

1 [Urging FDA Blood Regulations]

2 URGING THE U.S. FOOD AND DRUG ADMINISTRATION TO CREATE NEW BLOOD
3 DONOR GUIDELINES TO PREVENT DISCRIMINATORY IMPACT ON GAY MEN AND TO
4 INCREASE THE NATION'S BLOOD SUPPLY.

5
6 WHEREAS, Section 351 of the Public Health Services Act authorizes the United
7 States Department of Health and Human Services' Food and Drug Administration to develop
8 regulations on who may or may not donate blood; and,

9 WHEREAS, Title 21, Volume 7, section 640.3 of the Code of Federal Regulations
10 (hereafter 21CFR640) was established to regulate blood donation; and,

11 WHEREAS, 21CFR640 does not specifically state that men who have sex with men
12 may not donate blood; and,

13 WHEREAS, The Food and Drug Administration's Center for Biologics Evaluation and
14 Research develops guidance memorandums for blood collection agencies, such as the
15 American Red Cross, America's Blood Centers and Blood Centers of the Pacific, which are
16 subsequently adhered to by the blood collection agency; and,

17 WHEREAS, In a guidance memorandum dated April 23, 1992, the Food and Drug
18 Administration establishes "Criteria for the Exclusion of Unsuitable Donors Who Are at
19 Increased Risk for HIV" for determining the suitability of a donor; and,

20 WHEREAS, Persons are determined to be unsuitable if they are a person with a
21 known status of HIV infected; and,

22 WHEREAS, Persons are determined to be unsuitable donors because of their
23 increased risk for HIV if they are a past or present intravenous drug users; are a person with
24 hemophilia or related disorder; are a person who has engaged in sex for money or drugs
25 since 1977; are a person who has had sex with a person meeting the criteria of person who

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1 has engaged in sex for money or drugs since 1977 within the last 12 months; are a person
2 who has been treated for gonorrhea or syphilis in the last 12 months; and,

3 WHEREAS, The aforementioned criteria are intended to exclude persons based on
4 their known status as an HIV infected person or their behaviors which are known to spread
5 HIV or they have had sex with someone whose behaviors are known to spread HIV; and,

6 WHEREAS, Persons are also determined to be unsuitable donors because of their
7 increased risk for HIV if they are a man who has had sex with another man once since 1977;
8 and,

9 WHEREAS, HIV can be spread by all persons who have "unsafe sex", to wit, anal or
10 vaginal sexual activity between two persons without the use of a condom; and

11 WHEREAS, HIV can not be spread by any person who conducts non-insertive sexual
12 activity, including a man who has had sex with another man; and,

13 WHEREAS, The criteria of a man who has had sex with another man once since 1977
14 applies to almost every gay man and to many other men; and,

15 WHEREAS, By excluding from donating blood a man who has had sex with another
16 man once since 1977 almost all gay men who have always practiced safe sex are excluded;
17 and,

18 WHEREAS, A man who has had unsafe sex with a woman is at a higher risk of being
19 HIV infected than a man who has had safe sex with a man; and,

20 WHEREAS, All potential blood donors are pre-screened prior to donating in hopes of
21 excluding persons who have a high risk of HIV infection based on the above criteria; and,

22 WHEREAS, All units of blood are tested subsequent to donation to test for HIV in order
23 to be certain that persons who are unknowingly infected with HIV have not donated blood;
24 and,

1 WHEREAS, The Food and Drug Administration purports to determine the suitability of
2 a donor based on the donor's behavior or their status as an HIV infected person; and,

3 WHEREAS, The Food and Drug Administration nonetheless allows persons whose
4 sexual behaviors place them at high risk for HIV infection to donate blood yet categorically
5 disallows almost all gay men from donating blood whether their sexual behavior is risky or
6 not; and,

7 WHEREAS, HIV is transferred into the blood supply by a failure of the pre-screening
8 process and a subsequent test which fails to accurately reflect the blood as HIV infected (a
9 false negative in a laboratory test);

10 WHEREAS, HIV is transferred into the blood supply by a failure of the pre-screening
11 process and the inability of the subsequent test to recognize the blood is HIV infected
12 because blood can be infected with HIV and not demonstrate that until two or three months
13 after donation; and,

14 WHEREAS, HIV is transferred into the blood supply by a failure of the pre-screening
15 process and the inability of HIV tests to detect certain strains of the virus; and,

16 WHEREAS, There is a universal need for blood and blood products such as plasma;
17 and,

18 WHEREAS, The Food and Drug Administration Center for Biologics Evaluation and
19 Research (CBER) is currently drafting blood donor regulations to be submitted to the
20 Department of Health and Human Services for Review; and,

21 WHEREAS, The Food and Drug Administration CBER regulations will be published in
22 the federal register and subsequently undergo a public comment period; and,

23 WHEREAS, Publication of the CBER regulations in the Federal Register may begin as
24 early as June, 1999;

1 WHEREAS, The Food and Drug Administration has the opportunity to now change its
2 blood donor criteria to not categorically exclude the vast majority of gay men, regardless of
3 their HIV status and regardless of their sexual behavioral practices, from blood donation; now,
4 therefore, be it

5 RESOLVED, That the Board of Supervisors of the City and County of San Francisco
6 urges the U.S. Food and Drug Administration to create new blood donor guidelines to prevent
7 discriminatory impact on gay men and to increase the blood supply; and, be it

8 FURTHER RESOLVED, That a copy of this resolution be forwarded to Dr. Jay Epstein,
9 Director of the Food and Drug Administration's office of Blood Regulation and Review.

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City and County of San Francisco

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Tails

Resolution

File Number: 991180

Date Passed:

Resolution urging the U.S. Food and Drug Administration to create new blood donor guidelines to prevent discriminatory impact on gay men and to increase the nation's blood supply.

June 21, 1999 Board of Supervisors — ADOPTED

Ayes: 11 - Ammiano, Becerril, Bierman, Brown, Katz, Kaufman, Leno, Newsom, Teng, Yaki, Yee

File No. 991180

I hereby certify that the foregoing Resolution was ADOPTED on June 21, 1999 by the Board of Supervisors of the City and County of San Francisco.

JUL - 1 1999

Date Approved

Gloria L. Young
Clerk of the Board

Mayor Willie L. Brown Jr.