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## The Unjust Exclusion of Gay Sperm Donors: Litigation Strategies to End Discrimination in the Gene Pool

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**THE UNJUST EXCLUSION OF GAY SPERM DONORS:  
LITIGATION STRATEGIES TO END  
DISCRIMINATION IN THE GENE POOL**

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## I. INTRODUCTION

In May 2004, the Food and Drug Administration (FDA) announced a final rule to be published in the Federal Register that would establish eligibility criteria for persons seeking to donate sperm and other human cells and tissues.<sup>1</sup> Concurrently, the FDA issued a draft guidance document “that provides recommendations for complying with the requirements . . .”;<sup>2</sup> in the final version of that guidance document, the FDA enumerates twenty-nine “risk factors,” and instructs interviewers to screen potential donors for each identified factor.<sup>3</sup> The FDA affirmatively states that these “conditions and behaviors increase the donor’s relevant communicable disease risk.”<sup>4</sup>

In its guidance document, the FDA identifies “men who have had sex with another man in the preceding 5 years” (MSMs) as the *number one* risk factor.<sup>5</sup> The FDA does not, however, make a distinction between MSMs who practice safe sex and those who have unprotected sex, nor does it identify men who have had sex with women—be it with one or many female partners, protected or unprotected—as one of its twenty-nine risk factors.<sup>6</sup> Ultimately, when the final rule was published in the Federal Register, the FDA did not include the proposed risk factors it identifies in either its draft or final guidance documents as

<sup>1</sup> Eligibility Determination 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) [hereinafter Preamble]. The rule became effective on May 25, 2005.

<sup>2</sup> FDA Finalizes New Rule on Donor Eligibility for Human Tissues and Cells, <http://www.fda.gov/bbs/topics/news/2004/NEW01070.html> (last visited Jan. 2, 2008).

<sup>3</sup> DRAFT GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 1, 16-21 (May 20, 2004) [hereinafter Draft Guidance Document]. The document is the predecessor to several earlier issued guidelines, and the FDA invited interested parties to submit comments during the ninety-day period following its publication. In August 2007, the FDA released the final version of the guidance document to accompany the donor eligibility rule. See GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 1 (Aug. 8, 2007), <http://www.fda.gov/Cber/gdlns/tissdonor.pdf> [hereinafter Final Guidance Document].

<sup>4</sup> Final Guidance Document, *supra* note 3, at 14.

<sup>5</sup> *Id.*

<sup>6</sup> See *id.* at 14-20.

an outright bar to donor eligibility.<sup>7</sup> Instead, the rule simply states that persons who screen donors “*must*” review medical records for “*risk factors . . . for relevant communicable disease[s] . . .*”<sup>8</sup> Although subtle, the logical extension and effect of the rule’s language is that a person who “*must*” screen for “*risk factors*” will turn to the FDA’s guidance document to determine what those risk factors are.

The purpose of this Note is to highlight several litigation strategies that might be effective in ending discrimination against gay and MSM potential sperm donors. The Note does not advocate for one litigation strategy over another, nor does it purport to solve all of the problems involved with each. The overarching goal is to make a potential litigator aware of some of her strategic legal choices, to highlight the advantages and disadvantages of each choice, and to advocate for creative lawyering. The Note will discuss claims against the FDA under the Administrative Procedure Act (APA), and it will also analyze claims against the individual sperm banks and clinics that have adopted the FDA’s recommended eligibility requirements under the U.S. and various state constitutions.

Section II begins by giving a brief overview of the FDA’s guidance document, its promulgated rule, and the preamble to that rule, and it will highlight many of the inconsistencies and problems contained therein. Section III will lay out the framework for a lawsuit, and it will provide an example of a “perfect” plaintiff and his accompanying story, coupled with the reasons why he may be particularly persuasive in front of a judge or jury. It employs a legal narrative, and discusses the advantages of using stories to help an audience relate, sympathize, and change its mindset.

In Section IV, the Note outlines a claim against the federal government under the APA, which authorizes judicial review of “final agency actions.”<sup>9</sup> It first discusses the principles and case law that an attorney may use to argue that the FDA’s informal action—its recommended eligibility determination—is a final agency action. It then makes the argument that this final action is arbitrary and capricious, and is therefore unlawful.

The Note then switches its concentration from the government to public and private reproductive facilities that have incorporated the FDA’s recommendation into their official eligibility requirements. Section V focuses on claims under the Equal Protection Clause of the U.S. Constitution’s Fifth and Fourteenth Amendments. To show that an eligibility requirement that excludes MSM donors is discriminatory, it puts forth two potential arguments: the criterion violates the fundamental right to procreate articulated in *Skinner v. Oklahoma*,<sup>10</sup> and it violates a right to intimate, sexual privacy that the Supreme Court

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<sup>7</sup> Preamble, *supra* note 1.

<sup>8</sup> 21 C.F.R. §§ 1271.50(a) - (b)(1)(i), 1271.75(a)(1) (2007) (emphasis added).

<sup>9</sup> 5 U.S.C.A. § 704 (West 2007).

<sup>10</sup> 316 U.S. 535 (1942).

arguably alludes to in *Lawrence v. Texas*.<sup>11</sup> The Note emphasizes, however, that the Constitution has limited domain over private parties, and it discusses the various arguments available to show how private establishments may engage in the requisite “state action.” Contained in the subsections of Section V, the Note examines similar legal theories but does so under various state constitutions, highlighting the advantages and disadvantages of this choice-of-law strategy. It comments that the rights guaranteed under the U.S. Constitution merely represent the floor, and that states can and often do extend these rights under their own constitutions. In addition, it notes that many state constitutions do not require state action to reach private discrimination, and many more are ambiguous about such a requirement.

The Note concludes in Section VI with an analysis of the costs and benefits of the various litigation strategies, but stresses that the tactics listed herein are not all-inclusive; a more searching inquiry into various states’ anti-discrimination statutes and constitutional provisions may reveal alternative means by which an attorney can bring a claim and end the inequality at issue. Although it would be ideal, the Note does not ultimately unearth a clear winning strategy. Instead, it is a “guidance document” unto itself, and it is intended to help an attorney choose the litigation strategy that will best serve her client.

## II. BACKGROUND

The FDA was originally known as the “Division of Chemistry,” an entity primarily responsible for scientific research.<sup>12</sup> In 1906, Congress jump-started the FDA’s modern era when it enacted the Federal Food and Drugs Act, transforming the agency into a regulating body.<sup>13</sup> Today, the FDA is an agency of the Department of Health and Human Services responsible for regulating food, drugs, cosmetics, animal feed, biologics, and many other similar products.<sup>14</sup> Its primary purpose is to protect and promote the public health.<sup>15</sup>

In 2004, the FDA released a draft industry guidance document concerning eligibility criteria for sperm donors which listed “men who have had sex with another man in the preceding five years” as the number one risk factor that should be screened.<sup>16</sup> The guidance document recommended that any person who possesses any of the noted risk factors should be considered ineligible to

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<sup>11</sup> 539 U.S. 558 (2003).

<sup>12</sup> See John P. Swann, *History of the FDA*, <http://www.fda.gov/oc/history/historyoffda/fulltext.html> (last visited Nov. 18, 2006).

<sup>13</sup> See *id.* See also Federal Food and Drugs Act of 1906, 21 U.S.C.A. §§ 1-15 (West 2007) (repealed 1938).

<sup>14</sup> See Swann, *supra* note 12; U.S. Food and Drug Administration, <http://www.fda.gov/default.htm> (last visited Nov. 18, 2006).

<sup>15</sup> *Id.*

<sup>16</sup> Draft Guidance Document, *supra* note 3, at 16.

donate.<sup>17</sup> Soon after, the FDA's final rule concerning eligibility determinations for donors of human cell and tissue-based products went into effect.<sup>18</sup> In the preamble to that rule, the FDA explicitly declines to amend previous guidance documents that list MSMs as a risk factor, insisting that no new data warrants a revision.<sup>19</sup> Notably, however, the FDA makes the following acknowledgment:

Some comments disagreed with considering homosexual men to be "high risk donors" and disputed the scientific basis for excluding these men as donors. *Many* comments cited the efficacy of the blood test for HIV, with retesting after a 6-month quarantine, although one comment noted that HIV antibody testing is imperfect. *Many* comments disputed the public health benefits of the rule, although some applauded the agency for trying to craft safeguards to protect the public. Other comments asserted that the regulations would abridge the reproductive, civil, or constitutional rights of both donor and recipient, but did not provide an explanation of the scope of those rights or a legal analysis of how this rule would affect them. *Many* comments argued that the proposed regulations were discriminatory.<sup>20</sup>

The FDA's mission statement declares that its primary purpose is to protect and advance the public health.<sup>21</sup> Unfortunately, the FDA's attempt to protect and advance public health by excluding MSMs from the pool of available sperm donors does not comport with that stated mission, and has instead unfairly disadvantaged member of the gay community and those who do not identify within a narrow, sexuality defining box.<sup>22</sup> Although the FDA insists that excluding MSMs from the donor pool reduces the risk of HIV and AIDS transmissions, this proposition is unsupported by the facts.<sup>23</sup> To prevent disease transmission, the FDA has imposed stringent blood tests and waiting periods

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<sup>17</sup> *Id.*

<sup>18</sup> 21 C.F.R. §§ 210 et seq.

<sup>19</sup> Preamble, *supra* note 1, at 29,806.

<sup>20</sup> *Id.* at 29,805 (emphasis added). The FDA then states, "In response to the comments suggesting that FDA should allow establishments to rely on HIV test results alone, or on quarantine and retesting, without screening for risk factors, FDA rejects that approach at this time." *Id.* at 29,806.

<sup>21</sup> FDA's Mission Statement, <http://www.fda.gov/opacom/morechoices/mission.html> (last visited Oct. 29, 2007).

<sup>22</sup> Throughout this Note, the terms "gay," "MSM," and "sexual orientation" are used interchangeably to be inclusive of the various groups of men affected, and the labels to which many prescribe.

<sup>23</sup> *See infra* Part IV.C (making the argument that the agency action is arbitrary and capricious because it is not rationally based on the facts).

upon anonymous sperm donors.<sup>24</sup> A donor's blood is tested seven days before or at the time of the donation, his specimen is frozen for six months, and his blood is then tested a second time.<sup>25</sup> The FDA requires the six-month waiting period to ensure that if a person newly-infected with HIV does not test positive at the time of the donation, the virus or its antibodies will have appeared by the end of the quarantine period.<sup>26</sup> Additionally, the FDA explicitly recommends that fertility clinics use new forms of testing that can detect HIV and HCV antibodies within just days or weeks.<sup>27</sup>

Moreover, in a report released in February 2004, the Center for Disease Control (CDC) stated that the majority of reported HIV infections worldwide are transmitted by sexual contact between men and women.<sup>28</sup> The data contained in the report further showed that within the United States, thirty-five percent of HIV infections diagnosed between 1999 and 2002 were transmitted by sexual contact between males and females; of the 101,877 reported diagnoses in twenty-nine states, 36,084 were the result of heterosexual conduct.<sup>29</sup> While the CDC's report provides only part of the whole story,<sup>30</sup> it is an illuminating and effective tool in demonstrating that the threat of HIV transmission is not limited to members of the gay or MSM communities. The report affirmatively proves that notions of HIV as a "gay disease"<sup>31</sup> are outdated, inaccurate, and, quite lit-

<sup>24</sup> 21 C.F.R. §§ 1271.80, 1271.85(d) (West 2007).

<sup>25</sup> *Id.* The safeguards in place for testing sperm donors dwarf the precautions taken when testing blood donors where only one specimen is required from any potential donor. See John G. Culhane, *Bad Science, Worse Policy: The Exclusion of Gay Males From Donor Pools*, 24 ST. LOUIS U. PUB. L. REV. 129, 137-38 (2005).

<sup>26</sup> See Suitability Determination for Donors of Human Cellular and Tissue-Based Products, 64 Fed. Reg. 52,696, 52,706 (proposed Sept. 30, 1999) (to be codified at 21 C.F.R. pts. 210, 211, 820, 1271); See also Culhane, *supra* note 25, at 137-38.

<sup>27</sup> 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-vol1.pdf>. The letter was written on behalf of the Lambda Legal Defense and Education Fund, the Gay and Lesbian Medical Association, the Human Rights Campaign, and the National Center for Lesbian Rights.

<sup>28</sup> *Heterosexual Transmissions of HIV – 29 States, 1999-2002*, MORBIDITY MORTALITY WKLY. REP. (CDC, Atlanta, Ga.), Feb. 20, 2004, at 125, <http://www.cdc.gov/mmwr/PDF/wk/mm5306.pdf>.

<sup>29</sup> *Id.* The data represents HIV and AIDS diagnoses made over the course of four years in the twenty-nine states that met the CDC's reporting standards.

