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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Response to FDA Request for Comment on Establishment of Public Docket for Blood Donor Deferral Policy for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products
81 *Fed. Reg.* 49673 (July 28, 2016); FDA Docket No. 2016-N-1502

Gentlemen:

These comments are filed on behalf of Public Advocate of the United States ("Public Advocate"). Public Advocate is a Northern Virginia-based nonprofit educational organization exempt from federal income tax under Internal Revenue Code section 501(c)(4). Public Advocate's tax-exempt mission and purposes include education and litigation to protect the family, traditional values, civil liberties, including, but not limited to, freedoms and rights guaranteed by the U.S. Constitution, and proper interpretation of our federal and state constitutions, statutes, and regulations. More information about Public Advocate can be found at www.publicadvocateusa.org.

Comments

I. The FDA Has a Long History of Ignoring Scientific Evidence In An Effort to Appease the Homosexual Community.

The request for comments by the Food and Drug Administration ("FDA") about its decision to reconsider its policy for blood donations by homosexuals must be viewed in the context of the FDA's changing policy toward such donations in the past.

It is widely believed that, in the 1980's, "[t]he response of … the Food and Drug Administration (FDA) to the problem of acquired immune deficiency syndrome (AIDS) in the

nation's blood supply [was] inadequate and abysmal, unnecessarily slow, and woefully inept."[1] In fact, long after the Centers for Disease Control ("CDC") was reporting the dangers of HIV in the nation's blood supply, "[m]any people at the FDA [still] were not convinced that the disease existed…." *Id*.

During the early 1980's HIV blood crisis, the CDC suggested that the FDA adopt activity-related restrictions on blood donations.[2] The homosexual lobby, however, "objected, claiming it was too soon to implement [a request that gay men not donate blood] and arguing that there would be civil rights implications."[3] Indeed, homosexual interest groups such as the National Gay Task Force insisted that they "did not want gays to be stigmatized" and claimed that even "[d]irect or indirect questions about a donor's sexual preference are inappropriate." Russell at 7, 10. The FDA went along with these demands and, even though the CDC reported a link between blood transfusions and HIV as early as July 16, 1982,[4] the FDA did not restrict men who have sex with men ("MSM") as blood donors until over three years later — September of 1985. Draft Guidance at 2. Unfortunately, by then as many as 22,000 innocent Americans had been infected with HIV through contaminated blood transfusions. Russell at 22. Simply put, the FDA's track record in this area does not inspire confidence.

In December of 2015, the FDA transitioned to its current one-year deferral period, in order to again placate homosexual activists (discussed below), but this "compromise" apparently was not enough for some homosexual activists. Ignoring its role in the infection of tens of thousands of Americans with HIV in the 1980's, the National LGBTQ Task Force (the very same organization that was the National Gay Task Force lobbying the FDA against change in the 1980's) today makes the very same claim that it did back then — that "FDA's proposed 12-month deferral period has similar stigmatizing effects as did the indefinite deferral."[5]

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[1] *See, e.g.*, Lisa Russell, "The Inadequate Response of the FDA to the Crisis of AIDS in the Blood Supply," Harvard Law School Student Paper (1995) https://dash.harvard.edu/bitstream/ handle/1/8965576/lrussell.pdf?sequence=1.

[2] Indeed, HIV was initially known as "gay-related immunodeficiency disease" ("GRID") because of its initial prevalence only in the homosexual community. Institute of Medicine, "HIV and the Blood Supply: An Analysis of Crisis Decisionmaking," https://www.ncbi.nlm.nih.gov/ books/NBK232419/.

[3] Russell at 5.

[4] Russell at 3-4.

[5] National LGBTQ Task Force, "Public Comment Regarding Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," ("Task Force") http://www.hivlawandpolicy.org/sites/www.

Apparently, the Task Force believes that "a deferral of three months is … more than adequate." Task Force at 3. However, it is hard to understand why 12 months is seen as "stigmatizing" but three months would not be so considered. For that matter, it is unclear why "individualized assessments," which delve deeply into a person's homosexual history and activities, would not be seen as stigmatizing as well, especially since the Task Force opposed those very same "[d]irect or indirect questions about a donor's sexual preference" in the 1980's.

