questions for - yes, Doctor Bracey.

DOCTOR BRACEY: Can you give us an update on the status of the U.S. blood supply? In recent years, we have experienced shortfalls. Anecdotally, those of us in practice noticed that there have been shortfalls. What is the most recent status of the blood supply?

DOCTOR WILLIAMS: I can only give an observation and, perhaps, defer to Jerry Holmberg or others who might have more information.

It seems that we got through the holiday period this year without a national appeal. That had not been true for the several years previous, particularly, last year, as a very tough December and January for blood supply, probably due to the low level of the flu infection this year, combined with some of the warmer weather, perhaps, the impact this year was not great in keeping donors home.

But, I think I would be one of the first to say that the blood supply overall tends to be marginal and fragile, so that I think any policy that we consider is carefully balanced against loss of blood and loss of donors.

As far as actual measurement, this is now undertaken by Jerry Holmberg's shop at HHS, and he's

going to comment further on that.

DOCTOR HOLMBERG: Yeah, just -

CHAIRPERSON PRIOLA: State your name for the reporter?

DOCTOR HOLMBERG: Is this on? Can you hear me?

My name is Jerry Holmberg.

As far as the shortages over the last year, I agree with what Alan has said. We have sporadic shortages, for instance, New York is currently experiencing a shortage, and has gone out on appeal, I think, last week? Just for O-negs, however, there is a shortage currently.

And also, the New England area most recently experience some shortages because of the snowfall, but overall the country is pretty well supplied. We are talking about a three to five-day supply.

DOCTOR BRACEY: Is there any estimation in terms of the extent of donor loss that the system would be able to endure?

DOCTOR HOLMBERG: Well, I just did a quick calculation based on what Alan was projecting there, if we talk about three per 10,000, of course, that's not calculating in the people that received Euroblood

during that period of time, and we're talking 2,700 donors. So, I don't have a direct answer for you, but I think that you have to calculate in also the fact that, you know, what about those recipients of the Euroblood?

CHAIRPERSON PRIOLA: Mr. Fitzpatrick, did you have a comment?

MR. FITZPATRICK: Mike Fitzpatrick from America's Blood Centers, just for perspective, anybody that wants to can go to our website, you can make a comparison between the status of our inventories now and two years ago.

Our members are seeing about a 20 percent difference. They have about a 20 percent greater inventory now than they did two years ago, and we attribute that to recovery from 9/11, the vCJD deferrals all coming at the same time, and some very vigorous recruitment efforts.

But, to say that raising ourselves from a one to three-day supply, to a three to five-day supply, provides an adequate supply for the country, I think is a false statement. I think we had recommended previously that we need a seven-day supply in the country, increasing to a seven-day supply is an arduous task, and to go from a period of drought that

we have been in to a period of adequacy, if I can use that word, and I'm not sure that's the right word, sends a message that we are succeeding, but we certainly are not in what anyone would call an ample inventory method. There are shortages of Os throughout the country, and we've seen requests for Os throughout the country. There are surpluses of As and Bs, and we made it through the holiday period in a much better situation than we've had in the past, and we haven't seen cancellation of elective surgeries. But, in looking at the trend line in those inventories just today, it's starting to dip down a little bit. So, it may be a momentary improvement that we have to sustain.

CHAIRPERSON PRIOLA: Doctor Johnson?

DOCTOR JOHNSON: Yeah, I have two further questions about the Euroblood.

First of all, what countries primarily did it come from? Was it randomly through Europe, more Eastern Europe? My feeling is a lot of it was German blood, right?

DOCTOR WILLIAMS: I'm sorry, I should have mentioned that.

It was sourced from Germany, Switzerland and the Netherlands, exclusively.

DOCTOR JOHNSON: So that, at no time when Euroblood was being given have there been recorded cases of variant CJD in any of those countries, is that correct?

DOCTOR WILLIAMS: It sounds correct, yes.

DOCTOR JOHNSON: The second thing is, do people know if they've gotten Euroblood? I mean, the question is going to be, did you ever get transfused in New York City, and you are going to eliminate everybody, right? I mean, if some guy got knifed in the lower East Side, or upper West Side, whatever, and you said did you get Euroblood or did you get American blood, he's not going to know, is he?

DOCTOR WILLIAMS: I think it's very unlikely a patient would know that they received Euroblood. I think one other characteristic that probably is important to know is, it was likely Group O red cells that comprised Euroblood, but in terms of specifically notifying a patient that that unit of blood was collected in a U.S.-licensed New York Blood Center facility in Europe, no, I don't think that was transmitted.

DOCTOR JOHNSON: It seems to me that with no cases of CJD - variant CJD in the donor countries that we ought to take Euroblood off the table and talk

about France, as a personal opinion.

CHAIRPERSON PRIOLA: Other questions for Doctor Williams?

We have another comment?

DOCTOR HOLMBERG: Yes. Alan, just a point of clarification, on the deferral that the Netherlands put into place, was that for people that had been transfused in France, or was that overall transfusions in their country?

DOCTOR WILLIAMS: Transfusion ever anywhere.

DOCTOR HOLMBERG: Including the United States?

DOCTOR WILLIAMS: Yeah, I believe so.

CHAIRPERSON PRIOLA: Doctor Bird?

DOCTOR WILLIAMS: I'm sorry?

DOCTOR JOHNSON: What are the Netherlands using for blood?

DOCTOR WILLIAMS: I can't answer that.

DOCTOR JOHNSON: It's donors who have never been - so, they can take donors, but they can't have been transfused.

DOCTOR WILLIAMS: Right, that would cost, by their estimate, 8 percent of the donor supply, but, you know, far and away the majority of donors have not

been transfused, so they would still be eligible for donation.

MR. FITZPATRICK: Mike Fitzpatrick. We had some - I'm sorry.

CHAIRPERSON PRIOLA: In was going to ask Doctor Bird to go first.

DOCTOR BIRD: Just a point on Switzerland, although they have not had any variant CJD donors, Switzerland has been concerned about an increase in its numbers of sporadic Creutzfeldt-Jakob disease, and some work by the Medical Research Council's Prion Unit suggests that when you put BSE into mice there can be a bifurcation as to whether it materializes as variant CJD-like disease or a Type 2 sporadic CJD. So, there's a little bit of sort of basic science there that we are just a little bit concerned as to whether variant CJD is the only manifestation of BSE in humans.

CHAIRPERSON PRIOLA: Thank you.

Go ahead, Mr. Fitzpatrick.

MR. FITZPATRICK: Mike Fitzpatrick. We corresponded with Doctor van der Poel from the Netherlands prior to the meeting about this topic. They have a very robust blood program in the Netherlands, and when they put in the deferral for all

transfusion recipients they anticipated about a 10 percent loss. By his correspondence with us he says they have been able to absorb that and meet their needs.

CHAIRPERSON PRIOLA: Okay.

If there are no other questions from the Committee for Doctor Williams, I would suggest we take a brief break of about ten minutes, and then come back for the open - five to ten minutes, come back for the open public hearing, and then the final discussion and vote.

(Whereupon, at 4:34 p.m., a recess until 4:44 p.m.)

