Community Blood Bank

of the Lancaster County
Medical Society

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An FDA Licenced Facility
A Not For Profit Blood Center
Member of American Association
of Blood Banks
Member of America's Blood Centers

April 28, 2003

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

RE: SARS Guidance posted on FDA Web site April 18, 2003.

To Whom It May Concern:

The purpose of this letter is to express my concerns regarding the recent FDA SARS Guidance document. As the Chief Executive Officer of the Community Blood Bank, in Lincoln, NE. I find many difficulties in the implementation of the Guidance.

"Emergency" Issuance of Guidance bypassing Routine Review & Comment Procedures.

The guidance was issued as an "emergency" guidance and by-passed the normal public comment period, because "SARS may pose immediate safety risks to the blood supply". While it is possible that this risk may be documented in the future, at the time of issuance of the guidance there were 35 cases of SARS reported to the CDC.

Recommendation: FDA can use alternate methods to obtain representative input from scientific, industry experts, and the public by convening an emergency meeting of the Blood Products Advisory Committee in order to have input from the public, and the industry members affected.

Guidance Scope of Responsibility

The final guidance placed the full burden of responsibility for ensuring the safety of the blood supply on the blood centers. With the low incidence of cases of the disease, to screen out cases of the disease is "needle in the haystack" work. It is common knowledge that 100% screening for a low incidence event is ineffective.

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Recommendation: When inspecting for a low incidence factor it is best to target screening on a smaller more specific, at risk pool. In this case, to focus & limit screening & notification to individuals that have been classified as SARS contacts by Public Health Authorities would be much more effective. Since the Public Health Service is issuing written information to potential SARS contacts returning from affected countries it could easily include directives not to donate blood for 14 days after return from a SARS affected area or if affected with symptoms of the disease

Impact on Blood Supply (Section II.C). The assertion made by FDA is incorrect and inappropriate. A travel deferral such as this can significantly affect the blood supply even in areas such as Nebraska.

Recommendation: Since the ultimate spread of SARS is undetermined at this time, it is possible that geographical deferrals will make collections impossible in certain areas the US--creating a supply crisis. Providing unfounded assurances in guidance documents is not appropriate.

Impact on the Donor Screening Process. The added donor screening requirements in the guidance seriously complicates the donor screening process with no assurance that this method will be effective in eliminating the SARS risk from the blood supply.

Adding donor screening questions requires additional donor time, and donor focus, additional staff time, training, revision of donor forms, modification of computer systems, computer validation, etc.

The FDA's continuing practice of simply adding even one more "unvalidated" donor question or tier of questions simply causes increased false positive responses and further decreases the nation's available blood supply.

Recommendations:

1. FDA must begin to validate donor screening questions for understanding, effectiveness and determination of the false positive & false negative rates
2. FDA must refrain from simply adding another donor screening question. This is simply a "quick fix", not effective problem-solving and further decreases the number of blood donors and the blood supply.
3. FDA can consult with industry experts such as the AABB Uniform Donor History Questionnaire task force when considering a course of action with such a far-reaching affect on the public.

CGMP Compliance
Implementation of these guidelines in a cGMP environment in less than 30 days is problematic. There are SOP revisions, training, validation, software revisions, and process validation issues.

The recommendation that collecting facilities consult the CDC website "routinely and periodically" for updates cannot be implemented in a cGMP environment. Changes in the list of countries of the definition of close contacts require changes in SOPs, changes in donor registration forms, changes in information provided to donors before donation, changes in documentation that the questions were asked and the answers were acceptable, training of staff, etc.

"Periodically" is not a definable term in cGMP environment.

Recommendation(s):

1. FDA must waive such a documentation requirement.
2. FDA can issue guidance updates with time frames for implementation.

In summary, I am not convinced that the threat of SARS to transfusion safety rises to the level of emergency and action required by the Guidance. The current guidance document should be rescinded and replaced by a more reasonable approach. Additionally, the FDA must convince CDC to add a proscription from blood donation to PHS information already being provided to returnees from listed countries, as we have previously and repeatedly suggested as a simple, effective approach to prevent donation by at risk individuals.

Sincerely,

Phyllis Ericson
Chief Executive Officer

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