1 to clarify where we should go or what pitfalls we
2 should avoid.
3 ACTING CHAIRMAN ALLEN: Dr. Kuehnert?
4 DR. KUEHNERT: I mean, I think the concept
5 might be valid.
6 I mean, first of all, there are things
7 other than donor exclusion criteria which we've talked
8 about today that we might want to sort of emphasize.
9 One is the policy if someone's known to be SFV
10 positive, that they should be told that they should
11 not donate blood or other tissue.
12 The other is something that was discussed
13 in some conference calls, and I don't know how often
14 this occurs. But having donor drives in places where
15 there might be a high risk population, like having it
16 on zoo grounds or I saw the rate of the donation in a
17 facility in Canada. I wonder was there a donor drive
18 recently in that facility or around that facility. So
19 maybe that's some other things that could be
20 considered besides strictly a donor exclusion
21 criteria.
22 You know, concerning the criteria, it's
23 all in the details. I think it's very difficult for
24 me to put together any kind of a cohesive set of
25 criteria when you think about the spectrum of possible

1 exposure and given the lack of data we really have.
2 You know given that this can be transmitted through
3 saliva and some of the acrobatics that these nonhuman
4 primates can engage in. And I'm remembering the slide
5 about behavioral observations and even those people
6 could be considered possibly exposed.
7 So I guess I'm just having difficulty. I
8 mean I'm agreeable to the concept, but I'm having
9 difficulty trying to figure out how you would put that
10 in place practically.
11 The last thing was about, you know I think
12 we've got a handle on how many people currently could
13 be affected by this sort of exclusion if you ask are
14 you currently A, B or C. But we don't have a good
15 handle on if we ask were you ever exposed in A, B or
16 C. And although I don't think that still would make
17 a huge dent in the donor pool, it would be good to
18 sort of have a better handle on those data.
19 ACTING CHAIRMAN ALLEN: Dr. Lew and then
20 Dr. Strong.
21 DR. LEW: Based on what I just heard, it
22 makes sense to me as CDC is recommending potentially
23 wording just if you know that you have the virus,
24 you've been told, you've been tested, that you
25 probably should not donate. Because I think we all

1 agree that if you have this unknown retrovirus, even
2 though we don't know if it's truly pathogenic, there
3 are other models that such as SIV, etcetera, that we
4 need to be concerned about. But that's a very small
5 number of people.
6 And then beyond that, I can't see having
7 any other questions because we just don't know.
8 DR. STRONG: We talked this morning about
9 the problems with specificity in the anti-core assay.
10 I can tell you that almost all of our donor questions
11 suffer from a significantly worst specificity problem
12 than our antibody or our antigen assays do.
13 You know, we can say this might have a
14 very small affect on our donors but every time we add
15 a question, no matter what it is, we lose donors
16 primarily from lack of specificity.
17 So I also agree. I don't see how we could
18 construct a question. We've been around the block
19 with the xenogeneic transplant questions that one
20 would construct a question that wouldn't cause a lot
21 of lost donors, either from self-deferral or not.
22 And finally, I think the main thing here
23 is that we don't have any data. And we're supposed to
24 be basing these decisions on science.
25 ACTING CHAIRMAN ALLEN: Other comments?

1 Okay.

2 I personally would like to -- I think this
3 has been a helpful discussion even though it's
4 relatively late in the day. I certainly think that Dr.
5 Klein and Dr. Strong have, from a practical blood
6 banking perspective, raised some issues that need to
7 be carefully considered. I will look at it also from
8 a blood donor perspective, and that is that even
9 though we now have the opportunity under selective
10 circumstances, at least for an abbreviated donor
11 questionnaire, that just the total number of
12 questions, the complexity, the amount of information
13 that we're trying to get donors to focus on in a few
14 minutes of time is difficult. And, you know, we need
15 to look at ways to improve the quality of our data
16 collection from donors, quite apart from the issue of
17 the specificity of the questions.

18 I think we need to continue to address
19 these issues and try to come up with some sort of a
20 resolution. I'm not certain that given the data I've
21 heard today, that I ready to believe that we need to
22 add other questions or make other additions to the
23 process. But we clearly need to continue to evaluate
24 what might be done.

25 I think earlier Dr. Klein, the last

1 question Dr. Klein certainly raised the issue of the
2 potential for viruses from other animal species and
3 other situations. And I think these are broad based
4 issues that we need to continue to look at very, very
5 seriously.

6 ACTING CHAIRMAN ALLEN: Dr. Lew?

7 DR. LEW: If I could just get
8 clarification. Since there's such a small number if
9 people and they're being followed who are known to be
10 positive, is the point mute then because they've
11 already been told please don't donate blood? I'm
12 assuming that you wouldn't need to include -- I mean,
13 that's the only thing is a potential question is that
14 if you've been told you have this virus, I would think
15 it would be very good to make sure that those people
16 don't voluntarily donate.