EXECUTIVE SECRETARY FREAS: If you would take your seats, please. There are many Committee members that need to catch flights tonight, so I really would appreciate your cooperation in getting to your seat

CHAIRPERSON PRIOLA: If we could have all the Committee members take their seats, please, so that we can start the open hearing portion of this afternoon's session.

EXECUTIVE SECRETARY FREAS: Okay.

For this afternoon's open public hearing, we have three speakers lined up, and before we begin

these three presentations, that will be limited to a maximum of five minutes, the Chair has a statement that has to be read, if I could please ask everybody to take their seats, we'd appreciate it.

CHAIRPERSON PRIOLA: Okay.

Both the Food and Drug Administration, FDA and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the open public hearing session of the Advisory Committee meeting FDA believes that it is important to understand the context of an individual's presentation.

For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the Committee of any financial relationship that you may have with any company or any group that is likely to be impacted by the topic of this meeting.

For example, the financial information may include the company's or any group's payment of your travel, lodging or other expenses in connection with your attendance at the meeting.

Likewise, FDA encourages you at the beginning of your statement to advise the Committee if you do not have any such financial relationships. If

you choose not to address this issue of financial relationships at the beginning of your statement it will not preclude you from speaking.

EXECUTIVE SECRETARY FREAS: The first request we have to speak in the afternoon is Allene Carr-Greer, Deputy Director, AABB, Regulatory Office. She's going to make a statement on the potential deferral of blood and plasma donors for history of transfusion in European countries.

MS. CARR-GREER: I am an employee of AABB, and AABB is an international association dedicated to advancing transfusion and cellular therapies worldwide. For those who don't know, our members include more than 1,800 hospital and community blood centers and transfusion and transplantation services, as well as approximately 8,000 individuals involved in activities related to transfusion, cellular therapies and transplantation medicine.

For over 50 years, AABB has established voluntary standards for and to credit institutions involved in these activities. AABB has a focus on improving health through the advancement of science and the practice of transfusion medicine and related biological therapies, developing and delivering programs and services to optimize patient and donor

care and safety.

AABB believes that deferring donors who were transfused in France or other European countries would not significantly affect the blood supply. However, we are concerned about the increasing number of reasons for donor deferrals, some of them a very low risk benefit ratio. And, a few minutes ago Alan touched on some of the complexities involved in donor questioning and predictive value on negatively and positively the predictive values of questioning donors about history and trying to recall memory.

Continual addition of new questions distracts donor attention from the more significant risk questions, and decreases the likelihood that donor questioning will elicit important and significant information. Although each added deferral in and of itself may not impact supply, the additive effect will almost certainly adversely affect supply, so that the risk benefit must be carefully considered. And, today's discussions I think have been really thoughtful consideration of models for risk assessment, a great deal of discussion, of course, about some of the assumptions that went into that, and I must say I was struck by some of the descriptives that the speakers themselves were using in presenting

their material, when talking about risk assessment and uncertainties. And, after a while, I jotted down a couple of the statements, and we were hearing such things as, using a huge number of assumptions, extreme uncertainties, unknown uncertainties, and most recently I heard vast uncertainty.

It would be useful for FDA to examine all of the existing donor suitability criteria to determine whether each of these criteria is still necessary in light of current scientific knowledge and testing capabilities.

We believe FDA should consider whether it's essential for the blood banking community to focus efforts on this particular deferral issue, or whether there might be other concerns that would yield more benefit, and would greatly and positively impact donor and patient safety.

Thank you.

EXECUTIVE SECRETARY FREAS: Thank you very much for your statement.

The next requester is Doctor Michael Fitzpatrick, Chief Operating Officer, America Blood Centers.

MR. FITZPATRICK: Good afternoon, and I am gainfully employed by America's Blood Centers.

I'll make a departure from the written statement on occasion, but you have it before you. The first paragraph tells you about us, we are the network of the not-for-profit community blood centers in the United States, 76 members, including Hema-Quebec in Canada, and these centers serve more than 150 million people providing over 7 million collections annually.

When the FDA announced deferral of the criteria to reduce the risk of transfusion-associated vCJD in 1999, based on the application of a precautionary principle and the hypothesis that the prion responsible for vCJD could be transmitted by transfusion, the Committee reviewed the two cases of vCJD that had been associated with transfusion from individuals who later died from vCJD and did not recommend additional deferral actions, and that was October of last year.

Today, FDA asked the Committee to review the issue again, and asked whether individuals who received blood transfusion in Europe should be deferred as blood donors. The rationale for the timing of this discussion is not clear to us as we prepared the remarks. It has been made clear throughout the day, but as Doctor Williams stated

himself, there have been only a few changes to what has occurred.

The incident of vCJD has declined since the peak in 1999, total number of cases around the world about 160, it remains very small, only four new cases of vCJD were diagnosed in the U.K. in 2004. We do have a new one in Japan, but that remains to be evaluated, down from a peak of 29 in 1999.

The most telling fact this morning to me, as has always been, that no recipient of any plasma-derived coagulation factor in the U.K. has developed variant CJD, despite the fact that most of them have been exposed to thousands of donors who were at risk during the most peak periods of the epidemic.

If we review the model used by FDA to decide on the scope of the geographic deferrals for people that lived in the U.K. and the rest of Europe, it was predicated on balancing risk reduction with donor loss, and predicted a statistically-derived 90 percent reduction of the risk while deferring about 2 to 3 percent of the individuals who were already donating.

The recommendation to defer all European transfusion recipients, in order to decrease the almost unquantifiable residual risk, and from the

modeling today I think we can see that it is difficult to quantify, provides what amounts to an immeasurable contribution that would be statistically insignificant.

While most centers could absorb the minimal donor loss associated with deferral for transfusion in the rest of Europe, we are concerned about standing at the top of that slippery slope that is always discussed.

Broader deferrals for a history of transfusion will cost us as many as 5 to 10 percent of our donors. This is an unnecessary donor loss and unreasonable stigmatization of volunteer blood donors. It also sends recipients a very mixed message.

ABC, the Red Cross, AABB and FDA have frequently said over the past few years that the blood supply is safer than ever. Yet, now we are considering sending the message to recipients that the act of accepting the lifesaving, safe transfusion would defer them from ever passing on the gift by becoming a regular blood donor, but recipients have become of the best donor recruiters in the Nation and regularly donate themselves, as you saw from Alan's statistics.

If deferred for no known or real risk,

they will have survived their illness through transfusion to now live under a cloud of doubt, wondering if the blood they received was safe, and when and if they will begin to show signs of variant CJD or some other unknown disease, that's preventing them from being a donor. We feel that's an unwarranted stigmatization of a recipient.

I want to note a specific comment about geographic deferrals made in the briefing documents. We talked about post-donation information related to geographic exposures continues to comprise a high proportion of biological product deviation reports submitted to FDA, indicating that improvements in donor eligibility determinations are still needed.

In our opinion, and as we have stated in the past, post-donation calls are a sign of success of the system, not a failure, and a success of the screening process. Donors go home, think about the questions, or think about the question at their next donation, look at their passports, talk to their wives, and call back with more precise information. They want to tell us if they should be deferred.

