on a very specific group within the MSM subgroup to the entire MSM population. Moreover, the Advisory Committee established by FDA to review the exclusion believed the YMS study to be too limited to support the exclusion absent a greater scientific review.

c. The "Outdatedness" and Inaccuracy of the Sources Used to Justify the Exclusion

The FDA's two sources are skewed and inaccurately represent the rate of HIV and Hepatitis B transmission among MSMs. The CDC Report does not provide a justifiable explanation as to why MSMs are excluded from donating sperm and instead relies on a few isolated instances of HIV transmission and data from over twenty-five year old reports.⁸⁴ None of the instances described in the report concerns a transmission of HIV in the context of frozen sperm donation.⁸⁵

In the first case, the donor never received the required HIV test before making his donation.⁸⁶ In the second instance, the donation was made eight (8) months after the donor took the HIV test, which left a large window of time open for the donor to contract the virus.⁸⁷ The third case involved an emergency situation where waiting for the test results was not a viable option (this would not occur in the context of sperm that is quarantined for 6 months).⁸⁸ Finally the fourth instance involved a window problem, where the donor did not come up positive during testing, because the test was administered during the time of "seroconversion."⁸⁹ Again, the concurrent FDA requirement to test donors twice, once before the donation and again after the quarantine

⁸⁴ CDC Report, *supra* note 46, at 2.

⁸⁵ John G. Culhane, *supra* note 26, at 140.

⁸⁶ John G. Culhane, *supra* note 26, at 140 (citing CDC Report, *supra* note 46, at 2).

⁸⁷ *Id.*

⁸⁸ *Id.*

⁸⁹ *Id.*

period, has reduces instances of HIV transmissions through donation from occurring again.⁹⁰ Given the unique circumstance of the HIV transmission in each of these instances, no data exists to prove that there is a threat of transmission from an MSM, who has undergone the double testing and six-month quarantine requirement.⁹¹

In addition to referencing unrelated instances of HIV transmission, the CDC's reliance on outdated reports does not provide a reasonable justification for the exclusion in today's world.⁹² The earliest CDC report is from 1983, while the other two are from 1985.⁹³ Neither of these reports gives an in-depth analysis of the actual risk of HIV transmission from an MSM donation.⁹⁴ The CDC's 1988 release entitled "Perspectives in Disease Prevention and Health Promotion, Semen Banking, Organ and Tissue Transplantation and HIV Antibody Testing" has come close to giving a justification to the exclusion.⁹⁵ However, the release only emphasized the importance of freezing sperm donations and imposing a quarantine period without specifically discussing the reasons for the exclusion.⁹⁶ Ultimately, the old reports fail to provide an independent justification as to why the exclusion is a legitimate way to prevent the potential threat of HIV transmission in MSM donations.⁹⁷

Unlike the CDC Report that never provides a direct or justifiable explanation for the exclusion, the Advisory Committee Meeting directly addresses the issue by reviewing the data

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ The 1985 report is from the time when HIV-antibody testing was introduced to the public health community, and not a lot of information about HIV was known to the general public.⁹³ *Id.* at 141.

⁹⁴ *Id.*

⁹⁵ *Id.* (citing Ctrs. for Disease Control & Prevention, Perspectives in Disease Prevention and Health Promotion, Semen Banking, Organ and Tissue Transplantation, and HIV Antibody Testing, 37 Morbidity & Mortality Weekly Rep. 57-58, 63 (1988), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/00001037.htm> (last visited Sept. 13, 2012)).

⁹⁶ *Id.*

⁹⁷ *Id.*

compiled in the YMS study.⁹⁸ However, the data presented in the study creates an inaccurate illustration of the rate of communicable diseases among MSMs.

The study obtained its result from a small subset of MSMs: young men between the ages of 15 and 22 who engaged in sex with men and frequented venues with high rates of promiscuity.⁹⁹ Dr. Peter Lachenbrach expressed these sentiments at the meeting stating that the study had “gotten the most active participants in MSM, and that might lead to an upward bias in the rates [she had] gotten.”¹⁰⁰ In response to Dr. Lachenbrach’s statement, Dr. Valleroy justified her study by admitting that there was no plausible way to glean an accurate representation of the rate of communicable diseases among the MSM population.¹⁰¹

Mr. Leeland Terriman, Director of the Rainbow Flag Health Services and Sperm Bank in Oakland, California, also raised concerns about the results from the study.¹⁰² He believed that the FDA inappropriately applied the results of the study to all gay men, rather than narrowing it down to the subgroup of young men between the ages of 15 and 22.¹⁰³ He stated that applying sexual habits of young gay men to other gay men in their thirties and forties, or gay men in monogamous relationships grossly exaggerated the rate of communicable diseases among MSMs.¹⁰⁴ The YMS study was the only study the Advisory Committee had to determine whether MSMs posed a high risk of HIV transmission in sperm donation.¹⁰⁵ The Committee was forced to make a decision about the exclusion based on a study that exaggerated the rate of communicable diseases among MSMs.¹⁰⁶

⁹⁸ Advisory Committee Meeting, *supra* note 48.

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

The sources used by the FDA to support its exclusion illustrate a weak link between the rates of HIV transmission in sperm donation and the rate of transmission among anonymous MSM sperm donors.¹⁰⁷ The CDC Report's only refers to four instances of HIV transmission in sperm donation; however, none of the instances involve the sperm collected through the FDA mandated testing provisions.¹⁰⁸ The Advisory Committee Meeting transcript demonstrates that the committee itself questioned whether the available data accurately illustrated the threat posed by anonymous MSM sperm donation.¹⁰⁹ Neither the CDC Report nor the Advisory Committee Meeting provides evidence strong enough to justify the FDA's exclusion of MSMs.

