Vox Sanguinis (2003) 85, 48

LETTER

Vox Sanguinis

Response to the review 'Paying for blood donations: still a risk?'

J. M. Bult
Plasma Protein Therapeutics Association, Annapolis, MD, USA

In focusing exclusively on epidemiology, Dr van der Poel [1] provides a misleading conclusion as to whether compensating donors of blood or blood components constitutes a risk: any discussion should focus on the recipients and examine whether diseases are actually transmitted more often by donations deriving from compensated vs. non-compensated donors.

The Committee for Proprietary Medicinal Products (CPMP) committee of the European regulatory body, the European Agency for the Evaluation of Medicinal Products (EMEA), takes a similar patient-centred view and concluded [2] that:

There is no evidence from clinical studies and pharmacovigilance that donor remuneration increases the risk of viral transmission via plasma-derived medicinal products, which have been subject to proper screening at donation and a validated viral inactivation/removal step.

A number of independent scientific advisory groups and governmental agencies support this general view, for example the German Government's advisory Group (Arbeitskreis Blut, unpublished). The US Food and Drug Administration (FDA) has recognized [3] the absence of transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV) or hepatitis C virus (HCV) by plasma products manufactured from compensated donations since the introduction of these processes. Additionally, the US Centers for Disease Control (CDC), in commenting on plasma products derived almost exclusively from compensated donations, concluded in 2003 [4] that virally inactivated blood factor concentrates used to treat bleeding disorders are unlikely to transmit viral hepatitis. These studies, unlike Dr van der Poel's, are based on very recent data that more adequately reflect today's safety standards and environment.

Interestingly, in the Netherlands (where blood and plasma donations are exclusively from non-compensated donors) in 2000, five diagnosed cases of acquired immune deficiency syndrome (AIDS) were attributed to blood and blood products [5].

Dr van der Poel raises further unnecessary concerns in stating that viral-inactivation steps may not inactivate all viruses. One has only to look at the emerging infections of recent public health concern to see how effective the manufacturing process is. West Nile virus (WNV) is effectively inactivated by steps previously introduced to deal with a wide range of different viruses, and the regulatory authorities have acknowledged the effectiveness of the fractionation process in removing prions.

WNV and prions also raise doubt about the authors' statement that 'any time a new blood-borne infectious disease has emerged, paid donors have had higher frequencies of infection than unpaid ones'. There is no evidence that mosquitoes bite volunteer compensated donors more often than non-compensated donors, or that donor compensation leads to a greater risk for variant Creutzfeldt–Jacob disease (vCJD).

In the struggle to improve the health of blood product recipients, the scientific community has a duty to examine the real causes of transmission of infectious agents by today's transfusions. If we continue to look at the past and close our eyes to the current facts, we will be failing those who depend on us for their life-saving treatments.

References

1 van der Poel CL, Seifried E, Schaasberg WP: Paying for blood donations: still a risk? *Vox Sang* 2002; 83:285–293
2 EMEA/CPMP/BWP: *CPMP Position Statement: Non-Remunerated and Remunerated Donors: Safety and Supply of Plasma Derived Medicinal Products*. London, CPMP, 2002
3 Tabor E: The epidemiology of virus transmission by plasma derivatives: clinical studies verifying the lack of transmission of hepatitis B and C viruses and HIV type 1. *Transfusion* 1999; 39:1160–1168
4 Hollinger FB, Kirtava A, Oakley M, Soucie M, Evatt B: Blood safety monitoring among persons with bleeding disorders: US May 1998–June 2002. *MMWR Wkly Rep* 2003; 51:1152–1154
5 WHO: *Epidemiological Fact Sheet: 2002 Update*. Geneva, World Health Organization, 2002

Received: 20 February 2003,
accepted: 3 April 2003

Jan M. Bult
President, Plasma Protein Therapeutics Association
147 Old Solomons Island Road
Suite 100
Annapolis
Maryland 21401
USA
E-mail: jbult@pptaglobal.org