Impact of Differing MSM Donor Deferrals

Mark W. Skinner JD

IPFA / BCA Symposium – Future for Blood and Plasma Donation

28 September 2015

Dallas, Texas

Skinner IPA Ltd. 2015

The Short Answer

"It's complicated and potentially messy."

- Anonymous

Skinner IPA Ltd. 2015

Complicating Factors

- Politics
- Public health policy
- Civil rights
- Scientific evidence
- Risk tolerance
- Patient needs
- Global Harmonization
- Regulatory structures
- Commerce
- Economic sustainability
- …

Skinner IPA Ltd. 2015

Milestones US Health & Human Services Action

- 1983 – Deferral of sexually active homosexual or bisexual men with multiple partners
- 1985 – Deferral of even one MSM contact since 1977
- 2010 (June) – HHS ACBSA
- 2010 (September) – HHS Secretary research agenda announced
- 2014 (December) – FDA BPAC
- 2014 (December 23rd) – HHS Announces Policy Change
- 2015 (May) – FDA releases draft guidance

Skinner IPA Ltd. 2015

23 Dec 2014 – FDA Announce Policy Change



U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Search FDA

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

News & Events

Home > News & Events > Newsroom > Press Announcements

FDA Statement

FDA Commissioner Margaret A. Hamburg's statement on FDA's blood donor deferral policy for men who have sex with men

For Immediate Release December 23, 2014

Statement

The U.S. Food and Drug Administration is a science-based regulatory agency that works to protect and promote the public health. In this role, it is our responsibility to regulate the blood supply and to help ensure its continued safety for the patients who receive these life-saving products.

Over the past several years, in collaboration with other government agencies, the FDA has carefully examined and considered the available scientific evidence relevant to its blood donor deferral policy for men who have sex with men, including

Inquiries

Media

Jennifer Rodriguez
301-796-8232

Consumers

888-INFO-FDA

Share

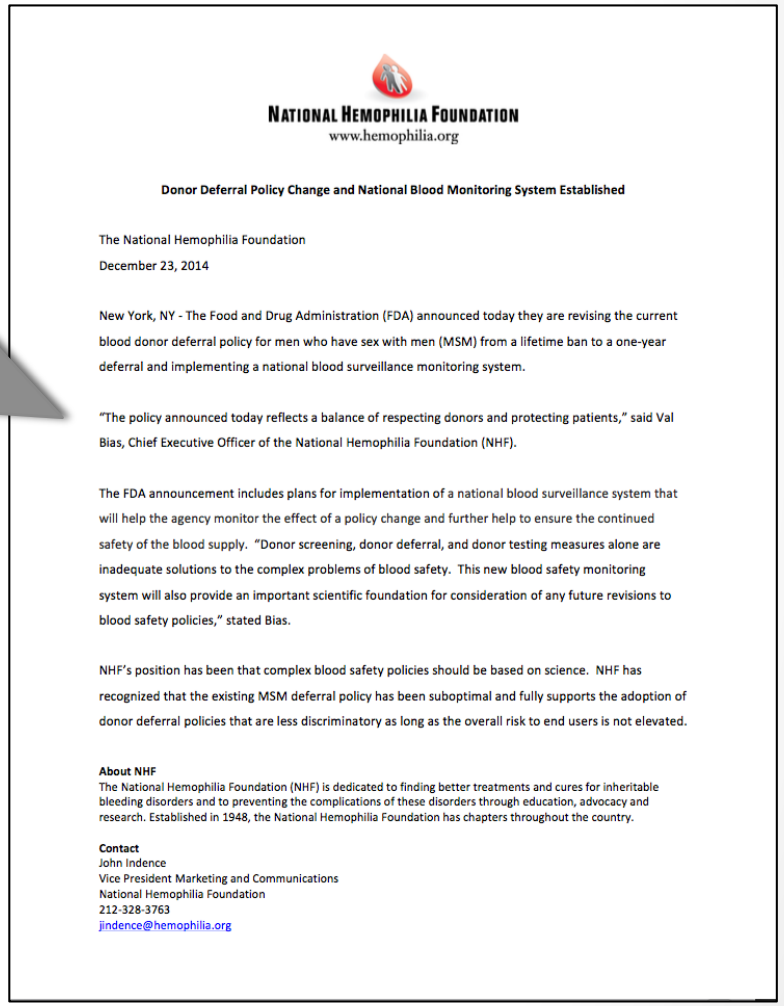
88

FDA News Release feed

NHF Response – 23 Dec 2014

"The policy announced today reflects a balance of respecting donors and protecting patients.

The new blood safety monitoring system will provide an important scientific foundation for any future revisions to the blood safety policies."



NATIONAL HEMOPHILIA FOUNDATION
www.hemophilia.org

Donor Deferral Policy Change and National Blood Monitoring System Established

The National Hemophilia Foundation
December 23, 2014

New York, NY - The Food and Drug Administration (FDA) announced today they are revising the current blood donor deferral policy for men who have sex with men (MSM) from a lifetime ban to a one-year deferral and implementing a national blood surveillance monitoring system.