IV. RAISING A CONSTITUTIONAL CHALLENGE TO THE EXCLUSION UNDER THE EQUAL PROTECTION CLAUSE.

By relying on unconvincing sources, the FDA's exclusion raises public policy issues about the government's treatment of the LGBT community.¹¹⁰ It stunts the LGBT movement, by perpetuating discriminatory behaviors upon the LGBT community. The exclusion requires gay men to either change their behavior or suppress their sexual identity from the general population.¹¹¹ A constitutional challenge to the exclusion can be raised under the Equal Protection Clause of the Fourteenth Amendment.¹¹² It places an additional burden on gay men, without placing similar requirements on sexually active heterosexual males.¹¹³ Additionally, it does not advance a legitimate state interest of protecting the public health, because the mandated testing period satisfies that state interest.¹¹⁴

a. The Exclusion Perpetuates the Discriminatory Behavior of "Gay Passing" and "Gay Covering"

¹⁰⁷ CDC Report, *supra* note 46, at 15; *see also* Advisory Committee Meeting, *supra* note 48.

¹⁰⁸ CDC Report, *supra* note 46, at 15.

¹⁰⁹ Advisory Committee Meeting *supra* note 48.

¹¹⁰ *See generally* Kenji Yoshino, *Covering*, 111 Yale L. J. 769 (2002).

¹¹¹ *Id.* at 772.

¹¹² U.S. CONST. amend. XIV; U.S. CONST. amend. V.

¹¹³ Draft Guidance Document, *supra* note 4 at 13-16.

¹¹⁴ FDA Regulation, *supra* note 2.

The exclusion perpetuates the discriminatory behaviors of “gay passing” and “gay covering” upon the LGBT community.¹¹⁵ Chief Justice Earl Warren Professor of Constitutional Law Kenji Yoshino highlights the types of discrimination the LGBT community faces in society through an analysis of three distinct forms of inequality: “gay conversion,” “gay passing,” and “gay covering.”¹¹⁶ Gay conversion requires a homosexual to convert their sexual identity, while “gay passing” merely asks a homosexual person to hide their identity.¹¹⁷ However, “gay covering” does not require a homosexual to hide their identity, but to downplay it.¹¹⁸ The government has implemented these inequalities in a variety of legislation.¹¹⁹ The exclusion on MSMs is no exception; it perpetuates “gay passing” and “gay covering” by requiring MSMs to either hide or downplay their sexual identity.¹²⁰

In the social context, “gay passing” is where society requires homosexuals to hide their sexual identity rather than convert it.¹²¹ In other words, “[p]assing is acting straight by feigning an interest in sports, by creating a fictitious girlfriend, [or] by laughing at the right jokes.”¹²² Passing, unlike conversion, occurs in a selective manner; an individual is faced with many closets to come out from and can choose to come out or pass given their level of comfort, *i.e.*

¹¹⁵ Kenji Yoshino, *supra* note 110, at 775.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 772.

¹¹⁸ *Id.*

¹¹⁹ The United States Military is an excellent illustration of the Government’s move from a “gay conversion” policy to a “gay passing” policy. In 1981, the administrative regulation held that “homosexuality [was] incompatible with military service,” which meant that the military only allowed heterosexuals to serve in the military. In 1993 Congress passed the “don’t ask don’t tell” (“DADT”) policy, which allowed homosexual people to enlist in the military so long as they did not reveal their sexual identity. If they reveal their identity, then they were immediately discharged from the military. DADT is an example of a “gay passing” policy, because instead of requiring homosexual people to convert, it required them to hide their sexual identity. *Id.* at 827-28.

¹²⁰ FDA Regulation, *supra* note 2.

¹²¹ Kenji Yoshino, *supra* note 110, at 813.

¹²² *Id.* (quoting JAMES D. WOODS WITH JAY H. LUCAS, *THE CORPORATE CLOSET: THE PROFESSIONAL LIVES OF GAY MEN IN AMERICA*, at xiv (1998)).

homosexuals can choose to come out to their friends, parents, co-workers, bosses or choose to remain hidden from all or some of these parties.¹²³

In the legal context, the state and federal government enforced certain legislations that encouraged the LGBT community to hide their identity.¹²⁴ The 1993, “don’t ask, don’t tell policy” (hereinafter “DADT”) was a “gay passing” legislation.¹²⁵ It required LGBT members serving in the military to hide their sexual identity, and if their identity was revealed during service, they were automatically discharged.¹²⁶ Under DADT, the number of exclusions of homosexual men from service far exceeded the exclusion of homosexual men from the military’s previous “gay conversion” policy of requiring homosexuals to convert to heterosexuality in order to serve.¹²⁷

Just like the DADT, the FDA’s exclusion on MSMs encourages “gay passing” among MSMs. The FDA regulation requires interviewers to ask potential donors about their medical and sexual history.¹²⁸ Through this process, the interviewer can learn whether a potential donor belongs to the MSM subgroup, and therefore is ineligible to anonymously donate sperm.¹²⁹ Because the guidance document excludes MSMs from anonymously donating sperm, MSMs would be more inclined to hide their sexual identity during the interview process.¹³⁰ An MSM could anonymously donate sperm, as long as he did not reveal his sexual identity to the sperm

¹²³ *Id.*

¹²⁴ *Id.* at 827.

¹²⁵ *Id.*

¹²⁶ *Id.* at 827-28 (citing JANET E. HALLEY, DON’T: A READER’S GUIDE TO MILITARY’S ANTI-GAY POLICY 33 (1999); 10 U.S.C. § 654(b)(1), (3) (1994)).

