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TESTIMONY TO THE NEW YORK CITY COUNCIL HEALTH COMMITTIVEE IN SUPPORT OF INCREASED MICROBICIDE RESEARCH AND DEVELOPMENT, AND AN END TO THE FOOD AND DRUG ADMINISTRATION (FDA) BLOOD BAN

April 13, 2010

Good afternoon and thank you for this opportunity to testify before your committee today. I am Janet Weinberg, Chief Operating Officer at Gay Men's Health Crisis. Today, I am here to address two issues that play important roles in working to end the HIV/AIDS epidemic and maintain quality of life for all affected.

First, current U.S. blood policy fails to maximize blood safety or to reduce unnecessary discrimination and stigma against gay and bisexual men. In recent years, leaders within the public health and blood bank communities, such as the American Association of Blood Banks, America's Blood Centers, and the American Red Cross, have voiced support for revising or lifting this policy.

Much of today's medical care depends on a steady supply of blood from healthy donors. Despite shortages in the nation's blood banks, FDA regulations mandate that if a man has sex with another man (MSM), even once since 1977, he is **permanently** excluded from donating blood. However, the policy does not consider the potential donor's HIV status, frequency or risk of sexual activity, or if he is in a monogamous relationship.

Alternative policies offer more promise to reduce risk to blood recipients while expanding the donor pool to include HIV- gay and bisexual men. The FDA should initiate changes to blood donor eligibility policies to reduce unnecessary anti-gay discrimination and stigma while improving blood safety and educating all donors of the realities of HIV risk factors.

There are two basic models that other countries have adopted with respect to MSM donors: [1] shortening the deferral period to one year; and [2] altering the deferral to focus on specific behavior rather than on group-based classifications. Less restrictive policies range from a one to five year deferral period to no blanket ban. The permanent deferral for MSM since 1977 should be replaced with a policy that defers high-risk MSMs, as defined by recent sexual history, for a period of time carefully tailored to known window periods, while permitting low-risk MSM donors to donate blood. In short, GMHC fully supports Resolution 80 that calls on the FDA to revise their longstanding and unjustifiable prohibition on homosexual men donating blood.

GMHC also supports Resolution 39 that urges passage of legislation to facilitate microbicide development. Microbicides are products being developed that could someday reduce the transmission of HIV during sexual intercourse. They are one of the most promising and exciting potential HIV and STD prevention options for men, women and children. Developing a microbicide would complement other HIV and STD prevention measures, including safer sex education, condom distribution, voluntary testing and counseling, testing and treatment, anti-stigma campaigns, safe blood supplies and (hopefully, one day) a vaccine. These poducts have the potential to be easily administered as a gel, film, sponge or even a vaginal ring and would give the user an opportunity to

take charge of safer sex. They could transform the HIV prevention landscape by offering a new method of HIV protection that is user-controlled, instead of partner controlled.

Over the past few years, vaginal microbicides have gained increasing attention because of their potential to empower women to take charge of their sexual health. Women are at the epicenter of the HIV/AIDS epidemic and represent almost half of the 33 million people currently infected with HIV worldwide. Many women face social and economic realities that limit their ability to make decisions about who they have sex with. This lack of power often results in situations where they are unable to avoid sex with men who may be HIV-infected or to insist on condom use. Unlike other barrier methods such as condoms, microbicides could be used without the cooperation or even the knowledge of one's sexual partner.

Scientists are currently testing many substances that have the potential to protect against HIV and other sexually transmitted infections, but so far a safe and effective microbicide is not available to the public. Substances being tested include at least eleven that have proven safe and effective in animals and are now being tested in humans. If one of these leads proves successful and sufficient investment is made, a microbicide could be available in five to seven years. While this is a long period of time, with sufficient research, support and funding, we sincerely hope a microbicide could be made available sooner. Mathematical models predict that even a partially effective microbicide could avert 2.5 million new HIV infections worldwide over three years.

GMHC urges City Council to adopt these important resolutions and calls for an end to the unjustifiable ban on MSM blood donors and also for support to strengthen and accelerate microbicide research and development.

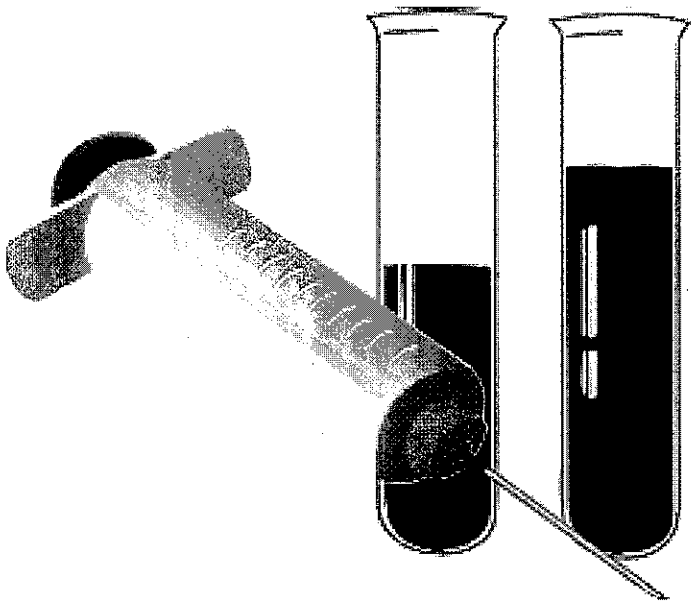
Thank you again for this opportunity to testify.

GMHC

FIGHT AIDS. LOVE LIFE.

A DRIVE FOR CHANGE: REFORMING U.S. BLOOD DONATION POLICIES

A Report by Gay Men's Health Crisis



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All views contained in this report are those of Gay Men's Health Crisis and do not necessarily reflect the views of Davis Polk & Wardwell LLP.

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EXECUTIVE SUMMARY

Under current federal policy in the United States, most gay and bisexual men are permanently excluded from donating blood. The Food and Drug Administration (FDA) has, since 1985, enforced a policy in which any man who has had sex with another man ("MSM"), even once, since 1977, is permanently "deferred" from donating blood, regardless of the man's actual HIV status. This policy, initially implemented during the early years of the AIDS crisis in an effort to protect blood transfusion recipients from inadvertently contracting HIV from infected blood, is one component of a set of donor eligibility policies that temporarily or permanently defer prospective blood donors thought to be at elevated risk of infection of HIV or other transmissible diseases like hepatitis.

The most restrictive permanent deferral applies only to a limited group of prospective donors: in addition to the MSM restriction, other groups permanently deferred are individuals who have received payment for sex since 1977, intravenous drug users, and individuals who have tested positive for HIV. The FDA has upheld the MSM policy through the years based on data that gay and bisexual men continue to be, as a group, at highest risk of contracting HIV. However, others at elevated risk of HIV or other transmissible disease are subject to significantly less restrictive deferrals—or to no deferral at all. A non-MSM individual who has had sexual contact with a commercial sex worker or HIV-positive partner, for example, is deferred from donating blood for only twelve months after that sexual contact. Certain groups now known to be at high risk of HIV, such as African American women, are subject to no deferral at all.

Given the apparent inconsistencies in the FDA's blood donor eligibility policies for MSM donors and others, the MSM ban has been criticized for many years as unfairly discriminatory against gay and bisexual men. Since many blood drives occur in workplaces and schools—participation in which is widely considered an important civic act—the policy may also stigmatize gay and bisexual men who do not participate.

More recently, criticism of the policy has also focused on its public health efficacy. First, the MSM ban excludes many prospective donors who are healthy and at little to no risk of HIV infection. In the face of chronic shortages in the nation's blood supply, the unnecessary exclusion of large numbers of donors may harm patients in need of blood transfusions. Second, significant advancements in HIV testing no longer require lengthy deferral periods. All blood is rigorously tested after donation for HIV and other infections and current testing technology can detect HIV in donated blood within days or weeks of infection. Consequently, donor eligibility screening that focuses on an individual's recent high-risk behavior, and defers only those donors who are within the "window period" between that high-risk behavior and the point at which HIV is detectable by post-donation tests, is likely to be as effective as a longer ban in protecting the blood supply.

Based on these considerations, many HIV specialists and public health experts, the American Red Cross and the other major blood bank organizations in the United States, and advocacy groups, now support reforms to the MSM policy. The FDA, in 2000 and 2006, considered changes to the policy, but has taken no action to date. Additionally, a number of other countries have recently adopted less restrictive blood donor eligibility policies for gay and bisexual men.

GMHC supports reforms to the FDA's blood donor eligibility policy that would enable gay and bisexual men at low or no risk of HIV to donate blood, while continuing to

prevent donations from any prospective donors who are at objectively high risk of donating blood that is infected with HIV or another transmissible disease. To advance the common goals of federal policy makers, the blood bank community, public health experts, and advocates—to ensure a safe, sufficient blood supply while minimizing unnecessary discrimination against gay and bisexual men—a sound blood donation policy must contain six key elements, summarized in a framework we call **D.O.N.A.T.E.** The six essential elements of an optimal blood donation policy are:

- Decreased risk to blood donation recipients of accidental HIV transmission;
- Objective risk factors as primary basis for blood donor policies;
- Non-discriminatory impact on gay/bisexual men and other groups;
- Awareness-raising of HIV prevention and transmission risks;
- Technology-driven donor screening and blood screening procedures; and
- Expansion of safe, eligible blood donor pool.

The current MSM policy falls far short on each of these factors: its treatment of different groups fails to minimize risk, while contributing to blood shortages, and the policy reinforces incorrect and outdated information about the spread of HIV that serves to discriminate against and stigmatize gay and bisexual men. Alternatives considered in the United States and already implemented elsewhere—such as temporary deferral periods for MSM donors or reformed screening procedures that screen all prospective donors based on objective risk—offer potentially significant improvements on each of the D.O.N.A.T.E. factors relative to the current policy.

It is time for the FDA to join the growing consensus favoring reform of blood donation policies for gay and bisexual men, and implement reforms that allow gay and bisexual men to donate blood while improving the overall safety of the American blood supply.

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INTRODUCTION

At the onset of the HIV/AIDS epidemic in the United States in the early 1980s, the disease was a terrifying mystery to the general public, the medical and public health communities, and policy makers. The earliest signs of AIDS appeared in the gay male population, leading experts to initially (and incorrectly) speculate that AIDS was a "gay" disease. It was only after AIDS cases began to emerge in other groups—including Haitians, hemophiliacs and others who had received blood transfusions, intravenous drug users, and heterosexual women, among others—that it became understood that AIDS was caused by a virus, HIV, that could be transmitted through certain contact with an infected individual's semen or blood, irrespective of the individuals' sexual orientation.

The emergence of HIV/AIDS cases contracted through infected blood—typically, through a blood transfusion with blood from an HIV-positive donor, or through reused, non-sterilized intravenous needles in medical settings and among illicit drug users—compelled the federal government and the nation's major blood bank operators, including the American Red Cross, to act promptly, and before the epidemic was fully understood, to secure the nation's blood supply and prevent inadvertent transmission of HIV to patients receiving blood transfusions. Among the earliest measures implemented in the mid-1980s were screening procedures that blocked blood donations from individuals from groups known to be at high risk of HIV, including men who had sex with men, Haitians, commercial sex workers, and intravenous drug users. These policies, coupled with rigorous screening procedures of donated blood, have been credited with virtually eliminating the risk of HIV transmission through the blood supply in the United States.

Individuals who fall into certain risk groups are temporarily, indefinitely, or permanently prohibited from donating blood: Under the current policy in place since 1985, any man who has had sex with another man, even once, since 1977, is permanently barred from donating blood, regardless of his HIV status or objective risk level. Although the critical importance of protecting the blood supply and the effectiveness of both the donor screening and post-donation blood screening procedures is universally recognized, the MSM policy for men who have sex with men has been long criticized as discriminatory against gay and bisexual men and contributory to the inaccurate and outdated view of HIV/AIDS as a gay disease.

It is now a quarter century after the FDA first instituted the current MSM donor deferral policy, initially conceived as an emergency response to the burgeoning and horrifying AIDS epidemic which, at the time, was still largely not understood by doctors, scientists, public health experts, or ordinary Americans. Great strides have been made in HIV/AIDS prevention, detection, and treatment over those 25 years, as well as in recognition that HIV/AIDS is not a "gay" disease, but is one that affects men and women, gay and straight individuals, and members of all racial, ethnic, and socioeconomic backgrounds. Despite these important developments—and the fact that the HIV epidemic in the United States of 2010, unquestionably serious in its own right, bears little resemblance to the vexatious and frightening AIDS crisis of 1985—America's blood donation policies for gay and bisexual men have remained wholly unchanged through the present day. The donor eligibility policies in place today are under-inclusive of gay and bisexual men, since many men who are HIV-negative and at no or low-risk of becoming infected may never donate blood, while being over-inclusive of individuals in other groups who are at objectively elevated risk of

Key Terms

Acquired Immunodeficiency Syndrome (AIDS): A disease of the immune system characterized by increased susceptibility to opportunistic infections; the disease is caused by the HIV virus.

Blood Products Advisory Committee (BPAC): FDA advisory committee that "reviews and evaluates data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases" and advises the FDA on blood donor eligibility and screening.

Antibody Test: Detects the presence of antibodies that are produced by the body as a reaction to HIV infection.

Deferral Period: Period during which a prospective blood donor is prohibited from donating blood, which can be temporary, indefinite, or permanent in duration.

FDA: U.S. Food and Drug Administration

Human Immunodeficiency Virus (HIV): The retrovirus that causes AIDS.

MSM: A male who has had sex with another male.

Nucleic Acid Test (NAT): Can detect the genetic structure of HIV in an infected individual, providing an average window period of two weeks or less.

Protected Sex: Sex with a condom that involves anal, vaginal, or oral penetration

Unprotected Sex: Sex without a condom that involves anal, vaginal, or oral penetration

Window Period: The period of time between the point at which an individual is infected with HIV and when the virus is detectable by HIV tests.

contracting HIV. As one striking example, a non-MSM individual who had sex with a partner known to be HIV-positive more than one year ago may, under the current policy, donate blood, whereas a man who has had sex with another man since 1977 may never donate blood.

Fortunately, the opportunity to improve the fairness—and overall effectiveness—of blood screening policies in the United States is stronger now than ever before. Over the last several years, each of the major blood bank organizations, including, most recently, the American Red Cross, have expressed support for abolishing the current policy for MSM donors, supported by contemporary blood screening technologies that minimize the risk of accidental HIV transmission through blood transfusions. The FDA has expressed willingness to change the policy if evidence can be shown that a new policy would not increase the risk of disease transmission to blood donor recipients. Growing opposition to the policy's discriminatory nature has depressed the number of Americans willing to donate blood—and the number of institutions willing to host blood drives. And a number of other countries have recently relaxed, or are considering relaxing, restrictions on MSM blood donors.

Given this coalescence of science, public opinion, support from the public health community, and international momentum toward change, the time is right to advocate for blood donation policy reforms in the United States.

This report calls for the FDA to initiate changes to blood donor eligibility policies, and the MSM policy specifically, that will reduce unnecessary discrimination against gay and bisexual men while both improving blood safety and educating both MSM and non-MSM donors of the true range of HIV risk factors. The report first provides an overview and history of the MSM policy in the United States, and then compares the policy to less restrictive policies recently implemented in other countries. Next, the report sets forth an analytical framework, which we call **D.O.N.A.T.E.**, for analyzing the fairness and effectiveness of the current MSM policy and possible alternatives, including temporary deferral periods or eligibility criteria based on objective individual risk. Applying the **D.O.N.A.T.E.** analysis, which considers six factors that a sound blood donation policy should include, the report concludes that the current MSM policy fails to maximize blood safety or to reduce unnecessary discrimination against gay and bisexual men, and that alternative policies offer more promise to reduce risk to blood recipients while expanding the donor pool to include gay and bisexual men.

BACKGROUND

For the past 25 years, any man who has had sex with another man, even once, since 1977, has been permanently prohibited from donating blood in the United States. The MSM policy was implemented—and has been periodically reviewed and left in place—by the FDA, the federal agency responsible for regulating the nation's blood supply.[1] The MSM policy is one component of the FDA's broader requirement that all blood banks, hospitals, and other facilities where blood donations take place screen all prospective donors to identify individuals who either are, or are at elevated risk of becoming, infected with HIV or other communicable diseases. Individuals identified as being in one or more high-risk groups are deferred temporarily or permanently from donating blood.

Although the intended goal of these requirements is to prevent HIV-infected blood from entering the blood supply and to minimize the risk of inadvertent transmission of HIV to blood recipients, the MSM policy has long been criticized as unjustifiably discriminatory against gay and bisexual men. Calls to change the policy have grown in recent years. This section provides an overview of the current MSM policy, its history, and recent developments that suggest the time has come to implement new donor eligibility policies that better promote blood safety while reducing discrimination.

The current FDA blood donation policy permanently defers blood donations by any male who has had sex with another male, even once, since 1977.

In recent years, leaders within the public health and blood bank communities have voiced support for revising or lifting this policy.