<sup>30</sup> Notably, the report does not break down the statistics in terms of reported HIV cases in relation to the per capita population of the identified groups, nor does the report specifically include statistics for men and women who have sex with members of both sexes. Furthermore, the report does not explain how the data might take into consideration inaccurate self-reporting of sexual activities and partners.

<sup>31</sup> For an analysis of how pop culture, for example, has contributed to the creation and perpetuation of the once (and arguably still) common belief that HIV and AIDS are "gay diseases," see Richard Goldstein, *The Implicated and the Immune: Cultural Responses to AIDS*, 68 THE MILBANK QUARTERLY 295 (1990). The author notes that jokes about gays and HIV continue to

erally, a danger to public health. Why, then, has the FDA failed to also address these alarming statistics in its final guidance document concerning risk factors?

Rather than modern science, the FDA's stance on gay sperm donors is based on archaic stereotypes and generalizations. It continues to classify MSMs as high risk, but refuses to acknowledge the increasing rate of heterosexual HIV transmissions, as well as the reality of today's technology. The policy also embodies a moral disapproval of certain kinds of sexual behavior over others, and lends support to recent criticism that, "[t]he once solid reputation of the U.S. agency and the science it produces has come to be regarded with suspicion due to the crumbling of the divide between science, politics, and religious ideology."<sup>32</sup> While its policy purports to promote public health, the truth is that the FDA has only succeeded in arbitrarily stigmatizing and excluding a minority group from participating in a socially valuable service.

### III. FRAMING THE ISSUE WITH STORYTELLING AND THE "PERFECT" PLAINTIFF

Many jurisprudential scholars have long emphasized the importance of personal experiences, alternative voices, and nontraditional views.<sup>33</sup> For instance, Professor Charles R. Lawrence III of Stanford Law describes the litigation process as "highly formalized storytelling,"<sup>34</sup> and states that "one story in-

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thrive in pop culture, and, in fact, "in some circles, 'gay' has come to stand for 'got AIDS yet?'" *Id.* at 303.

For a more modern example showing how society frequently seeks to hold gays responsible for the spread of disease, see the January 2008 response to scientists' discovery of a new strain of drug-resistant staphylococcus known as MRSA. "On Monday, a team of researchers led by doctors from the University of California at San Francisco announced that gay men were 'many times more likely than others' to acquire a new strain of drug-resistant staphylococcus, a nasty, fast-spreading and potential lethal bacteria known as MRSA USA300." Jesse McKinley, *After Linking New Strain of Staph to Gay Men, University Scrambles to Clarify*, N.Y. TIMES, Jan. 20, 2008, at A16. Following the announcement, many anti-gay groups quickly latched onto the report as ammunition for their homophobic causes, "citing the 'sexual deviancy' of gay men as leading to AIDS, syphilis and gonorrhea," and commenting that "[t]he medical community has known for years that homosexual conduct, especially among males, creates a breeding ground for often deadly disease." *Id.* In response to the report's widespread distribution by the media and the public's reaction, scientists at the University, surprised by the spin, attempted to clarify their findings. The University quickly issued an apology, noting that the release "contained some information that could be interpreted as misleading," and one of the report's authors, Dr. Henry Chambers, stated that, "[W]e deplore negative targeting of specific populations in association with MRSA infections or other public health concerns." *Id.*

<sup>32</sup> Alastair J.J. Wood et al., *A Sad Day For Science at the FDA*, 353 NEW ENG. J. MED. 1197, 1199 (2005). This article was written in response to the FDA's denial of an application to make emergency contraception available over-the-counter to women of any age. Michelle Fine & Sara I. McClelland, *The Politics of Teen Women's Sexuality: Public Policy and the Adolescent Female Body*, 56 EMORY L.J. 993, 1012, 1014 (2007).

<sup>33</sup> ROBERT L. HAYMAN, JR., NANCY LEVIT & RICHARD DELGADO, *JURISPRUDENCE CLASSICAL AND CONTEMPORARY: FROM NATURE LAW TO POSTMODERNISM* 461-62 (2d ed. 2002).

<sup>34</sup> Charles R. Lawrence III, *The Word and the River: Pedagogy as Scholarship as Struggle*, 65 S. CAL. L. REV. 2231, 2278 (1992).



vites another as people's worlds weave the tapestry of human connection."<sup>35</sup> Storytelling humanizes legal actors, and provides the faces and voices absent in the "sterile world of doctrines and rules."<sup>36</sup> Particularly for gays and other minority groups, the "right" story can help people deconstruct their mindsets, show that what they believe is "ridiculous, self-serving, or cruel,"<sup>37</sup> and provide "the way out of the trap of unjustified exclusion."<sup>38</sup> An attorney who gives life to her plaintiff and emphasizes that plaintiff's personal experiences in a written brief, in an oral argument, or in front of a jury will, therefore, succeed in provoking thought and laying a stronger foundation upon which to build her legal arguments.

Unfortunately, the drawback to finding a plaintiff who represents the "right" kind of story and who has the ability to connect with people and open minds is that this strategy necessarily excludes people who do not fit perfectly into that mold, or who would not *want* to fit perfectly even if they could. Framed against the backdrop of a monogamous, family-oriented couple, it might indeed be easier for a court to conclude that excluding gay men from the donor pool is discriminatory. Many gay men (and women), however, reject monogamy and traditional notions of family as forced assimilation into the heterosexual hegemony.<sup>39</sup> Truthfully, the very concept of the "perfect plaintiff" is a conservative proposal; it accepts and uses the status quo as a legitimate point of comparison. But while alternative counter-stories can raise consciousness and show "that there are possibilities for life other than the ones we live,"<sup>40</sup> it is often harder for minority groups to dismantle the status quo without first earning the credibility that comes from the very assimilation they wish to fight against.

In a purely practical, litigation-oriented sense, it is more difficult to undermine a policy designed to prevent the spread of sexually transmitted diseases if the plaintiff is a sexually active, un-partnered gay male who wants to donate sperm, even if he always practices safe sex. Society has stigmatized this male prototype, and it distrusts his lifestyle and questions his health. Hopefully this will soon become an outdated conception as gays and MSMs advance in the realm of legal rights and are able to tell *every* story. Until then, there is little choice but to accommodate bias. For the purposes of this Note, and more importantly, for litigation, the focus will be on the "perfect" hypothetical plaintiff. He exhibits many of the qualities with which a judge or jury may be sympathetic and relate. His story, which discusses how he met his partner, is intended

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<sup>35</sup> *Id.* at 2279.

<sup>36</sup> HAYMAN, *supra* note 33, at 464.

<sup>37</sup> Richard Delgado, *Storytelling: Re-Imagining Law Through Literature*, in JURISPRUDENCE CLASSICAL AND CONTEMPORARY: FROM NATURAL LAW TO POSTMODERNISM 503, 504 (2d ed. 2002).

<sup>38</sup> *Id.*

<sup>39</sup> See G.W. Dowsett, *I'll Show You Mine if You'll Show Me Yours: Gay Men, Masculinity Research, Men's Studies, and Sex*, 22 THEORY & SOCIETY 697, 699 (1993).

<sup>40</sup> Delgado, *supra* note 37.

to remind those in relationships of their own courtship. And the life he ultimately builds with his partner embodies the popular values of family, commitment, monogamy, community involvement, and financial responsibility. It is important to tell his and others' stories because they add faces to victims. A court or jury will find it more difficult to ignore the effects that the FDA's discriminatory policy has on real people if those effects are presented through the use of a story and characters which represent lives not much different from their own.<sup>41</sup>

\* \* \*

In 1995, during the spring semester of their junior years, mere chance brought Aaron and Josh together when a Professor assigned them to the same study group.<sup>42</sup> Groups had always made Aaron a little bit nervous, but he resigned himself to participate when necessary and stay quiet if at all possible. During the group's second official meeting, the self-appointed leader asked everyone to divide into partners and put together an outline. Aaron secretly hated partner work, mainly because he was always one of the last people still looking to pair up. He scanned the room, took a deep breath, and introduced himself to Josh—the only remaining partner-less person in the room.

Surprisingly, and to Aaron's relief, the two hit it off right away and hardly noticed the hours creep by as they worked together on the outline that night. They made so much progress, in fact, that they agreed to meet several more times that week to get a head start on studying for the midterm. Aaron loved that he and Josh had so much in common, and he felt like their low-key personalities really clicked. Over the course of the semester, they began to spend time together outside of class, and quickly became good friends. Before they knew it, it was time for finals and the semester was almost over. At lunch one day, Josh mentioned that he was looking for a new place to live for the upcoming year, and he asked Aaron if he was interested in being his roommate. Aaron, eager to finally live off campus, enthusiastically accepted Josh's offer.

When fall finally came, Aaron and Josh moved into their apartment and became even closer friends. They took classes together, developed a core social group, and even occasionally spent time with each other's families on the weekends. They had grown so close, in fact, that their friends began to comment on their relationship, and teased them about acting like "a couple." And it didn't end there. The "gay jokes" soon became a staple at social events. Aaron tried to laugh along with his friends, but secretly, he was struggling. He wanted to

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<sup>41</sup> But there is also the risk that even the "perfect plaintiff" may not successfully connect with a jury; despite obvious parallels to a "traditional" family unit, jurors may be blocked by, or be unsympathetic to, the struggle for sexual identity realization. Sadly, this is a potential barrier in any case in which there is discrimination based on norm-defying sexuality.

<sup>42</sup> Aaron and Josh are fictional characters, but many of the events described are based loosely on the lives of a real couple.

pass it all off as harmless joking, but he couldn't help but wonder whether there was some truth behind his friends' teasing. And if so, why did that bother him so much? Aaron was hopelessly confused. He knew that his feelings for Josh were strong—perhaps even unusually strong—but he had never seriously considered that he might be gay. Sure, he had questioned himself a few times. But it had never amounted to anything more than just that. Still, Aaron worried about whether something was different this time, and he wondered what was going through Josh's mind. After weeks of waging an internal battle, he decided that the only way to make sense of his situation was to be honest with Josh. And he was. Soon, the two friends found themselves talking to each other about things that neither had ever imagined he would say out loud. It came as a huge relief.

Aaron and Josh have now been together for twelve years. While Aaron's life with Josh was an unexpected turn, he has absolutely no regrets. He was finally honest with himself, and now, for the first time in his life, he is truly happy. Although their relationship is technically nontraditional, Aaron sees it no differently than any other: while together, neither he nor Josh has expressed interest in pursuing outside sexual relationships, and each has fully committed himself to monogamy; in 1999, they made it "official" by exchanging rings in a small ceremony with their family and friends; in 2001, they had finally saved up enough money to buy a house together; and just two years ago, they adopted their first son. Everyone who knows them describes the two as "the perfect couple."

Six months ago, Aaron read an article in the paper concerning the shortage of black sperm donors.<sup>43</sup> The article noted that "[b]lack couples looking for same-race sperm donors have a very limited number of options when choosing donors,"<sup>44</sup> and it attributed the lack of donors to the small number of black men who are graduates of a four-year college or university.<sup>45</sup> As a black man who had ultimately earned a master's degree, Aaron hoped that he would qualify. He made an appointment with a local fertility clinic and felt good about his decision to do what he could to help other families in need.<sup>46</sup>

During his screening interview, Aaron was asked a series of questions, all of which he answered with no trouble; he was in good health and had never engaged in what he considered "risky behaviors." He answered "no" to every

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<sup>43</sup> See *Sperm Donors from America's Most Selective Universities: Limited Choices for Black Women*, 25 J. BLACKS & HIGHER EDUC. 38 (1999). "At the nation's largest sperm banks, black donors are so few that black couples have almost no options in choosing donors with specific educational backgrounds, talents, or achievements." *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> The principle purpose of sperm banks is to help infertile couples conceive a child, and donating sperm is socially encouraged and applauded. Sperm donation is comparable to blood donation in that both acts help people in need. See Anne Reichman Schiff, *Frustrated Intentions and Binding Biology: Seeking Aid in the Law*, 44 DUKE L. J. 524, 562-63 (1994).

question as the nurse read down the check-list: he did not have hemophilia, he never injected drugs intravenously, he had never engaged in sex in exchange for money, and he had never been incarcerated.<sup>47</sup> The nurse seemed satisfied with his answers, but then asked one final question: “Have you engaged in sex with another man in the past five years?” Aaron grew mildly embarrassed, but answered honestly with a simple “yes.” The nurse made a few notes, looked grimly at Aaron, paused, and then said, “I’m sorry, sir. You are not qualified to donate semen at this time because engaging in sexual activities with another male increases the risk that you are a carrier of a relevant communicable disease.” Aaron sat stunned and motionless in his chair as the nurse politely excused herself.