Immense resources have been used to update deferral questions, screen and defer donors, and respond to questions from the deferred donors and

their friends. Adding a new layer of deferral will only require more resources, which possibly could be utilized in CGMP compliance and developing new screening techniques.

Deferral of transfusion recipients will not reduce the presumptive risk of transmission of CJD by transfusion in a measurable way.

And again we ask, as we did last time, that FDA initiate discussions of what could constitute an exit strategy. I was extremely impressed by the modeling that we saw today, and the thought, and the process that has gone into that modeling, and to me that modeling could be used as a first step, because the modeling is predicated on the assumption that there is a risk that is high, and we need to do something to prevent the risk.

Now that we have that modeling, perhaps, we can reverse that thinking, or use both lines of thought. Perhaps, there is not a risk, and, perhaps, we can use this modeling to show that there isn't a risk, and at some point have a strategy that says we have dealt with the epidemic, the peak has passed, and now it's time to move on, and you have models to show that it is not being transmitted in the rates and proportions that we thought.

So, I would suggest that we use those models and begin discussions with FDA on how we can assist to use those models to determine how to implement recognized safety measures, how to decide when and if people can donate again, and discuss the possibility of removing European countries which have had no human cases of variant CJD, all but France and Italy, from the deferral criteria.

The U.K. presentation was very telling, because we saw their use of modeling in advance to determine what actions they would take if something happened. I think we've seen that same emphasis from FDA today, to look at what to do if something occurs. We've seen that we have very little data to go on to support those models, but we would love to assist and work with FDA to use those models to determine both what should you do if the data changes and you should change the deferral criteria, and what should you do if the data does not change and we should remove the deferral criteria.

Thank you for the opportunity.

EXECUTIVE SECRETARY FREAS: Thank you very much, Doctor Fitzpatrick.

The third requester for this afternoon is Doctor Richard Davey. He's Chief Medical Officer, New

York Blood Centers.

DOCTOR DAVEY: I'm Doctor Davey, and I'm employed by the Blood Center, actually a former member of the Committee, and I do appreciate the opportunity to speak to the Committee today on behalf of the New York Blood Center.

The New York Blood Center is the largest independent blood center in the country. We collect over 450,000 units of whole blood and 50,000 apheresis platelets annually, which is about 5 percent of the Nation's blood supply.

As you've heard for over 30 years, the New York Blood Center imported blood from three European countries, Switzerland, Germany and the Netherlands, under our Euroblood Program. This blood was collected entirely from volunteer donors under the New York Blood Center's FDA license.

During the period from 1980 until the termination of the program in 2002, we imported about 4,700,000 units of red cells from these European blood centers. The data from '80 to '84 I had to estimate, but I think that number of 4,700,000 is pretty accurate.

In 2001, as you know, this Committee recommended the extension of the prohibition of blood

donation in the United States from those who had resided in the United Kingdom to other European countries. This resulted in the termination of the Euroblood Program in New York. We are encouraged, as Mike has also said, that since that time the number of vCJD cases has remained small, and the incidence of both BSE and vCJD has declined, and there has not been, as you've heard, not a single case of vCJD identified within the three countries that participated in the Euroblood Program, again, Germany, Switzerland and the Netherlands.

Very briefly, I'd just like to touch on a couple consequences of the extension in 2001 to the donation restrictions beyond the U.K.

As you know now, because of out of over 300 million Europeans, and tens of thousands of Americans who have lived or traveled in Europe, are now prohibited from blood donation in the U.S.

Another couple points. Actually, the viral marker rates, the blood we imported from Switzerland in 1999, and this is typical, was - this is for HIV, HCV and HBsAg, was 0.15 percent, the average marker rate in the U.S. is about 0.5 percent. So, when you look at that, it's not clear sometimes, and to my mind they are replacing blood drawn from

altruistic volunteer donors in Europe with blood drawn in the U.S. has really added a lot to blood safety.

Very briefly, I think as Alan mentioned, the blood that we did import from Europe was very rich in Group O, since we don't have that anymore it's thrown the ABO balance, at least in New York, somewhat out of balance, and now we are chronically short of O, and have too much A.

The cost of collecting blood in New York is much higher than blood collected and imported from Europe. We've had to pass those costs on to our hospitals and, of course, to third-party payers.

Just another point, there are some differences in the way these restrictions have been applied in the U.S. For instance, I lived in Geneva for a year when I was detailed from the NIH to the World Health Organization in 1990-'91, so I can donate blood in New York, but I can't here in Washington. I can donate blood in Seattle, I can't donate in Los Angeles. I can donate in Houston, I can't donate in Atlanta. It puzzles me why my risk of vCJD seems to fluctuate as I move around the country.

I raise these points just as an illustration that extensions of the precautionary principle, while they are made in good faith, might

have far-reaching and unintended consequences.

Now, a little bit more about Euroblood. If we prohibit donations from those who have received blood transfusions in Europe, we will by abstention implicate recipients of Euroblood in the United States.

If we assume a transfusion episode of about four units, which I think is accurate, about a million people, maybe slightly over a million people, were transfused with blood from European sources in the U.S., between 1980 and 2001, almost all of the New York Metropolitan Area. Most of these recipients are now deceased, because of the diseases they were transfused for, and also actuarial loss of life.

Living recipients are aware that they are receiving life-sustaining transfusions, but to the point of one of the speakers earlier, they don't know, as any blood transfusion recipient doesn't know, or shouldn't know, whether the blood came from Manhattan, from New Jersey, from Geneva, or from Amsterdam.

Actually, I did do a couple quick stats, if I could take one moment. If we look at, perhaps, a million recipients of Euroblood in the time period we are looking at, due to death fewer than 100,000, maybe far fewer, are still alive. If we look at New York,

about 3 or 4 percent of people donate blood, let's say 5 percent, there are maybe 5,000 living recipients of Euroblood that are donating blood. Again, these are recipients of blood from the Netherlands, Germany, Switzerland, their risks are unknown, vague and low, at very best.

So, also as Alan Williams pointed out, if we did take the route of identifying and notifying the recipients of the millions of units of European donors, and subsequent requirement for our hospitals to trace and notify those recipients, that would be an exercise in actually mind-boggling complexity, scope and expense. This is in addition to the chilling message for these recipients, that while there's no established figure to determine risk they may be harboring a fatal neurologic disease. Of course, they can no longer be blood donors. Counseling these individuals would also fall to the hospitals, and those are really ill-equipped institutions to perform these tasks.

I think personally that the bright line around the United Kingdom, which this Committee established years ago with this unfortunate experiment of prion disease and transmission is unfolding, remains a reasonable basis for the application of the

precautionary principle. Extension of these restrictions to donors and recipients from other countries opens up a slippery slope of extensions to increasing numbers of countries donors and recipients.

We must be mindful of evolving data for sure, as well as the consequences of actions based on limited or absent data.

In conclusion, blood safety remains a compelling priority for all of us. We must consider, however, that not having enough blood, or burdening health organizations with unmanageable issues of notification and deferral, also has major and compelling implications for the safety of the American blood supply.

Thank you.