¹²⁷ *Id.* at 833 (citing OFFICE OF UNDER SEC’Y OF DEF. (PERS & READINESS), REPORT TO THE SECRETARY OF DEFENSE: REVIEW OF THE EFFECTIVENESS OF THE APPLICATION AND ENFORCEMENT OF THE DEPARTMENT’S POLICY ON HOMOSEXUAL CONDUCT IN THE MILITARY (1998), available at <http://www.defenselink.mil/pubs/rpt040798.html>; see also Eric Schmidt, *Close Quarters: How is this Strategy Working? Don’t Ask*, N.Y. TIMES, Dec. 19, 1999, § 4, at 4).

¹²⁸ FDA Regulation, *supra* note 2.

¹²⁹ *Id.*, Draft Guidance Document, *supra* note 4, at 1.

¹³⁰ Draft Guidance Document, *supra* note 4, at 16.

facility; however, if his identity is discovered, then he will be subject to the exclusion.¹³¹ The exclusion perpetuates “gay passing” by encouraging MSMs to lie about their sexual identity, so that they can anonymously donate sperm.¹³²

Along with perpetuating “gay passing,” the exclusion also perpetuates “gay covering.” “Gay covering” allows homosexuals to be open about their sexuality, but requires them to downplay it.¹³³ In other words, covering discourages the LGBT community from displaying homosexual conduct in public, such as two men holding hands or kissing.¹³⁴ There are many other examples of activities that the LGBT community engages in which are subject to covering demands.¹³⁵ Thus, covering is distinguishable from passing in that passing focuses on controlling the visibility of homosexuality, while covering focuses on its obtrusiveness.¹³⁶

Gay covering also exists in the legal context, and has been influential in the employment of homosexuals in the civil service and the issue of child custody and visitation between divorced parents, where one parent is a homosexual and the other is a heterosexual.¹³⁷ In the employment realm, there have been several cases, where the courts have held that if an openly gay employee’s sexual identity affected their employment, then there is a justifiable basis to terminate them.¹³⁸ Regarding the custody and visitation of children, the courts have stripped

¹³¹ *Id.*; In addition to being subject to the exclusion, the FDA enforces penalties to individuals that violate the regulation. Under Section 361 of the Public Service Act, “any person who violates a regulation under [the Act] maybe punished by imprisonment for up to 1 year. “Individuals may also be punished for violating such a regulation by a fine of up to \$100,000 if death has not resulted from the violation or up to \$250,000, if death has resulted.” The FDA can also bring fines or penalties against the fertility clinics that approve MSMs by imposing fines from \$200,000 to \$500,000. *See* FDA Regulation, *supra* note 2.

¹³² Kenji Yoshino, *supra* note 110, at 827-28.

¹³³ *Id.* at 837.

¹³⁴ KENJI YOSHINO, COVERING 107 (Random House, 2006).

¹³⁵ Some forms of covering include 1) the abstention from any sexual intercourse amongst homosexual persons; 2) requiring homosexuals to act straight; 3) focusing on straight culture over gay culture; 4) being passive on LGBT issues; 5) primarily having straight friends over homosexual friends, and many more. *Id.* at 843-47.

¹³⁶ Kenji Yoshino, *supra* note 110, at 837 (citing ERVING GOFFMAN, STIGMA: NOTES ON THE MANAGEMENT OF SPOILED IDENTITY 102-04 (1963)).

¹³⁷ *Id.* at 850.

¹³⁸ *See generally* Dew v. Halaby, 317 F.2d 582 (D.C. Cir. 1963) (The Civil Aeronautics Authority discharged their air traffic controller, Dew, because he had engaged in homosexual behavior in his adolescence, and the D.C. Circuit Court

custody from homosexual parents, who engage in homosexual behavior in the presence of their children.¹³⁹

Gay covering also finds a place in the public health arena, through the FDA's exclusion. The exclusion encourages MSMs to cover their sexual behavior. The FDA exclusion not only punishes gay men for being open about their sexual orientation but does so based on homosexual activity irrespective of any consideration that the specific gay man they are excluding is at a lower risk than a straight man based on his *actual* sexual activity.¹⁴⁰ The guidance document specifically states that "[m]en who have had sex with another man in the preceding [five] 5 years" is a risk factor for communicable diseases.¹⁴¹ Conversely, the exclusion allows MSMs who have not been sexually active for the past 5 years to anonymously donate sperm.¹⁴² Abstaining from homosexual activity is the fundamental way in which a person can cover their homosexuality.¹⁴³ Since the exclusion applies to sexually active MSMs, it requires MSMs to cover their sexual identity in order to be allowed to anonymously donate sperm.¹⁴⁴

upheld the termination, because it was not "arbitrary or capricious" for an agency to consider pre-employment activity when determining an person's employment eligibility.); *see also* Singer v. U.S. Civil Serv. Comm'n, 530 F.2d 247 (9th Cir. 1976) (Singer, an openly gay clerk typist for the EEOC was terminated for openly professing his sexuality in the workplace, the Ninth Circuit upheld the termination stating that Singer was "openly and publicly flaunting his homosexual way of life and indicating further continuance of such activities, while identifying himself as a member of a federal agency.").

¹³⁹ *See generally* Chaffin v. Frye, 45 Cal. App.3d 39 (Ct. App. 1975) (The California Court of Appeal denied custody and visitation rights to a lesbian mother, stating that she was engaged in homosexual conduct with another woman and intended to raise her child in that environment); *see also* Scott v. Scott, 665 So.2d 760 (La. App. 1 Cir. 1995) (The Louisiana Court of Appeal denied custody to a lesbian mother, after hearing from several witnesses about her public display of affection with another woman that extended beyond what the court considered affection accepted between two women); *and* In re J.S. & C., 324 A.2d 90 (N.J. Super. Ct. Ch. Div. 1974), *aff'd*, 362 A.2d 54 (N.J. Super. Ct. App. Div. 1976) (The court granted visitation rights to a gay father under specific conditions: 1) no same-sex cohabitation with anyone aside from a legal spouse; 2) prevent children from frequenting gay establishments; and 3) prevent children from partaking in homosexual advocacy or publicity.).