It is worth noting that the National LGBTQ Task Force also supports easing restrictions on other categories of restricted donors, such as injectable drug users and sex workers — on the ground that a large percentage of homosexuals engage in these HIV-prone activities as well as homosexual sex! Task Force at 3, 5. Indeed, it seems evident that many in the militant homosexual community will not be satisfied until, in the name of "equality," there are **no restrictions** on the ability of HIV-prone homosexuals to donate blood.

Apparently it is more important to many homosexuals that the FDA adopt policies that make them not feel "ashamed for who they are,"[6] rather than policies that protect the American public from HIV and other contagious diseases.

At the end of the day, though, the desires of militant homosexuals are not the real danger. The real danger is the FDA's longstanding desire to move national blood policies in lockstep with the feelings of the homosexual community, and thereby to threaten public health.

II. The FDA's Prior Decision to Move to a One-Year Deferral Period Was Not Based on Science, But On a Continuing Desire to Pander to Homosexual Interest Groups.

It seems obvious that the FDA's December 2015 decision to move from an indefinite deferral period for homosexual men to a one-year period was based on the FDA's continuing desire to appear politically correct and pander to the homosexual lobby.

Now, in its July 28, 2016 *Federal Register* notice, the FDA suggests to eliminate deferral periods for MSM entirely, moving to a voluntary and subjective questioning system which the FDA's own data reveals to be wildly inaccurate. In doing so, the FDA continues to shirk its duty to protect the American blood supply.

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hivlawandpolicy.org/ files/Blood%20Ban %20Public%20Comment%20finalized-2.pdf.

[6] Task Force at 5.

In its December 2015 revised "Draft Guidance,"[7] the FDA devoted numerous pages to relaying the feelings of the homosexual community regarding the FDA's relaxed deferral policy, rather than explaining the science behind the FDA's decision. In revealing the opinions of the homosexual community, the FDA has shared with the American public some truly remarkable findings:

- First, the FDA reported that homosexual men "respond to questions posed by the [Donor History Questionnaire] as if they were answering the more general and subjective question in the self-assessed context of 'is my blood safe,' rather than providing an answer to the literal questions as asked." Draft Guidance at 4-5. Of course, this is simply an indirect way of saying that homosexual men **deliberately lie** when asked to give truthful answers about their sexual history.

- Second, the FDA reported that homosexual men "comprise approximately 7% of the U.S. male population [but] represented an estimated 2.6% of male blood donors." Draft Guidance at 5. This is in line with the FDA's finding that only 59 percent of homosexual men "reported they would comply with a change to a one-year deferral,"[8] which of course is another way of saying that 41 percent of homosexual men reported they would refuse even to comply with the FDA's current relaxed policy of a one-year deferral before donating blood.

- Third, the FDA noted that homosexual men "view the current policy as discriminatory and stigmatizing [and that] the most common response was that one year was 'acceptable as a compromise'…." Draft Guidance at 5-6. It is ironic that the FDA's supposedly "scientific analysis" so closely aligns itself with the perceived feelings of homosexual activists — which is another way of saying that it appears that the FDA searched for the result that would least offend homosexuals, and then deemed that result to be in line with "the best available scientific evidence." Once again, "science" followed the FDA's political preferences.

Roughly six months after the FDA issued its December 2015 revised Draft Guidance, the Congressional LGBT Equality Caucus — co-chaired by all six of the openly homosexual members of Congress — issued a press release on June 14, 2016, demanding that the FDA

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[7] Guidance for Industry on Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products," http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf.

[8] Draft Guidance at 6.

remove all restrictions from homosexuals donating blood.[9] These Congressmen claimed that the FDA's policy on blood donations should be based on "'remov[ing] every trace of institutionalized homophobia.'" *Id.*

Within just a few weeks of the Equality Caucus' press release, the FDA issued an entirely new *Federal Register* notice (81 *Fed. Reg*. 49673) stating that it is now considering removing all deferral periods for homosexual men, and instead moving to a system where each blood donor would be asked a series of questions to assess risk. In other words, homosexual political activists told the FDA to "jump," and the FDA has responded, "how high?"