EXECUTIVE SECRETARY FREAS: Thank you very much, Doctor Davey.

Is there anyone else in the audience now that would like to make comments to the Committee related to this issue before the Committee?

Seeing none, Doctor Priola, In turn the meeting over to you.

CHAIRPERSON PRIOLA: Okay.

So, it's now time for the Committee open discussion and vote on the two questions posed to us

by the FDA.

The first question is, based upon the available scientific information does the Committee recommend deferral of blood donors transfused since 1980 in France or in other countries of Europe? So, this question precludes the Euroblood issue, and I think from comments that Doctor Johnson made, and Doctor Hogan, and, perhaps, others around the table, that there is some hesitancy in even considering Euroblood in these deferrals because of the implications, is that right? Does anyone have any comments on that?

Doctor Bracey?

DOCTOR BRACEY: I'd just like to comment in terms of the Committee's moving toward this discussion.

I think one of the things that happened at the last meeting is that the discussion of this item came up toward the end of the day. There was lots of information, and there was some uncertainty. We've heard lots of information today which for me alleviates the concern. I think there's, as has been stated by many others, minimal gain to be had by extending the range of deferrals, and in my mind I think we've had a thorough discussion, and I think

that, in fact, the safety to be gained from adding other countries would be minimal.

CHAIRPERSON PRIOLA: Doctor Johnson?

DOCTOR JOHNSON: Yeah, was it correct that the French have eliminated donors in their own country who have had transfusions? So, we would be - I find it very convincing that we could look pretty silly if the catastrophe occurred, that someone got blood that even the French wouldn't use on their own.

DOCTOR BRACEY: Well, that's a point, but I think if we look at all of the issues, as far as donor management, we see that there's been a very cautionary approach taken by a number of countries, particularly, the European countries.

If we were to ask the question, well, why did we pick three months for the U.K.? We picked three months because we recognized that that would eliminate a certain number of donors.

If we ask the question, well, what if we went to two months instead of three months, would we - you know, what would be the incremental gain? What is that incremental gain, as opposed to adding France to the mix?

So, I think if we really were to sort of look at the added safety, that in the final analysis

I think it would be quite minimal, and I think that even though in France the donors, in essence, are not allowed to donate after - if they've been transfused, there really is no basis to support that.

CHAIRPERSON PRIOLA: Doctor Allen?

DOCTOR ALLEN: These are very difficult questions. I would absolutely concur that we were not asked about Euroblood, In think there's compelling reasons not even to consider the Euroblood program. So, you know, as I said, we are not asked that question, so that's good.

With regard to France and the deferral of their own donors in France, I would venture to say that if you go back historically that decision probably emanates from the failure to act rapidly in the HIV era, and as you may or may not know there were some French blood banking officials that rightly or wrongly were actually jailed because of that HIV incident.

So, you know, there are probably lots of decisions, or lots of reasons that go into some of these decisions.

The evidence, as far as I can - nonetheless, I agree with you that if France defers and the United States doesn't, and something happens,

it creates a very uncomfortable environment here. It seems to me that the risk is minimal. It's not zero, it clearly is minimal.

Making this additional deferral for France or for other BSE countries in Europe, complicates the selection of donors, and that tends to discourage people from coming. Doctor Williams presented information about inaccurate data that are collected when you are trying to ask donors and they are trying to recall. It does create additional regulatory burden, because the person - the donor that answers one way this time, and a different way three months or four months later, whenever they come back in to donate, then creates the need to go back and notify the FDA if the blood has already been released and transfused, and, you know, we do create additional problems for ourselves with these kinds of things.

You know, the issue of adding France alone, if the addition of France can be rolled into the question of, did you ever receive a donation in Great Britain, may not be difficult. I think the addition of other BSE countries in Europe makes it very complex.

One might ask the question then, should you just defer anybody that's received a transfusion

anywhere in Europe? And, that simplifies things from one perspective, it complicates it in others.

I personally am not sure exactly, In want to hear the rest of the discussion, where I'm going to come down. I probably am leaning slightly towards the inclusion of France only, but it isn't clear to me that we are really gaining a lot in terms of reducing risk, and there are clearly going to be some significant tradeoffs on this one.

CHAIRPERSON PRIOLA: Doctor DeArmond?

DOCTOR DeARMOND: Well, it seems like there's probably just a small - relatively small population of people who have received a transfusion in France.

The thing that kind of bothered me a little bit in the presentations today was - the presentation by Doctor Bird, of the sort of unknown cases of variant CJD - of BSE in France and, perhaps, the kind of extended period of variant CJD cases occurring, kind of not in a cluster, but just sporadic, suggesting that there's an underlying problem there.

If we can understand that, and, in fact, I'd like to hear more comments about her data, does it say that France does have some sort of special problem

with BSE and variant CJD?

And, I don't know, the rest of Europe didn't seem to be a problem, especially the Euro donors group.

So, I would kind of go along with the comments you made, Richard, about considering France and not considering the other countries, for the two reasons, they don't accept their own donors, their own transfused patients, and there seems to be a problem with BSE and variant CJD there still.

CHAIRPERSON PRIOLA: In think with respect to Doctor Bird's presentation, maybe she can clarify this, the overall point was that there's underestimation if you just base it on clinical cases, so not to just single out France, but any country where there's BSE or variant CJD surveillance there will be under-representation.

DOCTOR DeARMOND: Could you, I would like to know, I got a different perspective.

DOCTOR BIRD: No, I think the important thing, from my point of view in terms of France, is that the French team - that the majority of the exposure of the French population came from exports of bovine carcasses from the United Kingdom to France, and that 60 percent of our export of bovine carcasses

went to France. So, there's a very clear reason as to why France would be next in line.

There hasn't been much discussion here about Ireland, what we think of as the Republic of Ireland, which is not part of the United Kingdom, it's a separate country, and which has two countries - two variant CJD cases, and had a very high rate also of BSE in its cattle.

DOCTOR DeARMOND: So, you didn't implicate France, that France has a special problem, except in the case of importation from Great Britain.

DOCTOR BIRD: Primarily, in respect to importation from the United Kingdom, yes.

CHAIRPERSON PRIOLA: Doctor Nemo, did you have a comment?

DOCTOR NEMO: Yes, just from the availability standpoint, if you look at the history of transfusion in France, it's 1.4 per 10,000. If you look at, say, an average blood center that collects 200,000 units a year, that only comes out, I think, to a couple, two to three, donors a month that you'd lose. So, it's not - I think if my back-of-the-envelope calculations are correct - so, it's not a major loss as far as France is concerned.

CHAIRPERSON PRIOLA: Doctor DiMichele?

DOCTOR DiMICHELE: Well, I just wanted to say, you know, AABB, we do have our statement where we think we can absorb, you know, a loss from deferral due to France, but I would say that, you know, a donor lost is more than a donation lost. You know, anyone whose feelings are hurt when they are rejected, you begin to lose their neighbors, their friends, their family, their work site, and, hopefully, they were more than a once-in-a-lifetime donor to begin with. So, it is a greater loss than just, you know, a couple of units a month.

Thank you.

MS. CARR-GREER: I was just wondering if the U.K. was deferring individuals who had been transfused in France?