¹⁴⁰ Draft Guidance Document, *supra* note 4, at 14.

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ Kenji Yoshino, *supra* note 110, at 842.

¹⁴⁴ Draft Guidance Document, *supra* note 4, at 14.

In addition to requiring MSMs to cover by refraining from homosexual activity, the exclusion also requires sexually active MSMs to behave in a certain way.¹⁴⁵ Although the regulation excludes MSMs from anonymously donating sperm, it allows them to make directed donations.¹⁴⁶ The FDA rationalizes that a recipient of a directed donation would select an MSM who is free of any communicable diseases.¹⁴⁷ Both the exclusion and the regulation require MSMs interested in donating sperm to do so only through a directed donation.¹⁴⁸ This is similar to the courts requiring homosexual parents to behave in a specific way in order to preserve their custody and visitation rights.¹⁴⁹ Therefore, the exclusion and the regulation perpetuates gay covering on the LGBT community by either encouraging them to refrain from homosexual activity or behave in a specific way, *i.e.* to only make directed donations.¹⁵⁰

The government has passed various laws and regulations that have perpetuated three forms of inequality against the LGBT community: “gay conversion,” which required people to convert to heterosexuality; “gay passing,” which required them to hide their sexuality, and finally “gay covering,” which required them to downplay their sexuality.¹⁵¹ The FDA exclusion continues this government tradition, by perpetuating “gay passing” and “gay covering” inequalities against the LGBT community.¹⁵² The exclusion increases the propensity of MSMs to hide their sexual identity in order to anonymously donate sperm.¹⁵³ In addition, the exclusion also requires MSMs open about their sexuality, to either refrain from engaging in homosexual activity, or behaving in a specific way.¹⁵⁴

¹⁴⁵ FDA Regulation, *supra* note 2.

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*; Draft Guidance Document, *supra* note 4, at 14.

¹⁴⁹ Kenji Yoshino, *supra* note 110, at 858-63.

¹⁵⁰ FDA Regulation, *supra* note 2; *see also* Draft Guidance Document, *supra* note 4, at 14.

¹⁵¹ Kenji Yoshino, *supra* note 110, at 772-75.

¹⁵² FDA Regulation, *supra* note 2; Draft Guidance Document, *supra* note 4, at 14.

¹⁵³ Draft Guidance Document, *supra* note 4, at 14.

¹⁵⁴ *Id.*; *see also* FDA Regulation, *supra* note 2.

b. The Constitutional Challenges to the Exclusion of MSMs

Not only does the exclusion lack a reasonable justification and perpetuate discriminatory behavior, it also raises a constitutional issue under the Equal Protection Clause of the Fourteenth Amendment.¹⁵⁵ The exclusion violates the clause by placing a restriction on MSMs interested in anonymously donating sperm.¹⁵⁶ In addition, the exclusion fails the equal protection clause's rational basis test, because it does not satisfy a *legitimate* state interest, *i.e.* protecting the public from communicable diseases.¹⁵⁷

For many years, the judicial system has played a balancing game between respecting the government's power to implement legislation, with protecting individual liberties. *Skinner v. Oklahoma* is a perfect example of the Court preserving individual liberties over the government's attempts to maintain imprudent legislation.¹⁵⁸ The case dealt with the constitutionality of Oklahoma's "Habitual Criminal Sterilization Act," which stated that a "habitual criminal," a person convicted of two or more crimes involving "moral turpitude," could be rendered sexually sterile through a decision of a court or a jury, so long as the sterilization does not jeopardize their general health.¹⁵⁹ The sterilization can be administered by a vasectomy for a man or a salpingectomy for a woman.¹⁶⁰ The statute also indicated that individuals who committed "prohibitory laws, revenue acts, embezzlement, or political offenses" did not commit crimes involving "moral turpitude."¹⁶¹

¹⁵⁵ FDA Regulation, *supra* note 2; Draft Guidance Document, *supra* note 4, at 1; U.S. CONST. amend. XIV.

¹⁵⁶ U.S. CONST. amend. XIV.

¹⁵⁷ *See generally*, Draft Guidance Document, *supra* note 4.

¹⁵⁸ *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

¹⁵⁹ *Id.* at 536.

¹⁶⁰ *Id.* at 536-37.

¹⁶¹ *Id.* at 537.

The case arose after petitioner, Jack T. Skinner, (“Skinner”) was ordered to be sterilized after committing three offenses that the Oklahoma court considered to involve “moral turpitude.”¹⁶² Skinner challenged the constitutionality of the statute under the equal protection clause of the Fourteenth Amendment, and the Supreme Court of the United States held that the statute violated the equal protections clause, because it did not apply to all offenses equally.¹⁶³

The Court applied the strict scrutiny test to the statute arguing that it involved one of the basic civil rights of man, marriage and procreation.¹⁶⁴ Under a strict scrutiny test, the government needed to show a compelling state interest in maintaining the challenged statute that interfered with an individual’s liberties.¹⁶⁵ The Court did not find a compelling state interest in the Oklahoma statute and held it unconstitutional.¹⁶⁶ In his reasoning, Justice Douglas stated that “the power to sterilize, if exercised, may have subtle, far-reaching and devastating effects.”¹⁶⁷

