was an increase in West Nile.

ACTING CHAIRMAN ALLEN: Dr. Nelson.

DR. NELSON: Yeah, I mean, I'm sympathetic to the AABB issue about well beyond the 56 days do donors needs to be retested with individual NAP, and I think that that's a good idea, but I think that there obviously needs to be a time associated with that interval where ID NAT is not required, given the fact that everybody will be tested with mini pool NAT and maybe ID.

Maybe very low levels of virus could persist for some time, but not forever and probably not or very unlikely beyond three months. So if we were to make that recommendation, it should be linked to some time period, you know. If the donor comes back 57, 58 days, they should probably be tested. If they come back 120 days, they probably don't need to be, but I guess if the FDA is going to modify that recommendation or requirement, it needs to be made more specific.

ACTING CHAIRMAN ALLEN: Yes, and I would think based on the data I have heard today, I would be comfortable with 90 days. An alternative might be 120 days.

Dr. Kuehnert.

DR. KUEHNERT: Well, I was just going to say, I mean, the thing is we really don't know. I mean, those sound like reasonable suggestions, but you know, before we really -- two years ago, before two years ago, I mean, we would have said, you know, that 56 days would have been ridiculously long for viremia, and now we're saying that it's reasonable.

So I guess we just have to get more data. I'm not sure I'd be comfortable with saying any amount at this point, but you know, I think the data has to be collected.

DR. NELSON: But we've been shown data that most of the very low level viremia that occurs in the tail is accompanied by antibody that's theoretically neutralizing and coupled with that, if somebody, let's say, was unable to format, you know, some immune deficiency, they should be positive on the mini pool NAT still.

So to pick up the outlier case, the current recommendations would still pick up a weird case hopefully.

DR. KUEHNERT: Well, I think that's a good point. I mean, I think the presence of IgM, you know, makes me more comfortable, but we're not testing for IgM to confirm that. If we did, then I guess I would,

you know, alter my comments.

ACTING CHAIRMAN ALLEN: Dr. Nakhasi.

DR. NAKHASI: I just wanted to echo what Matt said because we are still collecting the data. Last year we did not know anything that we had 28 days. We got information now. We have 56 days. Who knows what will happen next year?

So I think putting a certain time line, we have to be careful about that. So I think before you put a time line, please make sure that we need to keep that idea in mind.

ACTING CHAIRMAN ALLEN: Of course, that is the FDA's decision anyhow, you know. I think I might agree with you if, one, the numbers of cases were considerably smaller than they are. I think, in fact, we've got a reasonably large number of cases. We've got extraordinarily sensitive testing that is available with a variety of different test parameters to look at. The data have been consistent from multiple organizations.

You know, I think we are in a situation today where we're far beyond where we would have been had this kind of a problem occurred 20 years ago.

I also think we have to remember that the primary obligation of the blood collection centers is

to collect blood that is safe. You know, I think we're getting out into de minimis risk at this point, and to the extent that every requirement throws up additional difficulties in terms of collecting blood effectively and efficiently, we're also not serving the purpose that we need to.

So these are balancing considerations.

DR. EPSTEIN: Jim, given the discussion that transpired in the last hour, I think it would be helpful to the FDA if we could get a vote of the committee on whether the available scientific data support continuation of a question to defer donors based on fever with headache in the week before donation.

And I'm hopeful that we could have that before we lose a quorum today.

ACTING CHAIRMAN ALLEN: Yes.

DR. KUEHNERT: Again, it's either the fever with headache or nothing; is that where we're at?

DR. EPSTEIN: I think that we didn't re-present the data on fever with headache. It was discussed at a previous BPAC meeting. Other symptoms, the problem with them was that they were either too nonspecific or they led to too much donor deferral,

and when the study was done by the CDC, the conclusion was that the symptom complex of fever plus headache had a very small compromise in sensitivity in return for substantial gain in specificity, but that it needed to be narrowed to one week and not three or two because of donor loss.

So that's how we got to where we are. I mean, it could all be put back on the table, but we did examine it based on the data available in 2002. We could re-examine it.

DR. KUEHNERT: You're talking about the three out of 14.

DR. EPSTEIN: Well, the study of the 14 was used to look at the sensitivity and specificity of questions related to different symptoms or symptom complexes, and the most highly sensitive and specific criterion was the combination of fever with headache.

So you know, again, as I say, we could reexamine those data, but that's what we learned in 2002 from the cases that were associated with transmission.

Now, part of trying to reexamine that would be that we have many fewer cases associated with transmission to examine in 2003 and 2004 because of screening, but that's how we got to where we are, and

I'm not disputing the reexamination. I'm just saying that it wasn't arbitrary.

DR. KUEHNERT: I don't want to be overly critical about it. I mean, I think that's where we were at. That's the data we had, but, you know, it was pretty thin, but it's all we had to go on. It's just that it seems like we have more data now. That's the only point I was trying to make.

ACTING CHAIRMAN ALLEN: Dr. Oryton.

DR. ORYTON: Yes. I was just talking to Susan Stramer about the database that we have now and that perhaps looking at some of the BSL data to see if we could actually merge the data set and get more information on the symptomatology and run some of these multivariates and see if there are perhaps better combinations if we decide symptomatology is still important to ask about.

ACTING CHAIRMAN ALLEN: Dr. Epstein, do you want a vote still based on that or do you want a sense of the committee that, yes, we believe that this issue merits continued evaluation with a decision subsequently in the future?

DR. EPSTEIN: Well, I think a vote would be helpful at this stage, and you know, if people do not think the data are adequate to recommend

discontinuing questioning, then they'll vote no.

