

Guarding against Unknown and Emerging Pathogens

**Statement from America's Survival, Inc.
on the Safety of the Blood Supply**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Committee on Blood Safety and Availability (ACBSA)

Current Food and Drug Administration (FDA) policy recommends that men who have had sex with another man (MSM) even one time since 1977 should be deferred indefinitely from donating blood. The deferral of MSM began prior to the availability of tests for HIV in early 1985. The deferral has existed in its current form since September 1985. This and other related FDA policies are designed to address the major sources of known risk to the blood supply as well as the theoretical risk of emerging infectious disease (EID) transmission. FDA has reviewed the policy periodically, most recently at a meeting of the FDA Blood Products Advisory Committee in 2000 and in an FDA-sponsored public scientific workshop in 2006. After considering both public discussions FDA retained its policy. FDA has noted its commitment to continue to review its donor deferral recommendations.

At the June 10-11, 2010 meeting, the HHS ACBSA will hear presentations and engage in deliberations on the current MSM deferral policy. Specifically, the ACBSA will be asked to discuss the following: what are the most important factors (e.g. societal, scientific, and economic) to consider in making a policy change; is the currently available scientific information including risk assessments sufficient to support a policy change at this time; what studies, if any, are needed before implementing a policy change; what monitoring tools or surveillance activities would need to be in place before implementing a policy change; what additional safety measures, if any, are needed to assure blood safety under a revised deferral policy?

Source: <http://edocket.access.gpo.gov/2010/2010-12326.htm>

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My name is Cliff Kincaid, president of America's Survival, Inc. (www.usasurvival.org). On behalf of our organization, I am pleased to present the testimony of Dale O'Leary, a writer, who has followed the AIDS epidemic since the beginning and written extensively on the subject of sexually transmitted diseases.

Those who are lobbying to have the current ban changed have focused entirely on improved tests for HIV.¹ They do not mention all the other infectious diseases epidemic among men who have sex with men (MSM), because the gay activists cannot argue that MSM are no more likely to be infected with a blood-borne disease than other populations.²

The CDC recently announced that the rate of new HIV diagnoses among MSM is 44 times higher than among other men and the rate of primary and secondary syphilis is 46 times that of other men.³ In addition, there have been outbreaks of various forms of hepatitis,⁴ herpes,⁵ drug-resistant gonorrhea,⁶ cancer-causing human

¹ GMHC, *Drive for Change: Reforming U.S. Blood Donation Policies*, (New York, 2010)

² FDA, "Vaccines, Blood, & Biologics,"

<http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/QuestionsaboutBlood>: "Men who have sex with men also have an increased risk of having other infections transmitted to others by blood transfusions." e, g. HBV, HCV HHV-8.

³ CDC, "CDC Analysis Provides New Look at Disproportionate Impact of HIV and Syphilis among U.S. Gay and Bisexual Men," (March 10, 2010). <http://www.cdc.gov/nchhstp/newsroom/msmpressrelease.html>

Also see, *Morbidity and Mortality Weekly Review* "Trends in HIV/AIDS diagnoses among men who have sex with men," (June 12, 2008)

William Smith, "What I didn't know about sexual health," <http://www.rhealitycheck.org>. "...syphilis infection in a sexual network can have devastating results both on its own and in increasing susceptibility to HIV infection."

⁴ G. Kelen, et al., "Hepatitis B and Hepatitis C in Emergency Department Patient," *New England Journal of Medicine*, 326, no. 21 (1992): 1399-1404.

⁵ Sabin Russell, "Unsettling re-emergence of 'gay cancer,'" *SLGate.com*, (Oct. 12, 2007). <http://www.sfgate.com/cgi-bin/article.cgi?f=/c/a/2007/10/12/MNEESFRG.DDTL.&type>

Goodell et. al, "Herpes Simplex virus Proctitis in Homosexual Men," *New England Journal of Medicine* (1983) 308: pp. 868-871.

⁶ K. A. Workowski, S.M. Berman, J.M. Douglas Jr. "Emerging antimicrobial resistance in *Neisseria gonorrhoeae*: urgent need to strengthen prevention strategies," *Annals of Internal Medicine* (2008) 148 (8): 606-13.