Skinner v. Oklahoma is the first instance where the Supreme Court recognizes the right to procreation as a fundamental right that is protected under the equal protection clause.¹⁶⁸ Just like the Oklahoma statute, the exclusion prohibits MSMs from their right to procreate.¹⁶⁹ For many gay men, fatherhood is limited to artificial insemination and sperm donation, but this exclusion limits this right.¹⁷⁰

Although the draft guidance document considers MSMs from anonymously donating sperm as a risk factor; it does not consider men who have unprotected sex with multiple women as a

¹⁶² In 1926, Skinner was convicted for stealing chickens; in 1929, he was convicted of robbery with firearms, and in 1934, he committed his third offense when he committed robbery with firearms. *Id.*

¹⁶³ In their analysis, the Court analyzed the petitioner’s first offense of stealing chickens and compared it to an individual who embezzles chickens, and reasoned that the person who stole chickens three times would be susceptible to sterilization, whereas a person who embezzles the chicken three times would not face the same punishment. *Id.* at 539-41.

¹⁶⁴ *Id.* at 541.

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ Luke A. Boso, *supra* note 38, at 869.

¹⁷⁰ *Id.*

risk factor that requires exclusion.¹⁷¹ In fact, the document is silent about the sexual activity of heterosexual males.¹⁷² It “lays an unequal hand on those who have committed” the same act as others and “has made an invidious discrimination as if it had selected a particular race or nationality for oppressive treatment.”¹⁷³ Just like the Oklahoma statute unfairly applied to identical offenders, the draft guidance document restricts one group from anonymously donating sperm because of their sexual activity, while remaining silent about whether the sexual activity of another group constitutes a risk factor.¹⁷⁴ Thus, under the Court’s holding in *Skinner*, the exclusion violates the equal protection clause.¹⁷⁵

The United States Supreme Court in *Skinner* applied a strict scrutiny test, which the Court has declined to extend to the LGBT community.¹⁷⁶ Instead, the Court has recognized that a statute restricting the rights of the LGBT community must satisfy a rational basis test.¹⁷⁷ In the 1996 case, *Romer v. Evans*, the Court held that an amendment to the Colorado statute restricting the rights of the LGBT community violated the equal protection clause under a rational basis test.¹⁷⁸

The case arose after the Colorado legislature amended the constitution to prohibit any special protected status to the LGBT community that might be implemented through state laws or municipal ordinances.¹⁷⁹ The Court analyzed the amendment to the Colorado constitution and

¹⁷¹ Draft Guidance Document, *supra* note 4, at 15-16.

¹⁷² *Id.*

¹⁷³ *Skinner*, 316 U.S. at 541 (citing *Yick Wo v. Hopkins*, 118 U.S. 356, 369 (1886)).

¹⁷⁴ Draft Guidance Document, *supra* note 4, 15-16.

¹⁷⁵ *Skinner*, 316 U.S. at 541; *see also*, Draft Guidance Document, *supra* note 4, at 15-16.

¹⁷⁶ 316 U.S. at 541; *see generally*, *Romer v. Evans*, 517 U.S. 620 (1996).

¹⁷⁷ “[A] law neither burdens a fundamental right nor targets a suspect class, we will uphold the legislative classification so long as it bears a rational relation to some legitimate end.” *Evans*, 517 U.S. 620, 631.

¹⁷⁸ *Id.* at 620.

¹⁷⁹ “No Protected Status Based on Homosexual, Lesbian or Bisexual Orientation. Neither the State of Colorado, through any of its branches or departments, nor any of its agencies, political subdivisions, municipalities or school districts, shall enact, adopt or enforce any statute, regulation, ordinance or policy whereby homosexual, lesbian or bisexual orientation, conduct, practices or relationships shall constitute or otherwise be the basis of or entitle any person or class of persons to have or claim any minority status, quota preferences, protected status or claim of discrimination. This Section of the Constitution shall be in all respects self-executing.” *Id.* at 624 (quoting Colo. Const., Art. II, § 30b).

held that the amendment barred the LGBT community from necessary legal protections in various areas including, real estate, housing, insurance, health, welfare, etc.¹⁸⁰ The Court applied the equal protection clause under a rational basis test, instead of the strict scrutiny test, because the LGBT community did not constitute a suspect class.¹⁸¹ Under a rational basis test, the amendment failed to advance a legitimate state interest, and imposed “a broad and undifferentiated disability on a single named group.”¹⁸² Therefore the Court held the amendment to the Colorado was unconstitutional.¹⁸³

Even though *Romer* limits the LGBT community to a rational basis analysis, the exclusion is still invalid under the equal protection clause because it fails to advance the legitimate state interest of protecting the public from the risk of communicable diseases.¹⁸⁴ The impact of the exclusion is defused by the strict testing and quarantine requirements associated with sperm donations.¹⁸⁵ The 6 month quarantine period ensures that the risk of communicable diseases in a sperm donation is significantly reduced.¹⁸⁶ There is no *legitimate* state interest that is advanced by excluding MSMs, because the state’s interest is sufficiently met through the testing and quarantine procedures.¹⁸⁷ Therefore under *Romer*, the exclusion is invalid under a rational basis review of the equal protection clause, because “if the constitutional conception of ‘equal protection of the laws’ means anything, it must at the very least mean that a bare...desire to harm a politically unpopular group cannot constitute a *legitimate* governmental interest.”¹⁸⁸

¹⁸⁰ *Id.* at 629.

¹⁸¹ *Id.* at 631.

¹⁸² *Id.* at 632.

¹⁸³ *Id.* at 633.

¹⁸⁴ *Id.* at 632.