DOCTOR BIRD: The U.K. defers any donor who has received a transfusion.

DOCTOR DiMICHELE: In the U.K.?

DOCTOR BIRD: The U.K. would not accept a blood donation from anybody who had received a transfusion, period, is the answer now.

DOCTOR DeARMOND: Is that ever and in any coun - from any country in Europe?

DOCTOR BIRD: That's correct, but, of course, we've only done this as of 2004, whereas,

France had made its decision in 1998, and part of our reason for delaying, it obviously had been a consideration in the U.K., was concern about the impact on the blood supply, but then confronted with blood-borne vCJD the action was then taken pretty quickly.

DOCTOR SALMAN: Is this transfusion in Europe? What if there was a donor who was transfused in the United States, for example?

DOCTOR BIRD: I think I am correct in saying that the U.K. would not accept as a donor somebody who had received blood transfusion, full stop.

DOCTOR SOLDAN: Well, perhaps, we have to clarify this for the Committee afterwards, because I'm not convinced, and we need to just check that for you to be absolutely certain. That's a key point, because my recall is that it may only be U.K. transfusions, but we'd like to check that for you.

CHAIRPERSON PRIOLA: That would be fantastic, thank you.

Doctor Bracey?

DOCTOR BRACEY: One of the issues that I think we need to get somewhat concerned about is this issue of taking that first step, because, clearly, if

you ask the question, you know, what is the minimal biological risk, of course, the minimal biological risk is not to receive - is to receive the blood of a patient who has never been transfused.

As we begin to take these small incremental steps and compare our policies to the policies of other nations, I'm just afraid that this may just be the first step, and then, well, then comes the next step. That's my concern.

And again, if we do this, in essence, because it's been done in France for, in essence, trying to develop some sort of uniformity, I'm just concerned about taking that first step and then, perhaps, there's another step that follows.

CHAIRPERSON PRIOLA: Doctor Hogan, did you have something you wanted to say? No?

Okay, Doctor Salman?

DOCTOR SALMAN: Well, my concern, if we start with France now, somebody will say, what about the Netherlands, and tomorrow another country in Europe decide to do the same thing as France, when we will stop. Either we have some risk assessment process that is going on and have from that some outcome before we can decide, or maybe we - like with all the day we spend on reviewing risk assessment

models, and now we are saying is, we go with this and exclude France or exclude other countries, so what's the purpose of risk assessment modeling we are reviewing?

CHAIRPERSON PRIOLA: Doctor DiMichele?

DOCTOR DiMICHELE: I'm going to play the devil's advocate again.

I think that, you know, when we are talking about deferring blood donors, I think the situation is a little bit different than what we've been talking about with respect to plasma derivatives. I think the plasma derivative issue is a very different kettle of fish, with respect to risk assessment.

I think we have evidence that - or certainly some evidence, I mean, maybe no incontrovertible evidence, but some evidence that this organism can be transmitted through a regular blood donation.

I would have to say that there's some people who are breathing a lot easier with our having deferred people transfused in the United Kingdom from our donor base, you know, now having, you know, found out quite later, after having made this decision, that there have been a few cases of transfusion transmitted

diseases. And, although I understand that this is an ongoing risk assessment, and I would actually second Mike Fitzpatrick's statement that there has to be an ongoing risk assessment as we make these decisions, so that we can reverse them should the time come, I would agree with those individuals who have said that in light of the fact that we know that this organism, this prion can be transmitted, or like I said, have fairly good evidence that it can be transmitted through blood transfusion, and given that there is the likelihood or the possibility that this situation could evolve in France as it has in the U.K., and given that France does defer its own transfused individuals from donating blood, I don't really see how we could not defer France, and people who have been transfused in France, at least as a precautionary measure.

CHAIRPERSON PRIOLA: Doctor Epstein, do you have a comment?

DOCTOR EPSTEIN: Yeah, I just wanted to comment that FDA's thinking in posing the question specific to France was not based on the policy in France to defer transfusion recipients, it was based on the epidemiology of BSE exposure based on importation, primarily, of U.K. beef, and it was based

on the relative proportion of vCJD cases, about 5 percent of that in the U.K., and that does make France stand out among non-U.K. European countries.

So, I just wanted to clarify that we didn't really see the driver here as the French policy decision, though it's certainly a matter that the Committee can discuss.

DOCTOR DiMICHELE: Yeah, but on the other hand I would have to say that the French saw their epidemiology as being a little bit of a risk factor, and that's probably why they made their decision.

So, I mean, in essence, it does come back down to the epidemiology.

DOCTOR EPSTEIN: Right, but the question is whether a policy decision should be based on the scientific risk assessment or looking at European policies per se, and I'm just trying to get us refocused on thinking it through from the standpoint of risk.

DOCTOR DiMICHELE: Well, what I would then say is that I would agree with you then that the epidemiology is the issue, and that the deferral in France of their own transfusion recipients, I think, is just confirmation that, you know, there is some concern about that epidemiology, and some concern that

should be taken here in the United States. I guess I'll reframe it that way.

DOCTOR EPSTEIN: I think we'd be more comfortable hearing it framed that way.

CHAIRPERSON PRIOLA: Doctor Salman?

DOCTOR SALMAN: Well, if we try to make it on the epidemiology of what happened with BSE in France, I think again I would emphasize, this is really unfair because there are plenty of countries now in which they have BSE cases, whether detected or not that's another issue.

Furthermore, when you look on the Eurostat, which is the most important statistical-based figures from Europe, there are plenty of countries in which they received U.K. meat, received MBM, meat and bonemeals, they have more cases if we go with that type of prediction.

So, I don't think we can pinpoint only on France, whether the French decided to go with that issue, I agree with Doctor Allen, is mainly because of their previous experience with the HIV, that's their reason to go that way.

So, if we go with the issue about epidemiology of BSE, In think there are plenty of other countries I can pinpoint in which like they

should be included with France.

CHAIRPERSON PRIOLA: Doctor Belay?

DOCTOR BELAY: But clearly, the French question is different because they have more vCJD, period, and that reflects what people have been saying in terms of the BSE exposure in France, whether it's from within France, BSE within France, or it's foreign material, imported material from the U.K. is higher than other European countries, and that's what the vCJD situation is telling us.

CHAIRPERSON PRIOLA: Although In suppose you could extend Doctor Salman's argument and say in those countries where there is poor BSE surveillance there's probably not much better vCJD surveillance.

DOCTOR BELAY: That's correct.

CHAIRPERSON PRIOLA: Doctor Bracey?

DOCTOR BRACEY: Perhaps, back to the issue of the Japanese case. Here's a case where a person was not in the U.K. for three months, they acquired the infection, so again, when we look at reducing risk are we really treating other countries in a fair manner, you know, when we decide for the U.K. that it is three months, because we want to maintain our donor base with a loss of 2 to 3 percent? I mean, where's the science in that decision? That was the decision,

based upon loss of donors. Should we go to a month for the U.K.? Would that decrease the risk relative to France?

CHAIRPERSON PRIOLA: Doctor DiMichele?