\* \* \*

Although Aaron is in a long-term, monogamous relationship, he is considered more likely to have HIV or AIDS because that relationship is with another man rather than a woman. Put simply, Aaron cannot donate sperm because he is gay. While both Aaron and his story are largely fictional, they illustrate the reality that many gay men in America face today. The story represents a lifestyle that the FDA and most sperm banks ignored when they implemented their policies. It paints a picture that is contrary to a common perception of gay life: a perception that identifies gays, and gay men specifically, as promiscuous and uninvolved in family matters. It also shows that many gay men are just like anyone else—or, more to the point, just like judges and jurors. For these reasons, the “perfect plaintiff” and his story are highly relevant from a litigation perspective.

#### IV. CLAIM AGAINST THE FEDERAL GOVERNMENT: THE FDA’S RECOMMENDATION IS AN UNLAWFUL AGENCY ACTION

In 2007, the FDA solidified its stance on gay sperm donors as a “risk factor” when it issued its final guidance document *recommending* that men who have had sex with another man in the past five years be ineligible.<sup>48</sup> The FDA emphasized that its proposed eligibility guidelines are not binding, do not “establish legally enforceable responsibilities,” and do not “create or confer any rights for or on any person;” the guidelines merely describe its “current thinking on a topic and should be viewed only as recommendations.”<sup>49</sup> In its final rule, however, the FDA requires that persons who interview potential donors screen for “risk factors.”<sup>50</sup> Notably, the FDA neglects to identify those factors in its

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<sup>47</sup> See Final Guidance Document, *supra* note 3, at 14-20. These questions represent four of the twenty-nine conditions and behaviors that the FDA considers risk factors. *Id.*

<sup>48</sup> Final Guidance Document, *supra* note 3, at 14.

<sup>49</sup> *Id.* at 1.

<sup>50</sup> 21 C.F.R. § 1271.75(a)(1) (2007).

regulation.<sup>51</sup> The only criteria that artificial reproductive facilities are given about which risks they must screen for in order to comply with the law, therefore, come from the FDA's "nonbinding" guidance document.<sup>52</sup>

In 1946, Congress enacted the Administrative Procedure Act (APA) as the code of rulemaking and adjudicative procedures applicable to federal agencies.<sup>53</sup> The APA establishes an independent cause of action for parties injured by unlawful agency regulations.<sup>54</sup> The statute provides that "[a] person suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action within the meaning of a relevant statute, is entitled to judicial review thereof."<sup>55</sup> Once a court finds that the agency's action is final, it may then consider six factors to determine whether that action is unlawful: (1) is it arbitrary or capricious, (2) is it unconstitutional, (3) is it outside of the agency's jurisdiction, (4) did the agency fail to follow statutory procedures, (5) is it unsupported by substantial evidence, or (6) is it unwarranted by the facts?<sup>56</sup>

Thus, when determining whether to challenge the FDA's guidance document as an unlawful agency action, there are several things to consider. Before evaluating the merits of the claim, one must determine whether the FDA's recommendation constitutes *final* agency action. But how do we know? Does the FDA escape judicial review of its recommendations because it did not officially codify them in its final rule concerning donor eligibility? Is the gay man or MSM who is turned away at the sperm bank left without recourse? Next, if the FDA's guidance document is in fact final agency action, which of the APA's six factors for determining unlawfulness will a court consider? Do any of these factors suggest that the FDA's action is unlawful? The Note will now attempt to navigate through these issues and examine each in turn.

#### A. *The FDA's Recommendation May be Considered Final Agency Action Subject to Judicial Review*

In *Franklin v. Massachusetts*, the Supreme Court provided helpful insight into what constitutes final agency action.<sup>57</sup> Quoting one of its earlier decisions, the Court stated that "[t]o determine when an agency action is final, we

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<sup>51</sup> Preamble, *supra* note 1, at 29,805-06 (stating that it specifically described risk factors in a guidance document, but would not specify those factors in the final rule).

<sup>52</sup> *Id.* at 29,786. Further, the FDA specifically rejects the proposition that establishments should be able to screen on HIV test results alone because "even that testing may fail to detect early stage HIV and other infections . . ." *Id.* at 29,806.

<sup>53</sup> 5 U.S.C.A. §§ 702-04 (West 2007).

<sup>54</sup> *Id.* at § 702.

<sup>55</sup> *Id.*

<sup>56</sup> 5 U.S.C. § 706.

<sup>57</sup> See generally 505 U.S. 788 (1992) (finding that the Secretary of Commerce's report to the President on the U.S. census and its effects on state Representative apportionment was not final action under the APA).

have looked to, among other things, whether its impact ‘is sufficiently direct and immediate’ and has a ‘direct effect on . . . day-to-day business.’<sup>58</sup> The Court reasoned that the action is not final if it is only “tentative,” and stressed that “[t]he core question is whether the agency has completed its decisionmaking process, and whether the result of that process is one that will directly affect the parties.”<sup>59</sup>

Building on the Supreme Court’s precedent, another court took the “final action” analysis even further.<sup>60</sup> In *PDK Labs Inc. v. Ashcroft*, the Drug Enforcement Administration (DEA) counseled an ephedrine supplier to forgo selling its product to a pharmaceutical company (PDK) that used ephedrine to make over-the-counter drugs.<sup>61</sup> The DEA claimed that it had not engaged in final agency action because it had merely offered advice on a hypothetical course of action.<sup>62</sup> The court rejected this argument, reasoning that “[f]inality’ must be interpreted in a flexible and pragmatic way,” and that an agency’s characterization of its own actions is not determinative.<sup>63</sup> Otherwise, an agency’s ruling could escape judicial review simply because the agency refuses to acknowledge its finality.<sup>64</sup>

The label an agency attaches to its actions is not determinative. The action may be reviewable even though [sic] it is merely an announcement of a rule or policy that the agency has not yet put into effect. *Indeed, agency action may be reviewable even though it is never to have any formal, legal effect.*<sup>65</sup>

Ultimately, the court held that the DEA had engaged in final action.<sup>66</sup> It stated that the DEA knowingly discouraged the business transaction because its statements undoubtedly communicated its desire for the supplier to refrain from selling ephedrine to PDK.<sup>67</sup> The court found that the “direct and immediate result” was that the DEA had threatened PDK’s business because it could not purchase the materials necessary to make its product.<sup>68</sup>

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<sup>58</sup> *Id.* at 796-97 (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 152 (1967)).

<sup>59</sup> *Id.* at 797.

<sup>60</sup> *See generally* *PDK Labs Inc. v. Ashcroft*, 338 F. Supp. 2d 1 (D.D.C. 2004).

<sup>61</sup> *See id.* at 3, 5.

<sup>62</sup> *Id.* at 10 (citing *Franklin*, 505 U.S. at 797).

<sup>63</sup> *Id.*

<sup>64</sup> *Id.* at 11.

<sup>65</sup> *Id.* at 10-11 (citing *N.Y. Stock Exch. v. Bloom*, 562 F.2d 736, 740 (D.C. Cir. 1977) (emphasis added)).

<sup>66</sup> *Id.* at 12.

<sup>67</sup> *Id.* at 11.

<sup>68</sup> *Id.*

Recently, agencies have bypassed traditional notice-and-comment rule-making procedures at an increasing rate, and have instead opted to release guidance documents similar to the FDA's at issue here.<sup>69</sup> Due to this trend, several courts have had the opportunity to examine whether such guidance or advisory documents constitute final agency action subject to judicial review.<sup>70</sup> Perhaps the case that is most closely on point is *Appalachian Power v. EPA*.<sup>71</sup> There, the EPA issued a guidance document that allegedly imposed unauthorized requirements on states' permit programs under the Clean Air Act.<sup>72</sup> The EPA's guidance document *required* "[p]eriodic monitoring . . . at a source subject to title V of the Act . . . ." <sup>73</sup> The document was not the product of notice-and-comment rulemaking, nor was it published in the Federal Register; the EPA, therefore, insisted that the document was not binding or final, and was not subject to judicial review.<sup>74</sup> In holding that the EPA's guidance document was, in fact, final agency action, the court stated, "the entire Guidance, from beginning to end . . . reads like a ukase [edict]. It commands, it requires, it orders, it dictates. Through the Guidance, EPA has given the States their 'marching orders' and EPA expects the States to fall in line."<sup>75</sup>

Of course, these opinions represent only a fraction of the cases that have dealt with what constitutes final agency action, and other courts have formulated additional tests for determining whether action is final. In sum, courts may apply one of the following four tests when determining whether informal agency action is "final action": (1) does it have a direct and immediate impact on regulated industries, (2) do regulated parties rely on the action, (3) has the agency expressed its final, crystallized position on the matter, *or* (4) is a high-level official directly responsible for the action?<sup>76</sup>

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<sup>69</sup> PETER L. STRAUSS, TODD D. RAKOFF & CYNTHIA R. FARINA, GELLHORN AND BYSE'S ADMINISTRATIVE LAW: CASES AND COMMENTS 1248 (rev. 10th ed. 2003).

<sup>70</sup> See generally, e.g., *Nat'l Automatic Laundry & Cleaning Council v. Shultz*, 443 F.2d 689 (D.C. Cir. 1971) (finding an agency head's advisory opinion to be final agency action because he did not indicate that it was tentative and subject to reconsideration); *Appalachian Power v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000) (finding the guidance document final agency action because it "dictates" to states a course of action and expects them to comply).

<sup>71</sup> 208 F.3d 1015 (D.C. Cir. 2000).

<sup>72</sup> *Id.* at 1019.

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 1020-21. Similar to the disclaimer in the FDA's guidance document referenced *supra* note 49, the EPA's guidance document included the following language: "The policies set forth in this paper are intended solely as guidance, do not represent final Agency action, and cannot be relied upon to create any rights enforceable by any party." *Id.* at 1023. The court noted, however, that the language was of little consequence because the EPA consistently includes the disclaimer in all of its documents. *Id.*

<sup>75</sup> *Id.* at 1023.

<sup>76</sup> 2 AM. JUR. 2D *Administrative Law* § 462 (West 2007) (finding that no specific provision of the APA governs informal agency actions, but that they are reviewable under its standards of general applicability).

In light of the case law and the widely acknowledged “final action” tests, the FDA’s informal guidance document likely constitutes final agency action. First, the FDA’s recommendations have a direct and immediate impact on the artificial reproduction industry, and second, the industry relies on those recommendations. Because the law requires sperm banks to screen donors for risk factors, many establishments will look to the FDA’s guidance document to determine what those risk factors are. The FDA is undoubtedly aware that this is the likely result. Otherwise, expending the resources necessary to issue both draft and final guidance documents would have been frivolous. When sperm banks and clinics find that the FDA has “offered advice” on the relevant screening factors (much like the DEA “offered advice” in *PDK Labs*), and recommends that men who have had sex with men in the past five years be ineligible to donate, many will implement the recommendation into their own eligibility requirements.<sup>77</sup> As an indication of the persuasive power of guidance documents, Hugh M. O’Neil, Vice President of the pharmaceutical company Sanofi-Aventis, recently commented that, while agencies’ guidance documents do not have the force of law, they “can have coercive effects” and “can impose significant costs” on the public.<sup>78</sup> Thus, because many in the industry will be persuaded by, and will rely on, the FDA’s guidance document, the direct and immediate impact on the artificial reproduction industry is two-fold: (1) the industry will see widespread implementation of the FDA’s recommendation, and (2) the industry will necessarily receive fewer sperm donations.

Third, the FDA has expressed its finalized view on the matter. Within the very guidance document, the FDA states that the provisions therein represent its “current thinking” on this topic,<sup>79</sup> and in the preamble to its final rule, the FDA states that it finds no new data that would warrant revising its previous guidelines.<sup>80</sup> Because the FDA has remained steadfast and unwavering in “its current belief” that men who have had sex with men within a five-year window should be ineligible to donate sperm, the facts strongly indicate that the action represents its final and crystallized position.

The fourth enumerated test—whether a high-ranking officer has direct responsibility for the action—is probably inapplicable in this situation because the guidance document is a collective work meant to represent the FDA as a singular entity. Regardless, it is only necessary to meet one of the four tests to

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<sup>77</sup> Unfortunately, research did not yield the number of establishments that changed their eligibility requirements following the FDA’s draft and final guidance documents. Further investigation into this statistic is needed.

<sup>78</sup> Robert Pear, *Bush Directive Increases Sway on Regulation*, N.Y. TIMES, Jan. 30, 2007, at A1.

<sup>79</sup> Final Guidance Document, *supra* note 3, at 1.