¹⁸⁵ 21 C.F.R. §§ 1271.80, 1271.85(d) (West 2007).

¹⁸⁶ FDA Regulation, *supra* note 2.

¹⁸⁷ *Id.*

¹⁸⁸ *Romer*, 517 U.S. at 634 (quoting *Dep’t of Agric. v. Moreno*, 413 U.S. 528, 534 (1973) (emphasis added)).

The FDA exclusion on MSMs from anonymously donating sperm places a cumbersome restriction on the LGBT community.¹⁸⁹ It perpetuates the discriminatory practices of “gay passing” and “gay covering.”¹⁹⁰ It requires MSMs to hide their sexual identity, refrain from homosexual activity, or behave in a specific way by making directed sperm donations.¹⁹¹ The exclusion also violates the equal protection clause of the fourteenth amendment.¹⁹² It applies an additional restriction on MSMs, while posing no similar restriction on promiscuous heterosexual males.¹⁹³ The exclusion does more harm than good to the public health arena; therefore, the guidance document and regulation must be amended and the exclusion must be removed.

V. THE CASE FOR AMENDING THE GOVERNING FDA REGULATION.

The FDA exclusion serves no actual purpose in protecting the public health from the risk of communicable diseases, and should therefore be removed from the guidance document and the FDA regulation.¹⁹⁴ Although the FDA’s initial intent in creating this exclusion has been to protect the public health, it effectively deprives the LGBT community from enjoying equal treatment.¹⁹⁵ The regulation and guidance document must be amended and the exclusion must be removed in order to promote the equal treatment of the LGBT community in the public health community.

- a. The FDA Regulation and Guidance Document Must Be Amended to Remove the Exclusion and Adopt the Alternative Method Advocated by Lambda Legal Defense Education Fund.*

¹⁸⁹ FDA Regulation, *supra* note 2; CDC Report, *supra* note 46, at 15; Linda Valleroy, et al., *supra* note 65 at 140.

¹⁹⁰ Kenji Yoshino, *supra* note 113, at 772-75.

¹⁹¹ Draft Guidance Document, *supra* note 4, at 16; *see also* FDA Regulation, *supra* note 2.

¹⁹² U.S. CONST. amend. XIV.

¹⁹³ Draft Guidance Document, *supra* note 4, at 15-16; U.S. CONST. amend. XIV.

¹⁹⁴ *Id.*

¹⁹⁵ John G. Culhane, *supra* note 26, at 144.

Since the implementation of the FDA regulation in May 2005, some groups have actively attempted to change the regulation and remove the exclusion.¹⁹⁶ The Lambda Legal Defense and Education Fund¹⁹⁷ (hereinafter “LLDEF”) has written and sent a letter to the FDA voicing their disapproval towards the exclusion.¹⁹⁸ In their letter, LLDEF suggests an alternative method of protecting the public health which does not require the continued implementation of the exclusion.¹⁹⁹ The FDA should adopt the LLDEF’s alternative method to screen potential donors, because it actively reduces the risk of communicable diseases without discriminating against the LGBT community.²⁰⁰

The LLDEF’s letter correctly points out that the public policy concerns of protecting the public from communicable diseases is not served by the exclusion.²⁰¹ In addition, the exclusion lacks a foundation in science, and is made ineffective by the FDA regulation’s double testing and six-month quarantine requirement.²⁰² As a result of the ineffectiveness of the exclusion, the LLDEF present an alternative method of protecting the public from the risk of communicable diseases.²⁰³

The LLDEF suggests the FDA should use “a more specific screening criteria that measures a potential donor’s high risk activities rather than his sexual orientation.”²⁰⁴ The LLDEF offers up

¹⁹⁶ Letter from John Givner, *supra* note 39, at 1; “[Rainbow Flag Health Service] are the only sperm bank in North America to actively recruit Gay and Bisexual sperm donors. Whether Gay, Bisexual or Heterosexual our donors wish to have children in their lives but do not wish to raise children. (Or, some men who already have children do not wish to raise more children.)” Home, RAINBOW FLAG HEALTH SERVICES, <http://www.gayspermbank.com/index.html>.

¹⁹⁷ “Founded in 1973, Lambda Legal is the oldest and largest national legal organization whose mission is to safeguard and advance the civil rights of lesbians, gay men, bisexuals, transgender people and those with HIV through impact litigation, education and policy work.” About Us, LAMBDA LEGAL: MAKING THE CASE FOR EQUALITY, <http://www.lambdalegal.org/about-us>.

¹⁹⁸ Letter from John Givner, *supra* note 39, at 1.

¹⁹⁹ *Id.*

²⁰⁰ *Id.* at 3-5.

²⁰¹ *Id.* at 1.

²⁰² *Id.*; FDA Regulation, *supra* note 2.

²⁰³ Letter from John Givner, *supra* note 39, at 3-5.

²⁰⁴ *Id.* at 5.

the HIV Medicine Association²⁰⁵ (hereinafter “HIVMA”) of the Infectious Diseases Society of America’s²⁰⁶ (hereinafter “IDSA”) screening procedures as the method the FDA regulation should adopt in its regulation to screen potential donors.²⁰⁷ HIVMA recommends that the following individuals be prohibited from donating blood or sperm:

1. [test] positive for HIV;
2. [use] illicit drugs within the previous [twelve (12)] months;
3. [have] a needle stick exposure to someone else’s blood within the previous 12 months; or
4. in the previous 12 months, [have] had unprotected oral, vaginal, or anal sexual intercourse with:
 - a. An individual with HIV,
 - b. An individual known to use illicit drugs, or
 - c. An individual of unknown HIV status *outside of a monogamous relationship*[.]²⁰⁸

