DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY

Twenty-Seventh Meeting

Volume II

Tuesday, September 20, 2005

9:05 a.m.

Bethesda North Marriott Hotel
and Conference Center
5701 Marinelli Road
North Bethesda, Maryland 20852

P A R T I C I P A N T S

Mark Brecher, M.D., Chairman
Jerry A. Holmberg, Ph.D., Executive Secretary

Judy Angelbeck, Ph.D.
Celso Bianco, M.D.
Arthur W. Bracey, M.D.
Paul F. Haas, Ph.D.
Jeanne Linden, M.D.
Karen Shoos Lipton, J.D.
Gargi Pahuja
Susan D. Roseff, M.D.
S. Gerald Sandler, M.D.
Merlyn Sayers, M.D., Ph.D.
Mark Skinner, J.D.
Pearl Toy, M.D.
Wing Yen Wong, M.D.

Non-voting Government Representatives

Jay Epstein, M.D.
James S. Bowman III, M.D.
CDR Michael Libby

C O N T E N T S

P R O C E E D I N G S

Call to Order

DR. BRECHER: Okay. I'd like to call this second day of the meeting to order. We're going to start with a roll call. Jerry?

Roll Call

DR. HOLMBERG: For the second day of our meeting, September 20th, Judy Angelbeck?

DR. ANGELBECK: Here.

DR. HOLMBERG: Celso Bianco?

DR. BIANCO: Here.

DR. HOLMBERG: Art Bracey?

DR. BRACEY: Here.

DR. HOLMBERG: Mark Brecher?

DR. BRECHER: Here.

DR. HOLMBERG: Paul Haas?

DR. HAAS: Here.

DR. HOLMBERG: Andrew Heaton is absent. Jeanne Linden?

DR. LINDEN: Here.

DR. HOLMBERG: Gargi Pahuja?

MS. PAHUJA: Yes.

DR. HOLMBERG: Karen Shoos Lipton?
MS. LIPTON: Here.
DR. HOLMBERG: Susan Roseff?
DR. ROSEFF: Here.
DR. HOLMBERG: Jerry Sandler?
DR. SANDLER: Here.
DR. HOLMBERG: Merlyn Sayers?
DR. SAYERS: Here.
DR. HOLMBERG: Mark Skinner?
MR. SKINNER: Here.
DR. HOLMBERG: Pearl Toy?
DR. TOY: Here.
DR. HOLMBERG: John Walsh is absent. Wing Yen Wong?
DR. WONG: Here.
DR. HOLMBERG: James Bowman will be here late. Jay Epstein?
DR. EPSTEIN: Here.
DR. HOLMBERG: Harvey Klein is absent. Matt Kuehnert is absent. Mike Libby?
COMMANDER LIBBY: Here.

Committee Discussion

DR. BRECHER: All right. We have a lot of discussion time today. We have a major charge. There are three documents I'd like to call everyone's attention to before we begin. One is a set of questions that Jerry has put together basically outlining what HHS would like from us.

It begins by saying: Does the committee believe there is a need for the Department to develop a strategic plan for detecting and preventing transfusion-transmitted complications in the 21st century? If a new strategic plan is recommended by the committee, what scope of issues does the committee believe that the plan should address? What role should the Advisory Committee and its subcommittees play in the development of the strategic plan? And then there are a whole series of questions that relate principally to the presentations that we heard yesterday. So I would encourage everyone to look this over because this is going to be our game plan for discussion.

The second document I'd like to call your attention to is, in your books, right in front of

the orange tab is the subcommittee report. Jeanne, maybe you could talk us through that. This is from your subcommittee; is that correct?

DR. LINDEN: Sort of, yes.

DR. BRECHER: Sort of, yes?

DR. LINDEN: Yes. I don't think of anything to add other than what I said yesterday.

DR. BRECHER: Okay. So why don't we just take a look at this. This basically summarizes what the subcommittee concluded.

The third item is on the other side of the orange tab. It's an e-mail from Paul Haas, our resident economist, with some thoughtful words about the last meeting. Maybe, Paul, you could just say a few words about what you concluded.

DR. HAAS: I think the fundamental message is that nothing happens anywhere without the use of resources. And as we go through our deliberation to come up with recommendations and have no concept of the resources necessary to do that, one, I don't think that's wise; and, secondly, I don't think it's politically wise. And so what I just want us

to do is try and keep the use of resources in mind, but not so constrain ourselves in the sense of saying we don't have it so we don't want to do it. I think we ought to push the envelope, but we better keep the resource question or issue there.

DR. BRECHER: Okay. Thank you, Paul.

So let's kick off--

DR. BIANCO: Mark, there is another issue that I'd like you to add to the agenda. The charter of the committee expires a year from now, next October, and it takes two to three years to write a new charter, as we all know. Maybe that's the opportunity to sharpen up or focus some of the questions. It's very vague, very unclear. And as we think strategically and all that, I think we should at least ask the question whether some of the things that are there in the charter should be revised or not and make that suggestion to the Assistant Secretary.

DR. BRECHER: Well, maybe we can be more specific and pull the charter for the next meeting and go through it and see what we think needs to be

changed.

DR. BIANCO: It's in our books, and it's way in the back close to where Jerry's report was. In front of the blue tab it was. I moved it, but I think that's where it was.

DR. HOLMBERG: It's actually following part of the supporting document for Dr. McClellan's response. If you go to, I think it's the lavender tab, Dr. McClellan's May 13th letter, and at the end of that is the letter to McClellan from Dr. Beato, and behind that is the charter for the Advisory Committee.

DR. BRECHER: I think that's--I'll just take a moment for everyone to take a look at the charter, and maybe we can discuss that briefly.

DR. BIANCO: I don't think we need to at this meeting. I think that as we think strategically we should have it mind.

DR. BRECHER: Jerry?

DR. HOLMBERG: As the Executive Secretary, I'd like to make a comment. As we go through this process today, I want to make sure that people

understand that their role on the committee is as subject matter experts and that their position here is to provide recommendations to the Secretary of Health and Human Services; and that sometimes we have personal agendas and we have to make sure that we put maybe our personal agendas aside and look at the well-being for where we feel the blood community should go.

So I just throw that out, that, you know, your role here is as a subject matter expert on this and not as a lobbyist for a special group.

DR. BRECHER: All right. Let's start with the easier questions. Should our committee recommend that a strategic plan for improving blood safety and availability in the 21st century be a goal of HHS? Does everyone agree with that? Okay. Because if we had said no, then we could have gone home.

[Laughter.]

DR. BIANCO: You should have told us before.

[Laughter.]

DR. BRECHER: No, that would have been biasing you.

Okay. So the second question is: What scope of issues should that strategic plan encompass?

DR. EPSTEIN: Mark?

DR. BRECHER: Yes?

DR. EPSTEIN: Back on the first question, whereas we have consensus, I think that in any recommendation we make it will fall to us to provide the rationale, and that may warrant a little bit of discussion.

DR. BRECHER: Okay. Fair enough. Jerry?

DR. SANDLER: The first question, as it's worded, says "detecting and preventing trans-fusion-transmitted complications." That's not the same as saying transfusion-related complications, and I'm wondering, are we excluding the whole subject area of errors, for example, from our discussion by limiting it to what looks like a discussion of infectious diseases.

DR. BRECHER: I would think if we inserted

the word "related" that it would include errors.

DR. SANDLER: Thank you.

DR. BRECHER: Now--go ahead, Jeanne.

DR. LINDEN: Just to clarify, that was the intent of the subcommittee. I agree that wording is suboptimal. I believe "related" would equally reflect our thoughts.

DR. BRECHER: Is it "complications" or "adverse events"?

DR. SANDLER: I think "adverse events." We've got TRALI. We've got errors. We've got a whole bunch of things. So I think "adverse events" is probably better. That would include immune modulation, whatever is coming along.

DR. BRECHER: Okay. Jay?

DR. EPSTEIN: Well, this also leaves out supply, unless you very indirectly consider, you know, shortages to be itself an adverse event, which is a reasonable point of view. But I think we actually had earlier wording, Jerry, about improving safety and availability, which is a broader construct. But I just think that it

shouldn't be so focused on adverse event.

DR. BRECHER: Did you want--you agree with that? Okay. Karen?

MS. LIPTON: I know this opens up sort of a can of worms, but we talked yesterday briefly about National Blood Policy and is there one still in existence, and, you know, in some ways if you--we don't have it in front of us, but if you look at it, that really is sort of a backdrop of what you're trying to achieve through the strategic plan. I think it's another way of saying what Jay is saying: What are we trying to accomplish through a strategic plan? But I guess what I'd ask is: Do we know if that still has any force and effect on what we do, the National Blood Policy?

DR. BIANCO: It's still on the books, and you were the last one to address it--I don't know--ten years ago?

DR. HOLMBERG: I'll remind people that in January 2004 we went back and we reviewed the National Blood Policy.

DR. BRECHER: See how memorable it was.

MS. LIPTON: So it is still in effect.
DR. HOLMBERG: Yes.
MS. LIPTON: So should we not in some ways also be using that to look at the strategic plan? I'm sorry. I didn't even think about it until now. But we just want to make sure it's consonant with the National Blood Policy.
DR. HOLMBERG: The recommendation at the time, 2004, the consensus from the transcripts was that it was still pertinent, and that although there were some words that could be refined to reflect today's language, it still covered the concerns of safety and availability of products. You know, it dealt with issues such as the different testing that was limited at that time. But it still brought in all the parameters of blood safety and availability.
MS. LIPTON: So would we want to reference it somehow and in discussion of a strategic plan? I mean, it almost seems as if we have this policy over here and then we're talking about elements of the strategic plan for blood. And somewhere we

probably want to put the two together, or at least reference it.

DR. BRECHER: We still, I think, need to get back to Jay's comment that we've had three meetings that have touched on this subject, and so we ought to conclude that there needs to be an improvement over what is currently in place based on those presentations. Jay?

DR. EPSTEIN: I think what this is about is setting priorities and communicating a vision of where we are versus where we want to be, and the key levers, if you will, to get us from Point A to Point B.

I'm not sure it's the same thing as the National Blood Policy because I think that that dealt a lot with the question of the underlying structure of our system. And I'm not convinced that the strategic plan needs to take on the question of restructuring, although that is, of course, open to debate. I think we have adequate structures and that, you know, we have our respective roles in a largely privatized system,

albeit regulated and publicly funded. And I think that what this is about instead is where should we be putting energy and effort. In other words, what are the big issues that we should be focused on?

Again, there may be others who feel that, well, we really can't do that without restructuring, but personally I think that that's not what's needed now.

MS. LIPTON: Well, I actually thought the policy wasn't so much about structure. I think that there was a lot that the private community did afterwards. I thought the policy really was about accessibility and supply. It was about availability, safety, and accessibility.