<sup>80</sup> Preamble, *supra* note 1, at 29,806. The FDA concedes that new data may justify changes to its guidance, and promises to “continue to examine the data on risk factors.” *Id.* But one could argue that this statement is too open-ended and vague to warrant a finding that the FDA’s guidance document does not represent a “final, crystallized position on the matter.”



find that an informal agency action represents the requisite final action necessary for judicial review.<sup>81</sup> Here, there is a strong argument that the guidance document satisfies at least three of the four tests. Although the FDA pointedly emphasizes that the recommendations “do not establish legally enforceable responsibilities” and “do[] not operate to bind the FDA or the public,” *PDK Labs* reminds us that the label an agency attaches to its own actions is not dispositive, and that even actions never intended to have a legal effect can be final.<sup>82</sup>

*B. The FDA’s Recommendation May be Unlawful if it is Arbitrary, Capricious, or an Abuse of Discretion*

If the FDA’s recommendation is indeed a final agency action subject to judicial review, the next step is to determine the scope of that review. The scope of judicial review will depend upon whether the recommendation came about as part of formal<sup>83</sup> or informal<sup>84</sup> agency rulemaking.<sup>85</sup> In light of the distinct differences between formal and informal agency actions, the rulemaking at issue here is clearly informal; rather than engaging in the court-like proceedings required of formal rulemaking or adjudication,<sup>86</sup> the FDA issued notice that it was promulgating a rule concerning donor eligibility requirements and then solicited comments regarding its draft guidance document.<sup>87</sup> The FDA’s guidance document, thus, appears to fall within the framework of informal rulemaking.<sup>88</sup> While the APA outlines six potential criteria that shall render an agency’s formal rulemaking unlawful,<sup>89</sup> the court’s review of informal agency action is more limited.<sup>90</sup> Thus, the court will determine (1) whether the agency had the

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<sup>81</sup> See *supra* note 76 (stating that “[i]nformal agency action may be final agency action . . . when *one or more* of the following elements is present.”) (emphasis added).

<sup>82</sup> *PDK Labs Inc. v. Ashcroft*, 338 F.Supp.2d 1, 10-11 (D.D.C. 2004).

<sup>83</sup> 5 U.S.C.A. § 553, 556-57 (West 2007).

<sup>84</sup> *Id.* at § 553(c).

<sup>85</sup> See *infra* note 90 and accompanying text.

<sup>86</sup> 5 U.S.C.A. §§ 556-57 (requiring a formal hearing).

<sup>87</sup> Preamble, *supra* note 1, at 29,787. (“We are now making final the donor-suitability proposed rule that was proposed on September 30, 1999. . . . The comment period for that proposed rule was closed on December 29, 1999.”). See also *FDA Finalizes New Rule*, *supra* note 2 (“Comments on the draft guidance should be received by August 23, 2004 (90 days from the publication date) to assure consideration in the final guidance.”).

<sup>88</sup> 2 AM. JUR. 2D *Administrative Law* § 159 (West 2007) (“In the case of informal rulemaking under the Federal Administrative Procedure Act, an agency must give interested persons an opportunity to participate in the rule-making process through submission of written data, views, or arguments with or without the opportunity for an oral presentation.”).

<sup>89</sup> 5 U.S.C.A. § 706 (West 2007).

<sup>90</sup> See *Citizens to Pres. Overton Park v. Volpe*, 401 U.S. 402, 414-15 (1971) (stating that “[r]eview under the substantial-evidence test is authorized only when the agency action is taken pursuant to a rulemaking provision of the Administrative Procedure Act itself . . . ,” and that de novo review of whether the action was “unwarranted by the facts” is authorized only when the

authority, (2) whether it complied with the proscribed procedures, and (3) whether its action was arbitrary, capricious, or an abuse of discretion.<sup>91</sup> Although it is possible to argue that the recommendation is unlawful under the first two factors, and indeed those claims may prove very effective, analyses of those arguments are beyond the scope of this Note.<sup>92</sup> Instead, the Note will focus on the claim that the recommendation is arbitrary, capricious, or an abuse of discretion.<sup>93</sup>

In *Citizens to Preserve Overton Park v. Volpe*,<sup>94</sup> the Supreme Court considered whether the Secretary of Transportation's authorization of federal funds to finance the construction of a highway was an unlawful action under the

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action is adjudicatory in nature); *CF&I Steel Corp. v. Econ. Dev. Admin.*, 624 F.2d 136, 139 (10th Cir. 1980) (finding that "[n]either the substantial evidence test nor de novo review apply to informal agency action"); *Anderson v. U.S. Dep't of Hous. & Urban Dev.*, 701 F.2d 112, 113 (10th Cir. 1983) (finding that the function of judicial review is to determine agency authority, whether the agency complied with procedures, and whether the agency's action is arbitrary, capricious, or an abuse of discretion). *But cf. Am. Petroleum Inst. v. Env'tl. Prot. Agency*, 540 F.2d 1023, 1028 (10th Cir. 1976) (stating that "[p]erhaps agency action which is not based on substantial evidence is arbitrary and capricious") (emphasis added).

<sup>91</sup> *Anderson*, 701 F.2d at 113.

<sup>92</sup> There may be a viable argument that the FDA does not have the authority to take this informal action, or that the FDA took the informal action without following the proscribed procedures. These arguments are, however, difficult to make. Because the FDA's enabling statute gives it the authority to regulate the public safety and health, and because the goal of the FDA's guidance document is to assist the industry in protecting the public safety and health, it is likely that the FDA has the authority to make this kind of recommendation in a guidance document. *See Food, Drug, and Cosmetics Act*, 21 U.S.C.A. §§ 301-99 (West 2007).

If a court finds that the guidance document is final agency action, it is less certain, however, whether the FDA complied with the procedures required by the APA. Because the FDA solicited comments on its draft guidance document prior to releasing the final version, it has the superficial appearance of informal rulemaking. But here, unlike in typical informal rulemaking, the FDA explicitly decries the legally binding nature of the document. Depending on whether the guidance document indeed constitutes final agency action with legal implications, the relevant inquiry may become whether the FDA complied with the required informal rulemaking procedures. This analysis is beyond the scope of this Note. An attorney who litigates this case may find it advantageous to probe deeper into these questions.

<sup>93</sup> For a more complete articulation of the appropriate level of judicial inquiry in determining whether agency action is arbitrary, capricious, or an abuse of discretion, see, e.g., *Transactive Corp. v. United States*, 91 F.3d 232, 237 (D.C. Cir. 1996) (stating that "agency action is arbitrary when the agency offered insufficient reasons for treating similar situations differently"); *Patterson v. Caterpillar, Inc.*, 70 F.3d 503, 505 (7th Cir. 1995) (stating that "[b]efore concluding that a decision was arbitrary and capricious, a court must be very confident that the decisionmaker overlooked something important or seriously erred in appreciating the significance of the evidence"); *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 686 (D.C. Cir. 1984) (finding that the APA's "substantial evidence" and "arbitrary, capricious, or abuse of discretion" provisions require the same quantum of factual support).

<sup>94</sup> 401 U.S. 402 (1971).

APA.<sup>95</sup> The Court concluded that although the Secretary is not required to include formal findings with his decision, the decision cannot be arbitrary, capricious, or an abuse of discretion under the APA.<sup>96</sup> In analyzing the decision's lawfulness, the Court stated:

[Courts] must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment. Although this inquiry into the facts is to be searching and careful, . . . [t]he court is not empowered to substitute its judgment for that of the agency.<sup>97</sup>

Essentially, the Supreme Court confirmed that administrative decision-making is reviewable under something akin to a rational basis test, and that agency action will be found valid provided that it is not wholly irrational.<sup>98</sup>

While this test affords great deference to agencies' informal actions, it is not entirely without bite. In *Motor Vehicles Mfrs. Ass'n v. State Farm*,<sup>99</sup> the Supreme Court held that the National Highway Traffic Safety Administration's (NHTSA) rescission of its regulation requiring all new automobiles to come equipped with passive restraints (automatic seatbelts or airbags) was arbitrary and capricious.<sup>100</sup> The NHTSA rescinded the requirement because the automobile industry had overwhelmingly decided to install detachable seatbelts in most cars.<sup>101</sup> Because passengers could easily remove their seatbelts, the NHTSA concluded that the regulation was no longer reasonable or practical.<sup>102</sup> In its opinion, the Supreme Court shed significant light on this "wholly irrational" test as applied to "arbitrary and capricious" agency action. The Court stated:

Normally, an agency rule would be arbitrary and capricious if the agency has . . . entirely failed to consider an important aspect of the problem, offered an explanation for its decision that

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<sup>95</sup> *Id.* Under federal law, the Secretary can only approve such financing if they determine that there is no feasible and alternative route. In this case, the Secretary approved the route without providing a statement that detailed his factual findings. *Id.* at 402, 408.

<sup>96</sup> *Id.* at 409, 416.

<sup>97</sup> *Id.* at 416 (internal citations omitted). The Court ultimately remanded the case for further fact-finding. It advised the lower court to avoid inquiring into decision-makers' mental processes when their decisions are accompanied by formal findings: such an inquiry is warranted only when there is a strong showing of bad faith or improper behavior. *Id.* at 420.

<sup>98</sup> See Merrick B. Garland, *Deregulation and Judicial Review*, 98 HARV. L. REV. 505, 532 (1985) (finding that courts afford agencies' findings of fact great deference under the minimum rationality or rational basis test).

<sup>99</sup> 463 U.S. 29 (1983).

<sup>100</sup> *Id.* at 46.

<sup>101</sup> *Id.* at 38.

<sup>102</sup> *Id.* at 38-39.

runs counter to the evidence before the agency, or is so implausible that it could not be ascribed . . . to the product of agency expertise.<sup>103</sup>

The Court ultimately concluded that the rescission was arbitrary and capricious because the NHTSA did not consider revising its standards to require airbags in light of the automobile industry's adoption of detachable seatbelts,<sup>104</sup> and because the NHTSA irrationally dismissed the safety benefits of detachable seatbelts.<sup>105</sup> The Court recognized that available data will not always satisfy a regulatory issue, and that agencies often exercise judgment to reach a policy decision.<sup>106</sup> But it also noted that "the agency must explain the evidence which is available, and must offer a 'rational connection between the facts found and the choice made.'"<sup>107</sup>

C. *The FDA's Recommendation to Exclude MSM Donations is Arbitrary, Capricious, and an Abuse of Discretion Because it is not Rationally Based on the Facts*

In response to the FDA's call for comments, Lambda Legal sent a letter to the agency in which it stressed that the exclusion of MSM donors is "unnecessary," "ill-conceived," and has no "legitimate scientific rationale."<sup>108</sup> The letter first argues that the five-year exclusionary period is excessive, citing multiple sources that show that the average person develops detectable antibodies two to three months after infection; only in extremely rare cases can it take six to twelve months to detect antibodies.<sup>109</sup> The letter further emphasizes the disparity by highlighting the availability of nucleic acid amplified testing (NAT) which "reduces the window between exposure and detection to a matter of days or weeks."<sup>110</sup> In fact, the guidance document specifically recommends that *sperm donors* "be tested with FDA-licensed NAT blood donor screening tests for HIV and HCV."<sup>111</sup> Moreover, the rate of error (false negatives) in testing is

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<sup>103</sup> *Id.* at 43.

<sup>104</sup> *Id.* at 46. Before the Court of Appeals, the agency noted several difficulties involved in a mandatory airbag system, including the hardships involved in installing airbags in small vehicles and the adverse public reaction. The Supreme Court, however, rejected these *post hoc* arguments because the agency had never discussed the possibility of a mandatory airbag system, and, therefore, did not submit formal fact-finding. *Id.* at 49-50.

<sup>105</sup> *Id.* at 51.

<sup>106</sup> *Id.* at 52.

<sup>107</sup> *Id.* (citing *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962)).

<sup>108</sup> Givner, *supra* note 27, at 1, 1-2.

<sup>109</sup> *Id.* at 3 & n.1.

<sup>110</sup> *Id.* at 3-4 & n.4.

<sup>111</sup> *Id.* at 4; Draft Guidance Document, *supra* note 3, at 31.

.05 percent, and double testing reduces the risk to almost zero.<sup>112</sup> The data illustrates the glaring incongruity between the five-year exclusionary period and the actual risk, especially in light of the FDA's mandatory six-month specimen quarantine and dual blood test requirements.

Next, the letter highlights the FDA's arbitrary distinctions between various risk factors, and the disparate impact that these distinctions have on gay men. The letter notes, for instance, that the five-year exclusion is "particularly questionable" when compared to the one-year waiting period recommended for any donor who "has had sex with someone he knows or suspects to be infected with HIV, HBV, or HCV," or any donor who has undergone tattooing or piercing with a shared instrument.<sup>113</sup> It also notes that *any person* who fails to use a condom during sexual activity increases the risk of disease transmission by twenty percent, and asserts that eligibility should be determined based on individual risk factors rather than on sexual orientation.<sup>114</sup>

The letter from Lambda Legal is just one source of factual data that the FDA has received regarding its recommendation against MSM donor eligibility.<sup>115</sup> In the preamble to its final rule, the FDA acknowledges that it has "received many comments opposed to a screening factor that would prevent men who have had sex with men from donating semen anonymously."<sup>116</sup> Conversely, the FDA reports that it received only one comment that warned against imperfect HIV antibody testing.<sup>117</sup> Still, the FDA disputes the ability of NAT testing to detect early stage infections (although it specifically recommends such testing in the guidance document), and refuses to acknowledge any new data that warrants a change in its policy against MSM donor eligibility.<sup>118</sup>

Although courts are required to afford informal agency action a high degree of deference, that deference is not a rubber stamp. This is a case where the facts do not rationally lead to the FDA's action, and, in fact, show that the FDA action is "wholly irrational."<sup>119</sup> First, applying the standard set in *Volpe*, a searching and careful inquiry into the facts reveals that the five-year exclusionary period is facially irrational. The FDA does not adequately explain in its guidance document or preamble why it might take five years to detect infection in gay men but only one year to detect infection in other potential donors.<sup>120</sup>

<sup>112</sup> Givner, *supra* note 27, at 4-5 & nn.5, 7.