Brian Alexander, "Incurable gonorrhea may be next superbug," <http://www.msnbc.msn.com/id/36229547>. "Resistant strains also tend to show up first in men who have sex with men."

papilloma virus,⁷ cytomegalovirus⁸, chlamydia,⁹ plus MRSA,¹⁰ and a host of other diseases.¹¹

The World Federation of Hemophilia points out that “By their very nature blood donor screening and deferral criteria are discriminatory... they are a method to reduce the risk of known, unknown, undetectable or emerging¹² viruses and/or other disease causing agents being passed to recipients of blood or blood products.”¹³

Randy Shilts’ *And the Band Played On*, a chronicle of the early days of the AIDS epidemic, documents how long it took to protect the blood supply after there was solid evidence that AIDS was a blood-borne disease.¹⁴ The gay community

⁷ C. Surawicz et al., “High grade anal dysplasia in visually normal mucosa in homosexual men: Seven Cases, *American Journal of Gastroenterology*, 90, no. 10 (1990):1176-1178.

Joel Palefsky et al., “Anal Cancer: In Gay and Bisexual Men,” (June 2000) <http://ari.ucsf.edu/science/s2c/anal.pdf>

⁸ L. Mintz, “Cytomegalovirus infections in homosexual men: An epidemiological study,” *Annals of Internal Medicine* (1983) 99: pp. 326-329;

S. Greenberg et al., “Lymphocyte subsets and urinary excretion of cytomegalovirus among homosexual men attending a clinic for sexually transmitted diseases,” *Journal of Infectious Diseases* (1984) 150 (3): pp. 330-333.

⁹ “Clinic-Based Testing for Rectal and Pharyngeal *Neisseria gonorrhoeae* and *Chlamydia trachomatis* Infections by Community-Based Organizations – Five Cities, United States, 2007,” *MMWR News Synopsis* (July 9, 2009).

¹⁰ Binh An Diep et al. “Emergence of Multidrug-Resistant, Community Associated, Methicillin Resistant *Staphylococcus aureus* Clone USA300 in men who have sex with men,” *Annals of Internal Medicine* (2008), 148 (4): pp. 249-257.

¹¹ **Shigellosis:** Demetre Daskaiskis, Martin Blaser, “Another Perfect Storm: Shigella, men who have sex with men and HIV,” *Clinical Infectious Diseases* (2007) 44: pp. 335-337: “...travel plays an important role in introducing *Shigella* species to populations at risk.”

Public Health Agency of Canada, “Outbreak of shigella flexneri and shigella sonnei enterocolitis in men who have sex with men, Quebec, 1999 to 2001,” <http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/o5vol31/dr3108a-eng.php?option=print>;

Tomas Aragen, et al., “Case-control study of shigellosis in San Francisco: The role of sexual transmission and HIV infection,” *Clinical Infectious Diseases* (2007) 44: pp. 327-334.

Lymphogranuloma venereum: Edwin Bernard, “LGV spreading throughout the UK, gay HIV positive men most affected,” *AIDS Map News*, (May 4, 2005);

Rutger Nieuwenhuis et al., “Resurgence of lymphogranuloma venereum in Western Europe: An outbreak of *Chlamydia trachomatis* serovar L₂ proctitis in The Netherlands among men who have sex with men,” *Clinical Infectious Diseases*, (2004) 39: pp. 996-1003.

Drug Resistant Syphilis: S.J. Mitchell et al., “Azithromycin-resistant syphilis infection: San Francisco California,” *Clinical Infectious Diseases* (2006) 42(3): pp. 337-45. Epub 2005, Dec.8. “All case patients were male and either gay or bisexual and 31% (16 of 52) were infected with HIV.”

Drug resistant HIV: Enrique Rivero, “Study predicts HIV drug resistance will surge,” *UCLANews.com* (Jan. 22, 2010). <http://newsroomucla.edu/oportal/ucla/study-predicts-hiv-drug-resistance-152122.aspx>.

Marc Santora, Lawrence Altman, “Rage and aggressive HIV reported in New York,” *New York Times* (Feb 12, 2005);

Thomas Maugh, “Transmission of drug resistant HIV reported” *Los Angeles Times* (July 1, 1998).

¹² Mary Chamberland, “Emerging Infectious Agents: Do They Pose a Risk to the Safety of Transfused Blood and Blood Products, *Clinical Infectious Diseases* (2002) 34, p. 797-805: “The current high level of safety is the result of successive refinements and improvements, ... nonetheless, blood and plasma products remain vulnerable to newly identified or reemerging infections... including several newly discovered hepatitis viruses...”

