



NATIONAL HEMOPHILIA FOUNDATION
for all bleeding and clotting disorders

MASAC Document #189

MASAC CONSENSUS STATEMENT ON PLASMA SAFETY

The following recommendation was approved by the Medical and Scientific Advisory Council (MASAC) on March 21, 2009, and adopted by the NHF Board of Directors on June 6, 2009.

Although the vast majority of individuals in the United States with hemophilia A and B are now using recombinant clotting factor concentrates, there are still many individuals with hemophilia A and B and von Willebrand disease who rely on safe plasma-derived concentrates. In addition, individuals with rare plasma protein deficiencies depend on safe plasma-derived concentrates and fresh frozen plasma to treat their disorders. Due to this continued need for plasma-derived therapies, it is imperative that manufacturers of these products ensure the highest level of safety possible. These safety measures also impact the general population of individuals who are recipients of blood and blood components.

In the past 20 years, plasma safety in the US has been enhanced by stringent donor selection, NAT and PCR testing of the donated units of plasma, and viral attenuation/elimination steps during the manufacturing process. Removal of infectivity via manufacturing processes is the most effective method of pathogen elimination, and high levels of clearance of known infectious agents, including prions, have been demonstrated for plasma-derived products currently licensed in the US.

In the US there are rare disorders for which there are no licensed products available. However, in some cases there are products for these same rare disorders that are licensed in other countries but not yet in the US. There is a need for a mechanism for these products to be tested and licensed in the US.

In order to maintain access to safe products, MASAC makes the following recommendations:

1. We encourage USDA to strengthen and strictly enforce rules regarding the surveillance and control of transmissible spongiform encephalopathy in US livestock.
2. We encourage FDA to implement the expanded feed ban originally scheduled to go into effect in April 2009.
3. We also encourage industry and the blood banking community to conduct research into pathogen elimination in plasma and cryoprecipitate for transfusion.
4. We encourage manufacturers of factor concentrates to produce specific products for specific rare plasma protein disorders.
5. We encourage the CDC to continue their surveillance efforts with regards to possible transmission of parvovirus B19 and other known and emerging pathogens by plasma-derived concentrates.
6. We encourage manufacturers to develop and seek approval of plasma- and blood product-sparing hemostatics and antifibrinolytics.



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7. Manufacturers should expeditiously perform clinical studies required for licensure in the US of prothrombin complex concentrates for warfarin reversal.

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