DOCTOR DiMICHELE: In think you bring up an excellent point, and what I was going to say is, that's not an issue that's on the table right now, but I would have to say that, you know, this case in Japan is going to have to be watched very carefully, and if there is further evidence, yes, I would agree with a deferral, a stricter deferral.

I mean, and it's going to be difficult, but I'm not sure what else we can do until we, you know, begin to understand how to test for this, you know, how to nip it in the bud as we have for other infectious diseases.

You know, fortunately, this case is not like West Nile, which, you know, we were able to get control of very quickly, but, you know, I don't know what else to do, I mean, the population still has - I mean, this is a terrible disease.

CHAIRPERSON PRIOLA: Mr. Bias?

MR. BIAS: Well, I guess - boy, hard decision when you open up this door, it's a very difficult decision. But, I guess what I'm - the

reason I'm sitting in this seat, and wasn't sitting here years ago in a seat like this, was because the Committee needs a human face. I've been independent on the blood supply my entire life, and I probably have everything that's been through the blood supply as a result of that.

So, before we make this decision, very few decisions can be made based on science alone, when we are talking about infusing it into people's arms. So, I would ask you all to keep that in mind as we make this decision.

I wouldn't make a decision that France is not willing to make themselves, and if they are deferring then I think we have to hold that line.

I think we got a model of a risk assessment tool, and I think we ought to use it, at least try to use it, or try to get information so that we can use it, before we start opening up the doors.

And then, I guess my final comment would be, is to think about that person on the end if we are wrong, and what we tell them, or what we have done to protect them. Are the blood banks talking about labeling blood or notifying that patient that you are getting European blood, or are they simply saying we are going to give you blood, and you are not going to

know?

And, I think that regardless of whether we get to make that decision at this Committee that has to be part of our thoughts, because once we make this decision it will be very difficult to reverse.

This is my fourth or fifth meeting, and at every one of these meetings I've heard the appeal from the blood collection industry to reduce the deferrals, to open up the gates because of the lack of cases, and every time I've heard the science say to us over and over again that we have one, two, three, four uncertainties that we're all concerned about, that we just don't know the answer to yet.

So, I would actually consider that as we make this vote, not taking one side or the other, but there are people here to be considered, and I would ask the Committee to consider that.

CHAIRPERSON PRIOLA: Doctor Rohwer, do you have a comment?

DOCTOR ROHWER: Yeah, thanks.

I would like to have this opportunity to stir this up a little bit more.

I think the science behind deferring transfusion recipients is just about the smartest thing you can do scientifically, and let me give you

the arguments.

Let me remind you that we have iatrogenic transmissions of this disease, at least 250 of them are known from human growth hormone and dura mater, so that's a fact, it does happen. And, the largest exposure that we have to human-derived tissues is probably through the blood supply and the use of blood.

This use of human-derived tissues is as close as we come to an analogous situation to what happened to BSE in cows. There we had a disease that was being recycled in that population for probably a decade at least before the first case was recognized. It's now estimated that there were probably somewhere like 100,000 animals that were already infected by 1985, that then showed up in that peak that we saw six, seven years later.

And so, the risk from these diseases is really the risk - the public health risk from them, and I'm talking about a population risk more than an individual risk, from the silent propagation of an infection with a very long incubation time, that doesn't reveal itself in symptoms until the last moments of the disease.

We also have heard today, or just since -

during this last year, that the prevalence of this disease may be much higher than we had ever expected from the tonsil/appendix survey, and something that hasn't come up today, but that has concerned me considerably about that study, is we have no idea what the ascertainment rate is for those tissues. It can't possibly be 100 percent, and we know that it's imperfect because the second transfusion case had neither an appendix or a tonsil signal, they found it in the spleen.

So, we are not getting them all that way, and we have no idea whether we are getting 1 percent, 10 percent, or whatever.

We also have all this new data about infectivity in muscles, which is extremely alarming to me personally, because it suggests that we may have completely underestimated the exposure. It may have been much greater than we actually thought. It didn't come, necessarily, just from SBOs and MRM and things like that.

So, and finally, we have these two transfusion transmissions that have already occurred, and this is giving us a warning that we may be on the same path to iatrogenic transmission that we saw with, you know, in 1985 there was one case of human growth

hormone transmission as well. Now, we've got 150 or something like that on the books.

Finally, let's consider what has worked in terms of the management of these diseases. We have a proven management method in the feed ban that was implemented in Great Britain. It took an epidemic that was expanding exponentially and stopped it in its tracks over about a four or five-year period. We are down, we heard down, down to 80 or something cases a year in Great Britain, from a high of 1,000 cases a week in 1993, I think, 1992, and that's amazingly effective.

The only analogous tool that we have right now for doing the same thing with these transfusion - with a potential for transfusion transmitted infections, is to defer transfusion recipients. It doesn't prevent a person from getting the disease from having been in the United Kingdom, or Europe, or something like that, but it does prevent the propagation of the disease, if, in fact, that's an issue, and we just don't know.

So, it is precautionary in that sense, but in terms of the science it seems to me, and always has seemed to me, that this is absolutely the most effective thing you could do to prevent a - to stop an

incipient epidemic that may be incubating in our midst from going anywhere.

CHAIRPERSON PRIOLA: Thank you, Doctor Rohwer.

Any other comments from the Committee?

I'm not sensing consensus in the Committee either way, so should we take a vote and see how people stand on this issue?

DOCTOR DeARMOND: An unofficial vote.

DOCTOR JOHNSON: How about a motion to vote?

CHAIRPERSON PRIOLA: Well, I don't know if - well, yeah, we can have a motion to vote.

DOCTOR JOHNSON: So moved.

EXECUTIVE SECRETARY FREAS: We don't need a motion.

CHAIRPERSON PRIOLA: Yeah, I guess my comment would be that if you vote and then you have to reverse, then you are not sure enough to vote yet about how you want to do this, you know, whether you want to vote for deferral or not for deferral in France and/or other European countries.

So, should we take a vote? Let's go around and vote.

EXECUTIVE SECRETARY FREAS: This will be an

official vote, and there are 16 voting members at the table, and, of course, at the end we'll ask the industry for their recommendation.

I'm going to start with you, Doctor Schonberger.

DOCTOR SCHONBERGER: In agree with the argument that Doctor DiMichele put forward, and I vote for the deferment of people from France for donations of blood.

EXECUTIVE SECRETARY FREAS: Next, Doctor Hogan?

DOCTOR HOGAN: I'm going to vote for it, but I'm concerned about how much everyone said, how much really we are significantly decreasing the risk. However, I'm compelled by Doctor Rohwer's argument, and that's that we have to be extremely cautious.

EXECUTIVE SECRETARY FREAS: Doctor Bracey?

DOCTOR BRACEY: I'll vote against the exclusion.

EXECUTIVE SECRETARY FREAS: Doctor Jenny?

DOCTOR JENNY: I'll vote for it, but I still have concerns about that we don't have enough information. I would have been - the person from France that was to be here, I think, could have helped this discussion a lot.

EXECUTIVE SECRETARY FREAS: Doctor Gaylor?

DOCTOR GAYLOR: May I abstain?