Overview of Current MSM Donor Policy

Currently, federal policy permanently bars any man who has had sex with another man since 1977 from donating blood, regardless of his actual HIV status.[2] This deferral policy effectively bans the vast majority of gay men, bisexual men, and other men who have sex with men from donating blood.

FDA regulations require blood collection establishments to screen potential blood and plasma donors for risk factors related to HIV and other infectious diseases.[3] To comply with the FDA's policy, blood donation centers are required to assess each prospective donor's medical, social, and sexual history on the date of the donation.[4] Although these regulations do not specifically identify MSM donors as a high-risk group,[5] the FDA has issued guidance materials identifying MSM individuals as among the high-risk groups that may not donate blood.[6]

To comply with donor screening regulations, most blood banks administer a Donor History Questionnaire (the "Questionnaire") to prospective donors; any individual deemed to be a member of a high-risk group based on his or her Questionnaire responses will be unable to donate blood on that day and for some period into the future. The current version of the Questionnaire, developed by the AABB (formerly, the American Association of Blood Banks), a national association of blood donation and transfusion facilities, was approved by the FDA in 2006 as "an acceptable mechanism that is consistent with FDA requirements for collecting donor history information."[7] In addition to approving the Questionnaire, the FDA provides non-binding guidance to blood facilities on administering it to prospective donors.[8]

The Questionnaire (reprinted in Appendix A) asks 48 questions about a potential donor's current health, medical history, blood donation history, sexual practices, drug use, and other behaviors.[9] With respect to MSM donors, the Questionnaire asks all prospective male donors: "From 1977 to the present, have you . . . had sexual contact with another male, even once?"[10] (The questionnaire's definition of sexual contact includes vaginal, oral, and anal sex.)[11] Any male who responds "yes"

to this question is, under current practice, permanently prohibited from donating blood.[12]

The Questionnaire's questions regarding high-risk sexual practices with respect to non-MSM donors are very limited. The Questionnaire does not ask prospective male or female donors whether they have engaged in *specific* high-risk sexual practices, such as unprotected sex, sex with multiple partners, anonymous sex, or sex with a partner whose HIV status was unknown to the prospective donor. Likewise, the Questionnaire does not ask any donor whether they always engage in no-risk or low-risk sexual behavior, such as condom usage or limiting sex to monogamous partners or partners whose HIV-negative status is known at the time of donation. In fact, the only questions that appear targeted to ascertaining high-risk sexual behavior of non-MSM donors are the following:

The donor history questionnaire used by American blood banks asks all prospective male donors:

"From 1977 to the present, have you had sexual contact with another male, even once?"

Under current policy, any man who ever responds "yes" to this question may never again donate blood.

- In the past 12 months, have you had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?
- In the past 12 months, have you had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?
- In the past 12 months, have you had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything <u>not</u> prescribed by their doctor?
- In the past 12 months, have you had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?
- Female donors: In the past 12 months, have you had sexual contact with a male who has ever had sexual contact with another male?
- In the past 12 months, have you had sexual contact with a person who has hepatitis?
- From 1977 to the present, have you received money, drugs, or other payment for sex?
- Have you ever had sexual contact with anyone who was born in or lived in Africa?

It bears noting early in this report that the twelve-month deferral periods for non-MSM donors who have had sex with someone who is *known to be HIV-positive*, has hepatitis, or has had sex with a commercial sex worker, is shorter than the permanent deferral for an MSM donor who has had sex with any man, regardless of the partner's HIV status.

Origins of the Policy

History

The first recognition of the illness that would later come to be known as HIV/AIDS occurred in the early 1980s.[13] In 1981, the Centers for Disease Control and Prevention (the "CDC") reported cases of a rare form of pneumonia that was affecting a small group of gay men.[14] In 1982, several heterosexual hemophiliacs who received regular blood transfusions were diagnosed with HIV/AIDS.[15] Around this time, some began to identify the role of blood transfusion in the spread of the disease, questioning the safety of the nation's blood supply,[16] and the MSM blood donation ban was first introduced.[17] In 1983, the MSM blood donation ban was initially issued, in the form of non-mandatory guidelines, by the U.S. Public Health

Service.[18] Under those guidelines, blood collection facilities advised prospective donors from "increased risk" groups to refrain voluntarily from donating blood.[19] The groups specified to be at "increased risk" of HIV infection included, among others, "sexually active homosexual and bisexual men with multiple partners."[20]

In 1984, the definition of increased risk groups was changed to remove references to sexual orientation and to instead defer all "males who have had sex with more than one male since 1979, and males whose male partner has had sex with more than one male since 1979."[21] The policy was then broadened in 1985 to exclude any man who has had sex with another man since 1977.[22] The 1985 change not only pushed back the operative date for determining MSM donor eligibility by two years from 1979 to 1977 (then believed to be the year the HIV virus first appeared in the United States), but it also, for the first time, excluded monogamous gay male couples from the donor pool.[23] In 1992, the FDA released recommendations rephrasing the ban as excluding all "[m]en who have had sex with another man even one time since 1977."[24]

The FDA continues to enforce the policy through various mechanisms, including: (1) promulgating regulations on blood donation practices; (2) periodically issuing guidance to the blood supply industry on conforming with the applicable regulations; and (3) requiring blood banks to screen potential donors and reviewing blood donation facilities' questionnaires, including the Donor History Questionnaire, for compliance with the rules and regulations.[25] The FDA has periodically reviewed and reaffirmed the MSM deferral policy, including, most recently, in 2000 and 2006.

Rationales

Since the inception of the MSM deferral policy, the FDA's rationale for the policy has been to prevent HIV-infected blood from entering the nation's blood supply and infecting blood recipients with HIV. Deferral policies are targeted to groups with high HIV infection rates. The MSM policy is based, at least in part, on the historically and presently high incidence of HIV among gay and bisexual men.

As the FDA explains on its website:

> Men who have had sex with other men, at any time since 1977 (the beginning of the AIDS epidemic in the United States) are currently deferred as blood donors . . . because MSM are, as a group, at increased risk for HIV, hepatitis B and certain other infections that can be transmitted by transfusion.[26]

The FDA's website also cites the following animating concerns supporting the policy:

- "Men who have sex with men account for the largest single group of blood donors who are found HIV positive by blood donor testing";
- Testing cannot "detect all infected donors or prevent all transmission by transfusions";
- A "window period" exists between the point at which an individual becomes infected and the later point at which the virus can be detected through an HIV test, such that currently available HIV tests cannot, by themselves, be relied upon to screen potential donors;

Timeline of Key Dates:

Pre-1981: HIV emerges in U.S.

1981: Cases of illnesses related to the disease later known as AIDS appear in the gay male population.

1982: The first AIDS cases are diagnosed in non-MSM blood transfusion recipients.

Jan. 1983: The CDC holds first public meeting on the AIDS virus and the blood supply, at which a ban on MSM donors is first considered.

March 1983: FDA recommends new procedures to decrease risk of donation of HIV-positive blood.

1984: The Public Health Service recommends deferrals for MSM donors who have had sex with more than one man or whose partners have had sex with more than one man "since 1979."

1985: FDA licenses first blood tests for HIV; widespread standard testing of donated blood begins; FDA broadens the exclusion to defer any man who has had sex with another man since 1977.

1990: FDA reemphasizes need for blood donor screening for MSM sexual behavior and other risks.

2000: FDA reviews the MSM ban, but does not take any action.

2002: New HIV testing and post-donation blood testing technologies improve testing accuracy and reliability.

2005: Red Cross joins other major blood bank operators in opposing MSM ban in its current form.

2006: FDA sponsors workshop to review the current policy and advancements in research, but takes no action to change policy.

2006-Present: FDA proposes new regulations applicable to blood and blood products that would not eliminate or revise the MSM blood donor deferral.

According to the FDA, ***"Men who have had sex with other men, at any time since 1977 (the beginning of the AIDS epidemic in the United States) are currently deferred as blood donors . . . because MSM are, as a group, at increased risk for HIV, hepatitis B and certain other infections that can be transmitted by transfusion."***

- Even though all donated blood is tested for HIV and other issues, human error may cause some infected blood to be transmitted to blood recipients;
- Changing the policy could potentially result in increased risk of transmission;
- Better alternatives for designing donor eligibility criteria so as to reliably identify a subset of gay and bisexual men who are not at increased risk of HIV infection are not currently available; and
- Men who have sex with men are also at increased risk of "having other infections that can be transmitted to others by blood transfusion."[27]

Blood Donation Policies for Other High-Risk Groups

MSM donors are not the only individuals who have been deferred as blood donors due to a perception that they present a higher risk of HIV infection. Over the years, the following non-MSM groups, believed to be at an increased risk of contracting AIDS, have been deferred from donating blood:

- persons with symptoms and signs suggestive of AIDS;
- sexual partners of AIDS patients;
- Haitian entrants to the United States;
- present or past abusers of IV drugs;
- patients with hemophilia;
- men and women engaging in sex for money or drugs;
- persons born in or emigrating from sub-Saharan Africa;
- prison inmates; and
- sexual partners of individuals at increased risk for AIDS.[28]

Certain deferrals based upon national/geographic characteristics have been justified by the fact that heterosexual activity is thought to play a major role in the transmission of particular types of HIV in those regions.[29] Over time, as blood establishments employed different types of antibody testing, the deferral of certain groups, including Haitians, has been lifted.[30] Additionally, only those blood collection agencies that do not use an HIV test approved by the FDA to screen for detection of Group O viruses, a category of HIV virus not usually seen outside West-central Africa, are currently required to defer prospective donors who were born in or have traveled to particular African countries and their sexual partners.[31]

It should also be noted that individuals at a higher risk of HIV are not the only risk group deferred from donating blood. Screening procedures also attempt to exclude individuals at a high risk of hepatitis, malaria, Chagas' disease, babesiosis, variant Creutzfeldt-Jakob disease ("mad cow"), and other diseases.

Impact of the Current Policy

Although the current MSM deferral policy is designed to prevent HIV-infected blood from entering the nation's blood supply and infecting blood recipients with HIV, it raises a number of issues regarding the manner in which such preventative measures are carried out. Collectively, the FDA's policies for blood donor eligibility and post-donation blood testing have effectively protected the nation's blood

supply, but they do so at the cost of imposing inordinate and unnecessary burdens on gay and bisexual men. Although the MSM policy is ostensibly based on high-risk behavior rather than on sexual orientation, in practice the policy effectively excludes virtually all gay and bisexual men, regardless of whether they have engaged in high-risk or low-risk sexual behavior. Because the MSM policy is not narrowly tailored to exclude only those MSM engaging in sexual behavior posing the highest risk of HIV infection, such exclusion reinforces negative stereotypes and perpetuates harmful stigmas against gays and bisexuals as a whole. The consequences of the FDA's current MSM policy can be especially problematic in light of the fact that the majority of blood donations occur during blood drives that take place in workplaces or schools. In such situations MSM individuals may worry about the possible employment or social ramifications of not participating in a blood drive.

The current policy also allows for non-MSM individuals who are at a high risk of HIV infection to donate blood, thereby increasing the risk of HIV entering the blood supply. As currently drafted, the FDA's policy does not distinguish between higher and lower risk sexual behaviors for any at-risk group. For instance, non-MSM donors who have had sex with an HIV-positive individual, regardless of whether such sex was protected or unprotected, are uniformly deferred for only one-year. Therefore, straight individuals who engage in risky sexual behavior are permitted to donate blood after the passage of some amount of time, while healthy MSM individuals who engage solely in safer sex practices are permanently deferred. This inequitable exclusion of low-risk MSM donors is not only discriminatory, but also results in a reduced blood supply.

The blanket exclusion of MSM blood donors reinforces negative stereotypes and perpetuates harmful stigmas against gays and bisexuals as a whole. In addition to banning healthy gay and bisexual male donors, the current policy permits non-MSM individuals at high risk of HIV infection to donate blood, thereby increasing the risk of HIV entering the blood supply.

Another consequence of the current policy of permanently deferring MSM donors from blood donation is a missed opportunity to promote public health and safer sex practices through the donation process. By designing a different questionnaire or other type of screening procedure aimed at excluding only those donors engaging in high-risk sexual practices regardless of the gender of their sexual partners, the FDA would have the opportunity to increase awareness of safer sex practices across the entire blood donor population.

Opposition to the Policy

In recent years, the MSM donor deferral policy has resulted in opposition to blood drives on a number of university campuses. The advent of the nucleic acid test (NAT), which detects HIV directly and has a "window" period of only 9-11 days after infection (see p. 15, below), has provided scientific and technological reasons to reconsider the policy. A number of student publications have printed editorials in opposition to the policy,[32] and various student groups have denounced the discriminatory effects of the policy,[33] while others have organized protests and demonstrations against it,[34] and in at least one instance a university suspended its sponsorship of an on-campus blood drive because of the MSM donor deferral policy.[35] During the 2006 FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era, concern was raised that student opposition to the MSM policy, based upon a perception that the policy is discriminatory, depletes the blood supply.[36] Both university and high school students comprise a highly desirable demographic for the blood bank community given their potential to become lifetime donors.[37] The potential to alienate prime donors through the perpetuation of a policy perceived as discriminatory, thus depleting the blood supply, is yet another consequence of retaining the current MSM donor deferral policy.

INTERNATIONAL CONTEXT

Although many countries have permanent bans on MSM donors similar to the current policy in the United States, a number of countries have recently considered reforms to their policies that would lift these lifetime bans and replace them with temporary deferral periods or other changes that would allow more gay and bisexual men to become blood donors.

Many Countries Have MSM Policies Similar to the U.S. Policy

The countries that, like the United States, impose indefinite deferrals on MSM donors include Canada, Denmark, Finland, France, Germany, Hong Kong, Iceland, and the Netherlands.[38]

MSM bans in these countries have also met with controversy based on concerns that the policies unfairly and unjustifiably discriminate against gay and bisexual men. Canada, for example, defers all men who have ever had sex with another man since 1977 based on "current scientific knowledge and statistical information that shows that men who have had sex with other men are at greater risk for HIV/AIDS infection than other people."[39] The Canadian policy recently attracted media attention when the Canadian Blood Services, a non-profit organization that manages the blood supply in Canada, filed a lawsuit against a gay man who admitted to having lied about his sexual history on multiple occasions when donating blood, even though the man is not HIV-positive. The man is countersuing the agency, claiming that the blood donation ban violates his charter rights.[40]

An Increasing Number of Countries Have Reformed MSM Policies

An increasing number of countries have begun to review their MSM bans and to consider less restrictive policies for gay and bisexual men.

Argentina, Australia, France, Hungary, Italy, Japan, Russia, South Africa, and Spain have all revised their policies in recent years. In May 2008, the Russian Ministry of Health and Social Development repealed a ban that explicitly prohibited gay individuals from donating blood.[41] Sweden announced on December 2, 2009 that it will implement a new policy on March 1, 2010. The countries with one-year and five-year MSM deferral policies are listed in the sidebar; Italy, Spain, and France defer donors solely based on high-risk behavior, not on a donor's history of MSM behavior.

Additionally, the United Kingdom, which currently employs a more restrictive policy than the United States, prohibiting any man who has ever had sex with another man, regardless of when that sexual activity took place, recently considered reforms to its policy.[42] In October 2009, the UK's Advisory Committee on the Safety of Blood Tissues and Organs met to discuss possible changes to the policy, motivated in part by an increased demand on the blood supply due to the swine flu pandemic.[43] At the time of this report in February 2010, no changes have been recommended or made.

These reforms are attributable to both a concern that the ban is ineffective and discriminatory, as well as a critical need in many countries for an increased blood supply.

Countries that have lifted the ban on MSM donors:

- **Russia**

Six-month deferral for MSM donors:

- **South Africa**

One-year deferral for MSM donors:

- **Argentina**
- **Australia**
- **Hungary**
- **Japan**
- **Sweden (effective March 2010)**

Five-year deferral for MSM donors:

- **New Zealand**

Donors screened for high-risk sexual practices rather than MSM behavior:

- **Italy**
- **Spain**
- **France**

Some Countries Ask Non-MSM Donors Questions About High-Risk Sexual Activity

As discussed above, the donor history questionnaire currently in use in the United States does not ask non-MSM donors about their specific sexual practices, such as whether they have had unprotected sex or sex with multiple partners. Several countries do, however, ask all male and female donors, regardless of sexual orientation, specific questions about high-risk practices. Examples include:

- France. France defers all prospective male and female donors who have had unprotected sex within the previous four months from donating blood. An individual with multiple sexual partners is deferred from donating blood until four months after the end of the multiple partner situation.[44]
- Italy. Italy advises all prospective male and female donors to self-defer if they have a personal history of sex at high risk of transmission of infectious diseases (listing as examples casual sex, promiscuous sex, sex for money, and sex with someone with a personal history of STDs, HIV, hepatitis, drug use, or other high-risk situations).[45]
- Sweden. Sweden asks all prospective male and female donors whether they have had a "new sexual partner" within the previous three months, or whether they have had "sexual intercourse with a person who has been exposed to the risk of blood contamination" within the previous six months.[46] Donors who answer "yes" to one or both of these questions may not donate blood. (As described below, Sweden will soon relax its restrictions for MSM donors, who will be deferred for 12 months after March 1, 2010.)