DR. EPSTEIN: Yes, but that was at the level of a statement of principles but--and I agree that it's important to have a statement of principles, and I also agree with the earlier conclusion that the principles articulated in 1974 remain sound. But I think that the underlying issue at the time that the National Blood Policy was promulgated was whether the American blood

system should be nationalized. And the conclusion was, no, we can do okay with a privatized system. And I think, you know, from my point of view, then there's the key structural question, and my answer is, well, it's still working okay, let's leave that part alone.

So I agree with you that the National Blood Policy also dealt with certain values and that they remain sound but that, therefore, I don't think they're the subject matter of any new strategic plan. We're not trying to change the values of accessibility, affordability--

MS. LIPTON: I think maybe that's what I was asking. Shouldn't we just say--you know, the strategic plan we're creating is really--it's supports the National Blood Policy or the values of the National Blood Policy.

DR. BRECHER: Maybe what we should do is lay out what we think are the priorities for the country and then decide how best to make them happen. Jeanne?

DR. LINDEN: Can we clarify again exactly

the role of this committee? I haven't looked at the National Blood Policy recently, but my recollection is, as has been said, it's the values of how we would like the structure to be, you know, volunteer donors and that sort of thing.

Jerry, is our role here to talk about the strategic plan, this is what we're advising the Secretary in terms of the public health approach and really what the Department should be doing--right?--as opposed to telling the blood centers and transfusion services what they should be doing. Can you just clarify a little bit our role?

DR. HOLMBERG: Right, and I think that that goes right back to what Karen was referring to. You know, I think that two years ago we did look at the National Blood Policy. The structure is there, the privatization of the blood community, that we are not moving to a nationalized blood program. And so the purpose of this is to lay direction on where the government's role should go in blood safety and availability and what should be

the strategic plan that government needs to put into place to make sure that we are detecting and preventing related transfusion-transmitted adverse events. And if, you know, Jay wants to--I realize that we've sort of included, but omitted, the blood safety and availability, you know, we can work that in there, too, in that question. But the question is designed just to get you thinking about that.

DR. BRACEY: I think that one of the things that the committee has a duty to do is to ensure that for the public, accessibility is something that is real. If we, in essence, look at a snapshot of today's picture and assume that the private set-up is adequate, that doesn't necessarily ensure accessibility for the long term. I mean, we're looking at an era when there are a number of blood products that will have very intense resource requirements, and I think that it would be our duty as a committee to make sure that there's not only availability but to focus also on accessibility and through the policy perhaps.

MS. LIPTON: And we spent the entire day

yesterday basically talking about access to care in certain settings. So I think that is an important issue to include.

DR. BRECHER: Jerry?

DR. SANDLER: Yes, and I'd very much support the drift that we're going on. We started with a document that refers to preventing transfusion-transmitted complications, and we're drifting toward the subject of blood availability and accessibility as a priority and safety. To me there's a mountain and a molehill.

The mountain is the 45 million people in this country who don't have insurance, which means they don't have real access to blood. We've heard about all kinds of people that don't have access to blood. And availability to me is a mountain.

The molehill to me, relative to this, is the fact that HIV, hepatitis C, hepatitis B, and West Nile virus were handled fantastically by the United States Public Health Service, at least relative to--relative to--the way the Department has handled reimbursement and availability. If I

had my druthers, the first thing I'd say is we would like to change the name to the Committee on Availability and Safety of Blood so that we prioritize the mountain and put the molehill where it belongs.

DR. BRECHER: Other thoughts? Merlyn, is your light on?

DR. SAYERS: Yes, it is, but I'm not going to be able to say anything evangelical in follow-up to what Jerry had to say. The light was on because I was going to go on a slightly different tack. So let this just be a short intermission.

You had mention of developing a big-item list where strategic attention might be devoted, and the last big-item list was the Blood Action Plan. And certainly there were strategic elements there, and there was a to-do quality to the Blood Action Plan.

I was just going to ask Jay how that Blood Action Plan was developed, who were the authors, because I think that was really an excellent product, which has served us in good stead since

1997, and there may well be elements of that Blood Action Plan which could be incorporated, because they are ongoing concern items, could be incorporated into a strategic plan.

So I'm just wondering, Jay, who were the authors of that.

DR. EPSTEIN: Well, first of all, the plan was initiated within the FDA in July of 1997, and the Acting Commissioner at the time, Mike Friedman, directed a group of us to develop a strategic plan. A small working group actually wrote it. I was a participant.

The reason for it was that we were, if you will, very beleaguered, you know, an agency under fire over blood issues. There was lack of consumer confidence on account of issues related to HIV and hepatitis C. And there had bee a series of incidents involving plasma fractionators related to breakdowns of GMP, very frequent product withdrawals and recalls. And there were a set of large issues that just cry out for resolution in terms of the donor standards and transparency in a

sense of notification issues, things like lookback.

And so there was a general sense that the only way to deal with that sort of broad set of problems would be to develop a plan and to bring it to public knowledge through, you know, communication and so forth. And we realized very early on that it would not be possible to effect this plan without very high-level interagency cooperation, for example, gathering of epidemiologic data by the CDC or funding of specific studies by the NHLBI.

And so we approached the Department about ownership of the plan, and I believe it was under David Satcher's watch that the plan was adopted in March of 1998--actually, I guess it was Donna Shalala. It was adopted as a departmental plan, and then it was modified once in November '99 under David Satcher. It was modified to add the whole issue of vCJD. And that issue itself triggered the need for closer supply monitoring because we for the first time were going to recommend donor deferrals, geographic-based deferrals that were going to have a very large and very rapid impact on

supply for which there was no antecedent experience. And so a commitment was made to initiate blood supply monitoring concomitant with the implementation of the vCJD-related risk deferrals.

So, you know, the history in a nutshell is that a small working group at FDA wrote it, and then it became adopted by the Department and then was amended over time. And we didn't come prepared to discuss it, but I can tell you that there have been hundreds of deliverables under that plan in the way of workshops, guidance documents, and rulemaking, in addition to simply organizing some of the effort of the agencies toward specific problem solving.

DR. BRECHER: For the committee's information, third tab from the back is the FDA Blood Action Plan.

DR. EPSTEIN: Right, but it lacks a summary of all the outputs.

DR. SAYERS: Some of the items on the Blood Action Plan, monitoring and increasing the

blood supply, emerging infectious diseases, I mean, still are big items for any strategic plan. You know, the comments that Jerry made earlier could well be another bit item to add to son or daughter of Blood Action Plan, however one wants to describe the follow-up.

DR. BIANCO: I see and I agree with what Merlyn just said, but those were the priorities in 1997. I think that as we look through it, most of the regulatory goals that were the agency goals or the public health goals were achieved. We have lookback. We have--all the items that were outside the agency were not achieved in terms of, yes, there is an increase in availability but there was a compensation of the losses that happened with the vCJD deferral. But there was nothing that was effectively performed--and I don't want to sound bad about it because I recognize the effort that was put into that. But that was the burden of the private sector. It was not the burden of the government. And that's why we have to ask the question, that is, what should be the role of the

government in those things, be it monitoring, be it increased availability, and other items that we can add to our priority list from which there was no funding. There was even limited funding for monitoring that didn't last too long, and I don't know where it is. But it was a success in terms of--in regulatory terms, in terms of compliance, in terms of safety. We have to recognize that.

DR. BRECHER: Jay?

DR. EPSTEIN: Well, I think that the funding issue always comes to the fore. When the Blood Action Plan was first envisioned, we had this concept that we could garner funds, rather significant amounts of funds, for certain of the issues, for example, the scientific re-examination of donor deferrals. Those funds never materialized, and I think instead the plan served the role of a road map in organizing our effort toward certain objectives within our existing structures and our existing funds. And I guess my view of the current situation is that we ought to be thinking in the same terms because I think the

likelihood that there would be any significant redirection of funds toward a current strategic plan or action plan is not likely. But, on the other hand, having a vision of where we're trying to go and a sense of how to get there can be very productive.

DR. BRECHER: Jerry?

DR. SANDLER: I want to pick up on that word, Jay, the vision, because that's exactly what I think that our job will be. Once we figure out what our priority is, we do have to put some things onto the strategic plan. The two that I would put: number one would be the development and evaluation of pathogen inactivation as an approach (versus business as usual). And the second one under that would be the development and evaluation of alternatives to human blood products, to human blood components to be perhaps more specific.

The intent here is that I don't see as a strategic direction from the Department initiatives. I think that investors and companies that want to do something come up to the FDA with some

studies and FDA tells them what's not meeting there. But I don't see a national strategy versus where we are now, which is an impossible situation of ten or more laboratory tests, et cetera, as the strategy.

DR. BRECHER: That may be a little too specific. Maybe just develop--encourage the development and evaluation of alternatives to present methodologies.

DR. SANDLER: You're on the right track. I mean, this is the kind of thing I think that we're supposed to be doing today once we get our priority sorted out as the mountain and the molehill, and we're going to have to look at the molehill a little bit, at least relatively, and that's the kind of thing I think we have to do.

DR. BRECHER: Jerry?

DR. HOLMBERG: Well, I think that the subcommittee did a great job in identifying some of the elements that they thought and put forward for a potential strategic plan. And one of those items was the element of research, and so I think that

many of the things that you just--the two items that you mentioned could be under that research element.

DR. BRECHER: Art?

DR. BRACEY: Perhaps, though, as we heard yesterday, you know, IVIG is not considered a blood product. I don't know where Factor VII sits. I don't know where Factor XIII, which is in development now, sits.

I think that rather than to have these things all in sort of wide-ranging, unorganized boxes, if we could consider the broad spectrum of blood-related products and make them inclusive, it's research, but yes, there are products that are here now that aren't labeled as blood products that I think the committee could do a job in bringing them into the fold.

DR. BRECHER: What I'd suggest we do is make a list of what we think are maybe the top ten priorities. Maybe then we can even narrow that to the top six priorities. So I'd encourage people to just take a minute to think about what should be

the priorities for the country. Let's put them on the table, and then we can think about how we can try to make them happen and what's the best structure to try to make them happen.

MS. LIPTON: So do you want us to actually use the list that we developed as possibly saying, well, we think that this is a high priority? Or are you just--

DR. BRECHER: Well, I think the list may be the starting point.

MS. LIPTON: Yes, okay.

DR. BRECHER: And I think looking at the FDA Action Plan may bring to mind one or two others. But let's try to come up with a complete list and prioritize them as to what we think is the biggest priority, the second biggest priority?

Jay?

DR. EPSTEIN: Mark, I think that's a useful exercise, but I think we need to get very clear whether we're trying to draft the strategic plan or action plan as a committee or whether our real objective is to request that the Department do

it. Because I'm not sure what the feasible quality of the output will be in, you know, a part-day meeting of this group. I mean, I think it's fair for us to call attention to certain areas, but wouldn't we want, you know, some body to be convened to do this in very thoughtfully?

MS. LIPTON: That's my thought, too, Mark. When I think about this, I think--I mean, the most that I believe I could say at the end of the day is well, I think that we should--there should be a process to develop a strategic plan. I'd like to figure out what our role is, if any, in it. I think we would have to say things like we think it needs to be broader than this group, it needs to include other stakeholders, because we have done some fact finding, but I don't think we really have a grass-roots--we haven't, you know, undertaken a grass-roots fact-finding initiative, and that might be part of it.