"The policy announced today reflects a balance of respecting donors and protecting patients," said Val Bias, Chief Executive Officer of the National Hemophilia Foundation (NHF).

The FDA announcement includes plans for implementation of a national blood surveillance system that will help the agency monitor the effect of a policy change and further help to ensure the continued safety of the blood supply. "Donor screening, donor deferral, and donor testing measures alone are inadequate solutions to the complex problems of blood safety. This new blood safety monitoring system will also provide an important scientific foundation for consideration of any future revisions to blood safety policies," stated Bias.

NHF's position has been that complex blood safety policies should be based on science. NHF has recognized that the existing MSM deferral policy has been suboptimal and fully supports the adoption of donor deferral policies that are less discriminatory as long as the overall risk to end users is not elevated.

About NHF
The National Hemophilia Foundation (NHF) is dedicated to finding better treatments and cures for inheritable bleeding disorders and to preventing the complications of these disorders through education, advocacy and research. Established in 1948, the National Hemophilia Foundation has chapters throughout the country.

Contact
John Indence
Vice President Marketing and Communications
National Hemophilia Foundation
212-328-3763
jindence@hemophilia.org

GMHC / GLADD Video Petition



Skinner IPA Ltd. 2015

Gay Blood Donor Drive – July 10, 2015



THANK YOU TO EVERYONE WHO PARTICIPATED!





Call On HHS & The FDA To En
Their Ban Against Gay & Bisexual
Male Blood Donors

ARCHIVED



Skinner IPA Ltd. 2015

APLUS 2010 MSM Research Agenda

1. Achieving a better understanding of known and emerging pathogens in specific populations including MSM and heterosexual populations;
2. Developing policy that recognizes societal aspects of the blood system's safety and risk tolerance;
3. Developing alternate donor deferral strategies and the risk of blood-borne diseases;
4. Establishing a framework for accelerated approval of pathogen reduction, removal and/or inactivation technologies for fresh components; and
5. Understanding the implications of a revision on the supply and availability of treatment products globally.

Presented HHS ACBSA Meeting June 2010

Skinner IPA Ltd. 2015

Blood is Local – Plasma is Global

- The phrase *"blood is local, plasma is global"* is noteworthy in the context of this discussion.
- The implications of a revision in the MSM deferral policy include the potential to impact the global supply and availability of plasma-derived medicinal products.
  - In 2010, 30.2 million liters of plasma (recovered/source) collected
  - 62% (20.4 million liters) from North America
- Will products manufactured from plasma pools containing MSM donors be suitable for importation, manufacture, sale or distribution within Europe or elsewhere?

Skinner IPA Ltd. 2015

MSM Deferral Policy Examples

12 Month Deferral

- ~~Argentina~~
- Australia
- Brazil
- Czech Republic (?)
- Hungary
- Japan
- UK (ESW only)
- US (date TBD)

5 Year Deferral

- Canada
- New Zealand

Behavioral

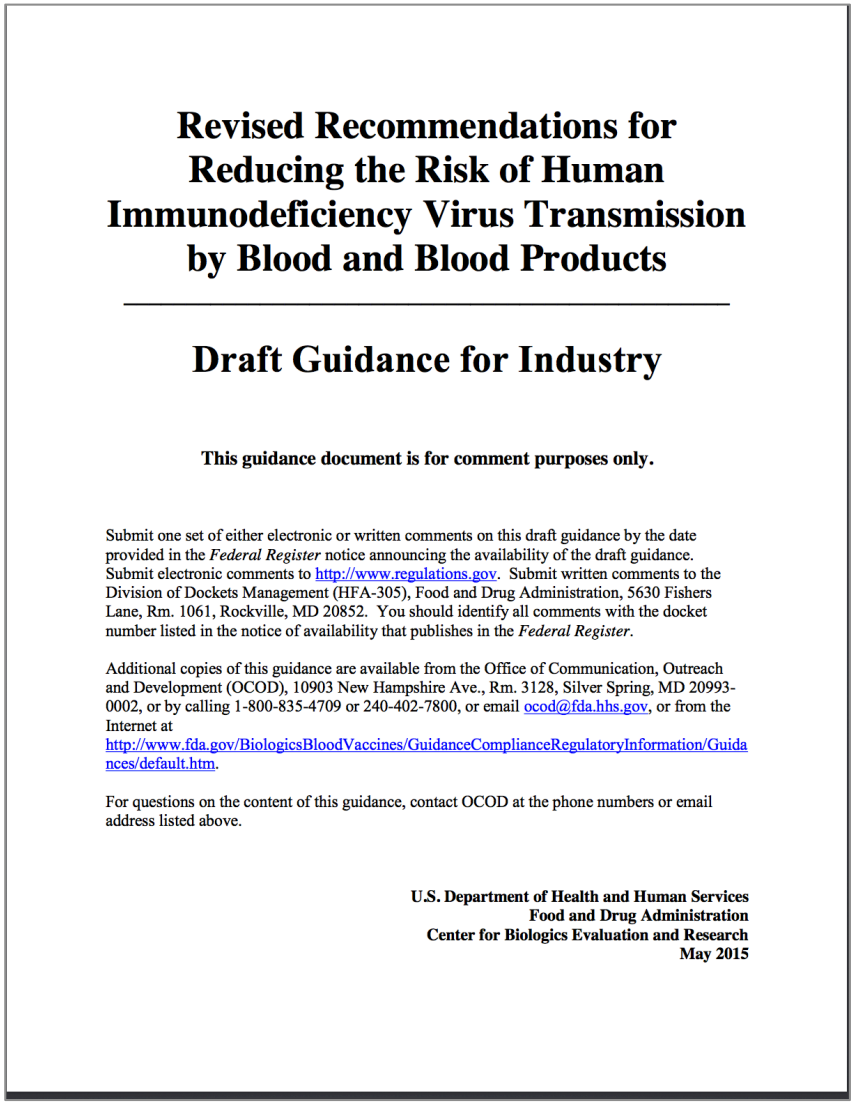
- Argentina
- Italy
- Mexico
- Poland
- Russia
- South Africa
- Spain