International Models for Reform

There are two basic models that countries have adopted with respect to MSM donors: (1) shortening the deferral period to one year; and (2) altering the deferral to focus on specific behavior rather than on group-based classifications.

- **Move from Permanent to Temporary Deferrals for MSM Donors**

Both Australia and Japan have instituted one-year deferrals on MSM donors, permitting a MSM donor to donate blood twelve months after the most recent date on which he had sex with another man.[47] Both countries previously had permanent deferrals for MSM donors.[48] Most recently, on December 1, 2009, Sweden announced that it will change its ban from a lifetime ban on gay blood donors to a new policy permitting donations by any gay man who has not had sex with a man for at least one year.[49] Swedish public health authorities cited the fact that a number of other European countries had instituted similar changes when announcing the new policy, which will go into effect in March 2010.[50]

- **Shifting Focus from MSM History to High-Risk Sexual Behavior**

Italy and Spain now only rule out donations from men who have engaged in risky sexual behavior.[51] They have adopted deferrals based on specific risky behavior, such as unprotected sex, rather than group-based deferrals.[52] Spain now asks all blood donors if in the last six months they have had sex with more than one person, a person who is HIV-positive, a person with many different partners, a person who is

an intravenous drug user, or a person who resides in a part of the world where HIV is widespread.[53]

After the amendment of these countries' donor deferral policies, including relaxing deferrals of MSM, the number of people in these countries who have become infected with HIV through donated blood has more than halved.[54] Experts suggest that this is partly because the new ban focuses on risky behavior rather than on banning an entire group.[55]

RECENT DEVELOPMENTS

Over the past decade, scientific and technological developments have advanced our understanding of the HIV virus, and produced more sensitive testing mechanisms to detect HIV infection both in individuals and in units of donated blood. Not only has the window period during which an individual may be infected with the disease and yet produce a negative test been drastically reduced, but improvements in technology have also helped reduce the number of HIV infections resulting from inadvertent use of blood that correctly tested positive due to human error. As discussed below, given the recent developments in HIV testing, the FDA, through its Blood Products Advisory Committee ("BPAC"), has re-examined the propriety of its MSM donor deferral policy twice in the past ten years. Although public health experts and the leading blood bank organizations in the United States presented new studies supporting a modification of the MSM policy on those occasions, the FDA has not taken any action to modify or replace the policy. Rather, the FDA is currently in the process of promulgating new blood donation rules that would reaffirm the current policy with regard to MSM donors.

Advancements in HIV Screening

There are two basic methods of testing for HIV, the antibody test and the nucleic acid test. However, neither test will detect the presence of HIV the moment a person is infected with the virus. The period from when a person has been infected with HIV to when a test would detect the virus is known as the "window period." The length of the window period varies from person to person, and also varies depending on what test is administered. [56]

The most common test is the antibody test, which tests for the antibodies that an infected individual will produce to combat the virus. It usually takes a number of weeks for the body to produce enough antibodies for the antibody test to detect; for most people the window period is between two to eight weeks, with the average being 25 days. [57] Some individuals, however, will take even longer to produce detectable antibodies, so the CDC recommends testing more than three months after a potential exposure occurs. Approximately 97% of persons will develop antibodies in the first three months, and in very rare cases it can take up to 6 months for antibodies to be detectable. [58]

The other test is the nucleic acid test ("NAT"), which is a newer test that is currently much less commonly used than the antibody test. [59] This tests for HIV directly and has a much shorter window period than the antibody test. Typically the test will detect the presence of HIV in 9 to 11 days after infection,[60] providing a window period significantly shorter than the more common antibody test.

While the antibody test is used most often to test individuals, the nucleic acid test is most often used to test blood after it has been donated.[61] Because the window period for the nucleic acid test is so short, the risk of HIV infected donated blood escaping detection is greatly decreased, posing a relatively new opportunity to revisit donor deferral periods, and more closely link donor eligibility to recent history of high-risk sexual behavior and other practices.

The two most commonly used HIV tests can detect the presence of an HIV infection several days to several weeks after the date of infection. Blood donated during this "window period" when HIV is undetectable poses the highest risk to the blood supply. The common antibody test has a window period of 2-8 weeks, while the newer but less common nucleic acid test presents a window period of just 9-11 days. Infected blood donated *after* the window period poses much less risk because it can be screened in post-donation testing.

Recent Actions by the FDA

In the last decade, the FDA, through its Blood Products Advisory Committee ("BPAC"),[62] has addressed the MSM deferral policy on two occasions. The current roster of BPAC can be found in Appendix B. During Committee meetings in 2000 and 2006, BPAC members and others discussed recent research supporting a less restrictive policy for MSM donors, and BPAC members and others expressed support for modifying the policy. Unfortunately, the FDA took no action to institute changes after either meeting.

2000 Review

On September 14, 2000, BPAC held a public hearing to address a question posed by the FDA about whether, based on available scientific data, the deferral period for gay and bisexual men could be shortened to five years.[63] FDA medical officer Dr. Andrew Dayton, led the presentations portion of the hearing, summarizing the results of an FDA-commissioned study that identified several risk factors affecting the accidental transmission of HIV and other viruses via blood donations. These factors included undetected window-period donations and so-called release errors, where HIV-infected blood that has been correctly screened by a test is nevertheless released into the blood supply, largely due to human error.[64]

With "tremendous caveats" arising from several assumptions about the number of MSM individuals in the United States and the actual prevalence of HIV and other infections in this population, the FDA data showed that changing the policy from a permanent deferral to a five-year deferral would result in a net change of *zero* window-period transmissions per year and up to 1.7 additional accidental transmissions of infected blood due to release errors per year.[65] In contrast, BPAC heard evidence that a change to a one-year deferral period could "conceivabl[y]" lead to a net change of three additional window-period transmissions and three additional release error transmissions per year.[66]

The hearing included presentations by AABB and America's Blood Centers, two of the leading national networks of blood donation centers, as well as from the Gay and Lesbian Medical Association ("GLMA"), the Human Rights Campaign ("HRC"), and Lambda Legal Defense and Education Fund, Inc. ("Lambda Legal"). Each of these groups urged BPAC to recommend to the FDA that it shorten the MSM deferral period to either one year or another discrete period that would be chosen based on "developments in medical technology on blood safety."[67] The American Red Cross (the "Red Cross"), the largest national operator of blood banks and supplier of blood products, spoke out against revising the policy, citing the increased risk of infectious blood that might enter the blood supply under the proposed deferral periods.[68]

At its meeting, BPAC ultimately voted 7 to 6 to uphold the permanent deferral for MSM donors.[69] During the Committee's deliberations, however, several Committee members raised concerns that the "iffy" nature of the assumptions on which the FDA's model relied, such as the data relating to the prevalence of certain infectious diseases among gay and bisexual men, might have overstated the actual increased level of risk associated with a shortened deferral period.[70]

2006 Review

The FDA and BPAC revisited the MSM deferral policy in March 2006. On March 8, 2006, the FDA convened a workshop entitled "FDA Workshop on Behavior-Based Donor Deferrals in the NAT Era."[71] NAT, an acronym for "nucleic acid test," refers to a newer test used to detect the presence of HIV in blood that is "more sensitive and

can detect viruses earlier than traditional antigen tests, reducing the window for which a donor can be infected but test negative."[72] As described above, the NAT test reduces the window period to an average of nine to eleven days, a marked improvement from earlier testing methodologies in which the window period averaged 25 days in length and could be as long as several months. The FDA's workshop included participants from the FDA, academia, and industry, and addressed a range of topics including the social dimensions of behavior-based deferral policies, virus transmission risks associated with blood transfusions, and donor history questionnaire design.[73]

BPAC held a meeting on the day following the FDA's workshop, at which it discussed the MSM policy and the research findings that had been presented at the workshop. Dr. Dayton, the FDA medical officer, highlighted new studies conducted since 2000 that took into account "substantial operational improvements in the past few years [that] have reduced risk of inappropriate release" of infected blood into the supply stream, as well additional prevalence data.[74] Dr. Dayton's summary also referred to an alternative model, presented at the workshop by Dr. Celso Bianco (then serving on BPAC as the industry representative). This model, which was based on somewhat different parameters than the FDA's model, "suggested a change in [d]eferral criteria for MSM from indefinite to one year could increase the risk of HIV by one in 46 million, or one case each 32.8 years."[75] Finally, Dr. Dayton summarized two presentations made at the workshop that addressed the "difficulty of designing a questionnaire and making questionnaires work." One of the presenters argued that questions pertaining to the recent past would result in more accurate answers.[76]

At the 2006 meeting, the Committee also heard a joint statement by the American Association of Blood Banks (AABB) and America's Blood Centers, which characterized the current MSM deferral policy as "medically and scientifically unwarranted," especially in light of the advent of NAT testing. The Red Cross reversed the position it had previously taken in 2000, and joined the statement by AABB and America's Blood Centers. The groups urged the FDA to modify its MSM deferral criteria to make it "comparable with criteria for other groups at increased risk of sexual transmission of transfusion transmitted infections."[77] The meeting concluded without Committee deliberations and without a recommendation to the FDA. Instead, Dr. Dayton indicated that the FDA "want[ed] to get all the modelers together and hammer out the last of the differences ... [then] consider bringing [the data] back before [BPAC] to decide what to do."[78]

2006 to Present

Despite the Committee's intention to continue to discuss the issue at the end of its March 2006 meeting, BPAC has not formally addressed the MSM deferral policy since that meeting. In the months following the meeting, the press reported that the FDA was still considering revising the policy.[79] But in October 2006, the FDA reaffirmed the policy when it issued its guidance recognizing the current version of the AABB Donor History Questionnaire as acceptable for donor screening. The Questionnaire asks male donors if they have had sexual contact with another male at any time since 1977. In May 2007, the press reported that the FDA reiterated the policy by posting updated information about it on its website.[80]

In November 2007, the FDA proposed a set of new federal rules to "revise and update the regulations applicable to blood and blood components . . . , to add donor requirements that are consistent with current practices in the blood industry, and to

more closely align the regulations with current FDA recommendations."[81] Section 630.10(f)(1) of the proposed rule requires blood collection facilities to "determine whether a donor has engaged in social behaviors associated with increased risk of infection."[82] This differs from the current rule by specifically requiring a screening procedure addressing a prospective donor's particular behaviors. Like the current rule, the proposed rule does not specifically define which "social behaviors associated with relevant transfusion-transmitted infections" would lead to a donor deferral, but rather notes that the FDA "ha[s] issued guidance on such deferrals and . . . will continue to do so."[83] However, the summary of the proposed rule specifically lists "men who have had sex with another man even one time since 1977" as one example of such "social behaviors" under current regulatory guidance.[84] During the extended period for comment on the proposed rule,[85] both the American Medical Association and Lambda Legal submitted public comments advocating that the proposed rule abandon the current policy of a permanent deferral for MSM.[86] To date, the FDA has not taken final action on the proposed rule.[87]

Despite this limited progress to date in changing the MSM deferral policy, the FDA's actions indicate the agency's willingness to revisit the policy and make changes if supported by scientific research. On its website, the FDA promises to continue to "publicly revisit" the MSM deferral policy and states that it would change the policy "if supported by scientific data showing that [the change] would not present a significant and preventable risk to blood recipients."[88]

THE **D.O.N.A.T.E.** FRAMEWORK: THE ESSENTIAL ELEMENTS OF A SAFE AND EFFECTIVE BLOOD DONATION POLICY

In recent years, a consensus has emerged among the leading blood bank operators, the public health community, and advocates, that the existing lifetime blood donation deferral for MSM donors needs reform. These various stakeholder groups and the FDA itself agree on the key problems with the existing policy, as well as on the essential components of an effective blood donation policy for both MSM donors specifically and all prospective donors in general.

The following framework establishes the contours for any safe, effective, and non-discriminatory blood donation policy. The six elements encompass the broad goals shared by the various stakeholders in this dialogue: to ensure a safe and sufficient blood supply for patients in need; to utilize fair, objective, and consistently applied policies for all prospective donors; and to educate prospective donors about HIV/AIDS and other conditions.

The six essential elements of the **D.O.N.A.T.E.** framework are:

1. Decreased risk to blood donation recipients of accidental HIV transmission

- Goal: The FDA's blood donation policies and screening procedures should minimize risk of inadvertent transmission of HIV and other conditions to blood donation recipients, with the goal of zero unintentional transmissions.
- Inquiry: Does the current policy effectively minimize risk? Do proposed alternatives reduce and/or maintain the level of risk relative to the risk associated with the present policy?

2. Objective risk factors as primary basis for blood donor policies

- Goal: Donor eligibility should be based on an individual's actual level of risk rather than status-based categories serving as proxies for risk.
- Inquiry: Do screening materials and donor history questionnaires define and target deferrals to high-risk practices? Are similar behavioral risks uniformly associated with similar donor deferral policies?

3. Non-discriminatory impact on gay/bisexual men and other groups

- Goal: Blood donation policies should be fairly applied to all prospective donors and should not discriminate—or be perceived to discriminate—on the basis of sexual identity, race, national origin, or other categories. The policy should not contribute to anti-gay stigma, create a hostile work environment, or reinforce inaccurate stereotypes about homosexuality.
- Inquiry: Does the policy create actual or perceived discrimination against certain identity-based groups, like gay and bisexual men, or subject members of such groups to stigma or adverse consequences in the workplace, schools, or elsewhere? Do the policies consistently impose similar eligibility standards for similar high-risk behavior, or do they burden some groups more than others?

The Six Elements of a Safe and Effective Blood Donation Policy:

Decreased risk to recipients

Objective risk factors

Non-discriminatory impact

Awareness-raising

Technology-driven procedures

Expansion of donor pool

4. Awareness-raising of HIV prevention and transmission risks

- Goal: Donor eligibility policies, as well as materials and information provided to prospective donors, should contain accurate information about the underlying rationales for each eligibility criterion. The blood donation experience should provide all prospective and actual donors accurate and up-to-date information about risk factors, safer sex practices, the relative risks associated with different sexual practices, and the ways in which HIV and other transmissible diseases can be contracted and spread. No policy should reinforce outdated or inaccurate information about HIV or give a false sense of security to non-MSM and/or heterosexual donors who engage in high-risk sexual practices.
- Inquiry: Do donor education materials and targeted screening questions promote an accurate understanding of HIV transmission/testing to prospective donors, or do they reinforce stereotypes or outdated information?

5. Technology-driven donor screening and blood screening procedures

- Goal: Donor screening and post-donation blood screening procedures should reflect the latest technology for testing blood for HIV and other communicable diseases, and should be periodically revisited to tailor donor eligibility to actual risk of testing error based on current technological advancements.
- Inquiry: Are current policies based on the most up-to-date technology for testing prospective donors for HIV and other conditions and testing donated blood before it is used? Can current or future testing technology effectively eliminate the risk of accidental transmission of donated blood carrying HIV and, if so, can pre-donation restrictions on donor eligibility be relaxed?

6. Expansion of safe, eligible blood donor pool

- Goal: Federal policy should ensure an adequate supply of blood at all times and avoid blood shortages during periods of high demand by increasing the pool of safe and eligible blood donors, and by promoting regular, lifelong blood donation by individual donors.
- Inquiry: Does the policy ensure an adequate supply of blood at all times and reduce the risk of shortages at times of need, including during natural disasters and regional or national emergencies? Does the policy encourage first-time donations from young donors who are likely to become lifelong donors?

Any effective blood donation policy should contain the six elements of the **D.O.N.A.T.E.** framework, which GMHC views as a useful tool for reviewing the problems with current policy and assessing the effectiveness and viability of potential reforms.

WHY THE CURRENT POLICY FAILS

Evaluating the current blood donation policy in light of the criteria described above, it is clear that although the current policy may result in an acceptable quantity of blood at an acceptable risk level for HIV transmission, the policy fails to promote many objectives that could lead to a more comprehensive blood donation policy from a public health perspective. This section analyzes the current blood donation policy, not merely the blood donation policy as it applies to MSM, in light of the criteria set forth above.

- **Decreased Risk of HIV Transmission?**

Although completely eliminating the risk of HIV transmission through the blood supply may not be possible,[89] the FDA has stated that it will only consider a policy change in the event that any new approach assures "that blood recipients are not placed at an increased risk of HIV or other transfusion transmitted diseases."[90] Given this statement, in conjunction with the FDA's guidance to the industry adopting the Donor History Questionnaire as an acceptable screening mechanism for blood donors, it can be concluded that the level of risk of HIV infection through the blood supply has been deemed acceptable by those responsible for promulgating the policy. However, the current policy still carries the risk of HIV infection from a number of sources.