¹³ World Federation of Hemophilia, “WFH Statement on Blood Donor Deferrals,” Feb. 19, 2007;

National Hemophilia Foundation, “NHF Statement on Blood Donor Deferrals,” March 19, 2010

¹⁴ Randy Shilts, *And the Band Played On*, (St. Martins: NY, 1987) pp. 220-226, 599.

Also see the DVD, *And the Band Played On*.

fought the current restrictions then, using some of the same rhetoric they are using today.¹⁵

In 1981, when the first cases were reported, there was already an epidemic of STDs among men who have sex with men.¹⁶ Dr. Selma Dritz, the infectious disease specialist for the San Francisco Department of Public Health, was also concerned in 1980 when she warned a meeting of STD specialists:

“Too much is being transmitted... We've got all these diseases going unchecked. There are so many opportunities for transmission that, if something new gets loose here, we're going to have hell to pay.”¹⁷

As Dr. Dritz spoke, HIV was already making its way through the gay community and soon thousands of gay men were dying of AIDS.¹⁸

In his 1997 book, *Sexual Ecology*, gay activist Gabriel Rotello predicted a dangerous future:

“Almost every researcher studying the epidemic is convinced of one overarching fact: that if gay men ever re-recreate the sexual conditions of the seventies, the same kind of thing will happen again with other microbes. There are already drug-resistant or incurable diseases circulating in the gay population--things like hepatitis C¹⁹, antibiotic-resistant gonorrhea, various strains of herpes²⁰ – and they all stand poised to sweep through the gay population the moment we provide them an opportunity to spread... And, say the experts there are probably many more microbes whose existence we know nothing about, just as we once knew nothing about HIV.”²¹

¹⁵ Ibid.

¹⁶ James Fluker, “A 10-year study of homosexually transmitted infection. *British Journal of Venereal Diseases*. 52 (1976): 155-160.

James Fluker, “Homosexuality and sexually transmitted diseases,” *British Journal of Hospital Medicine*, 26, no. 9 (1981): 267-286

¹⁷ Shilts, p. 40.

¹⁸ Nancy Hessel et al., “Prevalence, incidence, and progression of Human Immunodeficiency Virus Infection in homosexual and bisexual Men in Hepatitis B vaccine trials, 1978 to 1988,” *American Journal of Epidemiology* (1989) 130(6): pp. 1167-1178.: Testing of blood stored for a HBV vaccine trial revealed that in 1980 13.8% of the men in the study were HIV+. At the end of 1982, the prevalence had risen to 28.1%.

¹⁹ Liz Highleyman, “HCV may be sexually transmitted in HIV negative as well as HIV positive men,” (Feb. 2007) http://www.HIVandHepatitis.com/2007/icr/croi/docs/030207_html.

²⁰ C. Hill et al, “Epidemiology of Herpes Simplex Virus types 2 and 1 amongst men who have sex with men attending health clinics in England and Wales,” www.erosurveillance.org. Nov. 26, 2009, pp. 1-6.

²¹ Gabriel Rotello, *Sexual Ecology: AIDS and the Destiny of Gay Men*, (Dutton: New York, 1997) p. 7. Also see, Madeline Drexler, *Emerging Epidemics: the Menace of New Infections* (Penguin: NY, 2010) p. 219: “Drawing on his earlier work, [Paul] Ewald makes a new prediction: the pathogens behind many chronic diseases are probably transmitted either through sex or through some other intimate contact, such as kissing or

Now, in 2010, we can see the future Rotello feared.²² Thousands of gay men attend circuit parties, where sex and drugs are on the program.²³ Millions use the gay social networking site Manhunt to hook up.²⁴ Crystal meth use among gay men is epidemic and associated with unsafe sex.²⁵ Another disease could be hiding in their blood or tissues, one with a long incubation period. Or a well-known disease could mutate into a form not recognized by current testing, as happened recently in Sweden where a mutated form of chlamydia was missed in testing.²⁶

hugging. After all, these agents—unlike, say flue or Ebola viruses—depend on mobile humans to spread. And because they rely on people to get around, it it's not in their interest to quickly dispatch their hosts. According to Ewald, sexually transmitted pathogens “have to have tricks up their sleeves for avoiding the immune system.” They must be infectious for months and transmissible after a long period of infection. No wonder, he says, that today's leading cast of characters in chronic diseases – the Epstein-Barr virus, HHV8, the human papillomavirus, the hepatitis B, as well as HIV – are all spread through intimate contact. Those cunning pathogens are most likely to escape the immune system's security forces. “A tremendously disproportionate number of agents responsible for causing chronic diseases.” says Ewald “will be STPs – sexually transmitted pathogens.”