<sup>113</sup> *Id.* at 5; Draft Guidance Document, *supra* note 3, at 16-17.

<sup>114</sup> Givner, *supra* note 27, at 6 & n.9.

<sup>115</sup> While the FDA does not publish all of its received comments, the comments are public documents available for review pursuant to the Freedom of Information Act.

<sup>116</sup> Preamble, *supra* note 1, at 29,805.

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 29,806.

<sup>119</sup> See Garland, *supra* note 98, at 532.

<sup>120</sup> See Culhane, *supra* note 25, at 139, 141 (finding that the FDA cites a 1983 and two 1985 sources in support of the five-year exclusion, all of which are based on outdated science from before the time of HIV-antibody testing). The FDA also cites a 1988 CDC document that stresses

Rather, the data before the FDA indicated that in only the most extreme cases do antibodies manifest later than six months following transmission. This is true regardless of sexual orientation or sexual practice. Similarly, the FDA stresses that all testing is prone to error, human and otherwise, but has not provided facts that support the proposition that the rate of error diminishes after a year in some groups but not others. Thus, the FDA's five-year exclusionary period for MSMs treats similar situations differently,<sup>121</sup> and it is "wholly irrational" in light of the FDA's interest in protecting public health. "Under these rules, a heterosexual man who had unprotected sex with HIV-positive [female] prostitutes would be OK as a donor one year later, but a gay man in a monogamous, safe-sex relationship is not . . . ."<sup>122</sup>

The distinction between MSMs and men who have sex with women, without more, is not rationally related to the prevention of disease transmission. In *Motor Vehicles*, the court reasoned that agency actions are irrational if the agency fails to consider an important aspect of the problem.<sup>123</sup> In this case, an important aspect of the problem is unquestionably the growing number of new HIV transmissions resulting from heterosexual sexual activity. In fact, as previously discussed, the CDC recently found that the majority of new HIV transmissions worldwide result from heterosexual activity, and that these transmissions account for thirty-five percent of all transmissions in the United States.<sup>124</sup> This data is readily available to both the public and to the FDA. The FDA also acknowledges in its preamble that it has received numerous comments suggesting that there is no basis for singling out MSMs as a risk factor, and that to do so is discriminatory.<sup>125</sup> Because the FDA focuses on the sex of the parties engaged in sexual acts rather than the unsafe nature of any sexual act performed by any sexually active person, it ignores the reality of disease transmission. Accordingly, under *Motor Vehicles*, the FDA's failure to consider this important health aspect renders its action arbitrary and capricious.

These are merely two points which highlight the irrationality of the MSM exclusionary recommendation, but there are certainly others. For instance, why does the FDA ignore the evidence that double testing practically eliminates the risk of error? And why does the FDA fail to mention that there has not been a single case of HIV transmission from frozen, quarantined sperm

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the importance of freezing the sperm, but this document refers to the 1985 reports when it discusses risk factors. *Id.* at 141.

<sup>121</sup> See *supra* note 75 and accompanying text (discussing a decision in which the court held that agency action was arbitrary and capricious because it treated similar scenarios differently without justification).

<sup>122</sup> David Crary, *Despite Objections, FDA Set to Implement New Rules Rejecting Gay Men as Anonymous Sperm Donors*, ASSOCIATED PRESS, May 5, 2005, available at LEXIS. See generally Final Guidance Document, *supra* note 3.

<sup>123</sup> *Motor Vehicles Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983).

<sup>124</sup> *Heterosexual Transmissions*, *supra* note 28.

<sup>125</sup> Preamble, *supra* note 1, at 29,805.

to a recipient?<sup>126</sup> In light of the relevant facts, there is a convincing argument to be made that the five-year exclusionary period and emphasis on gay acts is based not on scientific evidence, but perhaps on the majority's desire to suppress a subgroup based on prejudice. While a court will recognize that the FDA's judgment is generally due great deference, an analysis of the data readily available to the FDA will prove that there has been a clear error in judgment, and that this particular policy is inconsistent, irrational, and the very definition of arbitrary and capricious.

#### V. CLAIMS AGAINST PRIVATE SPERM BANKS, CLINICS, AND OTHER ESTABLISHMENTS THAT SCREEN OUT MSM DONORS

Perhaps another way to end stigmatization and seek equality for gay men and MSMs is to take a more direct approach: file suit against the entities that affirmatively embrace the discriminatory "no gays allowed" policy. After all, not all of these institutions waited for the FDA to formally take a stance before rejecting MSM donors.<sup>127</sup> In fact, some have been excluding MSMs for well over a decade.<sup>128</sup> Bob Rigney, Chief Executive Officer of the American Association of Tissue Banks, predicted that the FDA's recommendation would have a limited effect on the industry because many tissue banks already "exclude[d] active homosexuals from anonymous sperm donations."<sup>129</sup> Consequently, the impact that these establishments have had on gay men has been even more prolonged and damaging.

There are several legal theories under which an attorney can bring a claim against an individual sperm bank or clinic. For the purposes of this Note, however, the focus is on some of the theories available under the U.S. Constitution and various state constitutions. The Note will now examine some of the rights and protections afforded by these constitutions, and it will discuss how a reproductive facility's exclusionary policy may be unconstitutional under each. It will also highlight the weaknesses and strengths of these arguments, as well as the advantages and disadvantages of bringing particular claims.

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<sup>126</sup> See Culhane, *supra* note 25, at 140 (finding that of the four reported HIV transmissions from organ donors to recipients, none occurred within the context of the frozen sperm and six-month quarantine rules).

<sup>127</sup> Rona Marech, *FDA Sperm Donation Rule Upsets Gay Rights Groups*, SAN FRANCISCO CHRON., May 6, 2005, at B3.

<sup>128</sup> Valerie Richardson, *Gays Barred from Sperm Banks; Rights Groups Say FDA Rule 'Based on Bigotry'*, WASH. TIMES, May 21, 2004, at A13.

<sup>129</sup> *Id.*

A. *Claims Under the U.S. Constitution*

1. Is There State Action?

While a party is free to bring constitutional claims against public sperm banks, clinics, or hospitals that screen out MSM donors, he faces some difficulty when that entity is private because the individual rights and liberties afforded by the Constitution apply only to federal and state governmental action.<sup>130</sup> If one intends to challenge the constitutionality of private action, he must, therefore, show that the defendant's actions constitute governmental or "state" action, and that an appropriate constitutional provision regulates that action.<sup>131</sup> Essentially, the Supreme Court has found private action to be governmental action for constitutional purposes when it is "fairly attributable to the state."<sup>132</sup>

The Supreme Court has historically found state action in three distinct circumstances and, debatably, it now recognizes a fourth. The situations in which private action may constitute state action are as follows: (1) when the entity engages in traditionally public functions, (2) when the state commands or encourages the private activity, (3) when there are sufficient mutual contacts between the government and the private entity, and arguably, (4) when there is significant government entwinement with the private entity.<sup>133</sup> In preparing for a potential suit against a private sperm bank or clinic, one must first decide which, if any, of the four state action doctrines are applicable. It is relatively safe to rule out the "public functions" doctrine as a potential route. This theory requires the private entity to engage in functions that the government has traditionally and almost exclusively operated.<sup>134</sup> In this case, the majority of establishments that collect human tissue and cellular donations are privately operated. Although the first of the four state action doctrines is likely inapplicable here, the Note will now analyze the likelihood that the private discrimination amounts to state action under each of the three remaining tests. To be sure, establishing "state action" will be no easy task.

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<sup>130</sup> 2 RONALD D. ROTUNDA & JOHN E. NOWAK, TREATISE ON CONSTITUTIONAL LAW: SUBSTANCE AND PROCEDURE, 758 (3d ed. 1999).

<sup>131</sup> *Id.* at 758-59.

<sup>132</sup> *Lugar v. Edmonson Oil Co.*, 457 U.S. 922, 937 (1982).

<sup>133</sup> See ROTUNDA, *supra* note 130, at § 16; see also Erwin Chemerinsky, *The Rhetoric of Constitutional Law*, 100 MICH. L. REV. 2008, 2024 (2002).

<sup>134</sup> ROTUNDA, *supra* note 130, at 771; see *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 353 (1974) (finding that because Pennsylvania did not have a duty to provide utility services, private utility company did not engage in a public function).



a. *Does the State Encourage the Private Sperm Bank's Activities?*

First, one can attempt to argue that the FDA *encourages* or *coerces* private clinics to discriminate against gay men. The Supreme Court has ruled that “[a] State can normally be held responsible for a private decision only when it has exercised coercive power or has provided such significant encouragement, either overt or covert, that the choice must in law be deemed to be that of the state.”<sup>135</sup> In *San Francisco Arts & Athletics v. U.S. Olympic Committee*,<sup>136</sup> the Supreme Court applied the “encouragement” doctrine to a federal statute that granted the USOC, a private entity, certain commercial rights to the word “Olympic.”<sup>137</sup> The statute stipulated that violators “shall be subject to suit in a civil action” brought by the USOC.<sup>138</sup> Pursuant to the federal statute, the USOC sued the SFAA, a nonprofit organization, because it used the word “Olympic” in its sponsored event.<sup>139</sup> The SFAA countered, arguing that the USOC violated the Fifth Amendment by discriminating in its enforcement of the right.<sup>140</sup> The Court found that that the USOC had not engaged in state action, and was thereby not subject to Constitutional provisions because there was no evidence that the government had coerced or encouraged it to exercise its rights in any particular manner.<sup>141</sup> The court reasoned that Congress did not *encourage* the USOC to enforce its exclusive rights to the word “Olympic” through a lawsuit, but merely stipulated in the statute that the option was available.

Here, however, an attorney can feasibly argue that the FDA directly encouraged and coerced private sperm banks and clinics to screen out MSMs. Unlike in *U.S. Olympic Committee*, where the government *did not require* the USOC to file suit to enforce its rights, the FDA mandates that all establishments *must* screen for risk factors.<sup>142</sup> While it has not codified specific risk factors, the logical conclusion is that its guidance document will effectively encourage and coerce the regulated industry to adopt MSM status as a risk factor. One sperm bank director has even expressed fear that the FDA could shut down an establishment that does not adopt the recommendations.<sup>143</sup>

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<sup>135</sup> Blum v. Yaretsky, 457 U.S. 991, 1004 (1982).

<sup>136</sup> 483 U.S. 522 (1987).

<sup>137</sup> See 36 U.S.C. § 380; 483 U.S. 522.

<sup>138</sup> 36 U.S.C. § 380.

<sup>139</sup> 483 U.S. at 527.

<sup>140</sup> *Id.* at 542.

<sup>141</sup> *Id.* at 547.

<sup>142</sup> 21 C.F.R. §§ 1271.50(b)(1)(i), 1271.75(a)(1) (2007).

<sup>143</sup> See Culhane, *supra* note 25, at 139 n.71. The article also suggests that, “[a]lthough recommendations are, by definition, not requirements, it seems highly unlikely that any establishment that wished to retain its license would ignore them.” *Id.* at 139.

Although the argument is certainly plausible, there is no guarantee that a court will find encouragement or coercion even under these facts. The Supreme Court has traditionally been unwilling to commit itself to any particular test, and continues to determine state action on a case-by-case basis.<sup>144</sup> A claim of state action under this theory also creates cause for concern when considering the significant percentage of establishments that have a long history of excluding potential MSM donors. Clearly it is difficult to argue governmental encouragement and coercion when the discriminatory practices existed prior to the government's public recommendations. Unless there is credible evidence that the government induced these long-standing MSM exclusionary policies, the available pool of defendants under this doctrine is limited.

*b. Are there Sufficient Mutual Contacts between the Government and the Private Sperm Bank?*

Second, the government may have so many mutually beneficial contacts with certain private facilities that those facilities' MSM-exclusionary policies effectively become its own. When analyzing state action under the "mutual contacts" doctrine, courts will consider whether the contacts between the private actor and the government represent a "symbiotic relationship."<sup>145</sup> A symbiotic relationship exists when a private entity's actions are tangentially beneficial to both itself and the government.<sup>146</sup> To break it down even further, the cases that generally arise under this doctrine are divided into three separate subcategories ("strains"): (1) where the government extensively regulates the private entity, (2) where there are wide-ranging physical and economic contacts between the government and the private entity, and (3) where the government directly aids or grants a subsidy to the private entity.<sup>147</sup> The Note will now briefly examine the applicability of each of these strains and their likelihood of success in this case.

