HIV-positive unit if the deferral is changed to five years.

We know HIV is transmitted by transfusion and yet this risk is acceptable because individuals choosing an alternate lifestyle are being discriminated against. At the same time, we are spending millions of dollars to perform a NAT test for HIV to detect three to five HIV-positive units a year.

"These two FDA guidances seem to be at cross purposes. Continuing to defer MSM donors permanently enhances the safety of the blood supply much more cost effectively than NAT. There is no additional cost to continuing to keep that one HIV-positive unit out of the blood supply. We will continue to spend millions to keep the other few out with NAT.

"I would recommend that the committee continue current deferral policies even in the face of possible cries of discrimination. There are less risky methods of increasing the donor pool than reinstating previously permanently deferred donors. If present, I would be voting against dropping the deferral to five years."

I just wanted to read that into the record from Colonel Fitzpatrick.

Yes?

DR. NELSON: I think this is a pretty tricky and delicate issue and difficult, but it isn't as difficult as

the CJD because we have to wait quite a while to get an answer on it. One of the things that occurs to me is I think the sort of bottom line is if we change the deferral criteria to five years, and I would think that if it would be changed at least initially that should be the change, not one year, until we have more data.

But if we change it to five years, we would have information on the prevalence in the additional population, whether it was 62,000, 160,000 or 10,000. We could get prevalence data on that population. If the prevalence significantly increased, then, even if it is one, or however small number, that might, for one reason or another, escape all the testing with NAT an antibody, et cetera, the policy could be reevaluated.

But if it turned out that there was no increase, then the benefit would be however many additional donors that yielded. The estimate was that the CJD policy decreased the donor pool by 2.5 percent, maybe more, of some units. This, it wouldn't increase it by 2.5 percent but maybe 1 percent. So it is not completely insignificant.

That is my thinking. I don't think that people, necessarily, have a right to be a blood donor. I can understand all the issues and that there are issues, but it isn't quite the same as a right to insurance or a right to a job or a right to many other things.

I think the instruments that we use in a busy blood bank, et cetera, will have to be sort of blunt and not totally personalized. So, therefore, I think we need a single question or two.

But I think we could change it to a five-year and before the risk of a unit slipping through, we would have data as to whether the risk has been increased.

DR. HOLLINGER: Thank you.

Dr. Schmidt?

DR. SCHMIDT: I don't think we are going to get any data asking people do they remember when; is it three years, four years, five years, et cetera. We are setting up an artificial situation where we are going to accept what we think they said. We wouldn't accept another test based on such--the terrible certainty of what the test would result. And this really is a test. So I am against making any changes until we do them all and do them right.

DR. HOLLINGER: Dr. Epstein?

DR. EPSTEIN: I just want to make a few points that I hope are clarifying. A lot has been said about the inconsistency of criteria that lead to twelve-month deferral versus lifetime deferral. The concept that emerged in putting forward these different deferral periods was that, in some cases, we were trying to address risks that presented themselves as discrete or one-time exposures where

the real issue was to wait for something in excess of a window period before permitting the blood collection on the notion that you would then have positive tests and could exclude use of the unit.

However, there was independently the notion that there were, in fact, some risk histories that connoted lifestyle choices that imply ongoing risk and where one could not be confident that simply waiting one window period from a discrete exposure was meaningful.

Those lifetime deferrals, as has been stated, were for history of intravenous drug use, sale of sex for money or drugs, or male sex with males since 1977 in the AIDS era. I think that it needs to be understood that two concepts were driving FDA thinking, that these relate to the whole notion of layers of safety; in other words, a series of overlapping safeguards to protect the blood supply.

The idea was that first you educate people so that they don't present as donors if they have known risk, that you then ask them questions to try to exclude them from donating if they might be a person at high risk either because of incidence or because of prevalence.

This is a very key point, that we have, forever and a day, tried to keep from collecting persons likely to have a positive collection because it would go into the quarantine inventory but there is finite risk that it would

come out in error. We have always done this.

Then, of course, the third layer of protection is testing deferral registries, quarantine management, et cetera. So, again, the deferral criteria have always been organized to try to capture both persons at high incidence but also persons identifiable as being in groups with high prevalence to prevent infectious units from entering the inventory at the blood center.

I would also like to address what I think is a misunderstanding whether FDA criteria are based on identification of self-identification of a group as opposed to behavior. The question that we ask of persons who may have had sex with males as males is not do you self-identify as gay or bisexual. We ask, "Have you, as a male, since 1977, even one time had sex with another male?"

I would contend that that is behavior. We also can look at it as lifestyle choice, identification, personal identity, whatever else. But the bottom line is we are not asking people to self-identify. We are asking whether they have engaged in a certain behavior.

I think that the current FDA policy has been very much misrepresented on this point. It is, indeed, behavior that we ask about. There is no question, in general, that the behavior, that history, is associated with known high prevalence and known high incidence of, at a minimum, HIV

and hepatitis B and, marginally, for HCV, as has been said twofold for HCV, but at least tenfold for hepatitis B and even higher than that for HIV.