But I don't know that beyond that I could sit here and say, well, this is the most important thing. I think I could say here are all the things

we think we need to address. Or maybe we could say availability is maybe the most important thing.

DR. BRECHER: Well, I think if we accomplish that, then I think we would have done our jobs. I worry also about trying to draft a strategic plan in this committee today. I don't think it can happen. But what we can do is, as Karen says, recommend that a strategic plan be developed and that that strategic plan should address the following points.

MS. LIPTON: And here's what we think our role might be in that. As Jeanne just said, that's kind of what our subcommittee recommended.

DR. BRECHER: Okay. Maybe we can put up on the screen for everybody the list. Is that possible, Jerry?

DR. BIANCO: Yes, the questions that were developed are questions that could be synthesized, at least in part, as that list of big issues that remain unresolved.

DR. BRECHER: Right. There are a lot of questions here, and I don't know that we can answer

them all, but if a committee is put together to make a strategic plan, they would need to address all these questions or make recommendations regarding these questions.

DR. LINDEN: Mark, if I can just clarify, the questions--we really do not have any intention of anybody specifically answering them, and especially not us today. It was really just some issues for people to think about that might, you know, trigger some additional thoughts of really to add to the priority list that we made or to clarify things or possibly delete things. That was really all.

DR. BRECHER: Okay. So what I've heard so far this morning is that the committee feels that we've heard enough to say that a strategic plan should be developed--should not be developed here in this room today--and that there are several items that we think that that strategic plan should specifically address and here's the list. So let's look at the list. Is that fair? Jay?

DR. EPSTEIN: Well, strategic planning

generally starts with what's called a situation analysis. And I think that really the next stage here is for someone to do an objective analysis of sort of the strengths and the weaknesses of the current system. And I think it's reasonable for this committee as a group of experts to comment on where we think the gaps are. So I think we could go that one additional step if we wish. In other words, as we identify an issue area and say it belongs under the plan, we could provide some commentary on what we think is the matter.

Again, it is along the same lines of rationale. In other words, why do we think that element belongs in a plan? There must be some reason. There's something that's bothering us. I think we ought to try to state it concisely.

DR. BRECHER: Okay. I think that's a good suggestion. So under each item, we'll put a couple of points as to why we think it needs attention.

T1B While Jerry's putting it up there, I will throw out one for discussion. When we talk about surveillance of adverse events, I know one item

that keeps recurring at these meetings is discussion of errors, and the biggest or the most fatal error that we're aware of is identification errors.

We know there's a potential solution out there, which is electronic identification of the patient, the sample, and the blood component. That's a complete circle. The government has said that they want an electronic system tracing drugs from start to finish, and it seems to me that we could come out and say that there should be some timeline for electronic traceability of samples and blood products in this country.

Does that sound reasonable? Sue?

DR. ROSEFF: It's definitely reasonable. I think it would be very helpful to hospitals to have that as a mandate because then we would have to do it. But what I've heard, too, from our hospital is because the mandate is for pharmaceuticals in a few years, we'll include blood at that time. So once that's in place for the pharmaceutical industry, we will have the

resources. So I don't know if it's necessary to have a separate mandate because, at least from my perspective, it's going to happen through the back door, almost.

DR. BRECHER: Jay?

DR. EPSTEIN: Well, the rule on bar coding does include blood products. The requirement for blood products is machine-readable code. The rule does not require the same codification scheme for the blood product as for the pharmaceutical, which was largely at the request of the industry, not to be forced to use the particular scheme specified for the pharmaceuticals. So there will be the need for dual systems, in other words, readers that can read one or the other.

That doesn't quite get to the level that Mark is addressing, which is that the sample from the recipient needs to also be electronically coded and to ensure that there's a system of matching at the time of dispensing and at the time of administration. And we know that electronic solutions exist. Progress in that field has been

expectant in the sense that we wait for manufacturers to bring forward candidate products and then we review them for their safety and efficacy, and we have approved one such system.

Jerry is actually an expert in this, and I think lectured on it even at the transfusion medicine symposium. We're talking about the need for establishing electronic traceability of the patient sample and the unit to ensure the proper match and whether that's a strategic issue because of the relationship to mismatch as a chief source of fatal error.

DR. SANDLER: The only comment I would make is that even a simple bar code system for a small hospital like Georgetown of 500 beds starts with an outlay of $1 million. The way to do it is to add a blood-tracing system as one of three new items on a medication-dispensing system. So as we look at blood-tracing systems with either electronic bar codes or radiofrequency transponders or tags, the way it's going to happen in the United States will be that the medicine-dispensing system

will go bar code, and once it's bar code, then you just take three empty slots on your medicine thing and you have red cells, plasma, platelets. And now you've put the blood-tracing system into your hospital piggybacked on medication.

That's where I see this field going, and I would like to see that as one of the strategic things to be looked at.

DR. BRECHER: Well, that doesn't necessarily link the patient sample into the electronic loop, though.

DR. SANDLER: Oh, sure. Yes, I mean, once you've got the bar code on the patient's wristband, and once the provider, the nurse, has a portable system, whether it's a scanner or whether it's a PalmPilot type of PDA, that can be beamed to a printer you make bar coded sticky labels right in the room. I mean, that's peanuts into the whole picture. Yeah, I mean, it's easy to do.

DR. BRECHER: See, what we're doing, Jerry, is we're saying that if we're going to generate a list and we can say addressing errors is

a major priority, we should have some justification for why we're saying that. And we would say that it is recognized that the largest cause of fatalities due to errors is identification and that an electronic system would address most of these errors. And so we would go through each point, point by point, saying that this is a problem and this is why we think it's a problem.

DR. SANDLER: I love it.

DR. BRECHER: So we have the list on the screen. So my question to the committee: Is this the list that we would like to submit, or do we want to change it? Art?

DR. BRACEY: The one piece that I think that's missing gets back to the appropriate use of blood, and so I would add a bullet that would address--yeah, we had it there before, but--yeah. Improving the clinical practice.

DR. LINDEN: Practice guidelines was on the list.

DR. EPSTEIN: Clinical practice standards for transfusion was actually on our original list.

DR. HAAS: While he's typing that, although it might be implied, we've been consistent over the last several years of also making sure we have recombinant and log issues up there, too. I don't think that's clear there.

DR. BRECHER: We'll work that in there as well. So if we have these items--Jay?

DR. EPSTEIN: I think that the discussions that we've had about IGIV availability have once again reminded us that we have a large issue of ensuring adequate reimbursement for indicated blood products. And that issue has come up every time we have technology innovation. Our system doesn't readily provide for paying for it. So I think there is a missing element, if you will, about something along the lines of ensuring, you know, funding for needed products and technologies, something like that.

MS. LIPTON: Yesterday we used the words "what's stable and sustainable," and maybe what we're talking about is stable and sustainable reimbursement policies that support--

DR. BIANCO: Actually, that has to go beyond that, Karen, to include the new technologies. That is, why aren't we at 100 percent leukoreduction? I think that money is the issue and things like that.

MS. LIPTON: Okay.

DR. BRECHER: So we need to get the point across that reimbursement is tightly related to access, and that without adequate reimbursement, access is not going to be a reality.

Jerry?

DR. SANDLER: I continue to see pathogen inactivation as a whole strategic topic of even greater importance than some of the other topics that are up on this list. I don't see it as another research item. The concept of doing hemovigilance and surveillance and then chasing after another test and adding another test I think is an overburden on the entire system, and I think strategically we have to look at pathogen inactivation in its broadest sense, maybe not even with current products. But it would seem to me it's a

bullet.

DR. BRECHER: I think it is a research item. It may be the first priority as a research item, and to be honest, it's not a reality now so we can't do it in this country at the moment. And, two, it may actually be more costly than doing all the tests.

Merlyn?

DR. SAYERS: Help me with this one. I can really only see three bullets there which are truly strategic. It's the first one, what strategies might you uncover to structure that process; the second one, how strategically might you consider the value of integrating those systems; and then the other one which looks strategic has to do with Jerry's point about reimbursement, what are the strategies there. Everything else is a to-do list.

DR. BRECHER: Yes, or examples--right, examples that would fall out from those three.

Jay?

DR. EPSTEIN: I think risk communication is strategic, but I think you could easily fold it

into a structured policy and decisionmaking process because it is linked.

DR. BRECHER: Okay. Jerry?

DR. SANDLER: I'll go back to the point of alternatives to blood components as a strategic item. It seems to me that those aren't minor research items. It seems to me that it's strategic that we look at alternatives to platelets, red cells, and perhaps preservative solutions or plasma solutions from a government initiative point of view rather than waiting for investors to be hit upon by someone with a hot idea, which is the catch-as-catch-go system we have right now.

DR. BIANCO: What about a research agenda for new products, not just a research agenda?

DR. BRECHER: Jay, you look like you've been thinking about--

DR. EPSTEIN: Yes, well, perhaps--Jerry was just starting to write the last bullet. If it's ensuring funding for promising new technologies, that's broader than saying pathogen reduction technology, but that could be the lead

item.

DR. SANDLER: I can compromise to that, but it doesn't really put it to the strategic concept of--you know, we're going in the wrong direction. You know, we're just going in the wrong--I mean, that might mean we found a way to fund Chagas' disease, and that's not what I'm thinking about. I'm thinking about a way to end all of this.

DR. BRECHER: Pathogen reduction would get rid of Chagas' disease.

DR. EPSTEIN: I think the problem here, Jerry, is you don't have consensus that we want to make a sea change to move away from screening and testing to inactivation. As you well know, that has been debated scientifically, and the lead experts in pathogen reduction do not think that you could do away with testing, at least for certain agents.

DR. SANDLER: Absolutely. There's no question about that, and we want the belt and we want the suspenders. But when the new virus comes

along, if it's in place, it's going to be good. I mean, the milkman is doing a wonderful job with pasteurization, and I think it's a great model for us to look at strategically. I just don't think that the half a dozen companies who have failed to get a product license have exhausted the strategic value of pathogen inactivation as a concept. And we did have a product on the market that was really terrific--Plas Plus--and for lack of money the thing just died. The stuff was fabulous, and it was a very, very good--a better product than the alternative.

DR. BRECHER: Well, there were other issues with that product than lack of money. To be fair, there were concerns about the size of the pools. There were concerns about coagulation problems with the product. So it wasn't quite as simple as lack of money.

Mike?

COMMANDER LIBBY: I think what I hear is two things: one is you're looking at technologies that are emerging; and the other thing, if you look

at research, you would think research that we haven't done yet or where we need to go.

DR. BRECHER: Art?

DR. BRACEY: Getting back to what Jerry was saying, you know, I think that we are assuming that blood will remain an important--and it probably will--element in medical care. But, on the other hand, if you do sort of strategically say, well, let's look and see if we can really focus on taking care of people using alternative therapies, I mean, you know, that I think is really strategic. It's not let's do pathogen inactivation. But let's look at strategies that will allow us to get an end product of a patient who is taken care of without the need to use components. I think that might be something to consider.

