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Dear Jay:

On behalf of the Task Force to redesign the blood donor history questionnaire, I would like to thank you for your willingness to become personally engaged at this time in the review of proposed changes to the questionnaire. The wording and content of the questionnaire have undergone rigorous evaluation by the Task Force, and before further validation takes place, your input and thoughts on the work to date are crucial for the success of the project.

FDA representation on the AABB Task Force is greatly appreciated. Through feedback from these contributing and highly engaged representatives, you are aware that so far the proposed revisions fall into two categories:

1. Simplification of FDA regulation- or guidance-derived questions. These questions have been exhaustively reviewed and revised through an iterative process by Task Force subcommittees, the entire Task Force - which includes two specialists in health survey design – and by Holland Laboratory-sponsored focus groups of prospective and current blood donors. FDA Error and Accident data were integrated, as well blood center input provided in the fall 2000 AABB Survey of Blood Centers to Identify Problematic Screening Questions. The proposed revisions and accompanying rationale are listed in **Attachment 1**. Data and protocols from the focus groups and AABB survey are not being submitted at this time because it is our understanding that the upcoming FDA review will be conceptual in nature.
2. Proposals to eliminate certain questions that are not required or recommended by the FDA. Virtually all of these questions are in the donor questionnaire as a result of AABB - not FDA - suggestions or Standards. **Attachment 2** contains these proposed changes.

The next step for validating the questions in the **first** category (**simplification**) will – if funding can be obtained – involve the performing of one-on-one cognitive interviews by the National Center for Health Statistics (CDC), which has a staff of methodological experts who evaluate in a cognitive laboratory how well survey questions “work.” We believe that this represents the best available approach for assessing comprehension of the questions and identifying whether portions of the revised questions could be difficult to answer or cause the interviewee to miss the point.

Two additional documents are referred to in the attachments and will be integral components of the final questionnaire: enhanced donor educational material and a “User’s Pamphlet” for the final product. *Both of these documents are under development and are not yet ready for review.*

We understand that FDA review of the proposed revisions is not only necessary but desirable. At this point, the Task Force is seeking conceptual and policy feedback on the questionnaire, rather than detailed wording changes. FDA review that is both expedited and consistent with this goal would ensure that we can meet the FDA’s stated 2001 deadline for final product submission. We are aware of the complex priorities facing CBER; however, in order for the Task Force to remain on schedule, it would be extremely helpful and greatly appreciated if comments on the attached documents – especially Attachment 1 - could be provided within the next few weeks.

Thanks for your involvement and help, Jay. We look forward to a constructive and productive dialog in the upcoming days.

Cordially,

Joy L. Fridey MD  
Chair, AABB Task Force to Revise the Donor History Questionnaire