Although continuing to claim that the one-year deferral period is "supported by the best available scientific evidence," FDA now unabashedly inquires into whether it should move away from that "best available scientific evidence" and instead towards fulfilling "the desire [of] many stakeholders … to move … to a deferral policy based on individual risk assessment." *Id.*

As part of its notice, the FDA asks for input regarding how this individualized questioning process should take place. Of course, as discussed above, the FDA admits that many MSM are not truthful when asked questions about their sexual history, and at least 41 percent of them donate blood even when they know they should not. Indeed, "[i]nterviews with HIV antibody-positive donors reveal that most recognize their risk but fail to exclude themselves."[10] Yet the FDA now proposes to develop a system based solely on obtaining truthful responses from those it believes will lie.

This is not "science." It is not even junk science. Rather, this is fraud — fraud based on the decades-old political desire of the FDA to pander to homosexuals in whatever way it can, disregarding the risk that it may pose to the American public.

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[9] "Quigley, House Members and LGBT Allies Push FDA to End Discriminatory Blood Ban on Gay and Bisexual Men," Press Release (June 14, 2016) https://quigley.house.gov/media-center/press-releases/quigley-house-members-and-lgbt-allies-push-fda-end-discriminatory-blood.

[10] Elizabeth Donegan, M.D., "Transmission of HIV by Blood, Blood Products, Tissue Transplantation, and Artificial Insemination," HIV InSite Knowledge Base Chapter (October 2003) http://hivinsite.ucsf.edu/InSite?page=kb-07-02-09.

III. The FDA Based Its Move to a One-Year Deferral Period in Part on Irrelevant Studies from Other Countries.

As support for its decision to move to a one-year deferral period, the FDA relied on a similar policy change in Australia. Draft Guidance at 6. But upon a closer inspection, the Australian experience is nothing like that in the United States, and cannot be relied upon as authority for what the United States might experience after a similar policy change.

First, the FDA's 2015 Draft Guidance claims that allowing a one-year deferral period for homosexual men in Australia resulted in a "$>$99.7%" compliance rate with the deferral period. *Id.* at 6. Notably, however, the FDA never tells us what the Australian compliance rate was **before** its policy change — only what it was **after** the change. However, FDA apparently believes that implementing a similar policy in the United States will obtain a similar compliance rate. FDA's unspoken conclusion is that taking the 41 percent of U.S. homosexual men who already lie on the questionnaire, and pandering to their wishes to eliminate a one-year deferral period, will cause almost all of them to suddenly tell the truth.

Next, the FDA claims that the Australia study can be used to predict patterns in the United States because Australia "has a similar percentage of men reporting male-to-male sexual contact at some time during their lives (5% compared with 7% in the United States)." *Id.* at 6. What FDA does not say, however, is that the HIV prevalence rate among homosexual men is as low as 8 percent in Australia[11] while it has recently been reported to be 15 percent in the United States.[12] This means that the **United States has, per capita, 2.625 times the number of HIV positive MSM than does Australia**.[13] That is not a statistically insignificant number. Additionally, most Australian MSM apparently are honest in answering questions about sexual history, while a large portion of American MSM are not, which means that MSM in the United States pose a far higher risk in contaminating the nation's blood supply compared to Australian MSM.

Further, regarding the Australian experiment, FDA admits that it is "[o]f note" that "donors in Australia must sign a declaration in the presence of blood center staff that they understand that there are penalties, **including fines and imprisonment**, for providing false or

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[11] The Kirby Institute for Infection and Immunity in Society, "Annual Surveillance Report 2014 Supplement: HIV in Australia," https://kirby.unsw.edu.au/sites/default/files/hiv/resources/HIVASRsuppl2014_online.pdf.

[12] POZ, "Gay Men's HIV Prevalence Varies Widely by City and State, With the South Hit Hard," https://www.poz.com/article/gay-mens-hiv-prevalence-varies-widely-city-state-south-hit-hard.