One source of potential risk to the blood supply is presented by non-MSM HIV-positive individuals that are not currently screened out under the current Donor History Questionnaire. Another source of potential risk is presented by HIV-positive individuals who donate blood by giving false or inaccurate answers to the donor history questionnaire. Individuals may provide false answers about their sexual history for a variety of reasons, including disagreement with the policy,[91] incorrect comprehension of the scope of certain questions (e.g., interpreting "sexual activity" with another man to be limited to anal sex rather than inclusive of all sexual practices), lack of knowledge about a sexual partner's HIV status or sexual history, or failure to remember relevant events from the past. Therefore, although the current policy carries an acceptable risk of HIV infection, there still may be ways to increase safety by eliminating or reducing the risk that exists under the current policy.

- **Objective Risk Factors?**

Although the current policy purports to be based upon "behavior-based" deferrals, the Questionnaire does not ask particular questions about an individual's sexual or medical history that would be directly relevant in assessing one's risk of being HIV-positive. For example, the policy currently fails to take into account the varying level of risk of HIV infection posed by different sexual practices, and does not inquire about the nature of a potential donor's prior practices.[92] Similarly, the current Questionnaire does not address a potential donor's consistent and proper condom use, universally agreed to be highly effective in preventing HIV transmission through all types of sexual activity,[93] number of sexual partners, or frequency of sexual contact with anonymous partners.[94] This means that gay men who always practice safer sex, or who are in monogamous relationships with partners who are HIV negative, are permanently excluded from eligibility to donate blood.

Additionally, the current policy is inconsistent in its deferral policies towards MSM as opposed to those for other donor groups. For example, the Questionnaire asks each prospective donor, "In the past 12 months have you had sexual contact with

anyone who has HIV/AIDS or has had a positive test for HIV/AIDS?" If the person answers "yes," they are deferred from donating blood on that date, but not permanently. The Questionnaire does not ask whether the individual has *ever* had sex with an HIV-positive individual; thus, someone who knowingly had sexual contact with an HIV-positive individual as recently as 12 months and one day ago could permissibly donate blood, whereas any man who has ever had sex with a man since 1977, regardless of the sexual partner's HIV status, would be permanently barred from donating blood.[95] Similar one-year deferrals apply to individuals who have had sexual contact in the last 12 months with commercial sex workers, intravenous drug users, and individuals in other risk groups.

- **Non-Discriminatory Impact?**

Although the FDA has long stated that its current blood donation policy is not intended to discriminate against potential donors on the basis of sexual orientation, the policy nevertheless operates as a *de facto* ban against nearly all gay and bisexual men. Regardless of the FDA's intent, in practice the policy excludes even those gay and bisexual men who pose no risk to the blood supply, while permitting non-MSM donors who may have engaged in high-risk sexual practices to donate blood. This discrepancy is inherently discriminatory against gay and bisexual men.

Further, the FDA justifies its "behavior-based" policy of deferring MSM upon statistics indicating that MSM as a group have an HIV prevalence higher than the general population. However, consistent application of a policy that ties donor deferrals to group-based HIV statistics would also result in the deferral of individuals based upon any demographic characteristic identified with being at an elevated risk of HIV infection. For example, in 2007, 50% of new HIV cases were diagnosed in African Americans, and 54% of new cases were diagnosed in patients between 30 and 49 years old.[96] Neither group, however, is singled out for deferral—or even more exacting screening—by the Donor History Questionnaire.[97] Movement toward using objective risk factors would eliminate the inconsistent application of group-based deferrals, and result in the screening out of high-risk MSM and non-MSM individuals.

Additionally, because many blood donations drives occur in workplaces and schools, some gay and bisexual men may rightly feel uncomfortable declining to participate in a blood drive and/or apprehensive regarding the consequences of non-participation, such as being "outed" as gay or bisexual to classmates or coworkers, being subject to workplace harassment or adverse employment action, or generally being subject to criticism for not participating.

- **Awareness-Raising?**

As currently administered, the donor history questionnaire tends to reinforce outdated stereotypes about how HIV is spread, and dangerously downplays the risk of HIV infection faced by non-MSM individuals. Specifically, by failing to ask non-MSM donors whether they have engaged in high-risk sexual practices yet creating a blanket exclusion on the basis of same-sex sexual activity between men, the questionnaire and the overall donation process may unintentionally suggest that high-risk sex between men and women is "safer" than any sex between two men. Further, the current policy misses the opportunity to reinforce information regarding safer-sex practices to this donor community. Moreover, because many gay men are aware of the policy and self-defer without ever participating in a blood drive, the

policy misses the opportunity to serve an educational function to gay and bisexual men about the differences between low-risk and high-risk sexual practices as well.

- **Technology-Driven Policies?**

The current MSM policy does not reflect technological advances in HIV testing and blood screening. Despite the many advances in both testing for HIV and controls on human based release error over the past 30 years, the policy in effect today is substantially unchanged from that originally proposed in the mid-1980s. Although technology has not completely eliminated the risk of HIV-infected blood entering the blood supply, the multiple and overlapping layers of protection to the blood supply offered by current testing practices has greatly minimized risk, justifying less restrictive policies for MSM donors than those now in place.

- **Expansion of the Donor Pool and Safe Blood Supply?**

A critical function of the FDA is to ensure an adequate supply of blood on an ongoing basis and in times of emergency. While the existing system generally ensures a sufficient blood supply, the FDA and the major blood bank organizations have warned of blood shortages and potentially insufficient supplies of blood during large-scale disasters. As the Red Cross states on its website, "[a]pproximately 38 percent of the population is eligible to donate blood" and "[o]nly five percent of the eligible population in the United States donates blood."[98] The MSM ban unnecessarily reduces the number of individuals who can donate blood—as well as the number of currently eligible donors who choose to participate. For example, as described above, opposition to the discriminatory nature of the MSM policy has resulted in student-led boycotts of blood drives held on college campuses, and at least one university suspended its sponsorship of a blood drive because it considered the MSM policy to violate its non-discrimination policies. Student comprise an important constituency of potential blood donors. By alienating young people, the current policy may contribute to shortages both in the near future and in years to come.

Conclusion

On balance, the FDA's current blood donation policy fails to satisfy the key public policy and public health goals assessed by the **D.O.N.A.T.E.** analysis. The next section explains why the introduction of less restrictive policies for MSM donors may actually improve the efficacy of the blood donation process while reducing the objectionable discrimination fueled by the current policy.

ASSESSING THE ALTERNATIVES

The shortcomings in the current policy as identified in the analysis above have been cited by public health professionals and advocates both in the United States and other countries as illuminating the critical need for reform. Using the **D.O.N.A.T.E.** framework, this section analyzes the most commonly proposed alternatives to a permanent deferral for MSM donors: (1) instituting a temporary deferral period of six months, one year, or five years for men who have had sex with another man; or (2) eliminating the permanent MSM ban and replacing it with eligibility criteria and screening procedures for *all* prospective donors based on objective risk factors.

ALTERNATIVE 1:

Institute a Temporary Deferral Period for MSM Donors

In the United States, the dialogue about reforming the MSM blood donation policy has focused primarily on replacing the current lifetime ban on men who have had sex with men even once since 1977 to a shorter deferral period. At the 2006 BPAC workshop, for example, one-year and five-year deferral periods were discussed.[99] As discussed above, most of the countries who have reformed their MSM policies have adopted such deferral periods. The country that most recently announced a shift from a permanent deferral to a one-year deferral, Sweden, considered but ultimately rejected a six-month deferral period.[100]

Under any of the temporary deferral periods, a prospective male donor's same-sex sexual activity outside of that deferral period would not automatically prevent him from giving blood. Unlike the current policy, in which a male who has ever had sex with a male since 1977 is *permanently* barred from donating blood, an individual prevented from donating blood on one occasion under a temporary deferral policy may become eligible to donate blood in the future if he has abstained from sexual activity with other men for the deferral period.

Five-year deferral period

Under a five-year deferral period, a prospective male blood donor would be deferred, or barred, from donating blood at any given time if he has had sex with another man at any time in the previous five years.

- **Decreased Risk of HIV Transmission?**

  A shift from a permanent deferral to a temporary five-year deferral is unlikely to increase the risk of HIV-infected blood inadvertently entering the blood supply. Five years is far longer than the window period for detecting HIV through post-donation tests under any presently used testing technology. Thus, the blood of a donor who contracted HIV more than five years ago, even if that donor is unaware of his HIV status, will be detected under the post-donation screening procedures and will not enter the blood supply.

  Additionally, the group of males who have not had sex with another male for over five years—which includes abstinent gay and bisexual men, as well as heterosexual-identified men with past same-sex experiences—may, as a group, be at an objectively lower risk of HIV infection than sexually active men who have sex with men.

Nevertheless, some risk still remains. The length of a five-year deferral period would exclude the large majority of gay and bisexual men from donating blood, and may, like the current policy, be viewed as unfair and encourage some men to lie about their sexual history and/or result in some men providing inaccurate information about their sexual history outside of the recent past. Any risk associated with lying and/or inaccurate information would remain whether under the current, more restrictive policy, or under a five-year deferral period.

- **Objective Risk Factors?**

  Like the existing policy, the five-year deferrals that have been considered treat MSM donors as a discrete group. A policy that merely replaced the Donor History Questionnaire question directed to male donors, "From 1977 to the present, have you had sexual contact with another male, even once?" with, "In the past five years, have you had sexual contact with another male, even once?" would continue to fail to distinguish between high-risk and low-risk same-sex sexual behavior. Because a large majority of gay and bisexual men have had sex in the last five years, such a policy would approximate a sexual identity-based ban similar in nature to the current lifetime deferral, rather than focusing on a donor's actual risk.

- **Non-Discriminatory Impact?**

  Although this policy would be less onerous for MSM donors than the current policy, it would still bar many or most gay and bisexual men from donating blood. Additionally, because the deferral would be five times longer than the one-year deferrals for a number of other high-risk groups, it would overly burden gay and bisexual men, regardless of their HIV status or risk of contracting HIV, while being under-inclusive as applied to high-risk groups, such as a donor who has had sex with someone known to have HIV (which is currently subject only to a one-year deferral).

- **Awareness-Raising?**

  By failing to ask direct questions about high-risk sexual behavior, and by overly burdening MSM donors relative to other risk groups, a five-year deferral is unlikely to promote awareness of the risk of HIV for non-MSM individuals or to significantly reduce stereotypes about gay and bisexual men.

- **Technology-Driven Policies?**

  A five-year deferral recognizes, to some degree, that blood donated outside a donor's window period can safely be screened prior to entering the blood supply or being provided to a blood donation recipient. Existing technology has shortened the window period under the most advanced procedures to a few days, and up to several months under other available methods; thus, the five-year deferral period would not closely align with recent technological advances.

- **Expansion of the Donor Pool and Safe Blood Supply?**

  This policy, by permitting some MSM donors to become eligible to donate blood, would expand the donor pool. Additionally, some non-MSM individuals who refuse to donate in protest of the discriminatory nature of

the current policy may reconsider donating for a policy considered fairer and less discriminatory than the one it would replace.

One-year deferral period

Under a one-year deferral period, a prospective male blood donor would be deferred from donating blood at any given time if he has had sex with another man at any time in the previous twelve months. After any 12-month period of abstinence from sex with other men, a gay or bisexual man would be eligible to donate blood.

A one-year deferral period for MSM donors would be consistent with current deferral periods for other high-risk groups, and would therefore be substantially less discriminatory against gay and bisexual men as a group.

- **Decreased Risk of HIV Transmission?**

  Existing data is inconclusive on the extent to which a one-year deferral period would increase risk, if at all. On the one hand, it would significantly increase the number of eligible MSM donors, some of whom might be HIV-positive and donate blood. On the other hand, although the number of units of HIV-positive blood being donated might increase, the risk that any such blood would ever be provided to a blood recipient is very small: the one-year period falls safely outside existing window periods, such that existing post-screening procedures will identify any infected units of blood that have been donated. Any negligible risk that post-donation procedures may fail would be identical to the risk for other, non-MSM HIV-positive donors who donate blood.

- **Objective Risk Factors?**

  Like the lifetime deferral and five-year deferral, a one-year deferral period for MSM donors, without targeted questions about high-risk behavior, would fail to distinguish between MSM donors at high-risk and those at low-risk of having or contracting HIV.

- **Non-Discriminatory Impact?**

  To date, the dialogue and debate over ending the permanent MSM deferral because of its discriminatory nature has focused on replacing it with a one-year ban, which would conform it with most other high-risk groups as identified on the Donor History Questionnaire. Given the consistency with other groups, the policy would be substantially less discriminatory against gay and bisexual men as a group, since only sexually active MSM would be deferred from donating.

- **Awareness-Raising?**

  A policy viewed as consistent with other risk groups would reduce the likelihood that the blood donation policy would promote stereotypes about gay and bisexual men or the myth that HIV is a "gay" disease. Unless the policy was tied to screening procedures linked to objective risk factors like recent history of unprotected sex or multiple sex partners, the policy would miss the opportunity to promote information about effective HIV prevention practices to MSM and non-MSM donors.

- **Technology-Driven Policies?**

  Existing post-donation screening procedures detect most HIV-infected units within days or weeks of a donor's infection. Because HIV detection time varies by donor, some HIV will not be detected for up to several months. A one-year deferral period would add a cushion of time to the known window

periods and, of the options most frequently considered to replace the existing policy, would most closely track existing science.

- **Expansion of the Donor Pool and Safe Blood Supply?**

  A one-year deferral period would enable many previously ineligible men to donate blood, and allow even presently deferred men the possibility of donating in the future after a one-year period of abstinence from sex with other men. At any point in time, however, the deferral would still bar many healthy, sexually active gay and bisexual men from donating blood. The one-year deferral would also substantially reduce objections from groups opposing the current policy, notably high school and college students, since the deferral would be linked to recent sexual history rather than a broadly over-inclusive category of men who ever had sex with men in the last 33 years, which essentially approximates gay or bisexual sexual identity rather than high-risk behavior. Consequently, blood drives at educational institutions would become more common, and many more non-MSM individuals might consider donating blood; a spike of young first-time donors would likely create a generation of regular donors. Thus, the increase of both MSM and non-MSM donors would expand the donor pool.

Six-month deferral period

Under a six-month deferral period, a prospective male blood donor would be deferred from donating blood at any given time if he has had sex with another man at any time in the previous six months. After any six-month period of abstinence from sex with other men, a gay or bisexual man would be eligible to donate blood.

- **Decreased Risk of HIV Transmission?**

  Under existing data, there is no meaningful difference between a deferral period of six months or one year: both deferral periods fall outside the window period during which HIV may be undetectable in donated blood. The one-year deferral period adds a cushion period to even a cautiously defined window period, but all or virtually all HIV will be detected within six months of infection.[101] Thus, increased risk would likely not be associated with a donor's HIV status but rather with the risks associated with human release errors. More research is necessary to determine whether the increase in the donor pool associated with a relatively short deferral period like a six-month deferral would increase risk of HIV or other infections.

- **Objective Risk Factors?**

  As with any permanent or temporary deferral period defined solely in terms of whether a prospective male donor has had sex with another man within the designated time period, even a six-month deferral would fail to take account of an individual's objective risk based on specific engagement in high-risk or low-risk sexual practices. A six-month deferral period would, however, be the most narrowly tailored to known window periods and, importantly, take into account that donor screening procedures should focus questions on a donor's recent past rather than overall sexual history, which promotes accurate answers and is most relevant to the blood donation process.

The current blood donation policy fails to distinguish between MSM at high, low, and no risk of HIV infection: A gay man who engages in protected sex with his HIV-negative partner is at no risk of HIV infection, whereas another gay man who has frequent unprotected anal sex with multiple partners is at substantially elevated risk of HIV.

- **Non-Discriminatory Impact?**

  A six-month deferral would enable many gay and bisexual men to donate blood at some point in their lives, if not on a regular basis, although it would continue to disfavor sexually active MSM who engage in low-risk sexual practices like protected sex or sex with one partner in a monogamous relationship. Because the deferral would be based exclusively on recent behavior, it would not amount to a total bar on donations by gay and bisexual men, as the current policy and longer deferral periods effectively accomplish.

  It should be noted that a six-month period would be shorter than deferrals for many other risk groups defined by sexual behavior, such that it could be argued that such a policy would actually *favor* MSM donors relative to other groups as defined by known levels of risk.

- **Awareness-Raising?**

  Of the various deferral periods discussed in this section, a six-month deferral period would best accomplish the goal of informing prospective donors and the general public that MSM behavior should not automatically disqualify an individual from donating blood. Without linking the policy to questions about specific low-risk and high-risk sexual practices, however, it would fail to provide donors information about safer sexual practices and HIV prevention.

- **Technology-Driven Policies?**

  A six-month deferral would best reflect contemporary information about the maximum length of a post-HIV infection window period and the ability of current testing methods to detect HIV in donated blood.

- **Expansion of the Donor Pool and Safe Blood Supply?**

  A six-month deferral would make many previously ineligible men eligible to donate, or at some point become eligible to donate, and would likely expand the eligible donor pool significantly. If the policy was broadly perceived to minimize the discriminatory nature of the current ban, it would also promote donations by non-MSM donors who currently refuse to donate or are unable to do so if their schools, employers, or communities do not hold blood drives in protest of the current policy.