So the real challenge, as I see it, is whether knowing that MSM, persons who have that behavior, in general, are at known high prevalence and high incidence, is there any way to identify a safe subset. That is the real question.

One attempt to do that has been to look at persons who deny that behavior within the last five years. I would suggest that issue is not merely whether we have captured window period. Of course, we capture window period in five years. The issue with moving to one year is whether we have really captured a safe cohort that are not engaged in ongoing risk behavior.

I think that is a fundamental difference between a one-year exclusion and a five-year exclusion. The point was brought up earlier, and I am sorry that Dr. Smith has left, but we have looked at, alternatively, the question of whether a person states that they are in a monogamous or mutually monogamous gay relationship as well as the question of whether they state that they practice only safe sex.

But, to our knowledge, based on data that have been made available to us by the CDC and actually are published in, I think, the paper from Valroe was put in the

packet, none of those criteria has yet been established to correlate with low risk.

In other words, in the face of stated monogamy, in the face of stated safe sex, persons who engage as males in sex with males still have indistinguishable risk from those who do not state monogamy and safe sex.

We can have a long discussion about why that is so, but the fundamental point here is that we still wish to try to identify safe donors before we put a needle in the arm. We want individuals at low prevalence and low incidence before we put a needle in the arm.

The question is have we gotten far enough in that direction with a floating five-year exclusion as opposed to a floating post-'77 exclusion, a lifetime exclusion. We all understand that it is somewhat nonspecific and undoubtedly captures uninfected individuals whose lifestyles may not put them at increased risk.

We understand this. It is nonspecific. It is overinclusive. But it works. It works because it captures the high-risk subset. The question is whether it is also safe to relax it in the way that has been described. That is really what the debate should be about.

So I hope I have clarified the distinction between a one-year deferral, a five-year deferral and a life-time deferral and what I think is the pivotal question.

DR. NELSON: Do you think monitoring the prevalence, if a change was made, and stating some sort of criteria is useful?

DR. EPSTEIN: I think it is a useful concept. We have never actually done it by implementing the change in the blood supply. In other words, when we contemplated this kind of change, we have usually moved towards studies, epidemiologic studies, that would predict for us what would happen if we made that change in the blood supply.

What is being suggested is that, if we think it is safe enough and, at some point, I assume there will be a vote, that the way to go about it is make the change but monitor it closely, hopefully on the notion that we could catch it quickly enough if it appeared that prevalence among donors was rising or incidence among donors was rising where, and I would hope not, but transmission rates were rising.

So that is a different model for how to go about change. I don't reject it up front but I think there has to be some notion that we would only apply that strategy for changes where we were fairly well convinced that it wouldn't cause decreased safety and we were just monitoring to make sure that we were right.

DR. SCHMIDT: Jay, your logical progression down the line omits something that we didn't discuss today at

all, and that was the concept of giving people the opportunity, after they had told us something, to say, "Oops; I lied," or, "I forgot," and, after they donated the blood, let us know to throw the blood away.

If we were doing that, then to say we are going to believe them now or that it was logical without that, it doesn't fit at all.

DR. HOLLINGER: Paul, I would like to go back to something you said earlier. While I might favor a one-year deferral, I think the reason for going to a five-year or something might be because of the question you just entered into, that it is maybe sometimes to know, or difficult to remember, what that last time was, so to speak and, therefore, that gives you an element of safety.

The other issue is that it is my intuition, if you will, that people who have not engaged in sex with another male for five years are probably not somebody who maybe engaged in sex previously, extensively. I may be wrong on that, but I think--that is just my feeling without any data, but we haven't had any data today, anyway.

Are there any other burning issues here before we bring this to a vote? Dr. Macik?

DR. MACIK: There are a couple of things that keep going through--I am really trying to decide where I stand on this. On the one hand, I am always opposed to a limitation

that brands all people for a possible risk in a subset of that group, which is basically what you are doing if you say everybody is excluded back to '77.

What ways do we have of finding, as Dr. Epstein said, the safe subgroup within the group. There are possibilities. Do these people get tested and come back? It was brought up earlier, what is the likelihood they are actually going to come back?

Well, if they want to be a blood donor, if that is really an issue for them, they will come back. If they were showing up just because it was part of the office procedure, then they won't come back. But it gives an option to a subset of people who maybe have not had sex in five years, maybe had a single encounter, who really want to donate, to give them an entry into it without branding them because of a single incidence or lifestyle that they have left behind or something.

We, ultimately, have to rely on our science test over our behavior test anyway because there are going to be so many liars, both intentional and unintentional people saying, "Well, I didn't do that," "I only did it once; that is not really going to matter. I am just going to answer 'no' to this question."

That is true whether we are dealing with men who have sex with men or whether we are dealing with

heterosexual groups that are at high risk or an I.V. drug user who is at high risk. Some assumption by this questionnaire is that people always tell the truth.

We, of course, know that that is not necessarily true. So I think some of the issues--I am leaning towards lifting the current restriction but, perhaps, looking a little bit more until we maybe get some more data. Is the prevalence really less in people who had sex one time or haven't had sex with a man in five years, if we can get that information in some way.

