FOOD AND DRUG ADMINISTRATION
Center for Biologics Evaluation and Research
Summary Minutes
125th Meeting of the Blood Products Advisory Committee
May 9, 2024

OPEN Session

Committee Members	**FDA Participants**
Sanjay Ahuja, M.D.	Anne Eder, M.D., Ph.D. (presenter)
Mark Ballow, M.D.	Sanjai Kumar, Ph.D. (presenter)
Sridhar Basavaraju, M.D., FACEP, (CDR-USPHS)	Peter Marks, M.D., Ph.D.
Evan Bloch, M.D., M.S.	Jennifer Scharpf, M.P.H. (presenter)
Melissa A. Cumming, M.S., CIC	
Brenda J. Grossman M.D., MPH+	**Designated Federal Official**
Frank Maldarelli, M.D., Ph.D.	Christina Vert, M.S.
Marisa Marques, M.D.+	
Traci Mondoro, Ph.D.	**Division Director**
Elena Perez, M.D., PhD., FAAAAI+	Prabhakara Atreya, Ph.D.
Jeremy Perkins, M.D., FACP, COL+	
Richard Scanlan, M.D.	**Committee Management Officer**
Kenneth Sherman, M.D., Ph.D.+	LaShawn Marks
Abdus Wahed, Ph.D.	
	Committee Management Specialist
Chair	Tonica Burke, B.S.
Zbigniew "Ziggy" Szczepiorkowski, M.D., PhD, F.C.A.P.	
Consumer Representative	
Susan U. Lattimore, R.N., M.P.H.*	
Industry Representative	
Suchitra Pandey, M.D.<	
Industry & Guest Presenters	+ Not in attendance
Susan A. Galel, M.D.-Roche	< Industry representative
Seymour Williams, M.D., M.P.H.-CDC	* Consumer Representative

These summary minutes for the May 9, 2024 meeting of the Blood Products Advisory Committee was approved on July 2, 2024.

I certify that I participated in the May 9, 2024 meeting of the Blood Products Advisory Committee and that these minutes accurately reflect what transpired.

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Christina Vert, M.S.	Zbigniew Szczepiorkowski, M.D., PhD, FCAP
Designated Federal Official	Chair

On May 9, 2024, at 9:30 a.m. Eastern Time (ET), Zbigniew "Ziggy" Szczepiorkowski, M.D. Ph.D., FCAP (Chair) called to order the 125th Meeting of the Blood Products Advisory Committee. The meeting, which was open to the public, was held virtually by Zoom web conference platform. The Designated Federal Official (DFO), Christina Vert, made administrative remarks, conducted roll call, invited members to introduce themselves, and read into the official record the conflicts of interest (COI) statement. Given that the topic of this meeting was determined to be both a Particular Matter Involving Specific Parties (PMISP) and a Particular Matter of General Applicability (PMGA) COI screening was needed and conducted for this meeting. It was stated that Evan Bloch, M.D., M.S. was issued a waiver under 18 U.S.C. 208(b)(3) in connection with the meeting.

Topic: The committee met in open session to discuss strategies to reduce the risk of transfusion-transmitted malaria by testing blood donations from donors at risk of malaria exposure.

The first presentation "Introduction and Charge to the Committee" was given by Dr. Anne Eder, Director, Office of Blood Research and Review (OBRR), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration (FDA). The second presentation "Public Health and Clinical Malaria in the U.S" was given by Dr. Seymour Williams from the U.S. Centers for Disease Control and Prevention (CDC). The third presentation on "Transfusion-Transmitted Malaria in the United States" was given by Dr. Sanjai Kumar, OBRR, CBER, FDA. The fourth presentation titled, "Molecular testing for detection of asymptomatic Plasmodium infections" was given by Dr. Susan A. Galel from Roche Diagnostics Solutions. The concluding presentation was "FDA's Policy Considerations for Testing Blood Donations for Malaria" given by Ms. Jennifer Scharpf, OBRR, CBER, FDA.

After the presentations, the Committee had a 25-minute break for lunch. the meeting proceeded with the Open Public Hearing (OPH). The Chair, Dr. Szczepiorkowski, read the OPH Conflict of Interest statement and the DFO, Ms. Vert, provided further OPH instructions.

