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Jeffrey L. Winters, M.D.
Division of Transfusion Medicine

January 13, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 02D-0362

To Whom It May Concern:

We are writing to comment on "Guidance for Industry Recommendations for Deferral of Donors and Quarantine and Retrieval of Blood and Blood Products in Recent Recipients of Smallpox Vaccine (Vaccinia Virus) and Certain Contacts of Smallpox Vaccine Recipients". We agree with the recommendations put forth in the document but feel that additional information should be released as part of the guidance.

The requirement for the person qualifying the donor to visualize the site of inoculation is necessary to determine donor eligibility. Contact with the site of inoculation, however, does represent a risk to the donor room personnel of acquiring vaccinia infection and potentially spreading it to other blood donors. As most blood donor room positions are entry level jobs staffed by younger individuals, they will not have immunity to vaccinia infection from previous vaccination. In addition, we would suspect that these individuals are not high priority to receive the smallpox vaccine. We feel strongly that the guidance document should explicitly state that there is a danger of acquiring vaccinia infection by coming in contact with the vaccination site. We further feel that guidance should explicitly state that the personnel should not touch the site of inoculation.

Related to the above, some institutions, such as the Mayo Clinic, are requiring that vaccinated individuals wear an occlusive dressing over the vaccination site in order to minimize auto-inoculation and inadvertent transmission. The requirement to visually inspect the site would require the removal of such a dressing. Again, this would mean that the donor room personnel could potentially be infected. In addition, vaccinia can be transmitted by fomites similar to smallpox so that the removed dressing would also represent a risk. We strongly feel that the guidance should also mention these dangers and recommend that donor personnel not remove dressings placed over vaccination sites but rather defer such donors until the dressing is no longer present and the site can be visualized.

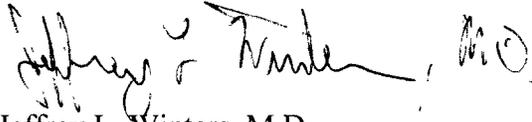
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We thank you for consideration of our comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Jeffrey L. Winters, M.D.", with a circular mark at the end of the signature.

Jeffrey L. Winters, M.D.
Medical Director, Donor Services
Transfusion Medicine
Mayo Clinic Rochester

JLW/bjp

cc: S. Breannan Moore, M.D.
Mary Foss
Sheryl Tran