This screening process effectively screens potential donors and does not perpetuate a discriminatory attitude toward the LGBT community.²⁰⁹ This screening procedure also satisfies the FDA’s concerns of screening out individuals that pose a risk of transferring communicable diseases.²¹⁰

The LLDEF’s letter to the FDA provides an excellent alternative method to the one proposed in the regulation.²¹¹ This screening method is already used by HIVMA and IDSA, which are dedicated to improving the medicine and procedures associated with HIV and other infectious

²⁰⁵ “The HIV Medicine Association is an organization of medical professionals who practice HIV medicine. We represent the interests of HIV health care providers and researchers and their patients by promoting quality in HIV care and by advocating for policies that ensure a comprehensive and humane response to the AIDS pandemic informed by science and social justice.” About HIVMA, HIV MEDICINE ASS’N, http://www.hivma.org/About_HIVMA.aspx.

²⁰⁶ “The Infectious Diseases Society of America (IDSA) represents physicians, scientists and other health care professionals who specialize in infectious diseases. IDSA’s purpose is to improve the health of individuals, communities, and society by promoting excellence in patient care, education, research, public health, and prevention relating to infectious diseases.” About IDSA, INFECTIOUS DISEASE SOCIETY OF AMERICA, http://www.idsociety.org/About_IDSA/.

²⁰⁷ Letter to John Givner, *supra* note 39, at 5.

²⁰⁸ *Id.* (emphasis added).

²⁰⁹ *Id.*

²¹⁰ FDA Regulation, *supra* note 2.

²¹¹ Letter to John Givner, *supra* note 39, at 5.

medicine.²¹² The new screening procedure satisfies the aim of the regulation, by screening out potential donors that pose a risk of transferring communicable diseases, without unfairly discriminating against an entire class of people.²¹³ The exclusion against MSMs should be abrogated and the FDA regulation should adopt the screening procedures in use by HIVMA and IDSA.²¹⁴

b. The Adoption of Sperm-Washing Techniques Provides an Additional Safe-Guard to the Risk of Communicable Diseases

If the FDA is not convinced that the LLDEF's proposed screening procedure would not effectively identify the risk factors in potential donors, then the regulation should be amended to require an additional safety provision.²¹⁵ Sperm-washing techniques are among the newest forms of reducing the risk of HIV transmission in artificial insemination.²¹⁶ In addition to adopting the new screening procedures, the FDA can also require each donation to go through a sperm-washing procedure.²¹⁷ This will ensure the FDA's goal of protecting the public health from the risk of communicable disease, while eliminating the discriminatory attitude toward the LGBT community.

The sperm-washing technique allows couples where the male partner is HIV positive to donate his sperm and impregnate his partner, without the risk of transmitting the virus.²¹⁸ It takes the HIV infected sperm and removes the infected portion from the non-infected spermatozoa.²¹⁹ The spermatozoa are the generative components of semen and are generally not infected by the

²¹² *Id.*; see also About HIVMA, *supra* note 207; About IDSA, *supra* note 208.

²¹³ Letter to John Givner, *supra* note 39, at 5; See FDA Regulation, *supra* note 2.

²¹⁴ Draft Guidance Document, *supra* note 4, at 14.

²¹⁵ Letter to John Givner, *supra* note 39, at 5.

²¹⁶ V. Savasi, et al., *supra* note 8, at 772.

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

HIV virus.²²⁰ The spermatozoa are then inseminated into the recipient's egg.²²¹ This technique ensures that the infection is not transmitted to a recipient during artificial insemination.²²² The FDA can require sperm washing done on all anonymous donations to ensure that the HIV virus is almost never transmitted.²²³

A study from January 2002 to January 2006 was conducted to measure the potential risk of HIV transmission in sperm washing procedures.²²⁴ The study surveyed 741 couples, where the male partner was HIV positive.²²⁵ The results showed that the rates of HIV transmission in newborns were drastically reduced.²²⁶ The study illustrated how sperm washing technique gave HIV positive men the chance to biologically father a child, without the fear of transmitting the virus.²²⁷

As a means to placate the FDA's concern about the risk of communicable diseases in the public health, the FDA regulation should be amended to include the sperm washing technique as an additional preventative measure.²²⁸ This will ensure that the goal of the FDA to protect and promote the public health is preserved.²²⁹ In addition, this will also encourage the FDA to discontinue the use of discriminatory policies like the exclusion on MSMs from anonymously donating sperm.²³⁰

²²⁰ *Id.* at 773 (defined as a mature male germ cell that develops in the seminiferous tubules of the testes). Resembling a tadpole, it is about 50 μm (1/500 inch) long and has a head with a nucleus, a neck, and a tail that provides propulsion. Developed in vast numbers after puberty, spermatozoa are the generative component of the semen. *Spermatozoa Definition*, THE FREE-DICTIONARY, available at <http://medical-dictionary.thefreedictionary.com/spermatozoa>.

²²¹ V. Savasi, et al., *supra* note 8, at 773.

²²² *Id.*

²²³ *Id.*; Eligibility Determinations for Donors of Human Cells, Tissues and Cellular and Tissue Based Products, 69 Fed. Reg. 29,786 (May 25, 2004) (to be codified at 21 C.F.R. pts. 210, 211, 820, 1271) the rule became effective on May 25, 2005.

²²⁴ V. Savasi, et al., *supra* note 8, at 774.

²²⁵ *Id.*

²²⁶ *Id.*

²²⁷ *Id.* at 775.

²²⁸ *Id.*; FDA Regulation, *supra* note 2.

²²⁹ FDA's Mission Statement, *supra* note 34.

²³⁰ Draft Guidance Document, *supra* note 4, at 14.

