

1 have two of these little devices, 80 percent of our units
2 are captured by us going out to churches, to community
3 centers. We are talking about having one of these devices
4 in our main center in Duluth and one in Minneapolis to
5 retain some of our most potentially committed donors.

6 So, I think with all due respect to Dr. Epstein's
7 calculations, caveat emptor, we can calculate ourselves into
8 amazing corners. Yet, I think the magnitude of the variance
9 request is really a much smaller question than what Dr.
10 Heintzelman has to deal with on his guidance document.

11 So, from our variance request, it is a modest
12 number of donors. By the way, I will provide the group the
13 data from Dr. Maria Gudino of Baxter where the median
14 actually was 20 per microliter, which actually drops the
15 number even smaller. So, the number of red cells in
16 apheresis plasma is pretty small, but you still have the
17 malarial guidance document to deal with.

18 DR. HALEY: Rebecca Haley, American Red Cross.

19 I would like to add my voice to the plea that Dr.
20 Paul Holland just made, and that is, that when we reject
21 donors and give them no alternative, that they do not come
22 back as readily or as frequently. We really have difficulty
23 retaining donors who have only given a time or two. People
24 who are traveling are young and active folks, people who may
25 have a long history of donation ahead of them, and again, to

1 Dr. Parise's statement, these are not--our daytime travelers
2 particularly have not show post-transfusion malaria or that
3 we have seen. I know Dr. McCurdy keeps saying it is
4 probably happening all the time and we don't see it.

5 We think that from the other kinds of cases that
6 we pick up, which are some very unusual cases, that our
7 people who take care of patients out there really are pretty
8 smart, and I think they pick these things up, and they
9 report them back to us, such as babesia, for instance, which
10 is a close relative of malaria.

11 So, I would add to my plea to Dr. Gorlin's and Dr.
12 Holland's, that if we at least tell the donor there is an
13 alternative for you, then, we have not given them the total
14 sense of rejection that we might have if we tell them no,
15 you are possibly infected and just can't come back for a
16 year.

17 DR. NELSON: Are we ready to vote on the first
18 series of questions here?

19 The first question is: Are the available
20 scientific data sufficient to conclude that it is safe to
21 prepare frozen plasma products for use in transfusion
22 despite a history of malaria risk in the donor--and I guess
23 you want us to vote on all three of these I guess--

24 DR. HEINTZELMAN: Yes.

25 DR. NELSON: The first one is when the plasma is

1 prepared by separation from whole blood.

2 How many will vote yes?

3 [Show of hands.]

4 DR. NELSON: "No" votes?

5 [Show of hands.]

6 DR. NELSON: Abstentions?

7 [No response.]

8 DR. NELSON: Industry?

9 DR. SIMON: Yes.

10 MS. KNOWLES: No.

11 DR. SMALLWOOD: The results of voting on Question
12 1(a). There were 5 "yes" votes, 10 "no" votes, no
13 abstentions. The voting strength is 15 today. The industry
14 representative agreed with the "yes" vote, the consumer
15 representative agreed with the "no" vote.

16 DR. NELSON: Are the available scientific data
17 sufficient to conclude that it is safe to prepare frozen
18 plasma products for use in transfusion despite a history of
19 malaria risk in the donor, when the plasma is prepared by
20 automated apheresis (any method)?

21 "Yes" votes?

22 [Show of hands.]

23 DR. NELSON: "No" votes?

24 [Show of hands.]

25 DR. NELSON: Abstentions?

1 [Two.]

2 DR. NELSON: Industry?

3 DR. SIMON: I agree with the "yes" votes.

4 DR. NELSON: And the consumer?

5 MS. KNOWLES: Yes.

6 DR. SMALLWOOD: The results of voting for Question

7 1(b). Nine "yes" votes, 4 "no" votes, 2 abstentions. Both

8 the consumer and industry representative agree with the

9 "yes" vote.

10 DR. NELSON: The third question is: Are the

11 available scientific data sufficient to conclude that it is

12 safe to prepare frozen plasma products for use in

13 transfusion despite a history of malaria risk in the donor

14 when the plasma is prepared by apheresis using the

15 Autopheresis C device?

16 "Yes" votes?