DR. BRECHER: All right. What I would propose is that we lay out the three or four strategies that we want to emphasize, and then underneath each of those we put a few bullet points as to why we think they're important and examples of areas that need attention. Does it sound fair?

Because the list right now--I think Merlyn's point was well taken--is they're not all strategies, and so we could reduce the list down to maybe four items.

[Pause.]

DR. BRECHER: Merlyn, help us here. Which items would you see as the major strategy items?

DR. SAYERS: Have we lost some bullets there, Jay?

PARTICIPANT: They're combined. He's lost some carriage returns.

DR. SAYERS: Let's go with a strategic approach to research.

[Inaudible comments off microphone.]

DR. SAYERS: Mark was talking about reducing this down to--yeah, so let's take that strategic research agenda as one of those four major categories.

[Pause.]

DR. BRECHER: Let's take them one at a time and flesh them out. Is that fair? Gargi?

MS. PAHUJA: I have a suggestion for a

sort of different approach just based on the experience we've had with how our messages are taken. The more focused and more concise the message, the better it's received. And I sort of see three main topics in which these could fall underneath those topics: increasing availability, increasing access, and increasing transfusion safety.

So, for example, under increasing availability, we would have increasing supply, donor retention and recruitment. Under increasing transfusion safety would be surveillance of errors, new research initiatives, alternatives to blood transfusion development. And under increasing availability, reimbursement issues and access issues--sorry, under increasing access, reimbursement issues. I feel like that might be--these are kind of subsets under sort of three main strategies or concerns that we have to address.

DR. BRECHER: I like that. I think that that's a nice simple structure. Other people,

everyone agree? Okay. So we're going to go with that there are three major priorities, and then we'll flesh each of those out. So let's do availability.

MS. PAHUJA: So under availability would be increasing supply, donor retention and recruitment, which could even be seen as a subset of that, but I think should be a separate point.

PARTICIPANT: It should go under retention separate?

MS. PAHUJA: No. Donor recruitment and retention is fine. I'm saying it could be a subset of increasing supply, but...

DR. BRECHER: Under safety, you would want error reduction.

MS. PAHUJA: Right, surveillance of--

DR. BRECHER: Adverse events?

MS. PAHUJA: Adverse events.

DR. LINDEN: Should infectious disease issues be under transfusion safety, or do we want to look at product safety and then safety of the transfusion process as separate issues? In other

words, all the infectious disease things would fall under here also.

DR. BRECHER: Right, so preventing infectious disease.

DR. LINDEN: Yeah, I'm just asking, is it enough to be a whole separate item or is it a key subset?

DR. BRECHER: I think it's a subset.

MS. PAHUJA: I think my concern is that if we have too many sort of strong points, then we kind of lose the focus and the attention span, you know, as we've noticed, is only so great.

DR. BRECHER: Say prevention or error reduction. There have to be more bullets for access than reimbursement.

MS. PAHUJA: Yes.

DR. BRACEY: Include alternative therapies under safety?

DR. BRECHER: Oh, yes.

MS. PAHUJA: Research and alternative therapies.

DR. BRECHER: I think it's therapies and

methodologies.

What about for access?

MS. PAHUJA: We could clarify what we mean by reimbursement, I mean, which is really--you know, for example, the problem that we talked about yesterday with--

DR. BRECHER: E.g., the current IVIG--

MS. PAHUJA: Right, or stress the coordination of, you know, CMS policy with current blood practices or current standards of clinical practices.

DR. BRECHER: I think that an example for each of these items might be helpful to the reader, a specific example.

MS. LIPTON: Under increasing transfusion safety, I guess two things: Art's clinical--I don't know if it's safety or availability, but the clinical guidelines. Development of those clinical guidelines I think is important. And then the other thing is this whole issue of the Public Health Service and really the way we--I mean, really the Public Health Service and the robustness

of the Public Health Service and how we interact and relate to them. I think that was a topic that we talked about a lot. I think it's of concern to us, but we need to capture it someplace up there. I guess under safety.

DR. LINDEN: Well, it goes beyond that. That almost could be like an introductory statement, I think.

DR. BRECHER: Well, let's go to the top of this list and let's begin drafting an introductory statement, something like: The committee concludes that a strategic plan for--how did we phrase it originally? The committee believes that there is a need for the Department to develop a strategic plan for improving safety and availability for the transfusion of blood and blood derivatives in the 21st century. Something like that.

The committee believes that there is a need for the Department to develop a strategic plan for improving safety and availability for the transfusion of blood and blood derivatives.

MR. SKINNER: Can we add there "and their

recombinant analogues"?

DR. BRECHER: Yes, we can say "/recombinant analogues in the 21st century." "...for improving safety and availability"--

MS. LIPTON: Do you like the word "increasing" better than "improving"? I mean, it's hard to improve on safety right now.

DR. BRECHER: That's fine. "Increasing" instead of "improving."

MS. LIPTON: Should we add to that initial statement access, since we have it identified as a topic here, safety, availability, and access?

DR. BRECHER: Well, we could argue about access is part of availability.

Jay?

DR. EPSTEIN: Yes, I wanted to make that point. I think that those are so tightly linked that I would put them together as one of the topic issues, increasing availability and access. But I'm saying additionally in the bullets that are below, the topic headers that are below, I'm inclined to merge availability and access because

they always go together when you try to solve a problem.

Also, I would ask the group, you know, what happened to the strategic issues on policymaking and on public health integration. They seem to have gotten lost here when we restructured the list. I think we have to find a way to bring them back.

MR. SKINNER: The other issue that's missing is having an integrated risk communication system under safety. Some of the broader issues that override all of this, as Jay was saying, fall out of this structure.

DR. BIANCO: Actually, what I suggest, Mark, that we do is we take the questions that are here. There are several things that we didn't put under the categories, like disaster, that I would put in increasing access. And the definition of roles of each one of the governmental agencies, I would also--

DR. BRECHER: Okay. I think that's good, but I think we're running ahead of our list. So

let's slow down for a minute.

DR. BIANCO: It's the excitement.

[Laughter.]

DR. BRECHER: Jay?

DR. EPSTEIN: I think in the opening sentence you really only need to say safety and availability, because those are the title heads of the committee and more or less everything related in some way or another to them. Because where you're headed by starting to enumerate is you're going to end up enumerating the whole list, and that's really not what you want to do.

DR. BRECHER: Say "plasma derivatives/recombinants."

DR. EPSTEIN: Well, derivatives are blood products, so if you want to say blood products including plasma derivatives or including analogous products. Blood product is already the biggest header.

DR. BRECHER: Yes, okay. Blood products and derivatives/analogues? I mean--

DR. EPSTEIN: Synthetic platelet isn't a

derivative. I mean, it's blood products and their analogues.

DR. BRECHER: Okay, blood products and their analogues. But if we have a synthetic platelet, I'm out of business.

DR. SANDLER: That's a strategic plan.

DR. BRECHER: To get me out of business?

[Laughter.]

DR. SANDLER: A safer product.

DR. BRECHER: Gargi?

MS. PAHUJA: So since we've sort of moved increasing access up to availability, perhaps a third could be that increased coordination where you could include the public--integration of the public health system, a coordinated risk communication effort.

DR. BRECHER: Coordination of the public and the government--public, governmental, and private sectors? Something like that?

DR. LINDEN: I'm not sure that's a separate item, though. I mean, wasn't the whole point that all of this should be coordinated

between public health and the private sector? I mean, that's why I'm suggesting this be sort of an overarching approach as well as Jay's, you know, concern about the structured process. I mean, don't all of these things sort of fall under both of those?

MR. SKINNER: Could we make those two concepts, the first two bullets, the structured process and the integration, part of our preamble and kind of as our overriding goals and then say as a part of that then we want to achieve these within that kind of framework of integration and--

DR. BRECHER: Yes, I like that so we're going to move that up to the preamble, put it as the second sentence.

Mark, how would you want to word that?

DR. LINDEN: I mean, I think we can really include what we said, that the decision-making process should be structured, open, and include collaboration between public health agencies and--

DR. BRECHER: So is it open, structured, and inclusive of all interested parties? Something

like that?

DR. HOLMBERG: Of all parties?

DR. BRECHER: For all parties?

DR. LINDEN: "Stakeholders" works, but it's awkward to include.

DR. : Yeah, not "open," but open.

DR. EPSTEIN: See, I think we're losing--Mark, if I could comment.

DR. BRECHER: Yes.

DR. EPSTEIN: I think we're losing the strategic issue here about policymaking in a structured process which is about the use of analytical tools--in other words, doing formal risk assessments, doing formal risk analyses, engaging in a more formal way in risk communication. So I think simply to say that these processes should be open and structured is fine, but it's not highlighting it as one of the strategic issues, something that we're trying to transform about how we do business now versus how we should do business.

DR. BRECHER: So that they should be

factually based.

DR. EPSTEIN: Well, that's, again, part of it, you know, that it should be scientifically based, that there should be outcome evaluations. It's a whole package of things. And I think simply putting it in the preamble misses the point that you really want to elaborate on it as one of the strategic issues.

DR. BRECHER: Okay.

DR. EPSTEIN: Again, I think the tension here is being too explicit in the preamble. A short point in the preamble might say that this should include an overview of decision-making and integration of blood policy with public health policy. And then you still have room to highlight it later. It shouldn't substitute for highlighting it as a strategic issue, I don't think.

DR. BRECHER: Okay. Say that again, Jay. "...including..."

DR. EPSTEIN: That this plan should include a review or attention to--just say "a review" of the process of decision-making for the

blood system and its integration with the larger public health system.

DR. SAYERS: Jay, when you first said that, though, you referred specifically to the integration being at a policy level. That sounded good.

DR. EPSTEIN: Oh, well, I think it's both, see. I think that we need to make blood safety decisions within the context of public health decisions. For example, when we talked about smallpox immunization, it became necessary for us to advocate quite strongly to get on the agenda the notion that if you started vaccinating people, you might also be deferring vaccinees for awhile and that could affect, you know, blood availability. And similar issues could be raised about pandemic flu; you know, if people start getting sick, how are you going to sustain the blood supply? What are your strategies?

So I do think that there's a need--and, you know, you could give other examples for emerging disease or error management, where the

decision-making about the blood system should be well integrated into the public health decision-making.

So I agree with that, but I also think that we're talking about structuring the blood system in such a way that there's better integration with the public health infrastructure. In other words, where is blood collected, how is blood delivered, should you get your IGIV in an outpatient physician setting or in a hospital infusion clinic? So I think that both things are integration issues.

DR. BRACEY: On another topic, I'd be interested in hearing from the folks from the consumer side here. We haven't really addressed enhancing or engaging the consumer so that that individual would be more informed and involved in, you know, transfusion decision processes. You know, this is the era of information, this is the era of patient involvement in terms of informed consent, et cetera. I'd be interested to see know what the consumer folks think about engaging the

public would be.

