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December 5, 2005

Commissioner Antonia C. Novello
New York State Department of Health
Corning Tower
Empire State Plaza,
Albany, NY 12237

Re: Department of Health Regulations Concerning Sperm Donation by Men Who Have Had Sex with Other Men (10 NYCRR §§52-3.4(a)(8)& 52-8.5(e))

Dear Commissioner Novello:

We write to you on behalf of Special Committee on AIDS of the Association of the Bar of New York City regarding the Department of Health's regulations concerning sperm donation, 10 NYCRR §§52-3.4(a)(8)& 52-8.5(e). The Committee has significant background and expertise with regard to the issues addressed by the regulations.

In light of recently implemented federal regulations assuring the safety of reproductive tissue or sperm donation, 21 C.F.R. § 1271.50(b), we request that the Department revise New York State regulations concerning tissue donor qualifications. See 10 NYCRR §§ 52-3.4(a)(8) & 52-8.5 (the "regulations"). In their current form, the regulations flatly prohibit any man who has had oral or anal sex with another man in the preceding five years from anonymously donating sperm. While we recognize that the purported purpose of these regulations is to prevent the transmission of sexually transmitted diseases, the regulations are far more prohibitive than is necessary to protect the health and safety of sperm donation recipients, their partners and their children.

We strongly support efforts to prevent the spread of HIV and other contagious diseases through science-based policies and programs, and we share the Department's laudable goals of protecting the public health and preventing the transmission of communicable diseases through sperm donation. However, as discussed below, we do

not believe that either public health or broader public policy objectives are served by the regulations' exclusion from anonymous sperm donation of every man who has had sex with another man within the five years prior to donation. For the reasons detailed below, we believe that the exclusion of all men who have had sex with men ("MSMs") is unnecessary and ill-conceived. We urge the Department to reexamine these regulations and to draft new guidelines that more fairly minimize risk without unnecessarily excluding classes of donors or perpetuating stereotypes. To that end, instead of the broad exclusion of MSMs, we suggest an individualized risk-based assessment that more accurately predicts a donor's actual risk of HIV or hepatitis exposure.[1]

1. Summary of State and Federal Regulatory Framework for Sperm Donation

a. New York State Regulations

Department regulations for live tissue donors state that "[p]otential anonymous donors with a history of behavior or factors which place them at increased risk for HIV infection or other infectious diseases, pursuant to section 52-3.4(a)(8) of this Part, shall be excluded." 10 NYCRR § 52-8.5(e).[2] The referenced provision, section 52-3.4(a)(8), mandates that allogenic tissue "shall not be released" without specific approval from the medical director if a donor has a "history of behavior or factors which place the donor at high risk for human immunodeficiency virus (HIV) infection." To that end, the regulations specifically state that "men who have engaged in anal intercourse or oral sex with another man at any time within the preceding five years" must be excluded from donation. 10 NYCRR § 52-3.4(a)(8)(ii).

Taken together, these provisions vest the medical directors of tissue repositories with discretion to accept sperm donations from directed donors who fall within these risk factors, but they flatly preclude men who have had oral or anal sex with another man in the previous five years from serving as anonymous donors.

b. Federal Regulations

In May 2004, the U.S. Food and Drug Administration published federal regulations governing sperm donation safety. The regulations, which went into effect in May 2005, provide that all anonymous sperm donors must pass mandatory "donor screening" and testing in order to be considered eligible for donation. *See* 21 C.F.R. §

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[1] While the regulations at issue do not specifically mention hepatitis B ("HBV") or hepatitis C ("HCV"), these viruses also "may adversely affect the quality of reproductive tissue or impair the recipient's and/or the offspring's health," 10 NYCRR § 52-8.5(a). This letter will address the extent to which the regulations are more restrictive than is necessary to prevent both HIV and viral hepatitis transmission through anonymous tissue donation.

[2] For the purpose of this provision, the term "donors" includes both "anonymous donors" and "directed donors." See 10 NYCRR § 52-8.1 (a), (e) & (f). Generally, a "directed donor" is a donor whose identity is known by the recipient, while an "anonymous donor" is a donor whose identity is not known by the recipient.