ACTING CHAIRMAN ALLEN: Dr. Smallwood, have you --

DR. EPSTEIN: We have a draft question.

ACTING CHAIRMAN ALLEN: It would be helpful if you could read that.

DR. WILLIAMS: Yeah, I can present the question. I apologize for the writing.

ACTING CHAIRMAN ALLEN: You had better present it because I don't think anybody can read it.

DR. WILLIAMS: The question is Question 4: do the available scientific data support continuation of the deferral of donors reporting fever with headache in the week prior to donation?

ACTING CHAIRMAN ALLEN: Discussion on that draft question?

DR. NELSON: Yeah, of those three, there were only one that occurred in the week prior to donation, and of the data presented by Dr. Fitzpatrick -- no, it was from the Blood Centers of the Pacific. The systems that occurred also occurred -- of course, it's all complicated. It's hard. I mean, there aren't adequate data to really make a hard judgment on this.

ACTING CHAIRMAN ALLEN: Dr. Goldsmith.

DR. GOLDSMITH: I think this was a question that was put into place at a time when we did not have adequate testing available. We now have adequate testing available, and we should relieve the blood centers of the burden of asking this question and losing donors when it has no specificity in terms of finding the disease that we're worried about.

ACTING CHAIRMAN ALLEN: Other comments or questions?

Dr. Tomasulo, very briefly.

DR. TOMASULO: Very brief. Peter Tomasulo from Blood Systems.

Each year we survey donors four times from all of our centers, and they're allowed to write comments in. The two comments that we most often get are the donation process is too long, and please stop asking us so many stupid questions.

And this is pertinent not just because we want donors to be happy,b ut availability of blood is related to how happy donors are, and that's a safety concern. So making the donation process simpler and shorter is a high priority when it comes to blood safety. There aren't scientific data supporting that question. We would love to get rid of it.

ACTING CHAIRMAN ALLEN: Are we ready for

the question?

Dr. Smallwood, would you read the question and poll the committee, please?

DR. SMALLWOOD: The question reads as follows: do the available scientific data support continuation of the deferral of donors reporting fever with headache in the week prior to donation?

Dr. Harvath?

DR. HARVATH: I believe there are insufficient data for me to answer this question. So I'm going to abstain.

DR. SMALLWOOD: Dr. Nelson?

DR. NELSON: I'm going to vote no based on, you know, there are relatively few cases, but there were a few that occurred despite screening, and I don't -- you know, of course, I suppose if they had answered this positively they would have been deferred. So there's no data really that supports this, but it's hard to answer at this point, but I would say no.

DR. SMALLWOOD: Dr. Kuehnert?

DR. KUEHNERT: Abstain. You can see my previous comments as an explanation to that. I think if the question were that you had to ask this with fever, with headache throughout the year, I think that

would be detrimental to public health concerning when you take blood availability into consideration.

DR. SMALLWOOD: Dr. Quirolo?

DR. QUIROLO: No.

DR. SMALLWOOD: Dr. Goldsmith?

DR. GOLDSMITH: No.

DR. SMALLWOOD: Dr. Schreiber?

DR. SCHREIBER: No.

DR. SMALLWOOD: Dr. Lew has left. Dr. Doppelt?

DR. DOPPELT: No.

DR. SMALLWOOD: Dr. Allen?

ACTING CHAIRMAN ALLEN: My vote is no. I also agree that the way in which the data collection has occurred has made it very difficult to get an adequate analysis of it. I will make a comment at the end, but my vote is no.

DR. SMALLWOOD: The results of voting on this question, there is six no votes, two abstentions.

ACTING CHAIRMAN ALLEN: Thank you.

My comment is I think this is very instructive. I know that this was put in place for very good reasons, trying to rapidly address an emerging problem that was not anticipated.

I think that there's an object lesson here

in terms of doing this to make sure that we do evaluation studies as we implement interim measures, and that obviously means that there needs to be funding and cooperation.

I'm impressed that the two largest blood collection centers in the United States, along with America's Blood Centers, do have research capabilities, and I think those research capabilities include not only laboratory capabilities, but epidemiological capabilities, and I think that's wonderful.

We need to be cautious as we move forward in the future in this, and I've got a vested interest here. I am on the Board of Trustees for Blood Systems, Incorporated, and Blood Systems Foundation, but I want to say that I think we hear so much negative government bashing in the media coming from politicians and others today.

I want to say that I think the system that we have in the United States today with our major blood collection centers with research capabilities, with a very collaborative working relationship with the regulatory agency, the Food and Drug Administration that is also supportive of research, the collaboration from the CDC and from the NIH has

given us a really unique capability here, and I'm just very impressed with the amount of data, as well as the ability to move forward to provide the safest blood possible for the people of the United States, and I think it's an excellent system, and I commend the way that we've all worked together.

Dr. Nelson.

DR. NELSON: Yeah, I'd like to recommend that a case control study be done on this question. Get some data. There's no data at the moment. You know, there may be difficulties in doing a case control study, but I don't think they're that difficult. I think it could be done if you had to paper. If you were interested in the answer you'd do it.

ACTING CHAIRMAN ALLEN: Thank you.

Any other final comments or questions? Dr. Epstein, Dr. Smallwood, anything else?

(No response.)

ACTING CHAIRMAN ALLEN: The meeting is adjourned.

Thank you all very much.

(Whereupon, at 1:22 p.m., the meeting in the above-entitled matter was concluded.)

CERTIFICATE

This is to certify that the foregoing transcript in the matter of: Blood Products Advisory Committee Meeting

Before: FDA

Date: October 22, 2004

Place: Gaithersburg, MD

represents the full and complete proceedings of the aforementioned matter, as reported and reduced to typewriting.