Lifetime Deferral

- Austria
- Belgium
- China
- ***European Union (?)***
- France (under review)
- Germany
- Ireland (under review)
- Netherlands
- Switzerland
- UK (NI)
- US*

Skinner IPA Ltd. 2015

FDA Draft Guidance Released – May 2015



Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products

---

Draft Guidance for Industry

This guidance document is for comment purposes only.

Submit one set of either electronic or written comments on this draft guidance by the date provided in the *Federal Register* notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-7800, or email ocod@fda.hhs.gov, or from the Internet at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
May 2015

- The recommendations contained in this guidance apply to the collection of blood and blood components, including Source Plasma

EU Blood Directive – Requirements for blood and blood components

European legislation distinguishes behaviors “at risk” and “at high risk” linked to temporary and permanent deferrals, respectively, albeit without further definitions of risk.

- *2.1.* ***Permanent deferral criteria for donors of allogeneic donations***
  - *Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood*
- *Blood and blood components imported from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood and human plasma, should meet the quality and safety requirements set out in this Directive.*

- Offergeld et al. VOX (2014)107;420-427
- COMMISSION DIRECTIVE 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

Skinner IPA Ltd. 2015

Council of Europe Task Working Group

- *One of the most controversial policies in blood transfusion worldwide is the permanent deferral from donating blood of men with sexual contacts to other men (MSM).*
- *…two surveys revealed the high diversity of DHQ among countries in Europe and worldwide and the resulting deferrals, despite the fact that nearly all of the European responders are obligated to follow EU law.*
- *In conclusion, even though the … expert group did not succeed in reaching a harmonized European approach to select donors with different sexual risk behaviour, areas of improvement of the donor selection procedure and consequently transfusion safety were identified…*

Sources: Offergeld et al. VOX (2014)107;420-427 & Council of Europe Resolution CM/Res (2013) available at: https://www.edqm.eu/sites/default/files/resolution_cmres_2013_3_on_sexual_behaviour_of_blood_donrs_that_can_have_an_impact_on_blood_safety.pdf

While the Demand for PDMPs is Increasing Demand for Blood Transfusion Decreasing

- The demand for PDMPs has been increasing and will continue due to:
  - Improved access to health in developing countries
  - Improved diagnostic capabilities reducing under-diagnosis and under treatment,
  - New PDMPs that treat other rare or more prevalent chronic conditions
- Growth in demand for whole blood has slowed
  - American Red Cross reports RBC transfusions decreased from 15 million in 2008 to 11 million in 2013 (20% decline)
  - Evolving economic implications for Blood Collectors

Skinner IPA Ltd. 2015

Now what?

- What are the implications
  - For donors
  - For patients
  - For blood / plasma collectors
  - For the plasma fractionation industry
- What does it mean for the global movement
  - Of plasma
  - Of finished PDMPs
- What are the economic implications on blood centers / source plasma collection centers
  - Are there differences between the sectors?
  - Should there be?

Skinner IPA Ltd. 2015

Range of Options, For example…

- Blood collectors could continue to differentiate plasma donations destined for fractionation between MSM and non-MSM donors;
- Plasma-derived products destined for international markets could be limited to plasma from female donors. However this potentially limits the antibody diversity which is important for the immune deficient population; or
- The MSM donor deferral could remain for source plasma collections and exclude recovered plasma from products destined for international markets.
- Determined by contract terms case by case
- …

Skinner IPA Ltd. 2015

Timing – What's Next

- Communicate with manufacturers / review contracts
- Final FDA guidance document – Date unknown
- Blood / Plasma collectors develop SOP Changes
- Revision of DHQ and Donor education materials
  - Staff training, Recruitment messaging
- Liaise with LGBT groups on donor education / messaging
- On-going communication with bleeding disorders community
- Regulatory filings require prior approval of FDA for revised DHQ and Donor education materials
- HHS (TBD) announcement on hemovigilance program
- On-going hemovigilance / implementation oversight

Skinner IPA Ltd. 2015