1271.50(b). Men who wish to donate sperm anonymously may do so only if they are "free from risk factors for, and clinical evidence of, infection due to relevant communicable disease agents and diseases," including HIV, hepatitis B virus and hepatitis C virus. 21 C.F.R. § 1271.50(b)(1). The regulations do not specifically exclude men who have sex with men from donating sperm anonymously.

The FDA currently is considering a draft guidance that lists "conditions and behaviors [that] increase the donor's relevant communicable disease risk" and recommends rejection of donations by anonymous donors exhibiting any of the listed behaviors.[3] In its draft form, the guidance suggests that a man who has had sex with another man within the past five years should not donate sperm. Notably, however, the draft guidance is not final. Moreover, even the final FDA guidance document, when it is adopted, will not be binding on sperm banks or state regulators. In other words, the Department retains authority, notwithstanding the FDA's draft guidance, to adopt a policy of donor deferral based on individualized risk that does not include a wholesale exclusion of MSMs.

2. The Regulations' Prohibition of Men Who Have Had Sex with Other Men from Anonymously Donating Sperm Lacks a Foundation in Sound Science.

We find no legitimate scientific rationale for preventing MSMs from serving as anonymous sperm donors. In light of the federal regulations' mandatory six-month quarantine and double testing of all donors' blood for relevant contagious diseases, we do not believe that New York's broad exclusion of men who have had sex with men is necessary or appropriate to minimize the risk of HIV or hepatitis transmission to sperm donation recipients. As discussed below, the regulations' MSM exclusion is unnecessary to prevent donations by men who recently have been exposed to HIV or hepatitis, but who do not yet test positive on standard assays. Nor is the exclusion necessary to protect against possible laboratory error during screening for relevant diseases. In short, the five-year exclusion of MSMs is excessive and does not serve New York's interests.

a. Concerns about donations during the "window period" do not support the five-year exclusion of MSMs.

First, to the extent that the Department bases its five-year exclusion on concerns about sperm donations during the "window period" in which a donor may transmit HIV or hepatitis without testing positive in standard assays, the five-year exclusion period is vastly out of proportion to the actual period of risk. A person exposed to HIV or HCV typically develops detectable antibodies within the first two to three months after infection, if not earlier, and the overwhelming majority seroconvert within the first six months.[4] People with HBV similarly test positive for the HBV surface antigen shortly

[3] *See* Draft Guidance for Industry, available at www.fda.gov/cber/gdlns/tissdonor.pdf. The Draft Guidance suggests deferral standards for anonymous donors, not directed donors. Like the state regulations, the federal regulations and Draft Guidance do not suggest restricting the right of sperm donation recipients to choose a man who has had sex with other men to serve as a known – or "directed" – donor.

[4] L. R. Petersen et al., Duration of Time from Onset of Human Immunodeficiency Virus Type I Infectiousness to Development of Detectable Antibody, *Transfusion* 1994; 34: 283; C. A. Ciesielski et al., Duration of Time Between Exposure and Seroconversion in Healthcare Workers with Occupationally Acquired Infection with Human Immunodeficiency Virus, *American Journal of Medicine* 1997;

after exposure.[5] Moreover, advances in testing technology are effectively shrinking these "window periods" even further.[6] The regulations' five-year exclusion far exceeds the actual period during which an HIV- or hepatitis-infected donor might test negative for these viruses.

Any concerns about the "window period" are even less well-founded in light of the availability of nucleic acid amplification testing ("NAT"). While an individual may experience a one- or two-month window between initial exposure to HIV, HCV or HBV and a positive test result on a standard antibody assay, NAT testing reduces the window between exposure and detection to a matter of days or weeks.[7] In light of the extremely small "window period" allowed by NAT testing, the Department's five-year exclusion for all MSMs lacks validity.