[13] .05 x .08 = .004; .07 x .15 = .105; .105/.004 = 2.625.

misleading information. No such declaration is required in the United States, nor are donors advised of penalties for providing false or misleading information." *Id*. at 6 (emphasis added). Of course, that is a pretty big caveat. It is similar to expecting marijuana use in Spain (10.6%) to fall to the level of Singapore (0.4%)[14] — with the caveat that personal use marijuana is perfectly legal in Spain, while carrying the possibility of the death penalty in Singapore.[15] In fact, we are unfamiliar with any federal criminal or civil sanctions that can be imposed for giving blood under false pretenses.

Aside from an apples-to-oranges comparison between countries, FDA has provided absolutely no hard evidence that its reduced deferral period will lead to higher rates of honesty among MSM in this country, or even provide any level of accuracy in screening out HIV-prone donors. Yet the FDA now proposes to eliminate even the most minimal restriction of a one-year deferral.

IV. Now Contemplating Removing All Deferral Periods for MSM, the FDA Puts Its Faith Entirely in the Availability and Reliability of Post-Donation Blood Screening.

The FDA and various homosexual interest groups claim that indefinite deferral for MSM is no longer necessary because of the "development of more sensitive HIV testing methodologies…." Draft Guidance at 2. The FDA claims that the current risk of contracting HIV from infected blood is approximately "1 in 1.47 million transfusions." *Id.* at 2. This was the sole reason supporting the move away from indefinite deferral to a one-year deferral, and it is again the sole reason given in favor of eliminating deferral periods entirely. Such an assumption rests the safety of the American blood supply entirely on the post-donation screening process. However, this is a dangerous proposition.

First, as the FDA amits, "HIV antibody tests fail to identify HIV-infected blood donated by HIV-infected persons who have not yet seroconverted."[16] Although HIV blood testing has become far more reliable and efficient than in its early days, the FDA still is unable to identify HIV positive blood where the donor has been infected for about 9 days or less.[17]

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[14] https://en.wikipedia.org/wiki/Annual_cannabis_use_by_country.

[15] Palash Ghosh, "Singapore: Drug Laws and the Death Penalty," International Business Times (June 22, 2011) http://www.ibtimes.com/singapore-drug-laws-death-penalty-292911; Suzanne Daley, "Marijuana Clubs Rise Out of Decades-Old Spanish Laws," The New York Times (July 10, 2014) http://www.nytimes.com/2014/07/11/world/europe/marijuana-clubs-rise-out-of-decades-old-spanish-laws.html?_r=0.

[16] *See* Donegan.

[17] Vanessa Schipani, "Debate Over Gay Blood Donations," FactCheck.org (June 24, 2016) https://www.factcheck.org/2016/06/debate-over-gay-blood-donations/.

Moreover, the FDA's current estimate of HIV transmissions through blood transfusions (about 1 in 1.47 million) is based only on the number of reported transmissions which can be traced back to a specific HIV-positive donor.[18] If such an explicit link cannot be established, the transmission is not counted. Indeed, "[e]stimated residual risks do not necessarily reflect the actual number of transfusion transmissions to recipients." *Id.* Although it is impossible to estimate the actual risk of HIV transmission through transfusion, it is certainly more than the FDA's estimates.

Perhaps even more importantly, there reportedly are numerous different types of HIV viruses, apparently some of which are not detectable with current testing.[19] The FDA states that "FDA scientists … are also working to improve blood donor screening tests to detect variant strains of HIV…."[20] "HIV transmission may still occur [through] [i]nfection with variant strains of HIV that may escape detection by current screening assays."[21] Moreover, while "[t]he US remains one of the most genetically homogeneous regions in terms of HIV-1 diversity, with >99% clade B infections … an increasing number of HIV-1 subtypes have been detected in US blood donors, and **a mix of subtypes could emerge**, similar to that seen in Europe."[22]

If one of these currently-undetectable subtypes or variants of HIV were suddenly to emerge in the United States at or higher than the levels of the 1980's AIDS epidemic, what assurances do Americans have that the FDA would react in time, before tens of thousands of innocent blood donors are again infected as they were in the 1980s?