The exclusion does not effectively protect the public from the risk of communicable diseases; instead, the FDA must adopt a more effective and less discriminatory procedure of screening out potential donors.²³¹ The LLDEF's proposal of substituting the FDA's current screening procedures with the ones used by HIVMA and IDSA will satisfy the FDA's concerns.²³² If the FDA is still worried about the threat of communicable diseases, it can require sperm-washing techniques to be applied to the anonymously donated sperm.²³³ This technique will significantly reduce the risk of HIV transmission in artificial insemination.²³⁴ These alternative methods satisfy the mission of the FDA regulation, while refraining from discriminating against a class of people.²³⁵

VI. CONCLUSION

Protecting the public health from the potential dangers of various diseases is not an easy task, and the FDA has the heavy burden to do just that.²³⁶ For years it has developed regulations to protect the public from the dangers associated with food, drugs, tobacco products, vaccines, and many more.²³⁷ Most of the FDA regulations successfully protect the public from potential dangers,²³⁸ however, there are those like the FDA Regulation on sperm donation that takes it too far.²³⁹ In its attempt to prevent the risk of communicable diseases, the FDA passes an exclusion that overreaches and perpetuates a discriminatory attitude towards the LGBT community.²⁴⁰

²³¹ *Id.* at 14.

²³² Letter from John Givner, *supra* note 39, at 1.

²³³ V. Savasi, et al., *supra* note 8, at 772-74.

²³⁴ *Id.* at 775.

²³⁵ FDA Regulation, *supra* note 2.

²³⁶ FDA Mission Statement, *supra* note 34.

²³⁷ See FDA Food, <http://www.fda.gov/Food/default.html> (last visited March 30, 2013); FDA Drugs, <http://www.fda.gov/Drugs/default.html> (last visited March 30, 2013); FDA Tobacco Products, <http://www.fda.gov/TobaccoProducts/default.htm> (last visited March 30, 2013); FDA Vaccines, <http://www.fda.gov/BiologicsBloodVaccines/default.htm> (last visited March 30, 2013).

²³⁸ See generally Margaret Hamburg, M.D., *50 Years After Thalidomide: Why Regulation Matters*, Food, Drug Administration, available at <http://blogs.fda.gov/fdavoices/index.php/2012/02/50-years-after-thalidomide-why-regulation-matters/>.

²³⁹ FDA Regulation, *supra* note 2.

²⁴⁰ *Id.*

As the world enters the second decade of the twenty-first century, society is becoming more aware of the need to provide equal treatment to various groups of people, including the LGBT community. In the past decade, there has been an increase in the number of states that have passed marriage equality laws granting the LGBT community the right to marry.²⁴¹ Statistics show that the younger generation of America believes that the LGBT community deserves the same rights as other groups of people in America.²⁴² And on March 26th, 2013, the Supreme Court listened to arguments in support and against the 1996 Defense of Marriage Act, which prevents same-sex marriage from being recognized by the federal government.²⁴³ Since the present direction is progressive treatment towards the LGBT community in the marriage arena, it only makes sense that that should be the same direction in the public health arena. The FDA regulation and the exclusion goes against this direction and maintains a discriminatory attitude towards the LGBT community.²⁴⁴

Although the FDA believes the exclusion against MSMs serves a functional purpose in reducing communicable diseases, there is an alternative method that delivers the same outcome without discriminating against an entire class of people. This method endorses the form of screening procedures advocated by HIVMA and considers the application of sperm-washing techniques to anonymous sperm donations.²⁴⁵ The FDA's exclusion is the product of flawed

²⁴¹ See generally *Goodridge v. Department of Public Health*, 440 Mass. 309 (2003) (the Supreme Court of Massachusetts held that it was unconstitutional to only allow heterosexuals to marry); see also, Civil Marriage Protection Act, House Bill 438, available at <http://mgaleg.maryland.gov/webmga/frmMain.aspx?ys=2012rs%2fbillfile%2fHB0438.htm>; An Act To Allow Marriage Licenses for Same-sex Couples and Protect, 19-A MRSA § 650-A, available at http://www.mainelegislature.org/legis/bills/bills_125th/billtexts/IB000301.asp; Same Sex Marriage, Engrossed Substitute Senate Bill 6239, available at <http://apps.leg.wa.gov/documents/billdocs/2011-12/Pdf/Bills/Session%20Laws/Senate/6239-S.SL.pdf>.

²⁴² *Americans move dramatically toward acceptance of homosexuality, survey finds*, UCHICAGONNEWS, available at <http://news.uchicago.edu/article/2011/09/28/americans-move-dramatically-toward-acceptance-homosexuality-survey-finds>.

²⁴³ *DOMA on shaky ground in court*, POLITICO, available at <http://www.politico.com/story/2013/03/doma-supreme-court-oral-arguments-89373.html>; Defense of Marriage Act, 28 U.S.C. § 1738C.

²⁴⁴ *Id.*; see generally Draft Guidance Document, *supra* note 4, at 14.

²⁴⁵ *Id.*; see also Draft Guidance Document, *supra* note 4, at 14.

research that grossly generalizes the behavior of a class of people.²⁴⁶ Since its implementation, new scientific techniques have greatly reduced the threat of communicable diseases that undercuts the intent of the exclusion.²⁴⁷ Therefore, amending the FDA regulation and removing the exclusion serves the dual function of upholding the FDA's mission to protect the public health, while protecting the dignity and integrity of an important community.²⁴⁸

²⁴⁶ See Advisory Committee Meeting, *supra* note 48.

²⁴⁷ V. Savasi, *supra* note 8, at 772-775.

²⁴⁸ FDA Mission Statement, *supra* note 34.