MR. SKINNER: I think that's an excellent point. I mean, the notion, when we talked about stakeholders or--I have a hard reading that because the print's awfully small, but whatever we said at the beginning about all the relevant parties. I'm not sure it's intuitive to everyone that the patients have a role or the consumers have a role, the end users, at each stage in the process; and somehow that that would be communicated.

Some of that comes under risk communication. And I like the way it was presented yesterday, talking about an integrated and interactive process, because communication has to be two-way, which then naturally involves hearing from the patients and having their feedback/return. So I don't know whether our plan--I wasn't wanting to get ahead of the discussion--is whether we're going to go back and make these complete sentences, each of the individual items under them, because I think some of these words just by themselves aren't going to communicate what we're talking about.

I had written down a sentence here somewhere, that we needed "an integrated and interactive process for timely risk communication," which implies that it has to occur with all of the stakeholders, which we define earlier; that it has to be a two-way dialogue; and that it has to be timely, that it's not just telling them at the end, after the government makes its decision that it's actually a risk. And somehow we have to embed those concepts in what we produce. The word "interactive" is not there. If you're integrated and interactive--

But I don't know where that falls in the final document. But I agree with you: That's missing, and I just don't know where it fits and what our discussion is. But I think each of these need to become sentences.

DR. LINDEN: I had a comment along that line, if I may speak.

We have things that are topics, and then we have basically our opinions of what the attributes should be or what some of the goals are.

And I don't know that we want full sentences, but--you know, say there's an issue--you know, risk communication. That is a topic. And then our thought is that it should be, you know, integrated with recipients, and so on and so forth. And even "blood policy is to develop a structured process." Well, the topic is really blood policy. We believe it should be structured process, and we should use analytical tools that include--you know, may include this, that, and the other thing.

So just a suggestion that maybe we can develop a sort of format we really want to use of, you know, topics versus goals to achieve.

My other, minor, comment is our frequent reference to the blood system. I don't know that I know what that is. The collectors in the blood banks, clearly, but does it include the donors, does it include the ordering physicians, does it include the nurses administering the blood, does it include the patients, the recipients? So we either might want to be more specific or define that somewhere.

DR. BRECHER: Or substitute for the word "provision of blood."

DR. : Provision of blood?

DR. BRECHER: Yeah.

DR. LINDEN: Could we also add "outcome monitoring"--I'm sorry, back under this process?

DR. BRECHER: Back under where?

DR. LINDEN: Analytical tools.

DR. BRECHER: What was that again?

DR. LINDEN: Outcome monitoring. It just seems that was a big piece that we don't always do very effectively and we thought that would be an important part, good decision-making.

[Pause.]

DR. LINDEN: Well, just on my point, I'm not sure "provision of blood" is really inclusive enough. I don't think we need to say anything. The first sentence, we already said what we're talking about, in terms of the safety and availability. Can't we just say "decision-making"? I mean, it's obvious what it relates to. Or you could say "related."

DR. BRECHER: This includes a review of the process of decision-making and integration with the larger public health system. Just kick that middle piece out, for the provision of blood. Just get rid of that.

DR. LINDEN: What's the larger public health system? As opposed to the public health system?

DR. BRECHER: Or is it the national health systems?

DR. LINDEN: Yeah. I mean, you're saying you want to include the state and local agencies as well as the federal? I mean, is that what that means?

DR. HOLMBERG: Can you just say public--

DR. BRECHER: With the health system?

DR. HOLMBERG: With the public health system. If you want to then maybe put parenthetically, local, state--

DR. LINDEN: You could say--I mean, I consider myself to be part of the public health system, personally, but--

DR. SANDLER: Nation's health system?

DR. BRECHER: Is that sort of like NationsBank?

DR. SANDLER: Lower-case n.

DR. LINDEN: National?

DR. BRECHER: Unless you want to say public and private health system? Which I don't think we want to say.

DR. EPSTEIN: I don't think the issue, again, is structure; it's function. Of course you have local, state, and national entities involved in blood and its, you know, preparation and delivery. The point here is that the decision-making process as it concerns blood policy should be well-considered with other public health policy.

So let me give you one example. Should you practice public health in the donor room? Should there be a national policy to offer things like, you know, cholesterol screens and PSA screens? Should there be more proactive medical referral? Should you link donor recruitment to

providing, say, advice on healthy lifestyles?

That's an example of the thought that I have. And that would be transformational. That's not what we do now. We don't look at the donor from the standpoint of an opportunity to practice public health. We have a reductionist idea. We exclude all the people who are ineligible, we do nothing to make them more eligible, like, you know, give iron to people who may need iron.

So I think that's the transformation that I'm talking about. And I've been using the word "transformation" because I think that, if this is a strategic plan, as opposed to simply an action plan--in other words, a punch list--then we ought to be thinking about what are the big-picture changes that we think are needed for our country and how it looks at blood? And all these things are important, but I'm not sure that they're all transformational.

So, for example, the whole mindset of being more prevention-minded; you know, to anticipate problems and address them and fund

initiatives in prospect rather than being reactive. And Jerry was making this point about pathogen reduction, because what you're saying in essence is let's get it in place before the next EID. And that's right. That's an example of being proactive, but it would be a transformation of our system. We don't think that way. We wait for the next EID and then we try to address it. And we do that pretty well, but we're always doing it in the reactive mode.

So, again, I think that there may be other large ideas for transformation of the system that I haven't focused on. But those are the things that are strategic. Everything else is an action item.

DR. BRECHER: Mark?

MR. SKINNER: I think it's the word "system" that maybe is troubling. I wonder if what Jay is talking about is public health policy, and then we need to define who we think are parts of that. Because in my mind, the word "system" also includes, you know, all the voluntary health organizations, which include the patient

organizations and all the nonprofit organizations, not just government institutions. And I think the word "system" is left for people to define. I'm wondering if we could change it to the word "policy," and then add a sentence that defined who all the players are that we should be thinking about integrating with.

DR. BRECHER: I like the word "policy." I don't know that we need to define it up there. I think if we keep the preamble short, it will be more easily absorbed by the reader.

Jeanne?

DR. LINDEN: I think we're getting very hung up on the term "strategic plan" and is this strategic and is that strategic. I mean, that was a term that the subcommittee came up with, but I wonder if we just call it "a plan" and--because we didn't set out to write a strategic plan. What the committee as a whole has really done is identify issues of concern where there needs to be additional work over the past few years. And we were trying to just synthesize a list of those that

continue to need attention. So I'm just wondering if we should just call it "a plan."

I agree with Jay. I mean, some of these are really action items. And that really was the point, that these are areas that need to continue to be looked.

DR. EPSTEIN: So then we're talking about an updated action plan. Because we have an action plan. It's still in effect, albeit nearly completed. So we're talking just about a new blood action--

DR. BRECHER: Well, except it may be broader than the FDA action plan, which was--

DR. EPSTEIN: Well, again, mind you, it started as an FDA action plan but it became a departmental action plan and many of its elements were inter-agency and, indeed, involved the private sector. So I wouldn't--I mean, to characterize it as FDA's action plan, we had a very large partner, to be sure, but it wasn't just FDA's action plan.

But be that as it may, I think what we're talking about is an updated or a current blood

action plan.

DR. BRECHER: Well, could you--

DR. EPSTEIN: But I think we lose something--again, it's not that I'm against having an action plan dealing with many of these issue areas. I do think we need it to focus attention. But I think that if we go that route, we are perhaps losing the opportunity to think strategically about transforming our current system and its processes. Because I do think that we need some of that.

DR. BRECHER: Do we have any--

DR. SAYERS: If I could just--

DR. BRECHER: Go ahead.

DR. SAYERS: Sorry. I'd like to endorse that. I'd feel happier about what we're doing now if we just called it something simple, like "a wish list." Because we've lost looking at the issues that confront us from a higher altitude, which would be an opportunity to think strategically. So if we do call this, what did you say?, an action plan, I'd stop complaining about where is the

strategic element here. Maybe looking at the industry strategically is something we should do at a different sitting at a different time, but it would give us an opportunity to talk about what is the role of the blood program in promoting public health. That certainly is a strategic issue. And there are other issues that we could develop an agenda for which would be exclusively strategic. But this is not.

But it's important. I'm not belittling this list at all. But it's not a strategic list.

DR. HOLMBERG: Let me just sort of go back and give you a little overview of some of the things that have transitioned within the Department of Health and Human Services since Secretary Leavitt has come on board, and that is that there is a 500-day and a 5,000-day plan. There's a vision, and then there's plans and products that go into that plan. And so I think what we're talking about when we talk about an action plan, we're actually talking tactical--how do we move forward with this. And strategic is an opportunity to give

an overview, a high level.

And I really--I like what Jay is saying, and I think that we may miss the opportunity to really lay out a high-level strategy of how are we going to transform. First of all, do we need to transform? Secondly, what is that strategic plan? And then we can work down into the tactical aspect of it, which would become an action plan.

DR. BRECHER: All right, it's now after 10:30. Why don't we take our scheduled 15-minute break and we'll come back and discuss becoming transformers.

[Break.]

Committee Discussion (Continued)

DR. BRECHER: If everyone will take their seat.

DR. HOLMBERG: Can we all get back to our seats, please?

DR. BRECHER: Okay. It was suggested during our break that what was really missing from our statement is justification for us making a statement, and so that what we need above is

statements of fact that there are current problems. So we need a couple of Whereas statements before we launch into our recommendation. So I wrote the first two, which we can wordsmith, but I think we--there are lots of problems and I think we could list them. But it would be nice if we had at least five Whereas's before we launched into our proposal.

Oh, yes, and Jerry has a quick comment to make.

DR. HOLMBERG: Actually, two comments. I was reminded this morning, when I was talking to Karen, about some of the comments that were made yesterday. And maybe as we're thinking through this strategic approach, we should keep this in mind. I think that--and somebody mentioned this yesterday, but in my words, I think we're victims of our own success. We've done things very well. And so, you know, maybe 25 years ago it wasn't done as well, but I think we've learned our lessons and we've moved forward.

And I have to say that even the Assistant

Secretary for Public Health, the emergency preparedness, had five questions that he routinely asked. And the fifth question was always, How is the blood supply? Okay? So there is an awareness of what is the blood supply.

The other thing I wanted to say--and maybe we could work into the--in this whole structure and the justification and that, and the mantra that I try to get across down to the people down at the Humphrey Building, is that blood is a critical element of health care infrastructure. And so trying to get that message across, I think, is very important. Because everybody just assumes that it's going to be there. And, you know, they think of maybe respirators and things like that as support items, but blood definitely is a support item.

DR. BRECHER: Well, maybe that should be one of our Whereas's. Whereas blood is a critical element of modern medicine. You could add--

DR. BIANCO: That should be--and while this is done, this has triggered another thought.

I think that we have to admit, as one of the first Whereas's, that there has been an incredible progress over the years. And so there have been many positive things done before this committee and through this committee, but there's still a lot of work to be done. And then--

DR. BRECHER: That may be our closing statement on this resolution, acknowledging that progress has been made but that more can be made, something like that. Should be made. Will be made. Shall be made.