*i. Does the Government Render the Private Sperm Bank a State Actor Through Its Regulations?*

On a basic level, the federal government and all private sperm banks have a certain degree of mutuality. The federal government regulates all sperm banks and clinics by making compliance with FDA regulations mandatory.<sup>148</sup> But the Supreme Court has been reluctant to find state action in situations in

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<sup>144</sup> ROTUNDA, *supra* note 130, at 783.

<sup>145</sup> JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW, 528 (6th ed. 2000).

<sup>146</sup> *Id.*

<sup>147</sup> *Id.*

<sup>148</sup> 21 C.F.R. § 1271.45(d) (stating that any establishment that determines who is eligible to donate human cells, tissues, and cellular and tissue-based products "must comply with the requirements contained in this subpart that are applicable to that function").

which an otherwise private actor is subject to extensive governmental regulation without something more. In *Jackson v. Metropolitan Edison Co.*, a woman sued a privately owned utility when it terminated her electric service without notice.<sup>149</sup> In analyzing whether the government's extensive regulation of the private company rendered the utility a state actor, the Court reasoned that the deciding inquiry is whether there is a "sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself."<sup>150</sup> The Court ultimately held that the utility did not engage in state action because, despite its regulation, the state did not "foster or encourage" the company's actions.<sup>151</sup> Therefore, the utility's actions could not be said to be those of the state.

Thus, it seems that the "something more" required when attributing state action to governmentally regulated entities is some form of encouragement. Essentially, this strain of the "mutual contacts" test is a mirror image of the "encouragement" test articulated above. Here, unlike in *Jackson*, the FDA has actively encouraged the exact conduct in question because it has consistently recommended in published documents that private entities implement the discriminatory eligibility requirements.<sup>152</sup>

ii. Do the Government and the Private Sperm Bank Have Enough Economic and Physical Contacts to Constitute State Action?

In reality, this strand of the mutual contacts doctrine has little substantive meaning, and is used primarily as a "catch all" provision.<sup>153</sup> When analyzing physical and economic contacts, courts weigh the particular facts and circumstances of each case.<sup>154</sup> Consequently, decisions have often been inconsistent, and the criteria remain unclear.<sup>155</sup> Because, however, this strand of mutual contacts tends to involve the economic relationship between the government and a private entity, it can easily be analyzed in conjunction with the third strand:

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<sup>149</sup> 419 U.S. 345, 347 (1974).

<sup>150</sup> *Id.* at 351 (citing *Moose Lodge No. 107 v. Irvis*, 407 U.S. 163, 176 (1972)).

<sup>151</sup> 419 U.S. at 358.

<sup>152</sup> *See supra* Part V.A.1.a.

<sup>153</sup> NOWAK, *supra* note 145, at 532. "[I]t may be said that when a private individual becomes so entangled with government policies that his actions appear to have the authorization of the state, it is likely that a majority of the Justices of the Supreme Court will find state action in his activities." *Id.*

<sup>154</sup> *See id.*

<sup>155</sup> *See generally* NOWAK & ROTUNDA, *supra* note 145.

iii. Does the Government Render the Private Sperm Bank a State Actor by Bestowing Subsidies or Direct Federal Aid?

In short, the answer is no. Health care in the United States is largely decentralized, and most public fertility services are unsubsidized and “develop within a lightly regulated . . . free market framework.”<sup>156</sup> Further, private fertility clinics receive virtually no government funding.<sup>157</sup> Therefore, the lack of an economic relationship in this case likely renders these two particular variations of state action through “mutual contacts” inapplicable.

In sum, the “mutual contacts” test is fractured, inconsistent, and not likely a viable route to claim that the private action at issue is “fairly attributable to the state.” The best chance for success under this theory is to claim that the FDA’s overall regulatory scheme encourages the private action. But as explained above, this is really just an indirect way of arguing under the first theory of state action—that the state encourages or coerces the action—and it provides little if any substantive advantage.

c. *Are the Government and the Private Sperm Bank Entwined?*

Before *Brentwood Academy v. Tennessee Secondary School Athletic Ass’n*, the Supreme Court had long rejected the notion that state action is present merely when a private entity and the government are entwined.<sup>158</sup> But in this 2001 decision, the Supreme Court found that a private athletic association engaged in state action for just that reason.<sup>159</sup> The Court reasoned that the “nominally private character of the Association is overborne by the pervasive entwinement of public institutions and public officials in its composition and workings . . . .”<sup>160</sup> What seemed to matter most to the Court was that eighty-

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<sup>156</sup> June Carbone & Paige Gottheim, *Markets, Subsidies, Regulation, and Trust: Building Ethical Understandings into the Market for Fertility Services*, 9 J. GENDER RACE & JUST. 509, 532 (2006).

<sup>157</sup> *Id.*

<sup>158</sup> See generally Megan M. Cooper, *Dusting Off the Old Play Book: How the Supreme Court Disregarded the Blum Trilogy, Returned to the Theories of the Past, and Found State Action Through Entwinement in Brentwood Academy v. Tennessee Secondary School Athletic Ass’n*, 35 CREIGHTON L. REV. 913 (2002).

<sup>159</sup> See generally *Brentwood Acad. v. Tenn. Secondary Sch. Athletic Ass’n*, 531 U.S. 288 (2001) (“The issue is whether a statewide association incorporated to regulate interscholastic athletic competition among public and private secondary schools may be regarded as engaging in state action . . . . The association in question here includes most public schools located within the State, acts through their representatives, draws its officers from them, is largely funded by their dues and income received in their stead, and has historically been seen to regulate in lieu of the State Board of Education’s exercise of its own authority.”).

<sup>160</sup> *Id.* at 298.

four percent of the association's membership was comprised of public schools.<sup>161</sup>

But what does the decision really tell us? How much entwinement is necessary before courts will find state action? The *Brentwood* Court does not specifically define entwinement, but instead finds state action because the relationship between the state and the private association created an overlapping identity.<sup>162</sup> In this decision, the Court seems to be moving in a direction in which it examines the totality of the circumstances, and where indirect, as opposed to direct, involvement with the challenged conduct may be enough to trigger state action.<sup>163</sup> The result is a less rigid and more inclusive means by which wronged parties may challenge otherwise private actors.

When applying the entwinement doctrine to private sperm banks and fertility clinics, the results will vary case-by-case. Whether there is government entwinement may depend on a number of factors, for example: whether the reproductive facility employs the services and staff of state hospitals or clinics; whether it receives reproductive samples from other public clinics; whether it sends its reproductive samples to other public clinics; whether its employees are guaranteed state benefits; and whether its decision-making process is controlled or in any way directed by public officials. A complete analysis of these and other similar criteria is necessary to determine whether, in a particular case, the totality of the circumstances supports a finding of government entwinement. When and if an attorney believes that she can make a convincing argument for a finding of state action in an otherwise private sperm bank, she may then consider which substantive claims to bring.

## 2. Possible Substantive Claims

### a. *Equal Protection and the Fundamental Right to Procreate*

In *Skinner v. Oklahoma*,<sup>164</sup> the Supreme Court engaged in an Equal Protection Clause analysis of Oklahoma's Habitual Criminal Sterilization Act.<sup>165</sup> The case involved a defendant who was convicted under the statute once for stealing chickens, and twice for robbery with firearms.<sup>166</sup> The statute provided that a court had the power to order the sexual sterilization of any person who

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<sup>161</sup> *Id.* at 299. The Court also noted that the Association's governing council consisted entirely of members of representatives from public schools, and that the Association's employees were eligible for retirement benefits established from a fund made for public school teachers. *Id.* See Cooper, *supra* note 158, at 923.

<sup>162</sup> See Cooper, *supra* note 158, at 983.

<sup>163</sup> *Id.* at 984.

<sup>164</sup> 316 U.S. 535 (1942).

<sup>165</sup> *Id.* at 536.

<sup>166</sup> *Id.* at 537.

had been convicted three times or more for felonies involving “moral turpitude.”<sup>167</sup> Unfortunately for the defendant, the crimes that he committed were included in those that the legislature had classified as amounting to moral turpitude.<sup>168</sup> If he had embezzled property amounting to more than twenty dollars rather than stealing from a stranger, however, the Act would not have applied to him.<sup>169</sup>

Justice Douglas opened the opinion with the following statement: “This case touches a sensitive and important area of human rights. Oklahoma deprives certain individuals of a right which is basic to the perpetuation of a race—the right to have offspring.”<sup>170</sup> The Court ultimately found the statute unconstitutional on a number of grounds, one being that it violated the fundamental right to procreate under the Equal Protection Clause.<sup>171</sup> The statute, by its emphasis on only certain types of felonies, essentially punished people differently who committed two similar crimes. The Court reasoned, “When the law lays an unequal hand on those who have committed intrinsically the same quality of offense and *sterilizes* one and not the other, it has made as an invidious a discrimination as if it had selected a particular race or nationality for oppressive treatment.”<sup>172</sup>

While the Act at issue in *Skinner* is not literally analogous to the FDA’s recommendation, it bears striking symbolic similarities. For many men who cannot—by virtue of their same-sex relationships—father their own children but want to have offspring, sperm banks and fertility clinics could provide the means.<sup>173</sup> While most establishments bar donations from men who have had sex with another man in the previous five-year period, they freely accept donations from other high-risk persons after one only one year has passed, and never bar men solely because they have had unprotected sex with a woman. Yet all of these “offenses” are of the same quality: each of the persons mentioned above poses a similar degree of risk (unless the man who has had sex with another man practiced *safe* sex, in which case his risk is much lower), but reproductive facilities lay an “unequal hand” upon each.

Many men choose to be in long-term, committed relationships with other men. Just like most other couples, these men might choose to express themselves and show their affection for one another through sexual intimacy.

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<sup>167</sup> *Id.* at 536-37.

<sup>168</sup> *Id.* at 538-39.

<sup>169</sup> *Id.*

<sup>170</sup> *Id.* at 536.

<sup>171</sup> *Id.* at 541.

<sup>172</sup> *Id.* (emphasis added).

<sup>173</sup> Fertility clinics also provide reproductive possibilities for single straight men and women, lesbian couples, and straight couples that cannot, or do not want to, biologically produce children on their own.

These men may also have the desire to produce genetic offspring,<sup>174</sup> and may feel that donating their sperm is their only procreative option.<sup>175</sup> However, unless these men choose to forgo sexual intimacy in their relationships for five years, most sperm banks will not consider them as potential donors. Because men in gay relationships (and perhaps the majority of all persons in romantic relationships) would not seriously entertain a five-year period of celibacy, the eligibility requirement serves as constructive sterilization. In effect, sperm banks classify persons who are eligible to procreate on the real or perceived basis of sexual orientation. As the court in *Skinner* cautioned, “The power to sterilize, if exercised, may have subtle, far-reaching and devastating effects. In evil or reckless hands it can cause races or types which are inimical to the dominant group to wither and disappear.”<sup>176</sup>

Because courts have yet to hold that classifications based on sexual orientation are suspect,<sup>177</sup> an argument that the eligibility requirement discriminates against gays would trigger only rational basis review.<sup>178</sup> While it is certainly possible to argue that the policy is not rationally related to an interest in promoting health,<sup>179</sup> ideally, one hopes to trigger strict scrutiny review. By framing the eligibility requirement as a significant interference with the fundamental right to procreate, however, a creative attorney may be able to do just that.<sup>180</sup> Under *Skinner*, if the eligibility criterion for donating sperm was found

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<sup>174</sup> See Carson Strong, *Ethical and Legal Aspects of Semen Retrieval After Death or Persistent Vegetative State*, 27 J. L. MED. & ETHICS, 347, 349 (1999) (citing many reasons that procreation may be important to an individual). “[W]hether one has participated in the creation of a person can be part of one’s self-identity. Similarly, whether one has gestated, reared, or obtained a certain kind of link to the future can be part of one’s sense of who one is. These reasons also suggest that procreating can contribute to self-fulfillment . . .” *Id.*

<sup>175</sup> One sperm bank, Rainbow Flag Health Services, recognizes that many gay men desire to biologically bring a child into the world. To address this very real need, it actively recruits gay donors. The sperm bank has implemented a policy in which a child born as the result of artificial insemination will know the identity of her donor. In return for the sperm donation, the bank does not pay donors for their semen. The bank reasons: “Your child will grow up knowing that the main reason their donor helped you bring children into your family was that he wanted children in his own life, even though he did not want to raise children himself. They will know [that] their donor’s main motivation was not the \$50 per visit most sperm banks pay donors.” Rainbow Flag Health Services, <http://www.gayspermbank.com/index1.html> (last visited Nov. 4, 2007).

