50 YEARS SHARING LIFE
Blood Bank of San Bernardino and Riverside Counties

February 12, 2001

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

Re: Docket # 00D1618

I am writing for additional guidance with respect to interpreting the Guidance for Industry "Variances for Blood Collection from Individuals with Hereditary Hemochromatosis."

The background information clearly explains that the intent of the Guidance is to protect the safety of the blood supply by removing any financial incentive for the patient with Hemochromatosis to don@ his/her blood for transfusion as opposed to undergoing a therapeutic phlebotomy (for which a fee would ordinarily be charged). The mechanism for removing the financial incentive espoused in the Guidance would be to eliminate fees for therapeutic phlebotomies for all patients with Hemochromatosis whether or not their blood was otherwise acceptable for allogeneic transfusion.

I would like to propose an alternative approach that I believe to be equally valid. I offer this alternative because our, analysis of the approach proposed in the Guidance (no fee for therapeutic phlebotomies) indicates that it would be cost prohibitive for our center (and, I assume, for most other blood centers). The percentage of diagnosed Hemochromatosis patients whose blood is otherwise acceptable for allogeneic transfusion is well under 50%. The expense of drawing so many donors whose blood could not be used would not be offset by the fees charged for blood collected and distributed from those patients who did meet allogeneic criteria. Thus, unless an alternative approach was acceptable, our center, and most other centers, will decide not to bother, and a measurable amount of otherwise usable blood will not be made available for patients.

My recommendation is that the Guidance be modified to allow an additional way for blood centers to eliminate the financial incentive. I propose that centers be allowed to continue to charge a therapeutic phlebotomy fee for ALL patients with Hemochromatosis, regardless of whether or not their blood is acceptable (and therefore made available) for allogeneic transfusion. If all patients are charged a phlebotomy fee, then there is no incentive to have one's blood made available for transfusion other than the same incentive that applies to other allogeneic donors: the knowledge that their blood might be lifesaving for someone else.

In my proposal, everyone wins: the blood center is reimbursed for the cost of the therapeutic phlebotomy (instead of having to do it gratis), the healthy Hemochromatosis patient gets that same good feeling as the allogeneic donor-(knowing that their perfectly safe blood'will 'not be simply discarded), and the community; or the specific patient, benefits by an augmented blood supply.

00D-1618

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I believe that if one approached the Hemochromatosis patient with the concept that they were going to pay for the service, but that they then had the option either to have their blood discarded or, providing it was otherwise acceptable and all screening tests were negative, made available for transfusion, many would respond appropriately and make their donation so available.

I appreciate your thoughtful response to this suggestion. I look forward to hearing from you.

Sincerely yours,

Arthur J. Silvergleid, MD
Medical Director and CEO

AJS:jkd/7575

ADMINISTRATION

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