Paul Ewald, “Guarding against the most dangerous emerging pathogens,” *Emerging Infectious Diseases* (1996) 2 (4): pp.245-256.

²² CDC, “Trends in HIV/AIDS diagnoses among men who have sex with men – 33 states, 2001—2006,” *MMWR*, 57 (2008): 681-686.

Lawrence Altman, “HIV study finds rate 40% higher than estimated,” *New York Times* (August 3, 2008).

<http://www.nytimes.com/2008/08/03/health/03aids.html>;

Kaiser Daily HIV/AIDS Report, “HIV Diagnoses among MSM ages 13-24 increased by 12% annually from 2001 to 2006,” (June 27, 2008). http://www.kaisernetwork.or/Daily_Reports.

Richard Wolitski, “The emergence of barebacking among gay and bisexual men in the United States: A public health perspective,” in Perry Halkitis, Leo Wilton, Jack Drescher, eds., *Barebacking: Psychosocial and Public Health Approaches* (Haworth Medical Press: Binghamton NY, 2005).

²³ Amin Ghaziani, Thomas Cook, “Reducing HIV infections at circuit parties,” *Journal of International Association of Physicians in AIDS Care*, (June 2005).

David Heitz, “Men Behaving Badly,” *The Advocate*, (July 8, 1997): 28-29: “The party's everywhere -- in nightclubs and sex clubs from Los Angeles to Miami and in private homes from Chicago to Atlanta. And as on Fire Island in the '70s, sex and drugs are on the invite list.”

²⁴ Michael Joseph Gross, “Has Manhunt Destroyed Gay Culture? A cost-benefit analysis of our quest to get laid,” *Out Magazine* (Sept. 5, 2008). <http://out.com/detail.asp?id=24005>.

Simon Fanshawe, “Society now accepts gay men as equals. So why on earth do so many continue to behave like teenagers?” *Guardian UK* (April 21, 2006).

<http://www.guardian.co.uk/commentisfree/2006/apr/21/gayrights.comment/print>.

²⁵ Bruce Kellerhouse, “Challenging the Culture of Disease: The Crystal Meth-HIV Connection,” in Milton Wainberg, Andrew Kolodny, Jack Drescher, ed., *Crystal Meth and Men Who Have Sex with Men: What Mental Health Care Professionals Need to Know* (Binghamton NY: Haworth Medical Press, 2006) p.12: “...crystal meth use is one of many shards that form this mosaic that might explain why more men are becoming infected with HIV. Other pieces include the perception that HIV is a manageable disease and that it is no big deal to live with it. Or the widespread use of the Internet as a private means of finding sex partners and the unexamined practice of bareback sex to avoid plastic sex, either on crystal or off.”

²⁶ Edwin Bernard, “New Swedish Chlamydia strain possible emerging threat to public health,” *AIDS Map News* (Oct. 11, 2007).

E. J. Savage, “Results of a Europe-wide investigation to assess the presence of a new variant of Chlamydia trachomatis” *Euro Surveillance* (2007) 12 (10) Epub.

Although testing for known pathogens has improved dramatically, current methods are not perfect and an increase in donations by MSM would increase the risk of infected blood reaching recipients.²⁷

But it is the diseases we don't know about -- and for which we don't have tests -- that we must guard against, and the only way to do that is to "discriminate" against high-risk groups.²⁸

MSM are a high-risk group because from the beginning of the AIDS epidemic, gay activists rejected proven public health measures.²⁹ When the gay activists can prove that the rate of STDs and HIV infection among MSM is no higher than the rate in the general public, then, and only then, should you even consider changing the rules on blood donation.

²⁷ FDA, op. cit. "...men who have sex with men and would be likely to donate have a HIV prevalence that is at present over 15 fold higher than the general population, and over 2000 fold higher than current repeat blood donors."

²⁸ Jerry Holmberg, "Meeting of the Advisory Committee on Blood Safety and Availability," Department of Health and Human Services, (March 21, 2010): "MSM have an increased incidence and prevalence of several currently recognized transfusion-transmitted diseases (e.g. HBBV, HIV, syphilis, and CMV) There is a theoretical concern that MSM populations may also be at increased risk for other unrecognized transfusion-transmitted agents."

²⁹ Rotello, p. 109. "Edward King speaking for many gay AIDS prevention workers and organizations... 'AIDS educators have a responsibility to aim only for the minimum necessary changes in individuals' lives which are needed to reduce the risk of giving and getting HIV.'"