17 ACTING CHAIRMAN ALLEN: Yes?

18 DR. HENEINE: Yes. I think the question is
19 more the infected persons that we have not identified,
20 rather the 15 cases that we have identified. And if
21 you go by the numbers that Dr. Lerche put together, if
22 you have a population of about 100,000 that are
23 exposed, then assume we're seeing a providence of 3.5.
24 Assume it is 1 percent or .3 percent. So you'd be
25 dealing with a substantial number of infected persons

1 that are not recognized. And the average of blood
2 donors among them, say it's like the general
3 population, 5 percent. So it'll be also another
4 substantial number of blood donors that are infected
5 that are donating blood. So that's the issue more
6 than the 15 cases that we've identified that we've
7 counseled them not to donate blood. That is what we're
8 discussing.
9 So, and even with the 15 cases we have
10 anecdotal information that specificity of the
11 counseling is in question, too. I mean, we had an
12 instance where one case contacted us back and says I
13 would like to donate blood for a paid donation. And
14 then he's checking with this whether this is a good
15 idea or not. So we're not sure if they will all
16 follow the counseling to them, so that's another
17 question.
18 And since I have the microphone, too, I
19 mean another way to think about the risk, is the other
20 discussions that were brought up, too, regarding
21 xenotransplantation regarding contamination of
22 vaccines. There I think we've kind of draw the line
23 a little bit differently.
24 And in the case of xenotransplantation we
25 said nonhuman primates are not permissible sources of

1 xenographs.

2 In the case of vaccines that are grown in
3 simian subcell substrates in primary cells, we screen
4 for foamy virus and we exclude cell substrates that
5 are foamy positive so we don't contaminate the vaccine
6 products with this virus. So here we're drawing a
7 different line and we're saying it's probably okay a
8 contaminated product, but not okay to have a vaccine
9 what is xenographed.

10 So I guess we have to sort through the
11 risks.

12 DR. BIANCO: I'm Celso Bianco, America's
13 Blood Centers.

14 Regarding the comments that Dr. Heneine
15 made, nonhuman primates are also not acceptable as
16 blood donors.

17 The second thing, Walid, donors -- paid
18 donors are part only to the industry of fractionation
19 of plasma. And that, luckily, is all viral
20 inactivated by processes that we know work very well
21 with retroviruses.

22 I was struck by the statement that Dr.
23 Kuehnert made a couple of times, but I think it has to
24 be emphasized. If we had done this at the time of
25 HIV, it would not have contributed to anything. That

1 transfer, that jump from the primate to humans of HIV-
2 1, HIV-2, HTLV-1, HTLV-2 probably didn't happen here.
3 It probably, as we know, happened in Africa. And it
4 probably is not the next time going to happen here in
5 one of our primate research facilities or zoos.
6 I think that we should and must give a lot of
7 attention to these, because that's where the potential
8 for our next epidemic, as a measure to protect the
9 blood supply.
10 I agree with Dr. Kuehnert that it would
11 have absolutely no impact, except for impact for the
12 donor in terms of creating more complex medical
13 history.
14 ACTING CHAIRMAN ALLEN: Other discussion
15 among Committee members? Yes, Dr. Goldsmith?
16 DR. GOLDSMITH: I think we should be
17 vigilant and we should be prudent. And we've seen a
18 path like this before. And I think we have to pay
19 attention to it. So I'd like to weigh in on the more
20 conservative side of this. At least the Committee has
21 heard that as well. That until we know more, maybe we
22 should take the most conservative path.
23 ACTING CHAIRMAN ALLEN: Do you have a
24 specific recommendation on that or just that's a
25 perspective?

1 DR. GOLDSMITH: That's a perspective, but
2 you would translate it into an action I think.
3 DR. KUEHNERT: Let me just say that I
4 would include under donor exclusion criteria not only
5 asking a question of donors, but the other things you
6 know that I mentioned as inclusive in that.
7 So I just wanted to make that clear that
8 I think it's maybe a boarder definition than what some
9 people might be thinking as far as, you know, putting
10 a question on the donor history questionnaire.
11 ACTING CHAIRMAN ALLEN: Well, and I
12 certainly think that that is a very appropriate
13 statement and parallels the recommendations that were
14 made in 1983 during the early days of the AIDS
15 epidemic when very clearly we solicited the support of
16 the gay community in cities and communities throughout
17 the country and said please talk with people who you
18 know to be gay and ask them not to donate blood. And
19 that's a first step. And certainly something very
20 analogous as well as broader applications are very
21 much open for consideration. We aren't necessarily
22 talking about something that has to happen in the
23 blood bank itself, blood collection centers, right.
24 We ready to vote question three?
25 Dr. Smallwood?