<sup>176</sup> 316 U.S. at 541.

<sup>177</sup> See generally *Romer v. Evans*, 517 U.S. 620 (1996) (applying only rational basis review to a Colorado constitutional amendment prohibiting all legislative, executive, or judicial action designed to protect homosexuals from discrimination).

<sup>178</sup> 16B AM. JUR. 2D *Constitutional Law* § 813 (2007) (“Governmental classifications that do not target suspect classes or groups or fundamental interests are subject only to the more deferential rational basis review.”).

<sup>179</sup> See *supra* Part IV.C.

<sup>180</sup> See *Regan v. Taxation Without Representation of Wash.*, 461 U.S. 540, 547 (1983) (stating that classifications are valid if they bear a rational relation to a legitimate government purpose, but are subject to strict scrutiny if they interfere with the exercise of a fundamental right or employ a suspect classification).

to interfere with a right to procreate, the court would then have to decide whether excluding men who have had sex with another man within the previous five-year period, but not men who have had sex with women (protected or not), is the least restrictive way to prevent the transmission of disease. By emphasizing the shorter exclusionary periods for other high risks and the lack of restrictions on unsafe heterosexual sex, a court would be disingenuous to find that the current restrictions are the least restrictive.

Unfortunately, the problem is one of convincing the judiciary that donating sperm falls within the definition of procreation. As artificial reproductive technology (ART) has advanced over the last decade, the American legal system has struggled with this very issue. How do we classify sperm donors? What protections are they afforded? Where does ART fit into our traditional understanding of what it means to procreate?

Early conceptions of the legal obligations and rights of sperm donors were limiting. The Uniform Parentage Act of 1973 stated that a child born as the result of artificial insemination from an anonymous sperm donor was the legal child of the mother's husband, leaving the genetic father out of the equation.<sup>181</sup> The legal protections for sperm donors remained sparse until a 2002 amendment to the Uniform Parentage Act expanded the definition of a legal father to include sperm donors who intend to be the parent of the child.<sup>182</sup>

While these and other recent acts have attempted to stipulate when sperm donors are and are not entitled to *parental rights*, they fail to address the separate issue of a sperm donor's *procreative rights*. Still, some courts seem to have meshed the two distinct concepts into one. For instance, in *Johnson v. Calvert*, the California Supreme Court resolved a custody dispute in favor of a biological mother over a surrogate mother, explaining that "she who intended to procreate the child—that is, she who intended to bring about the birth of a child that she intended to raise as her own—is the natural mother . . . ."<sup>183</sup> Does the California Supreme Court decision really stand for the proposition that one can only procreate when he intends to raise the resulting child? Would this decision imply that fathers and mothers who intend to abort a child or put a child up for adoption have not procreated? Because the court considered procreation in the narrow realm of parental custody, it is difficult to determine what, if any, differences might result if the court had more broadly addressed procreation as it relates to donors involved in ART.

Although the precise question has not yet been answered by American courts, foreign authority and academic commentary provide some insight. For example, in a property dispute over a deceased man's frozen sperm, a French court reasoned that sperm is the "genetic expression" of a person's fundamental

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<sup>181</sup> UNIF. PARENTAGE ACT § 5 (1973). See David D. Meyer, *Parenthood in A Time of Transition: Tensions between Legal, Biological, and Social Conceptions of Parenthood*, 54 AM. J. COMP. L. 125, 134 (2006).

<sup>182</sup> UNIF. PARENTAGE ACT § 703 (2002).

<sup>183</sup> 851 P.2d 776, 782 (Cal. 1993).



right to create life.<sup>184</sup> In addition, several commentators have written on artificial reproductive technologies, discussing the implications of donating sperm. One author classifies procreation simply as the “union of sperm and egg,” and lists as the known methods of procreation, “sexual intercourse, *artificial insemination*, and in vitro fertilization.”<sup>185</sup> Another author specifically distinguishes “procreation by means of sperm donations” from traditional definitions.<sup>186</sup> A third commentator, however, argues that a fundamental right to procreate exists only in conjunction with three elements: genetics, a social experience, and gestation.<sup>187</sup> “The introduction of a third-party surrogate [or sperm donor] alters the social understanding of procreation and cannot be understood to be an arrangement that is ‘implicit in the concept of ordered liberty.’”<sup>188</sup>

Obviously the question is still open for debate. Still, the recent advances in, and uses of, ART lend support to the argument that the right to procreate extends far beyond the historically recognized methods of procreation. The argument for an expanded definition of procreation, although challenging, is ripe for the making.

*b. Equal Protection and the Fundamental Privacy Right to Sexual Intimacy?*

As the Supreme Court developed its modern jurisprudence, it slowly began to identify certain privacy rights that stem from the Fourteenth Amendment’s guarantee of personal “liberty.”<sup>189</sup> These privacy rights, the Court explains, are guaranteed only if they are deemed “fundamental,” or “implicit in the concept of ordered liberty.”<sup>190</sup> Thus, the right to privacy is not without limitations. Some governmental intrusions may be warranted if a state “properly assert[s] important interests in safeguarding health, in maintaining medical standards, and in protecting potential life.”<sup>191</sup>

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<sup>184</sup> See Tribunal de grande instance [T.G.I.] [ordinary court of original jurisdiction] Creteil, Aug. 1, 1984, Gaz. du Pal. 1984, 2, pan. jurispr. 560; see also Gail A. Katz, *Protecting Intent in Reproductive Technology*, 11 HARV. J. L. & TECH. 683 (1998).

<sup>185</sup> Elizabeth Price Foley, *The Constitutional Implications of Human Cloning*, 42 ARIZ. L. REV. 647, 651 (2000) (emphasis added).

<sup>186</sup> See Schiff, *supra* note 46, at 567.

<sup>187</sup> Roger J. Chin, *Assisted Reproductive Technologies Legal Issues in Procreation*, 8 LOY. CONSUMER L. REV. 190, 209, 214 (1996).

<sup>188</sup> *Id.* at 214.

<sup>189</sup> See generally *Griswold v. Connecticut*, 381 U.S. 479, 486 (1965) (right to marital privacy); *Eisenstadt v. Baird*, 405 U.S. 438, 453 (1972) (right to privacy in individual’s decision to bear or beget a child); *Roe v. Wade*, 410 U.S. 113, 153 (1973) (right to privacy in woman’s decision to terminate pregnancy).

<sup>190</sup> *Palko v. Connecticut*, 302 U.S. 319, 325 (1937).

<sup>191</sup> *Roe*, 410 U.S. at 154.

In *Lawrence v. Texas*, the Supreme Court considered, but did not directly determine, whether a statute that criminalized same-sex sodomy violated a privacy interest.<sup>192</sup> In its opinion, the Court provided an in-depth discussion of the privacy interest at stake, and stated that the statute's penalties and purposes have "far-reaching consequences, touching upon the most private human conduct, sexual behavior . . ."<sup>193</sup> It went on to reason as follows: "When sexuality finds overt expression in intimate conduct with another person, the conduct can be but one element in a personal bond that is more enduring. The liberty protected by the Constitution allows homosexual persons the right to make this choice."<sup>194</sup> While the Court acknowledged that liberty affords "substantial protection" to matters pertaining to sex, it never directly states that the privacy right to sexual intimacy is fundamental.<sup>195</sup> Instead, the Supreme Court holds, without articulating a clear standard of review, that the statute serves no *legitimate* state interest.<sup>196</sup>

What legal principles come from the Court's holding in *Lawrence*? Does use of the language "legitimate interest" signal that the Court applied rational basis review, or does the discussion of the liberty interest in sexual intimacy mean that it found a fundamental privacy right subject to strict scrutiny? Recently, this question has been debated by numerous scholars. Some focus on the Court's use of the phrase "legitimate interest," and theorize that the *Lawrence* Court failed to identify a fundamental right and applied nothing more than rational basis review.<sup>197</sup> Another commentator proposes that the *Lawrence* Court took the first step towards ending the practice of identifying fundamental rights altogether.<sup>198</sup> This author suggests that the Supreme Court may be trying to prevent lower courts from applying a "mechanistic tiered approach to judicial review," and is instead encouraging a more "searching" evaluation of practices that disadvantage identifiable groups of people.<sup>199</sup> Still, others argue that the Court did, in fact, identify a fundamental right and applied strict scrutiny to an infringement of that right; these scholars reason that the court's extensive recitation of cases addressing and finding fundamental rights would have otherwise been unnecessary.<sup>200</sup> "The discussion places the claimed right in *Lawrence*

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<sup>192</sup> 539 U.S. 558, 564 (2003).

<sup>193</sup> *Id.* at 567.

<sup>194</sup> *Id.*

<sup>195</sup> *Id.* at 572.

<sup>196</sup> *Id.* at 578.

<sup>197</sup> Meghan M. Peterson, Note, *The Right Decision for the Wrong Reason: the Supreme Court Correctly Invalidates the Texas Homosexual Sodomy Statute, but Rather than Finding an Equal Protection Violation in Lawrence v. Texas, the Court Incorrectly and Unnecessarily Overrules Bowers v. Hardwick*, 37 CREIGHTON L. REV. 653, 707 (2004).

<sup>198</sup> Arthur S. Leonard, *Lawrence v. Texas and the New Law of Gay Rights*, 30 OHIO N.U. L. REV. 189, 209 (2004).

<sup>199</sup> *Id.*

<sup>200</sup> Dale Carpenter, *Is Lawrence Libertarian?*, 88 MINN. L. REV. 1140, 1156 (2004).

squarely within the context of the prior cases involving a fundamental liberty to engage in private sexual conduct.”<sup>201</sup>

Unfortunately, the *Lawrence* holding will remain ambiguous until the Supreme Court has a chance to reexamine the decision. Thus, if one chooses to argue that a ban on MSM sperm donors violates an alleged “right to privacy,” she must prepare for and analyze the merits of this claim under both rational basis and strict scrutiny review. The question then becomes this: is a liberty interest in sexual intimacy violated under the Equal Protection clause when a sperm bank inquires about and penalizes more harshly gay sexual acts? Undoubtedly, a sperm bank has both a legitimate and compelling interest in protecting health. Under rational basis review, however, their inquiry into sexual practices need only be rationally related to promoting health. As discussed in Part IV.C. of this Note, there is a strong argument that it is not.<sup>202</sup> If there is, in fact, a fundamental privacy right to sexual intimacy, however, the sperm bank must show that the penalization of gay sex acts, but not straight sex acts, is the least restrictive way to promote health. If an attorney can show that the sperm bank can protect health by inquiring into the *safety* of all potential donors’ sex acts rather than the biological (or even medically-altered) sex of their sexual partners, the analysis more clearly supports—and, arguably, dictates—a finding that the policy is not the least restrictive means. Once again, this is uncharted territory, and to win, a litigator must think and argue creatively.

## B. *Claims Under State Constitutions*

### 1. Is There State Action? Is State Action Even Required?

The U.S. Constitution ordinarily restrains private parties only when they are directly influenced by, act concurrently with, represent or engage in, or otherwise symbolize that their actions are those of the state.<sup>203</sup> This is a long-established principle deeply rooted in constitutional jurisprudence.<sup>204</sup> Whether state constitutions require government action to reach otherwise private discrimination, however, is not as clear. While many courts have considered state action in the context of speech and property rights, equal protection guarantees in state constitutions remain vague as to their effect on private parties.<sup>205</sup>

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<sup>201</sup> *Id.*

<sup>202</sup> *See supra* Part IV.C.

<sup>203</sup> John Devlin, *Constructing an Alternative to “State Action” as a Limit on State Constitutional Rights Guarantees: A Survey, Critique, and Proposal*, 21 RUTGERS L. J. 819, 821 (1990).

<sup>204</sup> *See id.* at 821-22 (“Rooted in both a general view of the role of constitutions and the particular language of the federal Constitution, the state action doctrine is a generalized limitation on virtually all federal constitutional rights.”).

<sup>205</sup> *Id.* at 838.

Part of the confusion stems from the divergent wording in various constitutions' equal protection provisions.<sup>206</sup> Some directly or implicitly require government action, and some expressly extend protection to private actors; but the majority does not textually address state action.<sup>207</sup> Not surprisingly, courts interpreting the textually ambiguous provisions have come down both ways. These decisions generally fall under two categories: those addressing textual provisions providing for "equal protection *of* the laws," and those addressing textual provisions providing for "equal protection *under* the law."<sup>208</sup> Although the majority of courts has ultimately concluded that state action is required under both variations, only in the "equal protection *of* the law" provisions has that sentiment been unanimous.<sup>209</sup> Those courts finding that government involvement is not requisite have "effectively read the phrase '*under* the law' out of the provision as a meaningful threshold restriction."<sup>210</sup>

For the purposes of this Note, an expansive survey of equal protection provisions in state constitutions and the level of state action that they require is unwarranted. But scholarly works on the subject are available.<sup>211</sup> An attorney considering whether to file suit against a private establishment under a state constitutional equal protection provision should also become familiar with that constitution's textual requirements and the courts' interpretations.