DR. SANDLER: I'd like to see one of the Whereas's say that Whereas blood shortages continue to occur in the United States. Or just "continue to occur."

DR. BIANCO: They occur in Washington, Jerry. They don't occur in other places.

DR. BRECHER: But that's intentional.

MR. SKINNER: I don't want to appear lost, but can you clarify for me? What are we doing right now? Are we developing an action plan or a strategic plan? Because even the Whereas's makes a

difference with what we're drafting and where we're leading. I mean, it would be helpful if we could just make a decision which is it that we're doing so that we're all moving in the same direction. Is there consensus, or do we need to take a vote so that we know what we're actually trying to achieve?

DR. BRECHER: Well, yes, we've had arguments for both. So a vote, I think, is appropriate.

So the question before us: Are we proposing a strategic plan or are we proposing an action plan? What's the committee's pleasure?

All those in favor of a strategic plan?

DR. LINDEN: Can I just ask a question? Are we proposing that we recommend--

DR. BRECHER: Yes.

DR. LINDEN: --that the Department develop one of these?

DR. BRECHER: Yes. That's correct.

DR. LINDEN: And are we identifying who would do it? I mean, there was discussion about the existing action plan.

DR. BRECHER: We haven't discussed that part, whether we would make a specific recommendation as to who would do it.

DR. LINDEN: Because I think there was discussion that we are not able to do this and there probably would not be funds to hire somebody outside. So are we suggesting that the agency do it?

DR. BRECHER: It may be some sort of inter-agency group with some liaisons from the outside. I think that's at HHS's discretion as to how they would want to do this. We could--

DR. LINDEN: Well, my concern--I mean, we can recommend that something be done, but it's going to cost funds and we don't have anything definitive. It may just be listened to as much as some of our previous recommendations.

DR. BRECHER: I guess we could pass the hat around the table.

DR. BRACEY: I thought what we're doing right now is basically laying the groundwork for why a strategic plan needs to be developed.

Because we can't develop one within the room; we don't have the resources to do so. But we can kind of lay out why one is needed.

DR. BIANCO: Before you go to the book, I think that we cannot have an action plan without having a strategy and knowing where we want to go. So I think both are linked, Mark. And I think that we have to have what some people--Jerry, I remember, the last one--talked about, the vision and what are the major issues we want to address. And then, the action plan derives from that. And actually, a good action plan will only come out after we have--after the strategic plan is developed.

DR. BRECHER: Well, we could even say, Whereas this committee does not have the resources and the time to develop the strategic plan."

DR. BIANCO: That's pessimistic.

DR. BRECHER: Okay. All right, we won't do that.

DR. BIANCO: We can it nicer.

DR. HAAS: I guess I'm still not clear,

that when we say "strategic plan," is that referring to all issues relating to blood? Or are we talking about what this committee's strategic plan would be?

DR. BRECHER: I think we've been taking the larger picture, and that's why we've given a little punch list at the bottom to say that any such plan would, at a minimum, include the following items. So it's a bigger picture that we'll take.

DR. EPSTEIN: I think the greatest service we can provide to the secretary is to outline what we think are the deficiencies of the current system that need to be addressed prospectively. And I think they're things like the fact that we continue to have periodic disruptions in supply availability and access; that we have persisting gaps in the development of products for small patient groups or narrow, albeit critical, indications; that we are slow and not directive in funding technology developments that could offer substantial benefits either to supply or safety; that we do not have a

comprehensive system to monitor the current safety and availability within our system; that we do not routinely monitor the outcome of decisions and actions affecting blood products; that we are slow to respond to certain recognized threats that have available interventions, for example, the misidentification of the unit and patient; and that we have had difficulty in optimizing risk communication to maximize public confidence and trust on the basis of honest communications.

So, I mean, we could go on. But I think that if we fail to suggest where the problems lie, there's sort of no point in the plan. I mean, there's still a point in having action items because the world's not perfect and there's certain work to do, and that's fine. Again, I'm not against an action plan. But it's the vision of why we need to be more strategic that's the issue. And unless we can say what's the matter with the system, then there's no point calling for this.

DR. LINDEN: So did you write those down?

DR. EPSTEIN: Yeah.

DR. LINDEN: Okay, so why don't we start there? I mean, I think what we were talking about was trying to go through some of these presentations and identifying weaknesses, and it seems to me you've captured virtually all of them. So can we start--

DR. HOLMBERG: If I can just say, when my subcommittee met, the idea of doing a SWAT analysis was really brought up, and the fact that, in the presentation of the material, how do you present. And the challenge that the subcommittee members were given was how to put those SWAT-type questions together to get the committee to be thinking. So I think that this is right online.

DR. BRECHER: Okay, Jay, slowly from the top.

DR. EPSTEIN: Well, I'm happy to do that, but also we could be more systematic. If we accept that the list of bulleted points in the subcommittee report is a good starting point, we could systematically go through them one-by-one and simply state what we think is the underlying

problem or set of problems that makes that an issue.

But that said, you know, a sort of the back-of-the-envelope stab at it is:

Periodic disruptions in supply availability and access.

Gaps or, if you will, unmet needs in development of products for small patient groups or rare indications.

Inadequate funding for implementation of new technologies.

DR. BRECHER: Implementation or timely implementation?

DR. EPSTEIN: Well, you can say "timely," sure. Again, this is a crude cut. We're going to polish all this.

Lack of adequate data to support monitoring of the blood system. That's the whole surveillance--

DR. LINDEN: Actually, you put it a different way before, which I thought was better, which is lack of a comprehensive system to monitor

blood safety and availability. Or, put another way, fragmented systems. That's really what we identified. We have a lot of different systems, but they're not coordinated.

DR. EPSTEIN: Right. You could say fragmented systems for monitoring--

DR. LINDEN: Safety and availability.

DR. EPSTEIN: --safety and availability.

And then we have this issue of failures in monitoring outcomes of policies or interventions.

Then we have the slowness in responding to recognized threats such as blood misidentification, errors.

DR. LINDEN: I think you said before "for which there is available technology," which I think is a good way of stating it.

DR. EPSTEIN: Recognized threats for which there are available technology solutions. Or they don't have to be technological, you know, just interventions.

DR. LINDEN: Solutions or interventions.

DR. EPSTEIN: Right.

DR. LINDEN: And what was your risk communication one, Jay? You had one.

DR. EPSTEIN: It was just "difficulties in communicating risks in a manner that can sustain public confidence and trust."

DR. LINDEN: Do we want to put "lack of integration" into the public health system as one?

DR. EPSTEIN: I think we ought to go back over each of the subject areas where we had a presentation, where we have a bullet, and ask ourselves to articulate what is the core problem. Where's the gap? What do we think needs fixing in that domain?

DR. : What comes after risk communication?

DR. EPSTEIN: In order to sustain public confidence and trust. That would sustain public confidence and trust.

I mean, I think this is also an issue of missed opportunities for public health in the management of blood donors.

DR. BRECHER: Provision of public health?

DR. EPSTEIN: Yeah, for practice of public health, or For enhancing public health, through the management of blood donors.

DR. LINDEN: And then maybe we want to put the absence of, you know, uniform clinical guidelines, put something in there about that.

DR. BRECHER: Evidence-based.

DR. LINDEN: Ah.

DR. BRECHER: Evidence-based.

DR. SANDLER: If I understand Dr. Epstein's suggestion, it's that we now reorder his order according to the list we've made. I'd like to suggest that his order is the one that I would have picked and that, if we just took his items and numbered them--in other words, Whereas 1, 2, 3, 4, 5--we would be able to cut and paste the things that we've done and put them in the paragraph below it to match his list. His prioritization is just great, as far as I'm concerned.

DR. BRECHER: Jeanne?

DR. LINDEN: The other item that had been on the list was insufficient disaster planning--do

we want to retain that?

DR. EPSTEIN: Yeah, I think we need to just say something about each bullet. We haven't said anything about the research agenda, disaster planning, funding promising new technologies, stable reimbursement. Again, I was just sort of sketching the idea of where we need to go here, which is to give some description of what we're trying to fix in each area.

DR. BIANCO: The reimbursement issue, Jay, is it should --[?]-- things because a lot of it you could trace back to reimbursement, or funding.

DR. EPSTEIN: Again, the problem--you can't just say "research agenda." What's the issue about the research agenda? The issue about the research agenda is that A) we don't have a consensus agenda based on a collective sense of priorities, and B) that it needs to become more proactive, future thinking. In other words, we want to--as you were saying, Jerry, right now we're waiting for the private sector to develop remedies. Right? Instead, we could say we have a national

priority to develop this technology because of its great promise, so we're going to--you know, we're going to have a Manhattan Project that delivers it. That's the difference. That's the transformation. It's not that we have no research agenda. There are lots of funded projects. It's that we don't have one that is directed toward certain goals.

DR. BRECHER: --the word "targeted" up there?

DR. SANDLER: I think that since the initiative comes from investors, which is really where it gets out to the market, whereas the initiative for research is not strategically directed toward public health issues but short-term--or primarily by economic or fiscal issues.

DR. EPSTEIN: Well, this is the biggest issue of all, is the, if you will, the rough edges between the privatized model, right, and the government-driven model. And I think that each time that we reexamine the national blood policy, we decide we don't want to nationalize the blood

system in America and that any such movement cannot be isolated from the broader question of national public health. And, you know, we always take a step back and say, well, we'll just do better with the system that we have and, you know, we trust the marketplace and we trust innovation. And I don't have a problem with that, but I think that we have to, at the same time, if we accept that model, recognize where it doesn't work and have strategies to deal with those, if you will, boundary issues.

And a perfect example of such an issue is generating products for rare disorders. There just isn't a market incentive. And, you know, you just can't expect that the market's just going to solve that problem. You have to do something more.

DR. BRECHER: Jerry, let's take this list and break them out into points, each one having its own line.

DR. SAYERS: While Jerry is fracturing this list, as far as the research agenda goes, what it lacks is any sense of appropriate priority. So we don't have a research agenda which encourages

development of solutions to those problems where the most benefit could be achieved.

DR. BRECHER: We could say proactive, prioritized, and targeted research agenda.

DR. LINDEN: Are we saying lack of proactive and targeted research agenda?

DR. BRECHER: Yes, lack of. It's a lack of.

DR. EPSTEIN: I think the issue is a goal-oriented research agenda. Lack of a proactive, prioritized, and goal-oriented.

DR. BRECHER: Okay. Goal-oriented. You mean besides publications?

DR. EPSTEIN: They're secondary, as you know, Mark.

DR. BRECHER: Fortunately, we have all the speakers from yesterday around the table, who made their presentations. Are there any items that you presented and discussed that we don't have on the list?

DR. HOLMBERG: Where's the policy?

DR. BRECHER: What do you mean the policy?

PARTICIPANT: The decision making is not there.

DR. HOLMBERG: Yeah. Decision making. And integration of the proper tools--the open transparency.

DR. BRECHER: Well, right now we're stating what the problems are, so we have to phrase it as that there's a current problem.

