

## 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