Summary of Temporary Deferral Periods

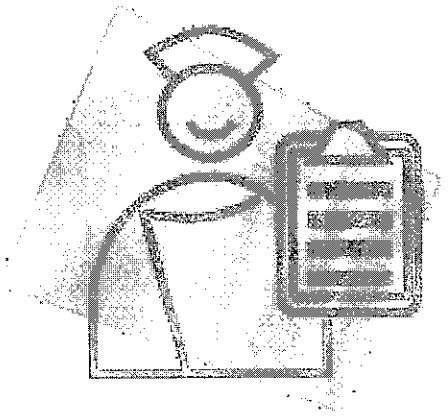
Implementation of a temporary deferral period of any length would pose virtually no risk of introducing HIV-infected blood into the blood supply, while improving the ability of some number of previously ineligible gay and bisexual men to become blood donors. Existing data suggests there is little marginal benefit to blood safety gained from longer deferral periods, as any HIV-infected blood donated outside the window period, which by the most conservative estimates is no longer than six months, will be detected by post-donation screening procedures. Thus, risk reduction and equality would be best promoted by a deferral period no longer than the most cautiously defined window period, which may continue to shorten as testing technology advances.

The critical problem with any temporary deferral period for MSM donors is that it continues to treat men who have sex with men as a singular class of people, with a

uniform risk of HIV infection, rather than a population within which individuals or certain subgroups have varying levels of risk based on sexual practices and other risk behaviors. A gay man who consistently uses condoms during sex with a monogamous partner who is HIV-negative, for example, will be at no risk of HIV infection; another gay man who has frequent unprotected anal sex with multiple partners, in contrast, will be at substantially elevated risk relative to the overall MSM population and the population at large. As long as a blood donation policy fails to account for or distinguish between such behavior-based groups, the policy will disproportionately burden gay and bisexual men relative to the rest of the population.

ALTERNATIVE 2:

Eliminate MSM Ban by Revising and Conforming Deferral Periods for All Prospective Donors Based on Objective Risk Factors



An alternative to a temporary deferral period limited to MSM donors would be to screen all donors for high-risk sexual practices. Such an approach would be more narrowly tailored to screening donors based on actual risk, rather than over-inclusive group-based classifications like the MSM ban, which necessarily prevent many otherwise safe and eligible individuals from donating blood.

As described above, some countries ask all donors questions about recent high-risk sexual practices, such as whether the donor has engaged in unprotected sex or has recently had sex with a new partner or multiple partners, and defer individuals who answer "yes" to these questions for some period of time, regardless of the sex of the prospective donor and/or his or her sexual partner(s).

Such a screening approach could take several forms. First, a donor history screening protocol could be gender-neutral, asking all donors about high-risk sexual practices without specific reference to same-sex sexual behavior. A second approach would identify individuals from high-risk groups and ask specific questions targeted to gauge those individuals' specific risk level. For example, an individual identified as MSM could be asked a series of additional questions about whether he has engaged in unprotected anal sex, sex with multiple partners, sex with an HIV-positive person or person of unknown HIV status, and other high-risk practices, answers to which might qualify or disqualify the donor from donating on that date. Either the first or second approach could be tied to a deferral period taking relevant window periods into account.

- **Decreased Risk of Transmission?**

  To date, most of the discourse in the United States about reforming the MSM blood donation policy has focused on instituting a temporary deferral period to replace the lifetime ban. Consequently, the various studies cited by the FDA and experts at the 2006 BPAC workshop have focused on the relative risks associated with temporary deferral periods. The limited discussion about identifying high-risk and low-risk sub-groups within the MSM population at the 2006 workshop indicated that there has been little research to date on designing a targeted screening process.

  However, some studies in related contexts, such as sperm donation safety, have offered promise that a detailed screening process that asks multi-level questions about an individual's sexual history greatly minimizes the risk that

an individual with HIV would be permitted to donate.[102] Further research into such a screening process should evaluate the usefulness of a more detailed questionnaire in identifying low-risk individuals, taking into consideration whether asking more detailed questions about an individual's sexual history is more or less likely to result in truthful responses.

- **Objective Risk Factors?**

  An appropriately designed screening process would inquire about and consider the various risk factors that establish an individual donor's level of risk. Such a screening system could weight membership in a high-risk group like MSM more heavily than groups with a historically lower risk, while still permitting an individual to demonstrate through his responses that his or her actual risk is lower (or higher) than the overall level of risk for the group.

- **Non-Discriminatory Impact?**

  This approach would assess each prospective donor's particular level of risk and either permit that individual to donate or defer him or her based on that assessment. Of all the approaches, this is the least discriminatory because it does not deny any individual the ability to donate blood on the basis of sexual identity.

- **Awareness-Raising?**

  A screening procedure that distinguishes between low-risk and high-risk sexual practices by both MSM individuals and others, accompanied by materials explaining those risks and their relation to eligibility to donate blood, would advance a critical public health interest in educating all prospective donors, regardless of their sexual orientation, about HIV prevention generally and in the context of the blood donation process specifically. To the extent that exposure to such questions, informational materials, and pre-donation consultations encourages all individuals to engage in healthier, less risky practices, the policy will result in a safer donor pool overall. Such a policy would also fill the glaring hole remaining in any permanent or temporary deferral policy that implies, incorrectly, that a non-MSM individual is inherently safer from HIV and other transmissible diseases than an MSM individual, even if the former engages in high-risk behavior.

- **Technology-Driven Policies?**

  An objective screening process should be accompanied with a sufficient deferral period for those prospective donors determined to be at high risk to account for testing window periods. Additional levels of post-testing protections for donors determined to be of moderate risk would also employ technology to expand the donor pool without sacrificing safety to blood donor recipients.

- **Expansion of the Donor Pool and Blood Supply?**

  A purely objective policy based on individual donors' specific risk levels would maximize the number of healthy donors eligible to donate, while decreasing the number of presently eligible donors who might also donate blood after being infected with HIV. More data is required to determine

whether the expansion of one group of donors (MSM donors) would outweigh any reduction in the other (non-MSM high-risk donors not currently deferred under existing policy). Since an objective policy would reduce any appearance of unfair discrimination on the basis of sexual orientation, this policy would also increase the number of non-MSM donors who do not currently donate in protest of the policy.

Summary of Risk-Based Screening Procedures

A policy in which donor screening is objective and screens each donor for high-risk behavior is the best approach for increasing the eligibility of healthy MSM donors to donate blood and to improve and ensure consistency in the policy's application to all groups. The current Donor History Questionnaire and screening procedures, the net result of nearly three decades of gradual efforts to adopt screening procedures that advance blood safety focusing on different risk factors, has become a patchwork quilt of individual (and sometimes grossly inconsistent) policies for different groups. Adopting objective risk-based criteria as the basis for a revised screening process would offer the FDA and the blood bank community the opportunity to come up with a singular set of criteria applicable to all donors. Even if MSM history is one relevant factor in an objective analysis of a prospective donor's eligibility, it need not be a decisive disqualifying factor if a meaningful, easily administered set of questions could determine that the donor posed no risk to the blood supply.

CONCLUSIONS AND RECOMMENDATIONS

Each of the above approaches offers both benefits and drawbacks relative to the current policy. Thus, some combination of these approaches may best ensure a safe, sufficient blood supply and a fair, consistent policy for all donors that does not unfairly or unjustifiably discriminate against gay and bisexual men.

Based on the **D.O.N.A.T.E.** analysis for the current FDA policy and the various alternative approaches, we conclude:

- **The current policy fails to achieve its own goal of ensuring a sufficient donor pool and adequate blood supply.** First, it excludes many potential donors who would safely donate blood based on criteria that are over-inclusive criteria as applied to MSM donors and under-inclusive as applied to other groups at elevated risk of HIV infection, including, among others, women who have unprotected sex with men, men and women with a history of sex with an HIV-positive person longer than one year ago, and certain racial minority groups. Second, the discriminatory nature of the policy has repelled many non-MSM potential donors and depressed the number of blood drives at educational institutions, thus losing many young people who may never become lifelong donors.

- **Neither the current policy nor any of the proposed temporary deferral policies adequately distinguish between low-risk and high-risk sexual practices by MSM donors or others.** Any policy in which a male donor is deferred because he answers that he has "had sex" with another man during a certain time period, whether since 1977, in the last five years, in the last one year, or otherwise, fails to address the fact that both MSM and non-MSM donors engage in low-risk sexual behavior (e.g., protected sex, monogamous sex with an HIV-negative partner, oral sex) and high-risk sexual behavior (e.g., unprotected anal sex, sex with multiple partners, sex with new partners, sex with HIV-positive partners or partners of unknown HIV status). Individuals who consistently practice low-risk sex pose little threat to the blood supply, whereas those who have recently and/or regularly engaged in high-risk practices pose a significant risk regardless of the sex of their partner(s). Using screening procedures to identify whether a prospective donor is low-risk or high-risk would likely yield more accurate results, minimize unjustified discrimination against gay and bisexual men, and play a valuable role in educating prospective donors about their own HIV risk and the relative risk of different sexual behavior.

- **Post-donation blood screening reduces risk for all blood donated outside an HIV-positive donor's window period.** As technology has evolved, modern blood testing approaches can now detect HIV within days of an infection; older, less sensitive technologies still in use can usually detect HIV within several weeks. Under any technology currently used, all HIV can be detected within months of an infection. All donated blood is tested several times using redundant procedures, and existing research shows it is nearly 100% effective in screening out blood with HIV or other transmissible infections. Thus, a window period must be built in to any effective screening procedure, such that a donor who has engaged in any objectively defined high-risk behavior within the several months prior to a donation date should be deferred. Deferral periods substantially in excess of known window periods, however, provide little

additional value to ensuring disease detection, but increase the potential for unnecessary discrimination against groups subject to those deferrals.

- **More research is needed to determine whether a screening process based on objective risk factors would increase or lower risk relative to the current policy.** To date, most research has focused on one- or five-year deferral periods that would continue to treat MSM donors and non-MSM donors as monolithic groups with equal risk across each group, rather than sets of sub-groups with varying levels of risk based on actual behavior. Additional data demonstrating that the latter approach would maintain or reduce current risk levels would be helpful in convincing the FDA to replace the current policy.

Based on these conclusions, we make the following recommendations:

- **Screen all donors for high-risk behavior.** The Donor History Questionnaire should be modified to screen all potential donors for high-risk behavior.
- **Only defer prospective donors determined to be at high-risk.** The permanent deferral for men who have had sex with men since 1977 should be replaced with a policy that defers high-risk MSMs, as defined by recent sexual history, for a period of time carefully tailored to known window periods, while permitting low-risk MSM donors to donate blood. An MSM donor's risk should not be measured solely in terms of the date of the donor's sexual encounters, but also in terms of whether the donor engaged in low-risk sexual practices like condom usage or monogamy. The highest-risk members of the MSM population, such as those who fall into several risk categories (e.g., IV drug users, commercial sex workers) or who report unprotected sex with partner(s) with HIV or with unknown HIV status, may justifiably be subject to lengthy or permanent deferrals.

The permanent deferral for men who have had sex with men since 1977 should be replaced with a policy that defers *high-risk* MSMs, as defined by recent sexual history, for a period of time carefully tailored to known window periods, while permitting *low-risk* MSM donors to donate blood.

- **Expand existing research to support change.** The FDA, blood bank community, advocates, and scholars should identify data needed to support changes to the donor screening policy, and undertake that research. The FDA's primary source of reluctance to change is what it describes as a lack of data to support, or reject, known alternatives. The problem is not that data shows the current policy is the best alternative, but that approaches likely to improve safety, effectiveness, and fairness simply have not been studied sufficiently. Studies into risk of testing error under various approaches, behavioral and psycho-social studies into effective screening procedures, and ongoing work in advancing HIV screening procedures will remain important in advocating for change.
- **Leverage the power of coalitions to support change.** At the present time, all three major American blood bank operators, HIV/AIDS and LGBT rights advocacy groups, many members of the medical and scientific communities, and even decision makers at the FDA itself view the current policy as insufficient to meet future demands for blood and needlessly discriminatory against gay and bisexual men. The emergence of this consensus in recent years provides a previously unavailable opportunity to advocate for meaningful and effective reforms through various means.

- **Participate in all regulatory proceedings related to blood donation policies.** When the FDA decides to take action on a rule or publish guidance affecting the MSM policy, advocacy organizations must be prepared to participate in the public discussion. Two opportunities for such public discussion would arise if: (1) the FDA institutes further action on its proposed rule for blood products, Proposed Rule 21 C.F.R. § 630.10, for which it solicited public comment in 2008 but has yet to take final action, or (2) any future workshops or meetings convened by BPAC to discuss and/or revise the policy.

QUESTIONS FOR FUTURE RESEARCH

Despite the growing consensus that the MSM ban is overbroad in its scope and under-inclusive in terms of screening prospective blood donors at actual risk of being infected with HIV, the FDA's resistance to change has centered largely on its view that sufficient data does not yet exist to support a less restrictive approach to MSM donors. The FDA website states, however, that the agency is open to change should data demonstrate that permitting some number of gay and bisexual men to become blood donors would not increase the overall risk to the blood supply.

This report's conclusion that sufficient evidence supports an immediate change is based on the existing body of scientific and public health research. Nevertheless, the development of additional research supporting a modification of the MSM policy would be helpful to advocating for the necessary reforms before the FDA.

To that end, we propose the following questions for further study by public policy, public health, and medical experts:

- **What are the risk levels associated with subgroups of the MSM population, and would permitting low- or moderate-risk MSM pose any significant risk to the blood supply?**

  Some portion of the MSM population—for example, men who have frequent unprotected anal sex, engage in unprotected sex with multiple and/or anonymous partners, or who use illegal drugs—are unquestionably at the highest risk of HIV and may reasonably be excluded from donating blood. In contrast, however, gay and bisexual men who always engage in safer sex practices – who, for example, consistently use condoms, have sex only in monogamous relationships with HIV-negative partners, and do not practice anal sex – are unlikely to be at significant risk of having HIV. If risk levels associated with the latter group are comparable to or lower than the risk associated with the general population and other risk groups screened by the blood donor questionnaire, excluding such men from the donor pool has no reasonable purpose.

- **Does the fact that gay men, as a group, are more likely to get regular tests for HIV than other men reduce the risk in ways not captured under existing risk models?**

  Because of the population's history with HIV/AIDS, gay and bisexual men are more likely to receive regular HIV tests as part of their routine medical care than others. Does it follow that gay and bisexual men are more likely to know their HIV status, and to self-exclude from blood donation if they are HIV positive? If so, is this self-screening adequately reflected in the existing risk models employed by the FDA to justify its current policy?

- **In what ways can donor screening protocols identify individuals from both the MSM and non-MSM populations that are at unacceptably high risk of donating blood while HIV positive?**

  There is little existing research on the effectiveness of more targeted screening procedures in identifying prospective blood donors at high risk of HIV. Some studies, however, suggest that questions targeted to a prospective donor's recent sexual history and other risk behavior may be effective. There will be great value in further research into screening procedures—whether in the form

of a questionnaire or other means—that can differentiate high-risk and low-risk donors at the blood donation site. Among other issues, research regarding such screening procedures should consider privacy concerns, the likelihood such screening will elicit truthful responses, time efficiency concerns, and the potential for unintended consequences, such as discouraging prospective donors from participation in blood donation.

- **What policies, instead of or in addition to donor screening policies, can the FDA implement or enforce that would reduce the risk of HIV entering the blood supply?**

  At the present time, the most significant point of risk to the blood supply is of post-donation blood screening procedures failing to exclude from the blood supply those. units of donated blood infected with HIV. Because donated blood typically goes through several levels of redundant screening, this risk is very small; nevertheless, there is some evidence that the risk of error is somewhat greater in hospitals than in blood bank settings. What policies or procedures could the FDA or the medical community implement that would reduce the higher risk in hospitals? Are there other sources of post-donation error that can be satisfactorily addressed in a way that would reduce the need for overly inclusive pre-donation donor screening procedures?

- **Are the less restrictive policies toward MSM donors recently implemented in other countries effective in maintaining or reducing risk to the blood supply in those countries?**

  The MSM policies implemented in other countries are too recent for a body of data on their effectiveness to exist. Careful study of these countries' policies—and similar ones that may be adopted in the years ahead—will be helpful in advocating for similar changes in the United States.