DR. BRACEY: Well, one of the things that I was thinking about from the clinical piece is our ability to impact practice. It sort of has been inef--well, I won't say ineffective, but it's been sub-optimal--limited. Limited ability to impact clinical practice or clinical use of blood.

DR. LINDEN: That's separate, though, I think.

DR. BRECHER: Okay. Other items? Okay. So now, we need to smooth this list so that it basically as, whereas, the following problems exist--yeah, so--

DR. BIANCO: The other item that we didn't put there was going through, because I don't know

if still we put the policy question that Jay raised about decision making? That is, we lack a clear mechanism for decision making in--

DR. BRECHER: Clear path? Or

PARTICIPANT: How about a clear process?

DR. BRECHER: Yes.

DR. LIPTON: I thought we had a path, but we didn't have--but some of the elements of good decision making I thought--we thought were absent, like us of analytical tools and--we do have the outcomes measurement.

DR. BRECHER: So it's path and for evidence-based decision making?

DR. LIPTON: Well, we could say decision making does not uniformly utilize--or follow good decision making practices or something like that.

DR. BRECHER: Yeah.

DR. LIPTON: Or recognized decision making.

DR. EPSTEIN: I think the gap as I see it is underutilization of formal analytical tools in our decision making process. I don't think we lack

a process. We know what our process is, but we don't commit ourselves to routine use of formal tools--you know, cost-benefit analysis, risk-benefit analysis, cost effectiveness, risk assessment, risk management, et cetera. We do that ad hoc, and we don't always do it. But we're not committed to it.

DR. BRECHER: Underutilization of formal decision making tools--

DR. EPSTEIN: In policy and decision making. I wouldn't say in creation of policy, but in policy and decision making.

DR. BRECHER: Yeah. We're not in the business of creation.

DR. EPSTEIN: Pardon?

DR. BRECHER: We don't--we're not in the business of creation.

DR. BRACEY: Yeah. Well, one of the things, and I think it fits partly under insufficient disaster planning, but I wonder whether it is something that ought to be stated and that's the lack of a strategic blood reserve.

Those, you know, that might be seeing that would perhaps--

DR. BRECHER: Or a minimum supply?

DR. BRACEY: Right. Exactly.

DR. BRECHER: I mean, for example, just to toss something out. You know, to be licensed as blood center. I mean the FDA may require that you have to have a minimum of six days supply, 95 percent of the time in the year. You can imagine a mandate like that.

Just tossing that out.

DR. BIANCO: Since you're talking about--that was one of the questions that we discussed yesterday. What is the ideal blood supply? And the other one is that we left aside a little bit--I tried to raise yesterday, but probably didn't communicate it well--was that I don't think that it's clear the responsibility of each one of the segments, be it the private sector, the transfusion service, the third-party payer, or the government, or the several agencies, and the whole blood availability scene in the donor

availability scene; that is, is this entirely a private sector, since Jay likes to put that. Since we are privatized, is this an entirely private sector activity or does the government play a role? And what is that role besides the regulatory role?

DR. EPSTEIN: So, Celso, are you saying that the issue is the lack of clarity of the respective responsibilities?

DR. BIANCO: With the lack of clarity comes the lack of involvement or the lack of demand. But, yes, I agree. The lack of clarity is the best way to express it.

DR. BRECHER: Jerry?

DR. SANDLER: I'd like to make an effort to clarify the underutilization of formal decision making tools in policy and decision making for systematic changes in blood products and transfusion practices. In other words, I think what we're talking about is all of sudden we get universal leukoreduction or all of a sudden we're testing for HTLV-1, and there is a lack of utilization of formal decision making tools for

such systematic changes that occur. Now, that's what I think it's intended to say, but I wanted to make it a little clearer.

DR. BRECHER: Is that okay now? So does that work for you, Jay? Systematic changes?

DR. EPSTEIN: Yeah. I have another comment; that I would quarrel with the examples because I think, you know, leukoreduction is an example where we did it up the wazoo, but that's--

DR. BIANCO: And the HTLV-1 is Jerry's fault.

DR. EPSTEIN: Yeah. I wasn't going to say that.

[Laughter.]

DR. BRECHER: We don't need to be that specific. Okay. Mark?

MR. SKINNER: I've lost what's at the top of the list that we're remembering, since we've got so far down, but did integration of the public health infrastructure; is that on that list somewhere? The decision making within the public health infrastructure?

That's a blood donors. No, I'm thinking--

DR. LIPTON: Part of it is under monitoring, because--well, how do we use the public health? Well, one could be in monitoring, you know--

MR. SKINNER: Yeah. But the issue I'm thinking of are issues like where the FDA approves a product as safe and efficacious, but CMS doesn't approve it for reimbursement purposes. And the integration between what the FDA is doing and what CMS is doing in terms of authorizing reimbursement and where do we--I mean if we're looking at creating a--

DR. BRECHER: Or even categorization--

MR. SKINNER: --a transition-

DR. BRECHER: Or even categorization of products?

MR. SKINNER: Yeah. Exactly. I mean if we're looking at creating a transition or a new beginning, I mean that's--one is perhaps a--to at least look at is how do we--do we want better integration between the HHS agencies--

DR. BRECHER: Right. So lack of integration between government agencies.

MR. SKINNER: Well, that was what I had interpreted and understood was part of yesterday was the second bullet--integration in the blood system within the public health infrastructure incorporated all of those kinds of issues. But.

DR. BRECHER: Lack of integration?

DR. EPSTEIN: I see it as part of the previous point. Inadequate funding for timely implementation of new technology that includes new products.

DR. BRECHER: No, but I think what he's saying is that you may all IVIG a blood product, but CMS might call it something else. So that's lack of integration. Alternative universes?

MR. SKINNER: Maybe it's more a part of fragmented systems? I mean maybe it's--'cause fragmented is, you know, we have a fragmented system or a non-integrated system, and that affects availability because it's an access issue. I mean maybe it's there. We're just not using the word

integration.

DR. BRECHER: I think it's--you know I agree. It probably--you could probably put it under fragmented, but it's not just for monitoring safety and availability, but it's also for classification and reimbursement--safety, availability, classification, and reimbursement?

DR. LINDEN: Didn't we mention reimbursement as an item, though?

DR. BRECHER: We did--

DR. LINDEN: I mean because that would link to--

DR. BRECHER: We said reimbursement as a function of access. But what we've neglected is that we have a fragmented reimbursement system. It's not just CMS. There are all these insurers out there. And they're--everybody does things a little different.

DR. LIPTON: So it's fragmented reimbursement policies and failure to integrate those with decision making?

DR. BRECHER: Yeah. So make it separate.

DR. LIPTON: Decisions made around blood safety and availability?

MR. SKINNER: I like that.

DR. LIPTON: I wish I could say it again, but I'll never in my life.

DR. BRECHER: Reimbursement policies.

DR. LIPTON: Oh, what did I say? Failure to integrate--

DR. BIANCO: I'd like to include not just reimbursement, but funding. That is, even what comes from an NHLBI or from CDC and other agencies that impacts blood is not coordinated.

DR. LIPTON: Okay.

DR. BIANCO: And so it's the funding of research; it's the funding of surveillance, or the development of clinical processes, conferences--

DR. LIPTON: Can I just put--I think and failure to integrate those policies with decisions affecting blood safety and availability. Those policies.

DR. EPSTEIN: Just suggest that fragmentation in our system then it seems to me

appears to be one of the strategic concerns. In other words, if you look at the extent to which fragmentation underlies many of the problems that we're talking about, you'll find that it's a pervasive theme. So I think that's one--emerges as a strategic issue; is should we transform ourselves to a less fragmented system?

DR. SAYERS: And against that background, this is becoming a mea culpa more than anything else. But I think somebody reading this could be--for assuming, given these comments, that we're running a blood industry which is based on a Third World model. And, you know, what we've really identified here are opportunities for improvement. And the fragmentation and the recognition of that is something for a strategic think tank approach.

But we could just as easily say given these opportunities for improvement, systems for monitoring funding. I just worry that we are labeling all this--all these items as faults, deficiencies, and sins on our part, 'cause a couple of you have said we've done pretty well, given some

challenging circumstances. And reading this lengthy apology makes it sound like we haven't.

DR. BRECHER: I guess some of our colleagues in New Orleans might think we are in the Third World. All right, Jeanne?

DR. LINDEN: Well, yeah, that was sort of--I think our thought originally, yes, we can identify the weaknesses or gaps, but you could also make it a positive thing that you'll--that these are things that we think could be worked on. We can improve, you know, continuity of supply, you know, as opposed to--that the disruption is a concern.

Just as a suggestion, the other comment just specific to the part about reimbursement. I don't think we want to say the blood policy should be driven by the reimbursement; that we're reacting to CMS. I think it should be the other way around. The reimbursement should really be following the blood policies. I mean even if that's not going to happen.

DR. LIPTON: So this may be failure of

those policies to support decisions affecting blood safety and availability?

DR. BRECHER: So it sounds like we need a preface sentence; something like overall, blood safety availability in the United States has been largely successful. However, we recognize that there are the following opportunities for improvement. Something like that?

DR. SAYERS: And then could you just go to the beginning, because it doesn't take all that much of a re-write. So then the first opportunity for improvement might be in the supply and access of blood products and their analogs rather than mentioning anything about periodic disruption.

And then the next one would the opportunity for improvement--would be development of products for--what was that?--small patients.

DR. BRECHER: Put a colon here.

DR. EPSTEIN: Small patient groups and rare indications.

DR. SAYER: Yeah.

DR. BRECHER: What was the first one? I'm

sorry.

DR. SAYER: The opportunity for improvement is in the supply and access of blood products and their analogs.

DR. BRECHER: It's minimizing disruptions. Minimizing disruptions. Disruptions. And here's the small patient groups. Meeting the needs of small patient groups for the development of products. For the development of--put in there products--or specific products.

DR. LIPTON: Can we say meeting the product development needs of small patient groups?

DR. BRECHER: Yeah. I like that. Product development.

DR. LIPTON: It gets so complicated then.

PARTICIPANT: The product development?

DR. BRECHER: Needs of small patient groups. Yeah. The product development needs.

DR. SAYER: Is there something other than small patient groups? I keep thinking of people that are stature challenged.

[Laughter.]

DR. LINDEN: Yeah. Can we talk about frequency? Infrequent or--you know, or rare disorders or--

DR. SAYERS: Rare disorders.

MR. SKINNER: Rare disorders really doesn't cover it, because rare disorders--anybody with 200,000 or less, at least as it's defined. And we're talking about smaller than that. We're talking about groups, you know, of a few hundred or less.

DR. BRECHER: Well, but they're still in that group.

DR. SAYERS: Yeah.

DR. BRECHER: They're just a subset of that.

DR. SAYERS: They're included in the rare.

DR. BRECHER: Okay.

DR. SAYERS: And the other--the next opportunity would just be funding for timely implementation of new technology.

So I don't think you need the inadequate, because the opportunity is funding. Right.

Reducing fragmentation. In system--reducing fragmentation in systems for monitoring safety and availability.