The following individuals presented during the OPH:

1. Jeffrey Linnen, Ph.D., Grifols Diagnostic Solutions Inc., *presentation with slides*
2. Jed Gorlin, M.D., M.B.A., America's Blood Centers, *statement*
3. Ralph Vassallo, M.D. The Association for the Advancement of Blood and Biotherapies, *statement*
4. Cole Williams, Pride and Plasma, *statement*

Following the OPH, Dr. Szczepiorkowski led the open committee discussion.

The following points for discussion were presented to the Committee:

1. Please comment on FDA's proposed strategies for selectively testing blood donations from donors at risk for malaria using an FDA-licensed NAT.

   Strategy 1A: Selective testing for history of malaria, history of prior residence in malaria-endemic country, history of travel to a malaria-endemic area

   Strategy 1B: One-time testing of all donors and selective testing for history of malaria and history of travel to a malaria-endemic area

Summary of Discussion: In general, the Committee preferred strategy 1A and commented that testing, in place of deferrals for malaria risk, has the potential to improve the availability and diversity of the blood supply. However, individual committee members expressed a wide range of opinions and comments on FDA's proposed selective testing strategies, included the following:

- Some members questioned whether the risk of transfusion-transmitted malaria merits the cost and complexity of testing, especially when the current risk-based deferrals seem effective at safeguarding the blood supply.
- Others commented that one-time testing (strategy 1B) of all donors for malaria would be expensive and low-yield. However, one member commented on the benefit of assessing risk in real time on all donors using the one-time testing strategy.
- One comment asked if the manufacturer of the licensed NAT test is committed to supporting a smaller market if selective testing is implemented. Others expressed concern with respect to single test manufacturer and the availability of critical supplies.
- Another committee member commented on the potential for increasing malaria in areas in the U.S. with warm climates.
- One member commented on the complexity of assessing prior residence in a malaria-endemic country, especially when malaria is eradicated in about 1-2 countries each year.
- One member commented that donors should not continue to be deferred when there is an available test that would permit donation.
- Some members questioned whether one-time testing would be sufficient to identify individuals with partial immunity to malaria with intermittent parasitemia.

- Members commented that selective testing based on questioning is complex and could also be error prone.
- Some members commented that while the current deferral approach is safe, there are other harms in preventing donations from donors in unrepresented groups.
- Some members noted that flexibility in addressing malaria risk (testing, deferrals) is warranted as there are limitations associated with all approaches.
- One member commented that transfusion-transmitted malaria is not on the same magnitude of concern as other transfusion-transmitted infections, such as Babesia.
- Some members questioned whether 3 months is the appropriate interval for testing following exposure to a malaria-endemic area and suggested a longer period to identify risk.
- Members comments that while it may be difficult to measure an increase in safety with testing, the advantage of having an improved blood supply is compelling.
- Members commented that risk modeling might help to evaluate the cost and benefits of testing.

2. Please comment on FDA's proposal that blood establishments should implement time-limited NAT screening of all donations collected in area(s) of the U.S. when a single case of local mosquito-borne malaria is reported by public health authorities.

Summary of Discussion: The committee members recognized the potential for increasing local malaria transmission in the U.S. and commented on FDA's testing proposal as follows:

- No committee members supported 1 reported case of local mosquito-borne malaria transmission as the trigger for universal testing in a defined area.
- Some members advised FDA should not define a specific trigger for test. Instead, FDA should have discretion to determine when testing is appropriate, in consultation with CDC and local health jurisdictions.
- Some members commented that there may not be much utility in universal testing when risk is still relatively low.
- Some members commented that vector-borne surveillance is an important consideration when assessing the risk of local mosquito-borne malaria transmission.
- Some members suggested that 8 weeks following the last reported case would be an appropriate timeframe to stop testing in a defined area. This timeframe aligns with the timeframe for public health surveillance following local transmission.

Following the committee discussion, Ms. Vert adjourned the meeting at 2:47 p.m. ET.

Additional information and details may be obtained from the transcript and the recordings of the webcast of the meeting that may be viewed at:
Blood Products Advisory Committee May 9, 2024 Meeting Announcement - 05/09/2024 | FDA

Direct Link to Recording of the Open Session:
https://youtube.com/live/eYsJqANKdmQ