1 DR. SMALLWOOD: Question three reads do
2 the available scientific data warrant possible
3 consideration of donor exclusion criteria for exposure
4 to nonhuman primates?
5 We're ready to vote.
6 Dr. Harvath?
7 DR. HARVATH: I will have to say the
8 available data do not convince me at this time. What
9 I would like to see is more studies involving with the
10 animal models leukocyte reduction and more research in
11 this area.
12 DR. SMALLWOOD: Will you be casting a yes
13 or no vote?
14 DR. HARVATH: That's at this time I would
15 say no.
16 DR. SMALLWOOD: Thank you.
17 Dr. Nelson?
18 DR. NELSON: I'd say no. But I would agree
19 that people who are known to be infected with Simian
20 Foamy virus shouldn't donate. But that's a small
21 number of people. But I wouldn't exclude people now
22 based on exposure to nonhuman primates until there was
23 more evidence.
24 DR. SMALLWOOD: Dr. Cunningham-Rundles?
25 DR. CUNNINGHAM-RUNDLES: No as well. But

1 I'm assuming that that number is going to grow because
2 I can't imagine that under question number one that
3 people would stop testing animal and nonprimate
4 handlers. And so I expect that number will increase.
5 And so that population will increase.
6 DR. SMALLWOOD: Dr. Kuehnert?
7 DR. KUEHNERT: I would say yes using my
8 expanded definition of donor exclusion criteria I
9 talked about before.
10 DR. SMALLWOOD: Dr. Quirolo?
11 DR. QUIROLO: No.
12 DR. SMALLWOOD: Dr. Goldsmith?
13 DR. GOLDSMITH: Yes.
14 DR. SMALLWOOD: Dr. Schreiber?
15 DR. SCHREIBER: I would say no. I think
16 there's just not enough evidence available and we
17 don't even prevalence in the population.
18 DR. SMALLWOOD: Dr. Lew?
19 DR. LEW: Can I get clarification of what
20 your expanded definition is? That's not clear to me.
21 What would you say? What is that?
22 DR. KUEHNERT: Again, I was including
23 under donor exclusion that if someone is known to be
24 SFV positive, they should be deferred. And also, you
25 know, I think this would yet to be defined, but

1 discussions about having donor drives in certain
2 places where there's known to be exposures considered
3 high risk should also be avoided. And that's just my
4 interpretation of this that that is a donor exclusion.
5 So that's why I was supportive of this.
6 I mean, I feel like this question is very
7 -- you know, warrant possible consideration that it
8 was hard for me to say no. So that's why I said yes.
9 DR. LEW: My only concern, though, is like
10 not going there to get blood or have donor drives is
11 you're implying those people are, you know, there's
12 something wrong. It's the same thing you had, even
13 though you know you had a bad test, by telling them
14 they can't come back, there's something wrong.
15 I would say no to this question with the
16 understanding that the people who are infected should
17 not donate.
18 DR. SMALLWOOD: Dr. Klein?
19 DR. KLEIN: I don't believe that being in
20 a primate center handling primates represents a risk.
21 I don't believe there's scientific evidence to show
22 that it represents a risk to the blood supply.
23 My answer is no.
24 DR. SMALLWOOD: Dr. Doppelt?
25 DR. DOPPELT: I have no hesitation in

1 voting no.

2 DR. SMALLWOOD: Dr. Davis?

3 DR. DAVIS: No.

4 DR. SMALLWOOD: Dr. Allen?

5 ACTING CHAIRMAN ALLEN: No, with the
6 caveat that we need to continue to consider the
7 information and collect all information as I know the
8 FDA will do.

9 DR. SMALLWOOD: And Dr. Strong, your
10 opinion?

11 DR. STRONG: I like Dr. Doppelt's answer.
12 No.

13 The results of voting on question number
14 three: Ten no votes, two yes votes and the non-voting
15 industry representative agrees with the no votes.

16 ACTING CHAIRMAN ALLEN: In question three,
17 the majority is no, there were a lot of qualifications
18 and other discussion.

19 Dr. Tabor, thank you very much for your
20 presentation.

21 DR. TABOR: Thank you and the rest of the
22 Committee, and all the speakers.

23 ACTING CHAIRMAN ALLEN: That concludes our
24 meeting for the day. We reconvene at 8:00 a.m.
25 tomorrow morning.

1 DR. SMALLWOOD: Correction. 8:30.

2 ACTING CHAIRMAN ALLEN: 8:30?

3 DR. SMALLWOOD: 8:30.

4 ACTING CHAIRMAN ALLEN: Whoa. We get a
5 leisurely breakfast.

6 DR. SMALLWOOD: Thank you.

7 ACTING CHAIRMAN ALLEN: All right. Thank
8 you all.

9 (Whereupon, at 5:26 p.m. the meeting was
10 adjourned, to reconvene tomorrow at 8:30 a.m.)

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CERTIFICATE

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

Before: FDA

Date: October 21, 2004

Place: Gaithersburg, MD

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