## 2. Same Claims, Broader Protections

"It is a well-recognized principle that a state court is free to interpret its state constitution in any way that does not violate principles of federal law, and thereby grant individuals more rights than those provided by the U.S. Constitution."<sup>212</sup> Indeed, many state courts have treated the U.S. Constitution as merely

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<sup>206</sup> See generally Devlin, *supra* note 203.

<sup>207</sup> See *Id.* at 839-40; see also Helen Hershkoff, *State Constitutions: A National Perspective*, 3 WIDENER J. PUB. L. 7, 20 (1993).

<sup>208</sup> See Devlin, *supra* note 203, at 843-47 (providing a summary and analysis of various decisions addressing the two contrasting constitutional provisions) (emphasis added).

<sup>209</sup> See *id.*

<sup>210</sup> *Id.* at 845-46 (discussing Pennsylvania courts' opinions, which have concluded that claims under the state constitution need not allege any degree of government involvement) (emphasis added).

<sup>211</sup> See generally, *e.g., id.* (providing an in-depth analysis of various state constitutional provisions and judicial opinions that interpret the provisions, and then proposing solutions to the state action dilemma); Hershkoff, *supra* note 207 (highlighting various rights and protections that state constitutions afford, how they differ from the U.S. Constitution, and why claims under state constitutions are strategically beneficial); Jeffrey M. Shaman, *The Evolution of Equality in State Constitutional Law*, 34 RUTGERS L. J. 1013 (2003) (analyzing state equal protection clauses specifically).

<sup>212</sup> JOHN E. NOWAK, RONALD D. ROTUNDA & J. NELSON YOUNG, *CONSTITUTIONAL LAW*, 21 (3d ed. 1986); See *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 81 (1980); *Cooper v. California*, 386 U.S. 58, 62 (1967).

the foundation upon which civil liberties are built,<sup>213</sup> and have greatly extended their own constitutional protections pursuant to state-vested police power. Such expanded protections have proved helpful in securing privacy rights for gays and other minority groups. As a result, litigators have increasingly looked to state constitutions as a source of protection for clients.<sup>214</sup> Because the Supreme Court has consistently held that procreation is a fundamental right under the U.S. Constitution<sup>215</sup> and that state constitutions shall not provide anything less than the rights provided by the U.S. Constitution,<sup>216</sup> an analysis of “the right to procreation” claims would be redundant. This section, therefore, will focus solely on the more ambiguous right to privacy.<sup>217</sup>

In a string of cases addressing state anti-sodomy statutes, courts have identified fundamental privacy rights that greatly exceed those provided by the U.S. Constitution. In *Powell v. State*, the Georgia Supreme Court explicitly stated that “the right to be let alone” provided by the Georgia constitution “is far more extensive than the right of privacy protected by the U.S. Constitution.”<sup>218</sup> The court then went even further and reasoned that it could not think of a right more fundamental than the right of consenting adults to “engage in . . . unforced, private, adult sexual activity.”<sup>219</sup> The court, applying strict scrutiny to the governmental intrusion into the right of sexual privacy, found that the intrusion was not “narrowly tailored” to the state’s interest in preventing sexual assault because it was “unduly oppressive upon the persons regulated.”<sup>220</sup>

More closely related to the eligibility criterion at issue here, the Montana and Kentucky Supreme Courts analyzed same-sex anti-sodomy statutes and found similar fundamental privacy rights, but addressed a different asserted state interest: protecting and promoting public health. First, in *Commonwealth v. Wasson*, the Kentucky Supreme Court provided a lengthy recitation of its cases concerning fundamental privacy rights and concluded that the Kentucky Constitution confers a privacy right to “be let alone” and to enjoy life “in the way most agreeable and pleasant.”<sup>221</sup> The court then engaged in an equal protection analysis, stating that the clause “protects minorities from discriminatory treatment at the hands of the majority. Its purpose is not to protect traditional values

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<sup>213</sup> See, e.g., *Commonwealth v. Wasson*, 842 S.W.2d 487, 492 (Ky. 1992) (“We are not bound by decisions of the United States Supreme Court when deciding whether a state statute impermissibly infringes upon individual rights guaranteed in the State Constitution so long as state constitutional protection does not fall below the federal floor.”).

<sup>214</sup> See Hershkoff, *supra* note 207, at 21-22 (noting that the American Civil Liberties Union has increasingly employed state constitutions due to their unique features and broader protections).

<sup>215</sup> See generally *Skinner v. Oklahoma*, 316 U.S. 535 (1942).

<sup>216</sup> See generally *Wasson*, 842 S.W.2d at 487.

<sup>217</sup> See also *supra* Part V.A.2.b.

<sup>218</sup> 510 S.E.2d 18, 22 (Ga. 1998).

<sup>219</sup> *Id.* at 24.

<sup>220</sup> *Id.* at 25.

<sup>221</sup> 842 S.W.2d at 496.

and practices, but to call into question such values and practices when they operate to burden disadvantaged minorities . . . .”<sup>222</sup> The state claimed that it has an interest in protecting health, and that the statute was justified because same-sex anal sodomy more readily transmits infectious diseases.<sup>223</sup> The court rejected the notion that the statute even *rationaly* related to the state’s interest due to the “stark evidence that AIDS is not only a homosexual disease.”<sup>224</sup> Medical evidence ruled out the distinction between male to male and male to female anal sex as a method to prevent disease transmission.<sup>225</sup> The court concluded that the statute’s purpose was to single out gays for different treatment.<sup>226</sup>

Next, in *Gryczan v. State*,<sup>227</sup> the Montana Supreme Court’s analysis of the privacy rights at issue was simplified because the state constitution explicitly grants such rights: “The right of individual privacy is essential to the well-being of a free society and shall not be infringed without the showing of a compelling state interest.”<sup>228</sup> In light of the provision, the court noted that there could hardly be a right more fundamental and deserving of protection than the right to consensual adult sexual activity.<sup>229</sup> Consequently, the court was left to determine whether the state’s same-sex anti-sodomy statute was narrowly tailored to its asserted interest in protecting public health. For the following reasons, the court reasoned that it was not:

The state’s assertion that the statute protects public health by containing the spread of AIDS relies on faulty logic and invalid assumptions about the disease . . . . [T]he State’s rationale assumes that all same-gender conduct contributes to the spread of the disease. This is grossly inaccurate. AIDS and HIV, the virus that causes AIDS, are transmitted through the exchange of HIV-infected semen or blood, as can occur during vaginal, anal and oral intercourse . . . . [H]eterosexual contact is now the leading mode of HIV transmission in this country. . . . [T]he incidence of AIDS (newly reported cases) is growing most rapidly among heterosexuals. In fact, the proportion of yearly reported AIDS cases resulting from heterosexual sex has increased steadily over time, multiplying by more than 5 times between 1985 and 1995. In this same time period, the risk group designated “men who have sex with men” has accounted

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<sup>222</sup> *Id.* at 499 (quoting *Watkins v. U.S. Army*, 875 F.2d 699, 718 (9<sup>th</sup> Cir. 1989)).

<sup>223</sup> *Id.* at 500.

<sup>224</sup> *Id.* at 501.

<sup>225</sup> *Id.*

<sup>226</sup> *Id.*

<sup>227</sup> 942 P.2d 112 (Mont. 1997).

<sup>228</sup> MONT. CONST. art. II, § 10.

<sup>229</sup> 942 P.2d at 123.

for a steadily decreasing proportion of newly reported AIDS cases, decreasing by more than 20% between 1985 and 1995.

. . . . In addition, the statute does not account for “safe” versions of the activities, i.e., use of a condom during any “sexual conduct” which greatly reduces or eliminates the risk of HIV transmission. Thus, the inclusion of behavior not associated with the spread of AIDS and HIV and the exclusion of high-risk behavior among those other than homosexuals indicate the absence of any clear relationship between the statute and any public health goals.<sup>230</sup>

The dicta contained in this analysis could hardly be more relevant or on-point.

Accordingly, for claims which allege that MSM exclusionary policies violate privacy rights, employing state constitutions as sources of civil rights and liberties provides at least three strategic benefits. First, as discussed above, many courts have interpreted state constitutions to provide broader privacy rights than those of the U.S. Constitution.<sup>231</sup> The broad definition that many states have adopted includes the fundamental right to engage in consensual sexual acts. Second, because the right to engage in consensual sexual acts is fundamental, the reproductive facility’s screening of same-sex sexual acts must be the least restrictive means to promote its interest in preserving health (which, as illustrated throughout the Note, it is not). Third, unlike the Supreme Court, several state courts have already addressed same-sex regulations drafted to “promote health,” and have found the underlying rationale to be “grossly inaccurate.”<sup>232</sup> In this case, the precedent weighs strongly in favor of a finding of unconstitutional privacy violations.

## VI. CONCLUSION

If representing a man who is denied the opportunity to donate sperm because of his sexual orientation or sexual practices, choosing the litigation strat-

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<sup>230</sup> *Id.* at 123-24.

<sup>231</sup> *See, e.g.,* *Jegley v. Picado*, 80 S.W.3d 332 (Ariz. 2002); *Gryczan v. State*, 942 P.2d 112 (Mont. 1997); *Campbell v. Sundquist*, 926 S.W.2d 250 (Tn. Ct. App. 1996); *Commonwealth v. Wasson*, 842 S.W.2d 487 (Ky. 1992); *Texas State Emp. Union v. Dept. of Mental Health*, 746 S.W.2d 203 (Tex. 1987); *State v. Sanders*, 381 A.2d 333 (N.J. 1977) (representing cases in which courts have interpreted the right of privacy guaranteed by state constitutions to extend beyond the rights provided by the U.S. Constitution).

<sup>232</sup> *Gryczan v. State*, 942 P.2d 112, 124 (Mont. 1997). The court further stated, “With few exceptions not at issue here, all adults *regardless of gender*, fully and properly expect that their consensual sexual activities will not be subject to the prying eyes of others or to governmental snooping or regulation.” *Id.* at 122 (emphasis added). But even if there is an interest in “snooping” into the sexual activities of consenting adults when it relates to the health of others, that interest in snooping is only legitimately advanced if it is “regardless of gender.” *Id.*

egy that best fits both the client's needs and the relevant legal environment is key. Who is the aggrieved party, and what is his story? Should he file suit against the FDA for recommending the eligibility requirement, or against the local sperm bank which implemented that recommendation? What are the available legal arguments? What are the strengths and weaknesses of each argument? What are the ramifications of a potential victory against the FDA? Against a specific sperm bank?

To file suit against the FDA and win would be groundbreaking. It would send a message to the entire industry that discrimination based on sexual orientation or the gender of a person's sexual partner is unacceptable, and the FDA would be forced to abandon its policy. Under the APA's provisions concerning judicial review, however, a suit against the FDA would trigger something akin to mere rational basis review, if not even less scrutinizing.<sup>233</sup> While the facts might weigh strongly against the lawfulness of the FDA's recommendation, the precise degree of deference that a court will choose to afford the FDA's fact-finding is unclear. How "searching and careful" will the court's inquiry be? Moreover, even if a court were to rule against the FDA, the ruling would not be binding on the regulated industry. Some establishments may choose to keep their own eligibility requirements in tact.

To file suit against a sperm bank or similar reproductive facility and win also has the potential to be groundbreaking, but only depending upon the ultimate choice of law. For instance, a win in federal court under the U.S. Constitution would reverberate nationally and shape the entire industry. The drawbacks, however, are that the Supreme Court has not explicitly articulated a right to privacy in sexual activity, and the issue of whether donating sperm constitutes procreation is novel. The arguments are certainly viable, but the precedent is not entirely on-point.

Conversely, a win in state court under any particular state constitution would not bind the rest of the country, and it would have minimal impact on the industry as a whole. But the advantage to this choice of law strategy is that under certain state constitutions, a court may review a privacy claim under strict scrutiny depending upon whether a particular constitutional provision has been interpreted to include the right to sexual intimacy under fundamental privacy rights. Unfortunately, while arguing under state constitutions may be a desirable choice of law strategy, many states' preliminary "state action" hurdle may prevent the court from deciding the case based on the merits if the entity at issue is private.

Each strategy has its faults, and none will guarantee a victory. Creative lawyering is thus essential. And apart from the legal theories discussed here, there may even be other more readily available alternatives. For instance, many cities and states have enacted anti-discrimination ordinances and statutes that may be applicable. Furthermore, some state courts have interpreted their consti-

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<sup>233</sup> See Garland, *supra* note 98, at 532 and accompanying text.



tutions to include sexual orientation as a suspect classification.<sup>234</sup> But regardless of the legal strategies employed, courts must reach the correct result: eligibility requirements should be based on science, not stereotypes.

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<sup>234</sup> See Shaman, *supra* note 211, at 1070-77.

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