APPENDIX A: DONOR HISTORY QUESTIONNAIRE

Full-Length Donor History Questionnaire: Version 1.1

	Yes	No	
Are you			
1. Feeling healthy and well today?	❑	❑	
2. Currently taking an antibiotic?	❑	❑	
3. Currently taking any other medication for an infection?	❑	❑	
Please read the Medication Deferral List.			
4. Are you now taking or have you ever taken any medications on the Medication Deferral List?	❑	❑	
5. Have you read the educational materials?	❑	❑	
In the past **48 hours**			
6. Have you taken aspirin or anything that has aspirin in it?	❑	❑	
In the past **6 weeks**			
7. Female donors: Have you been pregnant or are you pregnant now? (Males: check "I am male.")	❑	❑	❑ I am male
In the past **8 weeks have you**			
8. Donated blood, platelets or plasma?	❑	❑	
9. Had any vaccinations or other shots?	❑	❑	
10. Had contact with someone who had a smallpox vaccination?	❑	❑	
In the past **16 weeks**			
11. Have you donated a double unit of red cells using an apheresis machine?	❑	❑	
In the past 12 **months have you**			
12. Had a blood transfusion?	❑	❑	
13. Had a transplant such as organ, tissue, or bone marrow?	❑	❑	
14. Had a graft such as bone or skin?	❑	❑	
15. Come into contact with someone else's blood?	❑	❑	
16. Had an accidental needle-stick?	❑	❑	
17. Had sexual contact with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?	❑	❑	
18. Had sexual contact with a prostitute or anyone else who takes money or drugs or other payment for sex?	❑	❑	
19. Had sexual contact with anyone who has ever used needles to take drugs or steroids, or anything not prescribed by their doctor?	❑	❑	
20. Had sexual contact with anyone who has hemophilia or has used clotting factor concentrates?	❑	❑	

Full-Length Donor History Questionnaire: Version 1.1

	Yes	No	
21. Female donors: Had sexual contact with a male who has ever had sexual contact with another male? (Males: check "I am male.")	❑	❑	❑ I am male
22. Had sexual contact with a person who has hepatitis?	❑	❑	
23. Lived with a person who has hepatitis?	❑	❑	
24. Had a tattoo?	❑	❑	
25. Had ear or body piercing?	❑	❑	
26. Had or been treated for syphilis or gonorrhea?	❑	❑	
27. Been in juvenile detention, lockup, jail, or prison for more than 72 hours?	❑	❑	
In the past **three years** have you			
28. Been outside the United States or Canada?	❑	❑	
From **1980 through 1996**,			
29. Did you spend time that adds up to three (3) months or more in the United Kingdom? (Review list of countries in the UK)	❑	❑	
30. Were you a member of the U.S. military, a civilian military employee, or a dependent of a member of the U.S. military?	❑	❑	
From **1980 to the present**, did you			
31. Spend time that adds up to five (5) years or more in Europe? (Review list of countries in Europe.)	❑	❑	
32. Receive a blood transfusion in the United Kingdom? (Review list of countries in the UK.)	❑	❑	
From **1977 to the present**, have you			
33. Received money, drugs, or other payment for sex?	❑	❑	
34. Male donors: had sexual contact with another male, even once? (Females: check "I am female.")	❑	❑	❑ I am female
Have you **EVER**			
35. Had a positive test for the HIV/AIDS virus?	❑	❑	
36. Used needles to take drugs, steroids, or anything not prescribed by your doctor?	❑	❑	
37. Used clotting factor concentrates?	❑	❑	
38. Had hepatitis?	❑	❑	
39. Had malaria?	❑	❑	
40. Had Chagas' disease?	❑	❑	
41. Had babesiosis?	❑	❑	
42. Received a dura mater (or brain covering) graft?	❑	❑	
43. Had any type of cancer, including leukemia?	❑	❑	
44. Had any problems with your heart or lungs?	❑	❑	
45. Had a bleeding condition or a blood disease?	❑	❑	
46. Had sexual contact with anyone who was born in or lived in Africa?	❑	❑	
47. Been in Africa?	❑	❑	

Full-Length Donor History Questionnaire: Version 1.1

	Yes	No
48. Have any of your relatives had Creutzfeldt-Jakob disease?		
Use this area for additional questions		

APPENDIX B: ROSTER OF THE BLOOD PRODUCTS ADVISORY COMMITTEE

The current BPAC Charter, which is set to expire on May 13, 2010 unless renewed by appropriate action, provides for up to 18 committee members consisting of 17 voting members and one nonvoting industry representative. The current committee roster lists ten members—nine voting members and one nonvoting industry representative—indicating that up to eight vacancies currently exist, including the Committee Chairman.

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NOTES

[1] FDA, *Vaccines, Blood & Biologics, Regulation of the Blood Supply*, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/RegulationoftheBloodSupply/default.htm (last accessed Jan. 12, 2010).

[2] *See* FDA, *Vaccines, Blood & Biologics, Blood Donations from Men Who Have Sex with Other Men, Questions and Answers*, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood/ucm108186.htm (last accessed Jan. 12, 2010) [hereinafter MSM Q & A].

[3] *See* 21 C.F.R. §§ 640.3(b)(6), 640.63(c)(9) (2009).

[4] *See* 21 C.F.R. § 640.3(a).

[5] *See* 21 C.F.R. §§ 640.3, 640.63.

[6] *See* FDA, FDA STATEMENT: REVISED RECOMMENDATIONS FOR THE PREVENTION OF HUMAN IMMUNODEFICIENCY VIRUS (HIV) TRANSMISSION BY BLOOD AND BLOOD PRODUCTS (Apr. 1992), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/OtherRecommendationsforManufacturers/MemorandumtoBloodEstablishments/UCM062834.pdf (last accessed Jan. 12, 2010) [hereinafter REVISED RECOMMENDATIONS].

[7] *See* FDA, GUIDANCE FOR INDUSTRY: IMPLEMENTATION OF ACCEPTABLE FULL-LENGTH DONOR HISTORY QUESTIONNAIRE AND ACCOMPANYING MATERIALS FOR USE IN SCREENING DONORS OF BLOOD AND BLOOD COMPONENTS (2006), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm062915.pdf (last accessed Jan. 12, 2010) [hereinafter GUIDANCE FOR INDUSTRY].

[8] *See id.*

[9] *Id.* AABB has a more recent and revised version of the Questionnaire, which has not yet been approved by the FDA, on its website at http://www.aabb.org/Content/Donate_Blood/Donor_History_Questionnaires/AABB_Blood_Donor_History_Questionnaire/ (follow links under heading labeled "Blood Donor History Questionnaire Version 1.2 February 2007") (last accessed Jan. 12, 2010).

[10] AABB DONOR HIST. TASK FORCE, BLOOD DONOR HISTORY QUESTIONNAIRE VERSION 1.1: FULL-LENGTH DONOR HISTORY QUESTIONNAIRE 2 (2005), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/UCM164190.pdf (last accessed Jan. 12, 2010) [hereinafter QUESTIONNAIRE].

[11] AABB DONOR HIST. TASK FORCE, BLOOD DONOR EDUCATIONAL MATERIALS: MAKING YOUR BLOOD DONATION SAFE (2005), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/UCM164194 (last accessed Jan. 12, 2010).

[12] *See* AABB DONOR HIST. TASK FORCE, BLOOD DONOR HISTORY QUESTIONNAIRE VERSION 1.1: USER BROCHURE FLOWCHARTS 40 (2005), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/UCM164193.pdf (last accessed Jan. 12, 2010) [hereinafter QUESTIONNAIRE FLOWCHART].

[13] COMM. TO STUDY HIV TRANSMISSION THROUGH BLOOD & BLOOD PRODS., INST. OF MED., HIV & THE BLOOD SUPPLY: AN ANALYSIS OF CRISIS DECISIONMAKING 60-66 (Lauren D. Leveton et al. eds., 1995) [hereinafter HIV & THE BLOOD SUPPLY].

[14] *Id.* at 60.

[15] *Id.* at 66.

[16] *Disease Stirs Fear on Blood Supply*, N.Y. TIMES, Jan. 6, 1983, at B17.

[17] HIV & THE BLOOD SUPPLY, *supra* note 13, at 107-09.

[18] *See id.* at 107-09.

[19] *Id.* at 107.

[20] *See id.*

[21] *See* Steven R. Salbu, *AIDS and the Blood Supply: An Analysis of Law, Regulation, and Public Policy*, 74 WASH. U. L.Q. 913, 947-50 (1996), *cited in* Michael Belli, *The Constitutionality of the "Men Who Have Sex with Men" Blood Donor Exclusion Policy*, 4 J.L. SOC'Y 315, 339 (2003).

[22]CDC, *Update: Revised Public Health Service Definition of Persons Who Should Refrain from Donating Blood and Plasma -- United States*, 34 MORBIDITY & MORTALITY WKLY. REP. 547-48 (September 6, 1985), *available at* http://www.cdc.gov/mmwr/preview/mmwrhtml/00000606.htm (last accessed Feb. 22, 2010).

[23] *See id.*

[24] REVISED RECOMMENDATIONS, *supra* note 6, at 3.

[25] *See* GUIDANCE FOR INDUSTRY, *supra* note 7.

[26] MSM Q & A, *supra* note 2.

[27] *Id.*

[28] HIV & BLOOD SUPPLY, *supra* note 13, at 107; REVISED RECOMMENDATIONS, *supra* note 6.

[29] *See* Belli, *supra* note 21, at 339-42.

[30] *Id.* Belli notes that although national/geographic exclusions are justified by findings that heterosexual activity has a "major role" in the transmission of HIV in those areas, certain of these deferrals have been lifted with the improvement of testing methods rather than as a result of finding that heterosexual activity no longer played a "major role" in the transmission of HIV. *Id.* at 340.

[31] QUESTIONNAIRE FLOWCHART, *supra* note 12, at 52-53.

[32] *See, e.g.*, Editorial, *Straight Talk: Red Cross Needs to Re-Evaluate Blood Donor Screening Questions*, COLLEGIAN, Jan. 27, 1997, *available at* http://www.collegian.psu.edu/archive/1997/01/01-27-97tdc/01-27-97d07-001.htm (last accessed Jan. 12, 2010); Jeremy Patrick, *Blood Donations Law Overbroad, Underinclusive*, DAILY NEBRASKAN, Sept. 25, 2000, *available at* http://www.dailynebraskan.com/opinion/blood-donations-law-overbroad-underinclusive-1.1024529 (last accessed Jan. 12, 2010).

[33] *See, e.g.*, Julia Cooper, *A.S. Board challenges FDA's blood donor policy*, SPARTAN DAILY, Sept. 7, 2006, *available at* http://media.www.thespartandaily.com/media/storage/paper852/news/2006/09/07/News/A.s-Board.Challenges.Fdas.Blood.Donor.Policy-2260496.shtml (last accessed Jan. 12, 2010).

[34] *See* Andrew Keegan, *FDA Meeting Revisits Ban on Gay Blood Donors: College Students Organize Protest Over Current Policy*, WASH. BLADE, Mar. 10, 2006, at 19.

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[36] FDA, TRANSCRIPT OF WORKSHOP ON BEHAVIOR-BASED DONOR DEFERRALS IN THE NAT ERA at 329 (Mar. 8, 2006), *available at* http://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/TranscriptsMinutes/UCM054430.pdf (last accessed Jan. 12, 2010) [hereinafter 2006 WORKSHOP TRANSCRIPT] (statement of Dr. Celso Bianco: "Many of our centers are unable to collect blood, particularly in colleges and in other environments, because of a perception, and a real perception by many of the students, that we are being unfair about the issue that has been discussed all day today, that is, we have different criteria applied to different risk groups, and people don't understand the risk groups. These issues impact on our donations."); *id.* at 383-84

[37] *See id.* at 383-84.

[38] Canadian Blood Servs., *Questions and Answers MSM Policy Decision*, http://www.bloodservices.ca/centreapps/internet/uw_v502_mainengine.nsf/page/MSM_QA?OpenDocument (last accessed Jan 21, 2010).

[39] Canadian Blood Servs., *Indefinite Deferrals*, http://www.bloodservices.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/page/Indefinite%20Deferral?OpenDocument#03 (last accessed Jan 21, 2010).

[40] Andrew Seymour, *Ontario Man Makes Charter Challenge Against Blood-Donation Screening*, OTTAWA CITIZEN, Sept. 28, 2009, *available at* http://www.ottawacitizen.com/health/Ontario+makes+charter+challenge+against+blood+donation+screening/2043811/story.html (last accessed Jan 21, 2010).

[41] *Sexual Minorities Claim Gays, Lesbians Now Allowed to Act as Blooddonors*, INTERFAX, May 23, 2008; Christopher Mangum, *Red Gold*, THE ADVOCATE, July 15. 2008.

[42] Nat'l Blood Serv. for Eng. & Wales, *Who Can't Give Blood*, https://secure.blood.co.uk/c11_cant.asp (last accessed Jan 21, 2010).

[43] David Rose, *NHS Lifetime Ban on 'High-Risk' Gay Men Donating Blood to Be Reviewed*, THE TIMES, Oct. 27, 2009, *available at* http://www.timesonline.co.uk/tol/news/uk/health/article6891256.ece (last accessed Jan. 21, 2010).

[44] Etablissement Français du Sang [French Nat'l Blood Serv.], http://www.dondusang.net/rewrite/site/3/.htm?idRubrique=6 (follow links on left for "Indications / Contre-indications" and "FAQ" under heading "Puis-je donner ?") (last accessed Dec. 2, 2009).

[45] Associazione Volontari Italiani Sangue (AVIS), *Chi può donare* [*Who can donate*], http://www.avis.it/usr_view.php/ID=1404; Sicurezza e Test (Safety and Test), http://www.avis.it/usr_view.php/ID=1460 (last accessed Dec. 2, 2009).

[46] Information regarding Sweden's blood donation policies is available in Swedish on the website of the Swedish Blood Centre at http://geblod.nu. The guidelines for donation are available at http://geblod.nu/general.aspx?PageId=6 (last accessed Dec. 2, 2009).

[47] Australian Red Cross Blood Serv., *Frequently Asked Questions*, http://www.donateblood.com.au/page.aspx?IDDataTreeMenu=88#answer47 (last accessed Jan. 21, 2010); Steven W. Thrasher, *Blood, Sex, and the FDA*, THE ADVOCATE, Nov. 2009.

[48] *See* Rose, *supra* note 43.

[49] *Sweden to End Ban on Gay Blood Donors*, AGENCE FRANCE-PRESSE, Dec. 1, 2009, *available at* http://www.google.com/hostednews/afp/article/ALeqM5hWrZIkEwrAE075ou4Jy50wfDakEg (last accessed Dec. 1, 2009).

[50] *Id.*

[51] Peter Tactchell, *Blood Bigots*, GUARDIAN, Dec. 1, 2008, *available at* http://www.guardian.co.uk/commentisfree/2008/dec/01/gay-blood-donors (last accessed Jan. 21, 2010).

[52] *Id.*

[53] Ministerio de Sanidad y Política Social, *Cuestionario Unifacado Para La Seleccion De Donates De Sangre y Componentes Sangueineos* [*Uniform Questionnaire for the Selection of Blood and Blood Component Donors*], http://www.msps.es/profesionales/saludPublica/medicinaTransfusional/acuerdos/docs/cuestionarioUnificado.pdf (last accessed Jan. 21. 2010).

[54] Tactchell, *supra* note 51.

[55] *Id.*

[56] CDC, *Deciding If and When to Be Tested*, http://www.cdc.gov/hiv/topics/testing/resources/qa/be_tested.htm (last accessed Jan. 21, 2010).

[57] *Id.*

[58] *Id.*

[59] *Id.*

[60] *Id.*

[61] *See* FDA, *Complete List of Donor Screening Assays for Infectious Agents and HIV Diagnostic Assays*, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/InfectiousDisease/ucm080466.htm (last accessed Jan 21, 2010).

[62] BPAC, a standing advisory committee to the FDA's Center for Biologics Evaluation and Research ("CBER"), is charged with "[r]eview[ing] and evaluat[ing] data on the safety and effectiveness, and appropriate use of blood products intended for use in the diagnosis, prevention, or treatment of human diseases." Among other things, BPAC advises the Commissioner of Food and Drugs (the "FDA Commissioner") "of its findings regarding the safety, effectiveness, screening and testing (to determine eligibility) of donors ... and on the quality and relevance of FDA's research program which provides the scientific support for regulating [blood products]." FDA, *Charter of the Blood Products Advisory Committee, available at* http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/BloodVaccinesandOtherBiologics/BloodProductsAdvisoryCommittee/ucm121602.htm (last accessed Jan. 14, 2010).

[63] BPAC, TRANSCRIPT OF 67TH MEETING 200-01 (Sept. 14, 2000) [hereinafter 2000 HEARING TRANSCRIPT], *available at* http://www.fda.gov/ohrms/dockets/ac/cber00.htm#Blood%20Prducts (follow links for 9/14 and 9/15 transcripts under "Blood Products Advisory Committee" heading).

[64] *Id.*

[65] *Id.* at 214-15.

[66] *Id.*

[67] *Id.* at 247-55.

[68] *Id.* at 256-59.

[69] *Id.* at 311-12. Interestingly though, the majority of BPAC's voting members indicated a preference for making some change to the Policy. In the middle of deliberations, BPAC's Chairman Blaine F. Hollinger asked who would favor some change, and 8 out of 13 present voting members raised their hands. *Id.* at 286, 312.

[70] *Id.* at 277-315.

[71] 2006 WORKSHOP TRANSCRIPT, *supra* note 36.