In short, there are many good reasons to build redundancies into the blood screening system, and to stop relying simply on post-donation testing of blood. Humans can and do make mistakes, and it is a stark reality that HIV transmission through blood is still happening

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[18] Shimian Zou, Susan L. Stramer, and Roger Y. Dodd, "Donor Testing and Risk: Current Prevalence, Incidence, and Residual Risk of Transfusion-Transmissible Agents in US Allogeneic Donations," (2012) http://www.ammtac.org/data/images/fckeditor/file/Donor%20Testing%20and%20Risk.pdf.

[19] Avert, "HIV Strains and Types," (May 2015) http://www.avert.org/professionals/hiv-science/types-strains.

[20] FDA, "Have You Given Blood Lately?" http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048368.htm.

[21] Steven Kleinman, M.D., "Risk of HIV from Blood Transfusion," (2016) http://www.uptodate.com/contents/risk-of-hiv-from-blood-transfusion.

[22] "Human Immunodeficiency Virus Variants," AABB (August 2009) https://www.aabb.org/tm/eid/Documents/102s.pdf (emphasis added).

in spite of the advanced technologies used in post-donation testing.[23] Today's blood testing cannot uncover new HIV infections. And it is likely that the FDA is currently under-reporting the risk of HIV transmission through blood transfusions. Finally, there is always the risk that a less common form of HIV, for which blood testing currently is not effective, could gain traction in the United States, causing a pandemic of virus transmission through transfusions before the system can react.

Relying entirely on the testing of blood after donation to screen out infected blood is a recipe for disaster. Moreover, given the FDA's track record of failure in this area, Americans have legitimate cause for concern.

V. The FDA's Draft Guidance Operates in an "Alice in Wonderland" Type World of Dress-Up and Make-Believe.

Incomprehensibly, the FDA's 2015 Draft Guidance takes the politically correct (but scientifically incomprehensible) position that, when donating blood — a medical procedure — "male or female gender be taken to be self-identified and self-reported." Draft Guidance at 13. This means that a so-called "transgender woman" (*i.e.*, biological man) who has sex with men would no longer be considered to be a male homosexual prohibited from donating blood, but instead would be categorized as a "woman" with no restrictions on blood donation. This fairy tale, make-believe nonsense is even more troubling given the rate at which so-called "transgender women" (*i.e.,* biological men) carry the HIV virus. Indeed, the CDC estimates that 28 percent of so-called "transgender women" (*i.e.,* biological men) have HIV, which is almost double the rate for all homosexual men. Additionally, CDC estimates that 56 percent of black so-called "transgender women" (*i.e.,* biological men) have HIV. "HIV Among Transgender People," CDC (2016) https://www.cdc.gov/hiv/group/gender/transgender/. This means that a black so-called "transgender woman" (*i.e.,* biological man) **is more likely than not to have HIV**, and yet FDA pretends that he is a she and says "no problem" to his donating blood.

CONCLUSION

Longstanding restrictions on MSM blood donation are not designed or intended to "stigmatize" homosexuals. Rather, they are designed to protect the nation's blood supply from deadly diseases. Indeed, the restrictions are not based on sexual orientation, they are based on the widespread behavior of the homosexual community, and thus the diseases endemic to that community. It is not a secret that homosexuals, intravenous drug users, and sex workers

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[23] *See, e.g.*, "Russian Prosecutors Cite Negligence in Child's HIV Blood Transfusion," UPI (April 19, 2013) http://www.upi.com/Top_News/World-News/2013/04/19/Russian-prosecutors-cite-negligence-in-childs-HIV-blood-transfusion/UPI-85271366379369/#ixzz2R1SPw2WH.

engage in activities that expose them to numerous infectious diseases (not limited to HIV) at an exponentially higher rate than the rest of the American public.

For all of these reasons, the FDA should decline the homosexual lobby's invitation to eliminate all deferral periods for blood donation. Moreover, the FDA should return to its indefinite deferral system that was in place before the ill-advised change in policy in December of 2015.

Sincerely yours,

/s/

Eugene Delgaudio
President

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