

**PRESIDENT**  
Mark W. Skinner

February 13, 2008

**VICE PRESIDENT MEDICAL**  
Paul Giangrande, M.D.

Mr. José-Manuel Barroso  
President of the European Commission

**VICE PRESIDENT FINANCE**  
Rob Christie

Mr. Markos Kyprianou  
European Union Commissioner for Health

**VICE PRESIDENT PROGRAMS**  
Alison Street, M.D.

European Commission  
B-1049 Brussels, Belgium

**VICE PRESIDENT NMO**  
Gordon Clarke

Dear Mr. Barroso and Mr. Kyprianou,

**VICE PRESIDENT  
COMMUNICATIONS AND  
PUBLIC POLICY**  
David Page

The World Federation of Hemophilia (WFH) is writing to you in response to a letter that the International Federation of Blood Donors Organizations (IFBDO) recently sent to the European Commission and posted on their website, titled “Sufficiency of supply of blood and blood products within the European Union.”

**EXECUTIVE COMMITTEE**  
Anjelika Batorova, M.D.  
Paula Bolton-Maggs, M.D.  
César Garrido  
Nigel S. Key, M.D.  
Alok Srivastava, M.D.  
Aliakbar Tchupan

The WFH represents 109 patient organizations for patients with hemophilia and other genetic bleeding disorders around the world. Our membership includes 42 European countries and 26 of the 27 European Union member states. People with hemophilia and other bleeding disorders are chronic users of plasma-derived medicines – specifically clotting factor concentrates. These products mean the difference between life and death or disability for many patients. Because our community relies on plasma-derived medicinal products we are concerned about some of the statements made in the IFDBO letter.

**FOUNDER**  
Frank Schnabel

**PATRON**  
Jan Willem André de la Porte

**CEO/EXECUTIVE DIRECTOR**  
Claudia Black

The IFDBO letter questions the safety of treatment products made from the plasma of compensated donors as well as the traceability of the plasma. The WFH has studied these questions extensively and we do not believe that plasma-derived medicinal products made with plasma from compensated donors carry any greater risk than products made with plasma from “non-compensated” donors. In fact, because of inventory hold, donor screening and testing and the manufacturing process, these products are considered among the safest therapeutics on the market today (Mannucci PM. Hemophilia: treatment options in the twenty-first century. *J Thromb Haemost* 2003; 1: 1349–55.). Furthermore apheresis donors are frequent, repeat donors meaning that follow-up and tracking of their health status is easier than with sporadic donors. We also note that the plasma collection centres in the US are inspected regularly by US and European regulators. The manufacturing plants as well are highly regulated.

1425 René-Lévesque Blvd. West  
Suite 1010  
Montréal, Québec H3G 1T7  
Canada  
Tel.: (514) 875-7944  
Fax: (514) 875-8916  
E-mail: [wfh@wfh.org](mailto:wfh@wfh.org)  
Web site: [www.wfh.org](http://www.wfh.org)

The hemophilia community was devastated by the HIV epidemic (B. L. EVATT (2006) The tragic history of AIDS in the hemophilia population, 1982-1984 Journal of Thrombosis and Haemostasis 4 (11), 2295–2301.) and we have become diligent watchdogs over the safety of clotting factor concentrates. Since the introduction of viral-inactivation methods some two decades ago, these products have had an excellent safety record. However the greatest safety concern today is not infection but rather lack of access to products. All of the clotting factor concentrates currently produced in the world are consumed by patients and yet as many as 75% of patients have no access to treatment products. (Report on the WFH Global Survey 2006.) Any move which reduces supply, access or patient choice is detrimental to patient health and safety.

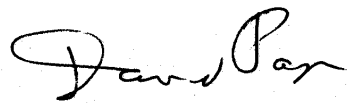
The WFH appreciates the gift that blood and plasma donors make. We encourage good blood collection practices and are very grateful towards every voluntary donor (paid and unpaid) who contributes their blood or plasma to make the life-saving products our community relies on. It is simply not possible for the “uncompensated” sector to provide a sufficient amount of the products that people with bleeding disorders need. Both the “uncompensated” sector, absolutely vital to the supply of fresh components, and the “compensated” sector, equally vital to the supply of fractionated blood products, can and must continue to co-exist.

We urge the Commission to continue its stance in defending patient access to a variety of safe products.

Sincerely,



Mark W. Skinner  
President, World Federation of Hemophilia



David Page  
Vice-President, Communications and Public Policy, World Federation of Hemophilia  
Chair, WFH Blood Products Safety Supply and Availability Committee