

September 5, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fisher's Lane, Room 1061
Rockville Pike, Rockville, MD 20852-1448

Docket No 00D-1267

**RE: Draft "Guidance for Industry Recommendations for Donor Questioning
Regarding Possible Exposure to Malaria"**

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The AABB appreciates the opportunity to comment on this draft guidance for industry: "Recommendations for Donor Questioning Regarding Possible Exposure to Malaria." Both the AABB interorganizational task force on the Donor History Questionnaire and the AABB Transfusion Transmitted Diseases (TTD) committee contributed to these comments. The interorganizational task force and the TTD committee includes representatives from the AABB, America's Blood Centers (ABC), the American Red Cross (ARC), the American Blood Resources Association (ABRA) and liaisons from the Center for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA.) We have examined the guidance not only for its scientific merits, but also in light of the expressed intent of the FDA to streamline and improve the donor history questionnaire.

The guidance document does not take note of the striking improvement in safety that has already occurred without any substantial modification of the screening procedures for malaria risk. Examination of the US Statistical Abstract shows that US travelers to all foreign countries increased eightfold between 1975 and 1997, and travel to Mexico even more in the interval. During the same time, the annual rate of transfusion-transmitted malaria reported to the CDC has remained essentially unchanged, ranging from 0 to 0.785 per million units transfused. Even the changes in screening made in 1994 may not have made a difference since there has been nearly a 20 percent increase in foreign travel by US residents between 1994 and 1999. Under any assumptions, current screening methods can thus be viewed as increasingly effective for prevention of transfusion-transmitted malaria screening during the past 25 years, and a need for wholesale changes to the screening process to address the issue of malaria risk is not pressing.

A review of US malaria cases during the past decade demonstrates that four percent of imported malaria originates from Mexico and the Caribbean, and that no cases of transfusion associated malaria have been attributed to these extraordinarily popular travel destinations in that interval. The impact on donor deferrals of this new guidance may be substantial and should be estimated before they are implemented.

The AABB also notes that before a new screening test is put into use by blood centers, or a new drug is licensed for use by doctors, it must be thoroughly tested and shown to be efficacious and without serious unintended effects. We would welcome the FDA applying the same criteria to screening questions, at least requiring evidence that the question will actually improve safety. At a minimum, questions should be validated to determine that donors actually understand the content and intent of the question. The AABB again offers to work with the FDA to formulate and pilot proposed questions either before they are published for comment or before the draft questions are finalized.

The AABB makes the following comments specific to this draft guidance document:

- 1. The AABB requests a quantitative assessment of the impact of this donor screening strategy on deferral of donors, especially those with travel to Mexico and the Caribbean prior to implementation of this guidance.**

To this end, members of the TTD committee including the chair, representatives from the CDC and the major blood organizations are discussing the construction of a sample survey to accurately determine the impact on donor deferral of malaria questioning.

- 2. The AABB requests an alternate approach to the proposed donor questions in Section III Recommendations number 5.**

The central issue for deferral for malaria is not where the person was born, but whether that person has resided in an endemic country for at least five years. The proposed questions do not adequately address this issue. For example, it would be possible for a person to be born in the U.S.; move to a malarious area and live there for five years or more; return to the U.S.; and then travel to a malarious area. This series of questions would allow such an individual to donate within one year of travel to the malaria area instead of the suggested deferral of three years for those who may have acquired a partial immunity, because residency in the malarious area would not be known. In addition, in many parts of the U.S. there is significant sensitivity about immigrant issues, and blood collection facilities do not wish to become involved in this controversy by asking all prospective donors whether they were born in the U.S.

The AABB suggests an alternate approach.

The first question would be the one already in use of the Uniform Donor History Questionnaire: *In the last three years, have you been outside the United States or Canada?*

If no, no further questions.

If yes, determine where the donor traveled

If the travel destination is not a malarious area – no further questions

If the travel destination is a malarious area – ask

Have you ever lived outside the United States or Canada for five years or more?

If no – defer for 1 year from departure from malarious area

If yes – defer for 3 years from departure from malarious area

This approach has several advantages. First, it specifically addresses the deferral criteria and is easy to explain. Second, it retains the question on the current donor history questionnaire without increasing the length of the printed form. The explanation and additional criteria can be included in the Standard Operating Procedure rather than on the actual donor questionnaire itself, which supports the FDA's interest in streamlining the questionnaire. The Standard Operating Procedure will also define how to document the answers and the deferral if indicated. Finally, the printing of new questionnaires will not be necessary.

3. The AABB requests clarification of terms.

The terms endemic country, endemic area, malarious area/region appear to be used interchangeably both in the Background information and in the actual recommendations. We believe that defining these terms or preferably using a single term such as area would eliminate confusion. Countries with focal /limited malarious areas and countries with distinct malarious and non-malarious areas should not be considered endemic countries.

4. The AABB requests clarification of the final paragraph in Section II Background to define how FDA will notify blood banks of malaria deferrals that differ from the CDC recommendations for chemoprophylaxis.

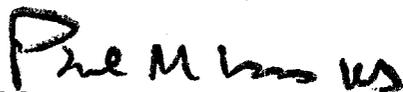
The final paragraph in Section II Background is confusing. The first sentence indicates that blood establishments should be utilizing the most recent revision of the "CDC Yellow Book" for determining deferral practices. However, the second sentence indicates that "risks for malaria that may not require chemoprophylaxis for travelers may result in deferral as a blood donor." The draft guidance does not indicate how blood banks will be made aware of such risks. We request that this paragraph be clarified.

5. Additional comments

Finally, the AABB suggests that the FDA or CDC provide guidelines/definitions to assist blood centers in the determination of urban vs. rural resorts in Mexico, the Caribbean or other countries with expanding urban centers. It would also be helpful if the FDA or CDC could provide maps for all or select countries with malarious areas showing the internal divisions, i.e. provinces, departments, states, etc. Such maps will make the deferral information easier to use.

Thank you for the opportunity to comment. Should you have any questions, please contact Kay Gregory, Director Regulatory Affairs, at kayg@aabb.org or 301-215-6522.

Yours truly,

A handwritten signature in black ink that reads "Paul M. Ness MD". The signature is written in a cursive style with a large initial "P".

Paul M. Ness MD
President