[72] *Health Agencies Reconsidering Some Blood Donor Deferrals*, FDA WEEK, May 12, 2006.

[73] 2006 WORKSHOP TRANSCRIPT, *supra* note 36.

[74] *See* BPAC, TRANSCRIPT OF 86TH MEETING 57 (Mar. 9, 2006), *available at* http://www.fda.gov/ohrms/dockets/ac/06/transcripts/2006-4206t1.pdf (last accessed Jan. 12, 2010) [hereinafter 2006 MEETING TRANSCRIPT].

[75] *Id.* at 58.

[76] *Id.* at 45, 58.

[77] *Id.* at 59-63; Steven Kleinman, Behavior-Based Blood Donors Deferrals in the Era of Nucleic Acid Testing (NAT), Statement Before the Blood Products Advisory Committee (Mar. 9, 2006), http://www.americasblood.org/download/releases/stmnt_060309_deferrals-msm.pdf (last accessed Jan. 12, 2010).

[78] 2006 MEETING TRANSCRIPT, *supra* note 74, at 58.

[79] *See* Rob Stein, *FDA to Review Ban on Gay Men Donating Blood*, WASH. POST, Mar. 18, 2006, at A06 ("FDA spokesman Stephen King said the agency would convene a [BPAC] meeting to formally reconsider revising the policy, probably later this year . . . . Agency officials are 'definitely interested in hearing all the science, and if there's hard evidence in place that changing the policy would not

endanger the blood supply they're definitely open to it,' King said."); *Health Agencies Reconsidering Some Blood Donor Deferrals*, FDA WEEK, May 12, 2006 (quoting Andrew Dayton as saying: "Once the FDA, NIH and CDC come up with a uniform recommendation, the agencies plan to make their recommendation to the FDA Blood Products Advisory Committee.").

[80] *See FDA: Gay Men Can't Give Blood*, CHI. TRIBUNE, May 24, 2007, at 10 ("Gay men remain banned for life from donating blood, the government said Wednesday, leaving in place – at least for now – a 1983 prohibition meant to prevent the spread of HIV through transfusion.").

[81] Requirements for Human Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, 72 Fed. Reg. 63,416 (proposed Nov. 8, 2007).

[82] *Id.* at 63,425.

[83] *Id.* In particular, the summary of the rule notes that "[t]o assist [the agency] in developing such guidance documents, [it] intend[s] to hold workshops and public meetings on social behaviors associated with increased risk of infection with a relevant transfusion-transmitted infection. The public will have the opportunity to submit comments on specific issues as they are presented." *Id.*

[84] *Id.*

[85] *See* Extension of Comment Period, 73 Fed. Reg. 1983 (Jan. 11, 2008) (extending the time for public comment on the proposed rule until August 4, 2008).

[86] Letter from Michael D. Maves, MD, MBA, Executive Vice President, CEO, Am. Med. Ass'n, to Andrew C. von Eschenbach, MD, Comm'r of Food & Drugs, FDA (Aug. 4, 2008) (advocating for consideration of "a shift to a 5-year deferral policy for blood donation from men who have sex with men" and attaching a report detailing the AMA's adoption of support for such a policy), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064806ad4ee (last accessed Jan. 12, 2010); Letter from Bebe J. Anderson, HIV Project Director, Lambda Legal, to Division of Dockets Management (HFA-305), FDA (Aug. 4, 2008) (requesting that the FDA "draft the Final Rule so as to make clear that the Final Rule is not recommending continuation of the ban on donation by men who have had sex with other men since 1977" and that the Comments to the Final Rule reflect the "FDA's intention to develop new guidance that will focus consistently on whether a potential donor actually has engaged in risk behavior within an appropriate time period"), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064806aebd3 (last accessed Jan. 12, 2010); *see also* Letter from J. Chris Hrouda, Exec. Vice Pres., Biomedical Services, Am. Red Cross, to Dockets Management Branch (HFA-305), FDA (Aug. 1, 2008) (commenting on proposed section 630.10(f)(1) by referring to the joint statement from AABB, Americas' Blood Centers and Red Cross stating that "the current lifetime deferral for men who have had sex with other men since 1977 is no longer medically and scientifically warranted"), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=09000064806a694d (last accessed Jan. 12, 2010).

[87] *See* HHS, SEMIANNUAL REGULATORY AGENDA - FALL 2009, at 68 (Dec. 7, 2009) (listing promulgation of new regulations as a long-term action), *available at* http://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a64db9 (last accessed Jan. 12, 2010).

[88] MSM Q & A, *supra* note 2. *See also* Requirements for Human Blood and Blood Components, 72 Fed. Reg. at 63,425 (announcing FDA's intention to hold future workshop to assist it in developing guidance with regard to behavior-based deferrals, including MSM); Stein, *supra* note 79 (quoting FDA spokesman Stephen King as saying, after the 2006 BPAC meeting, that the FDA officials are "definitely interested in hearing all the science, and if there's hard evidence in place that changing the policy would not endanger the blood supply they're definitely open to it"); Bob Roehr, *The Gift of Life: Gay Men and US Blood Donation Policy*, Liberty Education Forum, 2000, *available at* http://www.libertyeducationforum.org/downloads/1h_whtpa_pbl00.pdf (arguing that, in the early 2000s, the "opposition to changing the policy on blood donation by gay men does not come from the FDA staff").

[89] FDA, *Vaccines, Blood & Biologics, Blood & Blood Products*, http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/default.htm (last accessed Jan. 21, 2010).

[90] FDA, *Blood Donations from Men Who Have Sex with Other Men Questions and Answers*, http://www.fda.gov/biologicsbloodvaccines/bloodbloodproducts/questionsaboutblood/ucm108186.htm (last accessed Jan. 21, 2010).

[91] *See* David Keating, *Blood Drive Rules Test Ethics: Ban on Donations From Gays Leads Some to Lie*, WASH. SQUARE NEWS, Apr. 3, 2003, *available at* http://www.nyunews.com/2.6167/blood-drive-rules-test-ethics-1.646719 (last accessed 7/21/2009).

[92] While the actual rate of transmission for HIV infection through oral sex is disputed, the general medical consensus is that the rate is significantly lower than the risk of contracting HIV through anal sex. HIV InSite, *Roundtable Discussion on Risk of HIV Transmission by Oral Sex* (Mar. 14, 2003), *available at* http://hivinsite.ucsf.edu/InSite?page=pr-rr-05.

[93] Avert.org, *Condoms: History, Testing and Effectiveness*, http://www.avert.org/condoms.htm (last accessed Aug. 5, 2009).

[94] CDC, *Basic Information HIV/AIDS*, http://www.cdc.gov/hiv/topics/basic/#risk (last accessed Aug. 5, 2009).

[95] *See* QUESTIONNAIRE, *supra* note 10.

[96] Avert.org, *HIV & AIDS statistics for the US by Age & Race*, http://www.avert.org/usa-race-age.htm (last accessed Aug. 5, 2009).

[97] *See* QUESTIONNAIRE, *supra* note 10.

[98] American Red Cross, *We Depend on You*, http://www.redcrossblood.org/news/nyp/we-depend-you (last accessed Jan. 21, 2010).

[99] 2006 MEETING TRANSCRIPT, *supra* note 74, at 93-94.

[100] *See Sweden to end ban on gay blood donors*, AGENCE FRANCE-PRESSE, Dec. 1. 2009, *available at* http://www.google.com/hostednews/afp/article/ALeqM5hWrZIkEwrAE075ou4Jy50wfDakEg (last accessed Dec. 1, 2009).

[101] CDC, *Deciding If and When to Be Tested*, http://www.cdc.gov/hiv/topics/testing/resources/qa/be_tested.htm (last accessed Jan. 21, 2010).

[102] Leland Traiman, *Identifying a Sub-Set of Gay Men Who Are at Low Risk for HIV Infection*, http://www.fda.gov/ohrms/dockets/AC/01/briefing/3817b2_11.pdf.

the Center the Lesbian, Gay, Bisexual & Transgender Community Center

Hearing on Res. 80, calling upon the United States Food and Drug Administration to reverse their longstanding prohibition on homosexual men donating blood held by The Committee on Health of the New York City Council

Introduction

I am Andres Hoyos, a gay Latino immigrant and social worker and for over 20-years my practice has focused on the mental health needs of gay men. I am currently the Associate Director of Center CARE Wellness at the Lesbian Gay Bisexual & Transgender Community Center where I have worked for the past seven years.

Current situation and challenges

Current United States policy permanently excludes gay and bisexual men from donating blood, regardless of their level of HIV risk. However, their heterosexual counterparts are deferred from donating blood for a year if they are participating in higher risk behaviors, such as having unprotected anal or vaginal sex with a HIV-positive partner.

The context for this policy has changed significantly in the 25-years since its implementation. Importantly, technology for testing has reduced the window period for detection of HIV infection to less than two-weeks.

Sexual orientation or the gender of the persons involved in sexual encounters does not determine the risk for HIV transmission, nor do these factors risk our blood supply. We should take this opportunity to emphasize and assess the level of risk for HIV transmission individually, rather than focusing on identity-based factors. An extended focus on identity, rather than actual risk could be used to extend the blood donation ban to other groups with higher HIV-seroprevalence, including communities of color, women, children and people living in poverty.

Community impact

One of the painful lessons learned at the onset of the HIV epidemic in the 1980's was the stigmatization of groups who were often already disempowered and marginalized by focusing on identity rather than actual risk. This has a negative impact in the subpopulation of focus and our culture at large. It also contributes to stigmatization that is associated with increased discrimination and the potential of violence.

Even though the FDA blood donation ban is not intentionally discriminatory, its impact is. Applying the blood donation ban indiscriminately to gay men, regardless of actual risk, and not other groups with elevated HIV-risk, is harmful. It is harmful to gay men and it is harmful to our nation's blood supply.

The blood donation ban prevents gay and bisexual men from participating in a vital process of community building or what could be called cultural citizenship. This also sends an implicit stigmatizing message that gay and bisexual men are "damaged goods," "second class," "less than," "other," "diseased," and inherently contagious.

Paradoxically, it was this gay community – the same community that the FDA's policy implies is not good enough to ever donate blood – that first rallied to support those living with HIV and AIDS. This is the same gay community that has fought and struggled for nearly 30-years for services and effective prevention, diagnostic and treatment methods.

This sends the wrong message to the our gay community. While trying to encourage gay and bisexual men to periodically test for HIV, to reduce their risk and remain connected with the health care system as a prophylactic measure, we simultaneously a develop regressive and unscientific policies such as the blood donation ban. We tell our gay brothers they are not good enough to donate blood, and disengage them for life from a fundamental civic action associated with health and community.

And, sadly, we lose another opportunity to educate our communities about safer practices for everyone, especially those engaging in higher risk behaviors.

Conclusion

It is must then be obvious the screening of potential blood donors should be based upon assessment of risk behaviors for HIV transmission, while simultaneously promoting community involvement in healthier activities. Participants who donate blood should be supported, educated and encouraged to assess their own level of HIV risk and to make responsible and informed decisions. This in turn protects gay and bisexual men and all those at higher HIV risk from further stigmatization and discrimination.

The Center endorses a scientific and non-stigmatizing blood donation policy, in particular GMHC's six elements of a safe and effective policy – D.O.N.A.T.E.: **D**ecreased risk to recipients, **O**bjective risk factors, **N**on-discriminatory impact, **A**wareness raising, **T**echnology-driven procedures, **E**xpansion of donor pool.

The permanent deferral for gay and bisexual men should be replaced with a policy that is scientifically-based, is consistent with other higher-risk groups, and is substantially less discriminatory.

The Lesbian, Gay, Bisexual & Transgender Community Center supports the New York City Council as it speaks with the voice of over 8 million New Yorkers with resolution 80, calling upon the United States Food and Drug Administration to reverse their longstanding prohibition on gay men donating blood.

Statement on Resolution 80

Submitted by

Gay Men of African Descent

April 13, 2010

Thirty years ago we called each other on rotary phones and had to go to the library to learn the capital of Norway and never even imagined the scientific and medical advances we take for granted today.

And almost 30 years ago, the United States banned gay men from donating blood.

The blood ban remains a stark reminder and key evidence of the stigma that HIV has brought to our city, and our nation and our values. You probably don't know this but blood donation has a long history in this city. In the beginning of the HIV epidemic in New York City, the ban on gay men from donating blood was rooted in a lack of knowledge in a climate of fear. Thirty years of experience and thousands of studies later, it stands as evidence not of the fear of HIV contaminating our blood supply, but of the fear of change. Most Americans have never wanted to donate blood and most still avoid it. The Red Cross had huge mobilization campaigns before HIV arrived and after to get all Americans to donate and most still refuse to this day.

By targeting marginalized populations, local organizations were able to solicit the donations the blood banks needed for a small fee. From a city ripe with employment and housing discrimination came homosexual men and intravenous drug users ready and willing to donate. Our reward for turning the other arm was not acceptance and integration but rejection. But we still showed up to help time and time again.

History has it that the blood ban began when communities that depended on our blood for survival refused to tolerate us any more. Many called on the government and advocacy agencies to protect children from the blood of gay men. It wasn't until a "healthy" child contracted HIV that the Red Cross became the first of many to ban gay blood in 1983 and we saw some of the first decisive action on HIV at the federal level shortly after. Not a statement of support for our struggle to survive but the ban itself.

The real crime of the Blood Ban is the acceptable victim who demands that we few be blamed for a disease that we all have. The ban continues to cement the notion that all gay men have HIV and that all heterosexuals do not. The ban is proof positive that we would rather talk about minorities than a virus that is continuing to destroy this country. The only thing the ban is good for is adding insult to injury and further marginalizing our community.

In retrospect the ban failed to prevent heterosexuals from infecting hemophiliacs via blood donations that to this day are not seen as suspect. Over 1 in 70 New Yorkers is HIV Positive and rising; not merely a handful of gays in the village, yet we are the only ones who are impacted and screened away. Our diseases were just our diseases; we really are all in bed together and not just at the blood bank. If the FDA wants to protect the Blood Supply from HIV they can ether test everyone or ban everyone. It's the 21st century and you all have AIDS at this point, we just had AIDS first.

Gay Men of African Descent everywhere have long supported lifting the ban on blood donation. It stands as a hallmark of those early years and our resolution today shows how far we have come. We need to continue to be a community, to stand together and fight the virus without fighting each other. GMAD strongly and without reservation, supports the New York City Council resolution calling upon the United States Food and Drug Administration to reverse their longstanding prohibition on homosexual men donating blood.

Testimony of New York Blood Center (NYBC)
Robert Purvis, Vice President
before the
New York City Council Health Committee
April 13, 2010

Members of the City Council Health Committee, Ladies and Gentlemen, I am Rob Purvis, Vice President of the New York Blood Center. I sincerely thank you for your invitation to testify today, and also want you to know how much the New York Blood Center appreciates your support … and how much we depend on it.

Our CEO and President, Dr. Christopher Hillyer, wishes he could have attended today and sends his sincere apologies, but he is attending a prescheduled meeting with our Board of Trustees.

Since 1964, New York Blood Center has proudly served the 20 million people of New York City and our neighboring communities, by providing blood transfusion products and related services to our hospitals. Members of this committee, including the Speaker herself, have personally joined us at blood drives, and supported our special initiatives to increase the diversity of our blood supply.

It is our job to ensure the safety, reliability, and availability of New York City's blood supply, and we know everyone here shares our goals.

The resolution introduced by Speaker Quinn supports a reexamination of current donor deferral criteria. We are in favor of this reexamination, and would welcome a revision, if so determined by the Food and Drug Administration, of the questions people are asked when they come in to roll up their sleeves.

As one of the nation's largest non-profit, community-based blood centers, we are required to, and of course do, comply with federal FDA and state Department of Health regulations, and American Association of Blood Banks Standards. As such, we look forward to working with our regulatory authorities on their reexamination of eligibility criteria for all potential donors.

A meeting of the FDA's Blood Products Advisory Committee has been scheduled for July 26 and 27. New York Blood Center will offer to provide scientific and medical data and input, a role we have often played in deliberations over how to optimize the safety, reliability and availability of our blood supply.

Members of the Health Committee, we again thank you for your support and encouragement of our lifesaving mission, and welcome this reexamination in the spirit of our ongoing service to the people of New York City.

AVAC
Global Advocacy for HIV Prevention

Testimony of Kevin Fisher

before the

New York City Council Committee on Health

Kevin Fisher
Policy Director, AVAC: Global Advocacy for HIV Prevention
April 13, 2010

Good afternoon, and thank you for this opportunity to testify before your committee today.

My name is Kevin Fisher, and I am Policy Director at AVAC, based here in New York. AVAC is an international, non-profit organization that uses education, policy analysis, advocacy and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic.

I'd like to begin by commending Council leaders for their decision to focus on HIV prevention. You couldn't have picked a better (or more challenging) time to take on these crucial issues as the White House develops for the first time a National AIDS Strategy and here in New York, an estimated 105,000 people, or about one in 80 New Yorkers, live with HIV.