EXECUTIVE SECRETARY FREAS: Yes, you may abstain, yes.

Doctor Nemo?

DOCTOR NEMO: In vote for.

EXECUTIVE SECRETARY FREAS: Doctor Johnson?

DOCTOR JOHNSON: Aye.

EXECUTIVE SECRETARY FREAS: Doctor Allen?

DOCTOR ALLEN: Yes, but not strongly.

EXECUTIVE SECRETARY FREAS: Doctor Priola?

CHAIRPERSON PRIOLA: In vote no.

EXECUTIVE SECRETARY FREAS: Doctor Telling?

DOCTOR TELLING: I have no concern for voting for the deferment.

EXECUTIVE SECRETARY FREAS: Mr. Bias?

MR. BIAS: I vote for.

AUDIENCE: What was your vote?

DOCTOR TELLING: I voted for the deferment with no concerns.

MR. BIAS: I vote for the deferment.

EXECUTIVE SECRETARY FREAS: Doctor Creekmore?

DOCTOR CREEKMORE: In vote for.

EXECUTIVE SECRETARY FREAS: Doctor

DeArmond?

DOCTOR DeARMOND: We're talking about a small number of people that would be affected. France defers them, and I like Val Bias' argument that we have to consider the patient receiving transfusions, and they are the second largest number, they have the second largest number of vCJD cases, so I vote for.

EXECUTIVE SECRETARY FREAS: Doctor Belay?

DOCTOR BELAY: I vote yes for the deferment.

EXECUTIVE SECRETARY FREAS: Doctor Salman?

DOCTOR SALMAN: I vote against it.

EXECUTIVE SECRETARY FREAS: Doctor DiMichele?

DOCTOR DiMICHELE: In vote for it, and continue to urge, though, that we continue to evaluate every decision.

EXECUTIVE SECRETARY FREAS: May we get the industry opinion?

DOCTOR PETTEWAY: In think the decision in October is still the correct one, I vote no.

EXECUTIVE SECRETARY FREAS: Okay, that was an opinion, not a vote, for point of clarification.

So, we have two no votes, one abstention and the rest were for the deferral.

Oops, my math is not that good, it's three no votes, one abstention, and that should leave 12 yes votes.

CHAIRPERSON PRIOLA: Let's move on to the second part of the question, should we recommend deferral of blood donors transfused since 1980 in other countries of Europe?

So, let's go around and vote on the second part of the question then.

EXECUTIVE SECRETARY FREAS: Going around the table the same way, Doctor Schonberger?

DOCTOR SCHONBERGER: No.

EXECUTIVE SECRETARY FREAS: Doctor Hogan?

DOCTOR HOGAN: No deferral.

EXECUTIVE SECRETARY FREAS: Doctor Bracey?

DOCTOR BRACEY: No.

EXECUTIVE SECRETARY FREAS: Doctor Jenny?

DOCTOR JENNY: No.

EXECUTIVE SECRETARY FREAS: Doctor Gaylor?

DOCTOR GAYLOR: No.

EXECUTIVE SECRETARY FREAS: Doctor Nemo?

DOCTOR NEMO: No.

EXECUTIVE SECRETARY FREAS: Doctor Johnson?

DOCTOR JOHNSON: No.

EXECUTIVE SECRETARY FREAS: Doctor Allen?

DOCTOR ALLEN: No.

EXECUTIVE SECRETARY FREAS: Doctor Priola?

CHAIRPERSON PRIOLA: No.

EXECUTIVE SECRETARY FREAS: Doctor Telling?

DOCTOR TELLING: I vote no, but with the caveat that I'm concerned about the increased rise in cases in Switzerland, which has the second highest incidence of BSE in Europe, and the fact that new variant CJD may manifest in more than one molecular form.

EXECUTIVE SECRETARY FREAS: Mr. Bias?

MR. BIAS: I'm going to abstain.

EXECUTIVE SECRETARY FREAS: Doctor Creekmore?

DOCTOR CREEKMORE: No, with the comment, though, that I think we should remain vigilant, we should be continuing to investigate that situation, and consider using this risk analysis tool for both continuing to look at these other countries and also, as has been mentioned before, as we get down the road making decisions about changing policies we've already made.

EXECUTIVE SECRETARY FREAS: Doctor DeArmond?

DOCTOR DeARMOND: No, but with the same

caveats that Glenn and Lynne had.

EXECUTIVE SECRETARY FREAS: Doctor Belay?

DOCTOR BELAY: No.

EXECUTIVE SECRETARY FREAS: Doctor Salman?

DOCTOR SALMAN: No.

EXECUTIVE SECRETARY FREAS: Doctor DiMichele?

DOCTOR DiMICHELE: No, with - and I concur with careful reevaluation.

EXECUTIVE SECRETARY FREAS: And, industry's recommendation?

DOCTOR PETTEWAY: No.

EXECUTIVE SECRETARY FREAS: Okay.

We have one person abstained, and then it was unanimous no votes with caveats.

CHAIRPERSON PRIOLA: Okay.

So, we can move on to the second question, which is, based upon the available scientific information, does the Committee recommend deferral of source plasma donors transfused since 1980 in France or in other countries of Europe, and I guess this is with the caveat that there is probably some degree of TSE clearance in sourced plasma products.

Discussion from the Committee, comments?

Doctor DeArmond?

DOCTOR DeARMOND: As I recall, or I can't remember the details, of where plasma byproducts are obtained. Are they mostly from industry in Europe, or do we have a large industry here? As I recall, it's mostly European, but I don't remember.

CHAIRPERSON PRIOLA: Doctor Petteway, do you want to comment?

DOCTOR PETTEWAY: By byproducts, you mean where is the plasma obtained for U.S. products? It's U.S. plasma.

DOCTOR DeARMOND: And, where is it processed into the sub-fractions?

DOCTOR PETTEWAY: It depends on the company, yes.

CHAIRPERSON PRIOLA: But, the source of it all is U.S. blood.

Doctor Allen?

DOCTOR ALLEN: I'm concerned by the degree to which it's believed that the prion infectivity is in plasma, I think the figure that was mentioned was about 50 percent.

On the other hand, the processing seems to clear, and if one looks at the epidemiological data that has been cited several times, particularly, within England and looking at the absence of any

apparent cases in people who have received regular infusions of clotting factor and other products, you know, I'm convinced that it seems as though the risk is within acceptable limits at the present time, and I'm assuming the FDA will, of course, continue to monitor the situation carefully.

CHAIRPERSON PRIOLA: Doctor DiMichele?

DOCTOR DiMICHELE: In would just like to ask a question for clarification.

I think I understand that all of the deferrals so far for transfusion and for other reasons for the blood product industry also applies to source plasma, except for the clarification of greater than or equal to five years residence, travel in Europe, applying only to France for source plasma, is that correct?

CHAIRPERSON PRIOLA: In believe so. Would someone from - Doctor Williams will answer that.

DOCTOR WILLIAMS: Yes, that is correct.

DOCTOR DiMICHELE: That is correct?

DOCTOR WILLIAMS: That is correct.

DOCTOR DiMICHELE: Okay.