17 [Show of hands.]

18 DR. NELSON: "No" votes?

19 [Show of hands.]

20 DR. NELSON: Abstentions?

21 [No response.]

22 DR. NELSON: Industry?

23 DR. SIMON: I agree with the "yes" votes.

24 MS. KNOWLES: Yes.

25 DR. SMALLWOOD: Results of voting for Question

1 1(c). Ten "yes" votes, 5 "no" votes, no abstentions. Both
2 the consumer and industry representatives agree with the
3 "yes" vote.

4 DR. NELSON: Now, the second question is:
5 Balancing the risks and the impacts on supply, should FDA
6 continue its current policy to allow use of frozen plasma
7 products for transfusion when the donor provides post-
8 donation information positive for malaria risk?

9 I interpret this to continue the present policy,
10 and I guess 1(c) addressed Dr. Gorlin's policy although it
11 said are the data sufficient, it didn't say FDA should
12 modify or change, but nonetheless, I think it does deal
13 directly with his request for a variance.

14 So, what we are now talking about is current
15 policy of frozen plasma, but the current policy, does it
16 allow frozen plasma other than source plasma?

17 DR. SIMON: This would be fresh frozen plasma for
18 transfusion that they are allowing to go ahead and use.
19 Source plasma, you wouldn't recall.

20 DR. HEINTZELMAN: Malaria is not an issue because
21 it is specifically mentioned in the regulations.

22 DR. SIMON: So, we are okay on source plasma, and
23 the question is should the FDA continue its current policy,
24 what we called the "grand experiment" or not so grand
25 experiment, of allowing the fresh frozen plasma to stay on

1 the shelf and continue to be used when the donor has
2 provided post-donation information of malarial risk.

3 DR. McCURDY: Source plasma is not affected. How
4 about recovered plasma for fractionation for further
5 manufacture?

6 DR. SIMON: The same thing. It wouldn't be
7 affected, right?

8 DR. HEINTZELMAN: Well, I mean fresh frozen plasma
9 outdates and becomes recovered plasma, and then most of the
10 recovered plasma will then be pooled in the vats right along
11 with source plasma for further manufacture.

12 So, it would undergo solvent detergent treatment,
13 heat inactivation, the typical safety factors built in for
14 plasma derivative manufacture.

15 DR. McCURDY: But a certain amount of fresh frozen
16 plasma goes immediately as recovered plasma. I mean it
17 isn't just outdated.

18 DR. HEINTZELMAN: That is correct. You are
19 correct, more correctly I should have said that fresh frozen
20 plasma can become recovered plasma, and that is correct.

21 DR. NELSON: Do you want to vote on this question?
22 How many would vote yes?

23 [Show of hands.]

24 DR. NELSON: "No" votes?

25 [One.]

1 DR. NELSON: Abstentions?

2 [No response.]

3 DR. NELSON: Industry?

4 DR. SIMON: "Yes" vote.

5 MS. KNOWLES: Yes.

6 DR. SMALLWOOD: Results of voting on Question 2.
7 Fourteen "yes" votes, 1 "no" vote, no abstentions. Both the
8 consumer and industry representatives agree with the "yes"
9 vote.

10 DR. HEINTZELMAN: Thank you very much, sir.

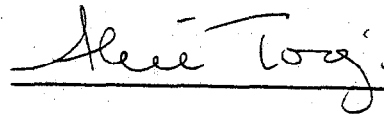
11 DR. NELSON: Unless there are any terminal
12 speeches or anything, I guess that is the end of the
13 meeting. Thanks to everybody for contributing to a very
14 interesting meeting.

15 [Whereupon, at 11:50 a.m., the meeting was
16 adjourned.]

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CERTIFICATE

I, ALICE TOIGO, the Official Court Reporter for Miller Reporting Company, Inc., hereby certify that I recorded the foregoing proceedings; that the proceedings have been reduced to typewriting by me, or under my direction and that the foregoing transcript is a correct and accurate record of the proceedings to the best of my knowledge, ability and belief.



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