I am here to offer our support for both 1) Resolution 39, urging the U.S. Congress to reintroduce and pass legislation that would amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other diseases; and 2) Resolution 80, calling upon the United States Food and Drug Administration to reverse their longstanding prohibition on homosexual men donating blood.

Resolution 39 is an important endorsement for the need for safe and effective microbicides. HIV continues to ravage New York and communities around the world. HIV rates among gay men and other men who have sex with men remain shockingly high. At the same time, women are increasingly at the epicenter of the HIV/AID epidemic, representing nearly half of the 33 million people worldwide currently infected with the virus. Even in the US, women face unique challenges in managing their own health and the health and well-being of their families. Both women and men urgently need access to safe, effective and self-initiated HIV-prevention options at affordable prices. Microbicides are one such experimental option which is being actively pursued in the US and internationally.

As you know, microbicides are products that are being developed for vaginal or rectal use to reduce the transmission of HIV during sexual intercourse. Microbicides could take the form of a gel, film or sponge, or be contained in a vaginal ring that releases the active ingredient gradually. Several of the newer experimental microbicide candidates use antiretroviral drugs that are also used successfully for treatment.

Since the Microbicide Development Act was introduced by then-Senator Obama and Representative Jan Schakowsky, steps have been taken toward a number of the goals of that act. Funding for microbicide research has increased at the NIH and the Microbicide Trials Network has been established to test new microbicide candidates.

Still, the Microbicide Development Act remains critically important. The Act is a very important educational force around this important work. It can leverage further increases in public-sector funding and support the work of the microbicide program in the NIH's Office of AIDS Research. The Act will also continue to support the work of the Microbicide Trials Network, a successful and admired prevention trial network that is based at the University of Pittsburgh and has several New York-based partners.

Recent advances, and momentum need to be safeguarded. Pressures from a fragile economy and funding cutbacks, and disappointment results in recent microbicide trials have led to hand-wringing about the inevitable demise of microbicides as an HIV prevention technology. This is unfair, inaccurate, and uninformed: the power of the microbicide concept is as important and valid today as it ever has been. We need to keep sending that message. The Microbicide Development Act does that.

Resolution 80 is also timely for, as I'm sure you are aware, the Advisory Committee on Blood Safety and Availability is scheduled to meet in June to discuss the current policy on blood donations. Legislation in areas of scientific decision-making is a matter to be taken with great caution. Fortunately, the science supports reevaluation of the current FDA policy. We believe the decades-old blood donation policy lags behind science, and our nation is long overdue for a review. Such a review could allow gay men who present no danger to our nation's blood supply to participate in a life-saving act of altruism and civil responsibility from which they are currently barred.

Current FDA policy that have excluded all men who have had sex with another man (MSM) even one time since 1977 from donating blood. AVAC supports the recommendations of the Gay and Lesbian Medical Association (GLMA) and the National Alliance of State and Territorial AIDS Directors (NASTAD) that healthy gay men in certain situations (such as men who are not sexually active or who are in safe, monogamous relationships) should be allowed to donate blood or blood components. This is change is also warranted because improvements in technology in detecting early HIV infections provide another backup system to protect the nation's blood supply.

The MSM ban excludes many prospective donors who are healthy and at little to no risk of HIV

infection. The change in this restriction is unlikely to have an immediate impact on national blood donations (which total approximately 14 million annually), but over time could provide additional capacity for the blood supply.

Thank you and I would be happy to answer any questions you might have.

* * *

For the Record

NATIONAL HEMOPHILIA FOUNDATION

for all bleeding and clotting disorders

NHF Statement on Blood Donor Deferrals

March 19, 2010

The National Hemophilia Foundation (NHF) believes that any decision to revise current blood donor deferral policies must put safety first and be made solely on the basis of scientific evidence. For this reason, NHF will be an active participant in any review and discussions on changing the donor deferral policy for men who have had sex with men (MSM) even once since 1976.

The bleeding disorders community is heavily reliant upon blood and plasma donations for the manufacture of the essential life-saving therapies on which we depend. We are grateful to all those who donate—without their generosity, treatment would not be possible for many in our community. We welcome discussions on ways to improve the safety of the nation's blood supply not only for the bleeding disorders community, but for all who may need a blood transfusion at some time, be it for surgery or an emergency situation.

NHF asserts that any proposed changes to current donor deferral policies must satisfy the Precautionary Principle. In this context, the Precautionary Principle implies that decisions must err on the side of caution in the absence of a scientific consensus that harm would not result from changing these policies. Unless there is evidence that a proposed change will not elevate the risk to the nation's blood supply, we must maintain current policies to protect the recipients of blood and blood products.

It is critical to remember that our community has been devastated by death and illness resulting from contaminated blood products. People with bleeding disorders, including hemophilia A and B, von Willebrand disease and other rare bleeding disorders, continue to depend on a safe blood supply to lead healthy lives. We must avoid repeating our tragic history, which will only be possible through constant vigilance and application of the Precautionary Principle to scientific review.

NHF looks forward to participating in the discussions of the Advisory Committee on Blood Safety and Availability of the Department of Health and Human Services and with others on the existing donor deferral policies related to MSM to determine whether the current state of science supports modifications to the existing policy.

NHF also strongly supports the statement by the World Federation of Hemophilia on blood donor deferrals.

For the Record

WFH Statement on Blood Donor Deferrals

February 19, 2007

In the context of public and political challenges to existing blood donor deferral criteria in the Netherlands, Canada and elsewhere, and specifically those related to men who have had sex with other men, the World Federation of Hemophilia (WFH) takes the position that the establishment of donor restrictions, and any modifications to them that are contemplated, must be based on the Precautionary Principle and science.

The Precautionary Principle applied in the context of human actions that concern human health implies that, in the absence of a scientific consensus that harm would not ensue, decisions must err on the side of caution; i.e. to protect the recipient of a blood donation.

Donating blood is an altruistic act and the WFH expresses its appreciation to every person wishing to give of themselves to help others. However, our community has been devastated by death and illness resulting from tainted blood products. Constant vigilance, caution, state-of-the-art scientific review and the application of the Precautionary Principle are the only ways to avoid repeating that tragic history.

Many people with bleeding disorders—hemophilia A and B, von Willebrand disease, and other rare bleeding disorders—receive plasma-derived blood products on a regular basis. Moreover, all people with bleeding disorders have a higher-than–average chance of needing fresh blood components such as red blood cells, platelets and fresh frozen plasma. These latter products cannot be virally inactivated during the manufacturing process.

Our concerns are also for the millions of other people worldwide who need fresh blood components; for example, those with thalassemia, sickle cell disease, chronic anemias and cancer, and those who have had a serious accident or who require surgery. In addition there are those people who need fractionated blood products to treat, for example, primary immune deficiencies.

By their very nature blood donor screening and deferral criteria are discriminatory; however, they are justifiable where they provide increased protection to public health. Criteria for donor deferrals must put safety of the recipient first and be based on scientific and epidemiological evidence about large groups of people (populations). Epidemiology, which is the study of patterns of disease in populations and provides the strongest scientific analysis of blood donor deferral criteria, is in fact a science based on discrimination. Donor deferrals are not judgments about the individual donor. Rather they are a method to reduce the risk of known, unknown, undetectable or emerging viruses and/or other disease causing agents being passed to recipients of blood or blood products. Testing and inactivation technologies are not perfect and it continues to be necessary to decline donations from some populations based on established epidemiological evidence.

The goal of blood collection centres is to collect sufficient safe blood for therapeutic use by selecting donors who have the lowest risk of transmitting disease to recipients. While individual tests are performed on each donation for several known disease agents, blood donor deferral criteria, based on epidemiological data, are intended to provide an added layer of safety in the event of a test failure regarding a known disease threat, and primary protection

against unknown threats and known disease agents for which there are poor or no screening tests..

In recent decades the development and application of sensitive screening tests for known blood-borne pathogens such as hepatitis B, hepatitis C and HIV has significantly reduced the risk of infection for these diseases for blood recipients from donors. However, it is important to remember that the risk is never zero and, no matter how small that risk may be, 100% of it is borne by the recipient and none is borne by the donor. The recipient of blood has the right to be as free from the risk of blood-borne pathogens from donor blood as is possible.

Examples of permanent deferrals to safeguard the blood system, based on epidemiological data and analysis of known blood-borne pathogen risks, and the application of the Precautionary Principle, are:

* people who have taken illegal drugs or illegal steroids with a needle, even one time;
* people who have taken money or drugs for sex, even one time;
* men who have had sex with a man, even one time;
* people who have ever taken clotting factor concentrates, such as hemophiliacs;
* people who have visited certain countries in Africa where a strain of HIV not detectable by current tests is prevalent.

Also permanently deferred in most jurisdictions are people who have resided in the United Kingdom or France between 1980 and 1996. This regulation is intended to reduce the risk from variant Creutzfeldt-Jakob disease (vCJD), caused by the ingestion of bovine products infected with bovine spongiform encephalopathy (BSE) or Mad Cow Disease.

The WHF recognizes that donor deferral policies are discriminatory; however, legal decisions have upheld the legality of such discrimination if they are judged to be justified in the interest of public health.

Decisions on blood donor deferral policies must continue to put safety first and be made on the basis of epidemiology, and not as a result of public or political pressure.

World Federation of Hemophilia
Blood Product Safety, Supply and Availability Committee

For the Record

American Red Cross
in Greater New York

Theresa A. Bischoff
Chief Executive Officer

April 13, 2010

The Honorable Maria del Carmen Arroyo
Chair-New York City Council Committee on Health
250 Broadway
New York, NY 10007

Dear Chairperson Arroyo & Members of the Committee:

Thank you for the opportunity to submit a written statement on City Council Resolution 80. Please accept my apologies for not being able to attend the Committee's hearing in person.

Working in conjunction with the New York-Penn Blood Services Region, the Greater New York Chapter collects blood products in the New York City Metropolitan Area. The top priority for our chapter, the New York-Penn Blood Region and the American National Red Cross – which is the nation's leading supplier of blood products – is the safety of the donor and the patient who receives blood. We believe that accurate donor histories and medically supported donor referral criteria are critical to the continued safety of blood transfusion.

While the American Red Cross is obligated to follow all Food and Drug Administration (FDA) guidelines to the blood industry regarding donor eligibility, the organization believes, along with the American Association of Blood Banks (AABB), and America's Blood Centers (ABC), that the current lifetime deferral for men who have had sex with other men is unwarranted and donor deferral should be modified and made comparable with criteria for other groups at increased risk for sexually-transmitted or transfusion-transmitted infections.

The American Red Cross is dedicated to fairness and equality in the formulation and administration of donor selection criteria in order to ensure a safe and plentiful blood supply for all patients regardless of beliefs, race, gender or sexual orientation.

The organization supports the use of rational, scientifically-based deferral periods that are applied fairly and consistently among donors who engage in similar risk behaviors.

In closing, one of our organization's seven fundamental principals is Neutrality. As such while the American Red Cross in Greater New York cannot officially support or oppose Resolution 80, the chapter does applaud the City Council for raising this issue for discussion and debate.

The chapter remains thankful for the City Council's support and partnership as we continue to provide assistance and services to meet the needs of New Yorkers throughout our city.

Respectfully,
Theresa A. Bischoff

For the Record

From: ryoung@barnard.edu [mailto:ryoung@barnard.edu]
Sent: Monday, April 12, 2010 1:57 PM
To: Bottcher, Erik
Cc: lkay@barnard.edu; wsimpkin@barnard.edu
Subject: blood donation discrimination

Dear Mr. Bottcher,

I was greatly heartened last week when I saw an email message from Council Chair Chris Quinn regarding her position on the policy of excluding gay and bisexual men from blood donation. I am unable to attend tomorrow's hearing on this issue, but I would like to submit these comments for your consideration.

I am a sociomedical scientist with particular expertise in HIV/AIDS (I have conducted HIV research for more than 20 years). I have long maintained that the policy of excluding gay and bisexual men is an irrational holdover from the early days of the AIDS epidemic when there was no clear way to determine who posed a risk to the blood supply. Continuing this exclusion makes no sense epidemiologically at this point.
Moreover, it actually reinforces several ideas that actively block effective response to the HIV/AIDS epidemic:
1 - It reinforces the notion that heterosexual men and women are inherently safe from HIV.
2 - It reinforces the idea that nothing gay or bisexual men can do will prevent their getting infected. This is especially dangerous to young gay and bisexual men, who need all the support our communities can muster to help them stay safe over the long haul.
3 - It generally undermines the public health focus on the use of condoms or other preventive measures (e.g., practicing "outercourse" if condoms aren't available) to avoid HIV, instead focusing on the identity of sexual partners.

For these reasons, the ban should be rescinded. Our communities need blood, and we also need a rational approach to HIV prevention.

My thanks to Councilwoman Quinn for addressing this important issue. If you have any questions or would like further information on any of the points I have raised, please feel free to contact me either via email or telephone.

Best regards,

Rebecca M. Jordan-Young, Ph.D.
Assistant Professor of Women's Studies
Barnard College
3009 Broadway
New York, NY 10027
212-854-9088

For the Record

Dear Mr. Altman and Mr. Mancino:

Thank you for your invitation to attend and provide testimony at the upcoming hearing on New York City Council Resolution. No. 80, calling upon the United States Food and Drug Administration (FDA) to reverse its policy on blood donor deferral of men who have had sex with other men (MSM). A copy of this resolution was sent to Mr. Bryan Emery, the Designated Federal Official, Blood Products Advisory Committee. We appreciate your interest in this important matter.

The primary responsibility of FDA is to ensure the safety of blood and blood products for patients who require these products. Our blood donor deferral policies are based on scientific data that demonstrate that certain medical, behavioral, and geographical factors are associated with an increased risk of transfusion transmitted diseases, such as HIV, hepatitis B and C, and variant Creutzfeldt Jakob disease.

We understand that there are different viewpoints on how best to maintain the safety of the blood supply. FDA continues to monitor and evaluate our blood donor deferral policies, including the MSM deferral. Alternative strategies that maintain blood safety may be considered as new scientific data become available.

As you are aware, the Department of Health and Human Services' Advisory Committee on Blood Safety and Availability (ACBSA), comprised of national experts and DHHS officials, will examine the MSM deferral policy at an upcoming public meeting in June 2010. Therefore, we respectfully decline your invitation.

With respect to New York City Council Resolution No. 39, urging the United States Congress to reintroduce and pass legislation that would amend the Public Health Service Act with respect to facilitating the development of microbicides for preventing transmission of HIV and other diseases, the FDA has no testimony to provide in this matter.

Sincerely,

Walter Gardner
Chief, Consumer Affairs Branch
Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
Walter.gardner@fda.hhs.gov 301-827-3743

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 80

☒ in favor ☐ in opposition

Date: 4/13/10.

(PLEASE PRINT)

Name: ANDRES HOYOS

Address: 208 W 13TH ST. NY NY 10011.

I represent: THE LESBIAN GAY BISEXUAL & TRANSGENDER COMMUNITY CENTER.

Address: 208 W 13TH ST. NY NY 10011

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 80

☑ in favor ☐ in opposition

Date: 4/13/10

(PLEASE PRINT)

Name: TOKES OSUBU

Address: 44 COURT STR BKLYN NY 11201

I represent: GAY MEN OF AFRICAN DESCENT

Address: 44 COURT ST #1000 BK 11201

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 80

☒ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Lopez, Oscar

Address: 24 West 25th - 9th FL NY 10010

I represent: Latino Commission on AIDS

Address: same address

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 394 80

☑ in favor ☐ in opposition

Date: 4 13 10

(PLEASE PRINT)

Name: Janet Weinberg

Address: 119 W 24 St

I represent: GMHC

Address:

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 0080-2010

☐ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Rob Purvis

Address: 370 E 67TH ST

I represent: New York Blood Center

Address:

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

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☑ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Antonio Centeno JR.

Address: 864 Southern Blvd #6D Bronx, NY 10459

I represent: _____

Address: _____

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THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 39-80

☒ in favor ☐ in opposition

Date: 4/13/10

(PLEASE PRINT)

Name: Pei Desrosiers

Address: 318 W 139 St.

I represent: Women's HIV Collaborative

Address: 318 W. 139th St

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 80

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(PLEASE PRINT)

Name: MARC FLIEDNER

Address: 560 W 43rd St. 31D NY, NY

I represent: Myself

Address:

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THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 80

☒ in favor ☐ in opposition

Date: _____

(PLEASE PRINT)

Name: Henry Rebin

Address: 291 Seventh Ave

I represent: Human Rights Campaign

Address: Washington, D.C.

Please complete this card and return to the Sergeant-at-Arms

THE COUNCIL
THE CITY OF NEW YORK

Appearance Card

I intend to appear and speak on Int. No. _____ Res. No. 39/80

☒ in favor ☐ in opposition

Date: 4/13/10

(PLEASE PRINT)

Name: Kevin Fisher

Address: 142 Smith Street.

I represent: AVAC=Global Advocacy for HIV Prevention

Address: 101 W. 23rd St NY NY 10011

Please complete this card and return to the Sergeant-at-Arms