So, there's already a special precaution for France in source plasma that doesn't apply to, from what I'm understanding, I mean, there's already

a special exclusion, or in the absence of exclusion of Europe for blood donors there is an exclusion - no, wait a second - there is - what I want to say is, is that France is out for source plasma anyway, with respect to five years of residence and travel, I think, from what I'm understanding here then.

So, there has already been sort of a caution relating to France already.

Am I reading this correctly?

AUDIENCE: Yes.

DOCTOR DiMICHELE: Yes, okay.

So, I would have to say that, you know, this is a tough question, because I think that the epidemiology of it isn't quite clear. In one way we are being told that certainly source plasma donors are the younger donors, they are the ones we have to worry about with new variant CJD by and large, rather than the older donors. We know that 58 percent of the CJD is in plasma, so we can't say that plasma is not a source of concern.

By the same token, most of it is going into plasma derivatives, you know, and, you know, we are a little less concerned about plasma derivatives.

On the other hand, I would have to say that there's already a caution for France, so I would

have to say that this would have to be considered seriously.

CHAIRPERSON PRIOLA: Other comments from Committee members?

If there are no other comments or questions, should we take a vote on this second issue then? Okay, let's do that.

EXECUTIVE SECRETARY FREAS: Same order?

CHAIRPERSON PRIOLA: Let's reverse the order, so that Steve doesn't have to wait so long.

DOCTOR PETTEWAY: Appreciate that, I vote no for both A and B.

EXECUTIVE SECRETARY FREAS: Okay.

Doctor DiMichele?

DOCTOR DiMICHELE: In don't think I quite answered my own question yet. Oh, gee, I don't know that I'm ready for this vote, if I have to -

EXECUTIVE SECRETARY FREAS: You may pass and we'll come back and get you.

DOCTOR DiMICHELE: Okay, well, yeah, I think I have to abstain, because I'm just not sure.

EXECUTIVE SECRETARY FREAS: Doctor Salman?

DOCTOR SALMAN: No.

EXECUTIVE SECRETARY FREAS: Doctor Belay?

DOCTOR BELAY: I vote yes.

EXECUTIVE SECRETARY FREAS: Doctor DeArmond?

DOCTOR DeARMOND: Well, based on the epidemiology I'd have to say no.

EXECUTIVE SECRETARY FREAS: Doctor Creekmore?

DOCTOR CREEKMORE: I'd like to pass.

EXECUTIVE SECRETARY FREAS: That's an abstain.

DOCTOR CREEKMORE: Or abstain.

EXECUTIVE SECRETARY FREAS: Okay. If it was a pass we'd come back and get you.

Mr. Bias?

MR. BIAS: Can you state the question one more time?

CHAIRPERSON PRIOLA: It's, based upon the available scientific information does the Committee recommend deferral of source plasma donors transfused since 1980 in France?

MR. BIAS: Yes.

EXECUTIVE SECRETARY FREAS: Doctor Telling?

DOCTOR TELLING: Yes.

EXECUTIVE SECRETARY FREAS: I'm sorry, Mr. Bias, your answer was?

MR. BIAS: Yes.

EXECUTIVE SECRETARY FREAS: Okay.

And, Doctor Telling, yours was yes, too.

Doctor Priola?

CHAIRPERSON PRIOLA: No.

EXECUTIVE SECRETARY FREAS: Doctor Allen?

DOCTOR ALLEN: No.

EXECUTIVE SECRETARY FREAS: Doctor Johnson?

DOCTOR JOHNSON: Yes.

EXECUTIVE SECRETARY FREAS: Doctor Nemo?

DOCTOR NEMO: No.

EXECUTIVE SECRETARY FREAS: Doctor Gaylor?

DOCTOR GAYLOR: In abstain.

EXECUTIVE SECRETARY FREAS: Doctor Jenny?

DOCTOR JENNY: Abstain.

EXECUTIVE SECRETARY FREAS: Doctor Bracey?

DOCTOR BRACEY: No.

EXECUTIVE SECRETARY FREAS: Doctor Hogan?

DOCTOR HOGAN: No.

EXECUTIVE SECRETARY FREAS: Doctor Schonberger?

DOCTOR SCHONBERGER: Yes.

EXECUTIVE SECRETARY FREAS: My count, five yes votes, four abstain, and the rest would be no votes.

The yes votes were Doctor Schonberger,

Doctor Johnson, Doctor Telling, Mr. Bias and Doctor Belay.

There are 16 people voting, so it's 5-7-4.

CHAIRPERSON PRIOLA: Yes, so seven no.

EXECUTIVE SECRETARY FREAS: Seven no.

CHAIRPERSON PRIOLA: Five yes, seven no, four abstain.

As to the second part of the question, deferral for source plasma donors transfused since 1980 in other countries of Europe.

DOCTOR PETTEWAY: No.

Oh, Doctor Petteway already voted.

EXECUTIVE SECRETARY FREAS: Okay.

DOCTOR DiMICHELE: No.

EXECUTIVE SECRETARY FREAS: Doctor Salman?

DOCTOR SALMAN: No.

EXECUTIVE SECRETARY FREAS: Mr. Belay - Doctor Belay?

DOCTOR BELAY: No.

EXECUTIVE SECRETARY FREAS: Doctor DeArmond?

DOCTOR DeARMOND: Using Doctor Schonberger's epidemiology argument, I still say no.

EXECUTIVE SECRETARY FREAS: Doctor Creekmore?

DOCTOR CREEKMORE: No.

EXECUTIVE SECRETARY FREAS: Mr. Bias?

MR. BIAS: No.

EXECUTIVE SECRETARY FREAS: Doctor Telling?

DOCTOR TELLING: No.

EXECUTIVE SECRETARY FREAS: Doctor Priola?

CHAIRPERSON PRIOLA: No.

EXECUTIVE SECRETARY FREAS: Doctor Allen?

DOCTOR ALLEN: No.

EXECUTIVE SECRETARY FREAS: Doctor Johnson?

DOCTOR JOHNSON: No.

EXECUTIVE SECRETARY FREAS: Doctor Nemo?

DOCTOR NEMO: No.

EXECUTIVE SECRETARY FREAS: Doctor Gaylor?

DOCTOR GAYLOR: No.

EXECUTIVE SECRETARY FREAS: Doctor Jenny?

DOCTOR JENNY: No.

EXECUTIVE SECRETARY FREAS: Doctor Bracey?

DOCTOR BRACEY: No.

EXECUTIVE SECRETARY FREAS: Doctor Hogan?

DOCTOR HOGAN: No.

EXECUTIVE SECRETARY FREAS: Doctor Schonberger?

DOCTOR SCHONBERGER: No.

EXECUTIVE SECRETARY FREAS: Unanimous no.

CHAIRPERSON PRIOLA: Okay.

With that, that concludes the meeting. I appreciate everybody's efforts. These were not easy questions.

Thank you all for being here, and I'd like to thank all our speakers, especially the speakers from the U.K. Their input was greatly appreciated.

(Whereupon, the above-entitled matter was concluded at 5:49 p.m.)

CERTIFICATE

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

Before: DHHS/FDA/CBER

Date: February 8, 2005

Place: Silver Spring, Maryland

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