Moreover, applicable federal regulations already address any "window period" concerns by requiring the quarantine of all anonymous donations for at least six months to allow for retesting of donors. Indeed, the U.S. Food and Drug Administration explained that "[t]he requirement to retest the donor was intended to provide an important added measure of protection by addressing the 'window period' between the time of infection and the presence of detectable levels of antigens and/or antibodies to communicable diseases and agents such as HIV." *See* 69 Fed. Reg. at 29800; *see also* 64 Fed. Reg. 52696, 52706 (September 30, 1999). This six-month quarantine eliminates any concern about false-negative testing during the "window period," rendering the additional five-year deferral for MSMs unnecessary.

b. **In light of the rarity of testing error and the double-testing of all anonymous donations, concerns about testing error cannot justify the exclusion of MSMs.**

102(5B):115; S. Lindbäck et al., Diagnosis of Primary HIV-1 Infection and Duration of Follow-up After HIV Exposure, *AIDS* 2000; 14:2337; Centers for Disease Control and Prevention, Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, *Morbidity and Mortality Weekly Report* 2001; 50 (No. RR-5):11-12.

[5] Centers for Disease Control and Prevention, Recommendations for Preventing Transmission of Infections Among Chronic Hemodialysis Patients, *Morbidity and Mortality Weekly Report* 2001; 50 (No. RR-5): 2-9.

[6] *See* B. Weber et al., Reduction of Diagnostic Window by New Fourth-Generation Human Immunodeficiency Virus Screening Assays, *Journal of Clinical Microbiology* 1998; 36(8): 2235-2239; D. P. Kolk et al., Significant Closure of the Human Immunodeficiency Virus Type 1 and Hepatitis C Virus Preseroconversion Detection Windows with a Transcription-Mediated-Amplification-Driven Assay, *Journal of Clinical Microbiology* 2002; 40(5): 1761-1766.

[7] *See* S. Stramer et al., Detection of HIV-1 and HCV Infections among Antibody-Negative Blood Donors by Nucleic Acid-Amplification Testing, *N. Eng. J. Med.* 2004, 351(8): 760-768; S. Zou et al., Probability of Viremia with HBV, HCV, HIV, and HTLV among Tissue Donors in the United States, *N. Eng. J. Med.* 2004, 351(8): 757. *See generally* Human Cells, Tissues and Cellular and Tissue-Based Products: Risk Factors for Semen Donation, Blood Products Advisory Committee (BPAC) Meeting, Hilton Silver Spring Hotel, December 14, 2001, testimony of George Schreiber.

Second, to the extent that the five-year MSM exclusion reflects a concern about testing error, the danger is similarly overstated and similarly overbroad. While rates of testing error vary depending on the quality of particular testing programs, lab error in HIV and HCV testing is extraordinarily rare. For instance, a 2000 study of false-negative testing errors in routine blood donor screening found that the rate of procedural errors in the testing process was .05 percent.[8] Applying this error rate to the donor pool as a whole, the authors estimated a false-negative HIV test error rate of approximately four per 10 million. An earlier review of 5.4 million HIV-1 antibody tests conducted by the U.S. Army between 1985 and 1992 reached a similar conclusion, finding an error rate of .000588 percent.[9]

Moreover, these error estimates were based on the assumption that each donor will be tested once, not twice, as the FDA's Donor Eligibility Rule requires for anonymous sperm donors. *See* 21 C.F.R. § 1271.85(d). The FDA's requirement that each anonymous donor submit to two separate rounds of testing reduces the risk to nearly zero that any donor infected with HIV or hepatitis unwittingly will pass the donor screening process as a result of laboratory error. As Roy, *et al.* noted in the *Journal of the American Medical Association*, testing error, while exceedingly uncommon, "can be best controlled by repeating all procedures twice."[10]

3. The Regulations Should Suggest Donor Deferral Criteria That Are Based on Individualized Risk Assessments Rather Than Sexual Orientation.