What better way to get that information if we offer them the ability to test and, if they test negative, to donate. If they don't, they we actually have some information, some data, to go into our prevalence file. So I think there are a lot of things that we need to address here.

I just hate to exclude an entire group without giving some options for how to get them back.

DR. HOLLINGER: Clearly, if know if we really want to get subsets, we could really get a clear subset. Young males who have sex with a male who is black who has had an STD. You could really focus in on it, but I think you have to paint with a broader brush than that, unfortunately, because, while that might grab the majority, there is still a fairly large number outside that who you might not pick

up.

I think those are important with any question you have.

DR. MACIK: But going broadly by saying have you not had sex in five years--that is the broad subset.

DR. HOLLINGER: If there are no other burning questions, Andy, could you have the question put up please, or would somebody please put the question.

For the record, I will read the question for the committee. "Do the available scientific data support the concept that men who have sex with other men, MSM, can be deferred from donating blood for a period of five years following MSM activity rather than being deferred for any MSM behavior since 1977?"

All of those who are in favor of that question, please raise your hand.

[Show of hands.]

All those opposed?

[Show of hands.]

Abstaining?

[No response.]

The consumer representative?

MS. KNOWLES: Yes.

DR. HOLLINGER: The industry representative?

DR. SIMON: Yes.

DR. SMALLWOOD: The results of voting on the question as read, there are six "yes" votes, seven "no" votes, no abstentions. Both the consumer and industry representatives agree with the "yes" vote.

Dr. Epstein?

DR. EPSTEIN: For the record, you had a straw poll and I wonder if we could record that voting because I think it was a pertinent question. You had asked how many of the committee favored some change in the donor question. You only asked those in favor to vote, of whom there were eight. By implication, had there been no abstentions, there would have been five votes against.

I think that is also useful information to the FDA, especially given the closely divided vote.

DR. SMALLWOOD: I'm sorry; I didn't record the straw vote because it wasn't the question that we had before us. Sorry.

DR. HOLLINGER: Are there any other comments from the committee? This has been a very difficult issue. Dr. Linden?

DR. LINDEN: I don't know if I can speak for the other people who voted no, but I felt that the data that we have been presented, particularly today, did not allow me to vote yes for this. But I very much endorse the concept of trying to change this, trying to identify subgroups, looking

at this as a reentry mechanism.

So, even with my no voting, I would encourage FDA to continue to pursue this issue, to look at possible options where this could be changed in a safe fashion.

DR. HOLLINGER: What would we look for as additional data that would help you make that decision. What kind of data would you want?

DR. LINDEN: I think additional data on the prevalence in this or other subpopulations would be helpful. That was missing from what we had today. The assumption was that the prevalence and MSMs as a whole are the case for this population. I am not sure that that is the case. It would useful to look at that particular issue as well as generally, perhaps, looking more thoroughly at the issue.

Dr. Dayton did a wonderful job with this, but I know it was put together very quickly and I am sure that, given more time, there are, perhaps, other things that could be looked at.

DR. HOLLINGER: Thank you, Jeanne.

Dr. Nelson?

DR. NELSON: There are two key pieces of information that are missing. One is the left side of that equation. If you change the questionnaire, what would happen and how many people would you get and how many would respond adequately and how many would the ratio remain the

same. That is completely unclear.

The other issue is what is the prevalence. What is the size of the population under five--we were presented some data on that--we were presented data on the size of the population which may or may not be correct, but we have no idea how many of those would be blood donors if there was a change, and we have not the vaguest idea as to whether the prevalence in that population is the same as the prevalence in all MSM.

My guess is that it is probably far lower if you exclude all the other risk behaviors that are currently excluded, drug use, et cetera. But some of those data could be obtained, I think, like the prevalence in that particular population would be very useful.

If it turns out it is 8 percent or 30 percent, then I would say that we probably shouldn't change the criteria. But if it turns out it is closer to the heterosexually active population, then it is not really changing the risk at all. I think that is key.

And maybe some surveys could define that. The only way we would know who would donate blood would be changing the criteria and see what happens, I think.

DR. HOLLINGER: Dr. Stuver?

DR. STUVER: It would seem to me that a mechanism for trying to evaluate how some of these changes in

questions would have an effect would be within the context of this task force. I would think there would need to be some specific evaluation of, well, if you change the question, this is what is going to happen. These people will respond differently if is this way or that way. These are the kinds of people that respond in the affirmative or not.

It seems logical that would be a place to try to get at some of this exact information, for not just this risk factor but for some of the other permanent deferral risk factors.

DR. HOLLINGER: Thank you, Sherri.

Anybody else have a comment? I appreciate the committee's staying. It was a long day today. Tomorrow, we will start at 8 o'clock and the plans are to go until 4:00.

Thank you very much.

[Whereupon, at 6:10 p.m., the proceedings were recessed, to be resumed on Friday, September 15, 2000 at 8 o'clock a.m.]

CERTIFICATE

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

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