The regulations effectively prohibit most gay and bisexual men from providing anonymous sperm donation, regardless of their individual risk of HIV or hepatitis infection. This prohibition does not reflect the reality that an individual's likelihood of exposure to HIV and hepatitis corresponds to the specific high-risk activities in which he engages, not to the sex of the person with whom he has intercourse. Indeed, different sexual practices pose drastically different risks to the participants. For instance, receptive anal sex poses roughly one hundred times as much risk of HIV transmission as insertive oral sex.[11] Additionally, the transmission risk of any sexual act increases approximately twenty-fold if the participants do not use condoms.[12] The regulations do not recognize these distinctions, instead treating protected oral sex between two men in the context of a

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[8] M.P. Busch et al., False-Negative Testing Errors in Routine Viral Marker Screening of Blood Donors, *Transfusion* 2000, 40:585-589.

[9] M.J. Roy et al., Absence of True Seroreversion of HIV-1 in Seroreactive Individuals, *JAMA* 1993; 269(22): 2876-2879.

[10] *Id.* at 2878. *See also* Human Cells, Tissues and Cellular and Tissue-Based Products; Risk Factors for Semen Donation, BPAC Meeting, Hilton Silver Spring Hotel, December 14, 2001, testimony of George Schreiber ("Testing error is very small, and with the quarantine, . . . it's reduced almost to zero.").

[11] Centers for Disease Control and Prevention, Incorporating HIV Prevention into the Medical Care of Persons Living with HIV: Recommendations of CDC, the Health Resources and Services Administration, the National Institutes of Health, and the HIV Medicine Association of the Infectious Diseases Society of America, *Morbidity and Mortality Weekly Report* 2003; 52 (No. RR-12): 9.

[12] *Id.*

monogamous relationship the same as unprotected anal intercourse between male strangers. Merely asking whether a donor has had oral or anal sex with another man within the preceding five years tends to screen donors on the basis of sexual orientation rather than on the basis of actual risk.

To remedy this problem, the regulations should require more specific screening criteria that measure a potential donor's high-risk activities rather than his sexual orientation. We believe that there are many possible behavioral screening devices that would determine HIV risk more accurately than the current criteria. For example, the HIV Medicine Association of the Infectious Diseases Society of America ("HIV Medicine Association") has adopted a set of criteria that the HIV Medicine Association suggests should be used to screen potential blood donors, but that we suggest can be applied equally in the context of sperm donation as well. The purpose of the HIV Medicine Association's criteria is to screen for HIV risk while ensuring "that individuals are excluded based on risk factors and not solely based on sexual orientation or country of origin." The HIV Medicine Association recommends that the FDA should prohibit donation by any individual from the United States[13] who:

1. has tested positive for HIV;
2. has used illicit drugs within the previous 12 months[14];
3. has had a needle stick exposure to someone else's blood within the previous 12 months; or
4. in the previous 12 months, has had unprotected oral, vaginal, or anal sexual intercourse with:
   - An individual with HIV,
   - An individual known to use illicit drugs, or
   - An individual of unknown HIV status *outside of a monogamous* relationship.

We urge you to consider substituting a screening protocol like this one that screens potential donors on the basis of individual risk without subjecting them to stereotypes based on sexual orientation.

Conclusion

We object to the current regulations' exclusion from anonymous sperm donation of all men who have had anal or oral sex with other men within the preceding five years, particularly in light of the flexibility granted to sperm banks and state regulators by the applicable federal regulations. This screening tool is not tailored to health goals and

[13] The HIV Medicine Association's suggested criteria for donors from other countries is slightly different.

[14] As noted above, in order to address concerns about donation during the seroconversion "window period," federal regulations require six-month freezing and quarantine of all sperm donated anonymously. The HIV Medicine Association's criteria adopt an even more conservative 12-month deferral period to address the window period. While the 12-month standard may not be strictly necessary for the reasons discussed above, it does not give rise to the same concerns about gross disproportionality as New York's current five-year standard.

suggests falsehoods about the nature of testing and transmission risks. We urge you to revise the regulations, and we request the opportunity to discuss this with you further, either by telephone or in person. We are happy to meet with you any time. Thank you for considering this letter.

Sincerely,

Bettina B. Plevan

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