DR. LIPTON: What about instead of reducing fragmentation to make it more positive--integrating. To use a positive word. You know, integrating systems for monitoring safety and availability and then integrating reimbursement and funding.

DR. LINDEN: Integrating or coordinating?

DR. LIPTON: It could be both. Integrating again, and Jeanne just said maybe integrating and coordinating just for these--

DR. BRACEY: One of the things that we may not want to include this in the preamble, but to think about is again focusing on the importance of blood as a resource in the provision of medical care. It's somewhat self-serving, but Jerry mentioned that it's--we hear that all the time.

DR. BRECHER: Yeah. I think it's down on the list.

DR. BRACEY: It's down below?

DR. BRECHER: Yeah.

DR. BRACEY: Thanks.

DR. LIPTON: Should it just be integrating and coordinating reimbursement and funding?

We have to change the next part, too.

DR. LINDEN: I would propose coordinating reimbursement funding policies and integrating decisions on blood policies into those reimbursement policies or practices in a timely fashion.

DR. EPSTEIN: How about aligning reimbursement policies. I don't think you need the word funding. Aligning reimbursement policies. Aligning reimbursement policies with decisions on blood products and technologies with safety and--well, just with decisions on--yes.

DR. LINDEN: Should the reimbursement vary with availability? That makes it sound like a supply and demand thing.

DR. EPSTEIN: Well, the idea is you're trying to make a product available, but it won't get paid for.

DR. BRECHER: Okay. Let's do the--how are we going to make the next one opportunity.

DR. EPSTEIN: Decisions on blood products and technologies. I'm back to aligning reimbursement policies with decisions on blood products and related technologies. I'm trying to get away from the availability thing. Just with decisions on blood products and related technologies.

DR. LIPTON: When we say--don't we want to suggest somehow that those decisions improve blood safety and our availability?

DR. BRECHER: You could say and to optimize blood safety and availability.

DR. LIPTON: Well, it would be decisions that optimize blood safety and availability. Can I make a suggestion about this editing. I mean if we capture it, you know, one or two of us went through, and kind of did the grammar and everything run during lunch, because it just seems so--it's very hard to read up and down and unless we're all looking at it all; maybe rather than doing a

group--as long as we have the concepts.

DR. BRECHER: I tell you what. Why don't a small group stay here for the next 23 minutes and wordsmith it, and we'll take until 1:00 o'clock for lunch. That gives us an hour and 20 minutes? Okay.

DR. DUBIN: We don't want to forget a dose of humility. We're not doing everything right, and if we soften the entire document, the Secretary is going to say everything is fine. We just need to integrate a little more.

What I heard yesterday is if I'm a patient with primary immune deficiency, I'm fighting the same battle I was fighting in 1998. That doesn't tell me everything is okay.

And while I agree, Dr. Sayers, that we have done a good job in safety and availability and improved immensely from the heyday of the '90s, I'm concerned that if you take all the strong language out, all of out, no one is going to hear you.

I think they still need to see there are areas where people are really hurting, be it in

primary, immune or elsewhere. And I think we as Americans tend to think we're the best at everything, and sometimes we forget to have the humility to know we're not so great. The good example recently is the 1,500 Cuban doctors that were to be sent here, and you notice the New York Times, the Washington Post, and the L.A. Times had banner headlines that say the U.N. believes the Cubans are the best at disaster relief from hurricanes in the world.

I think sometimes we got to step back. I agree with most of the document, but I don't want to make it so soft that the Secretary or the new ass coming in doesn't see the problem. Jerry it's what you were saying to me earlier about preparing for a new Secretary--a new Assistant Secretary. I'm hopeful that Secretary reads that and says, well, here's some areas we really have to work on.

DR. BRECHER: Maybe we can compromise. Why don't we say--instead of saying for--

DR. DUBIN: That's all I wanted to add.

DR. BRECHER: --opportunities--

DR. DUBIN: Thank you.
DR. BRECHER: --why don't we say significant opportunities at the top?
We recognize that there--that the following--yeah. Recognize the following--opportunities for improvement. Does that capture that thought somewhat?
DR. LINDEN: Do you want to get something maybe across of these areas need improvement, you know, for needed improvement or rephrase the whole thing the strengthen?
DR. BRECHER: Yeah. We can say--
DR. LINDEN: Not just that we can tweak, but that we really need some fundamental changes in some cases.
DR. BRECHER: Yeah. We can say for a needed improvement. Does that get to it, Corey? Okay. Merlyn?
DR. SAYERS: How about prompt attention?
DR. BRECHER: Prompt attention. So needed for prompt attention rather than needed improvement--well, we've already reworded

everything for improvement. We've already sort of reworded things for improvement. Plus the following--to these--for needed improvement or say prompt attention? I guess we could do that.

DR. LINDEN: Or in a timely fashion.

DR. BRECHER: Okay. Jay?

DR. EPSTEIN: Since we're phrasing each of the issues as an opportunity, maybe we don't have to call them opportunities in the opening paragraph. Maybe the opening paragraph can just be strengthened so it--recognize the following needs for improvement. But then the way we phrase them doesn't, you know, damn ourselves. But that would strengthen it.

DR. BRECHER: Needs for improvement and prompt attention.

All right. It's--Celso.

DR. BIANCO: Yeah. I recognize that half an hour will be great for a group to wordsmith it. But I don't think that it's going to take us more than half an hour after that to wrap it up.

DR. BRECHER: So you'd rather work through

it and skip lunch or?

DR. BIANCO: Well, either that or take our half an hour break and do it and then go for lunch.

DR. BRECHER: Yeah. We could do that. Okay. You want to take a half an hour break and then we'll re-adjourn let's say at 12:15 p.m.? Okay. And let's--the group who's interested in wordsmithing it, come up here and let's do it.

Is that okay with everyone or you guys want to have lunch and then finish it? That's the Committee's pleasure. All for having a lunch before we finish it, raise their hands. Three.

All those who rather skip lunch? Okay. Take an half an hour break, and if anyone wants to come up here and anyone wants to come up here and help wordsmith it, let's do it.

[Luncheon recess.]

A F T E R N O O N S E S S I O N

[1:17 p.m.]

Committee Discussion (Continued)

DR. BRECHER: So we could get this done before everybody comes--gets back from lunch. We do.

DR. SAYERS: I move adoption. I move adoption.

DR. BRECHER: Do we hear a second? Let's read it into the record first.

Jerry, you want to read it into the record?

DR. HOLMBERG: Blood is a critical element of modern medical care and ensuring an adequate supply of safe blood is a national responsibility.

Although there have been dramatic improvements in blood safety and availability in the United States in the last two decades, the Committee finds that there are compelling needs for improvement in some areas: minimizing disruption in the supply of and access to blood products and their analogs; meeting the product development

needs for patients with rare disorders; timely findings--funding--I'm sorry. I can't see. Yes. I only have one contact. Timely funding to ensure appropriate utilization of new technologies; integration or--I'm sorry--integrating presently fragmented systems for monitoring blood safety and availability; aligning reimbursement and funding policies with product approvals; and other decisions intended to optimize blood safety and availability; modifying reimbursement policies as needed to sustain access to blood products and their analogs for all patient groups, e.g., IGIV; reassessing policies and their related interventions based on evaluation of their impacts; intensifying efforts to influence clinical practices related to blood transfusion and alternate therapies based on scientific evidence; accelerating responses to threats, e.g., patient, specimen, unit misidentification for which there are available interventions; utilizing formal risk communication strategies targeted to blood donor, patients, and care providers to enhance scientific

comprehension and public trust; pursuing opportunities to enhance public health in the management of blood donors; promoting comprehensive disaster planning, including sustaining the inventories necessary for an effective crisis response; establishing a proactive, prioritized, and goal-oriented research agenda; utilizing formal assessment tools more routinely and policy development in decision making; further clarifying the respective roles of government agencies and their private sector and management and oversight of the blood system.

Therefore, the Committee believes that the Department should develop a strategic plan for increasing safety and availability for blood products and their analogs. This plan should include a review of the process of policy and decision making for blood issues and its integration with broader health policy making--public health policy making.

Such a plan should encompass structured process for policy and decision making, integration

of blood systems within the public health infrastructure, surveillance of adverse events related to blood donations and transfusions, risk communication, error prevention in blood collection centers, transfusion services, and clinical transfusion settings, donor recruitment and retention, clinical practice standards for transfusion and strategic research agenda.

DR. BRECHER: Comments? Jerry?

DR. SANDLER: My compliments to the Writing Committee. I think it's a superb document, and I think we should endorse it.

DR. BRECHER: Okay. So we have a motion to accept? Second?

DR. SAYERS: Second. Can I amend that?

DR. BRECHER: Mm hmm.

DR. SAYERS: And add to the endorsement the instruction to require that the Chairman submit this document as correspondence to the Secretary?

DR. BRECHER: Yes. That's the way all these resolutions are passed to the--well, actually, to the Acting Assistant Secretary. Jay?

DR. EPSTEIN: I think just for parallel structure, it would help to indent the first set of bullet items just the way you've indented the last set of bullet items.

DR. BRECHER: Yeah. We'll work on the formatting.

DR. HOLMBERG: There is one area here that I thought as I was reading the--there was something singular and something plural, and I don't know if anybody else caught that?

DR. LINDEN: What the process thing is sort of awkward, but technically, that's singular. But it might be able to be rewritten to be clearer.

DR. HOLMBERG: What one is that?

DR. LINDEN: It may be in the conclusion paragraph. I don't recall the--we had the process for something or other. Oh, yeah. This--to include a review of the process?

DR. HOLMBERG: Review of the process?

DR. LINDEN: And its integration?

DR. HOLMBERG: Is that okay?

DR. LINDEN: It's okay as it is. It's

just a little awkward. I don't know if that's what you were thinking of or not.

But I think grammatical changes, minor tweaking, you can do offline?

DR. BRECHER: Yes. I think--if the Committee is agreeable to that, we'll tweak it a little bit. Mark and then Jay.

MR. SKINNER: I mean I'm sorry. I missed the--is this the top of the resolution?

DR. BRECHER: Correct.

MR. SKINNER: I mean there's one thought that's just somehow missing to me in here. I mean we don't define the players or the stakeholders. And I'm thinking about this recommendation. We're asking the Secretary to do it, but we're not suggesting anyway in how they do it. So the role of this committee to me after this point is unclear and the fact that the Secretary should do it in a broadly representative stakeholder group that includes all the various interests isn't clear.

I mean I'm a little bit concerned if this becomes purely an internal process within the

Department to address these issues, and a group like this that's broadly representative of all the stakeholders is not a part of the process.

And nowhere in here do we seem to indicate that this needs to be developed in an open and a comprehensive and an inclusive manner.

DR. BRECHER: Well, if we were to do that, that would be in the paragraph down below, where we make our recommendation.

Jay?

DR. EPSTEIN: In our discussion yesterday, we decided that there were two additional categories for the strategic plan. In my notes, I indicated them as stable and sustainable reimbursement, and funding for promising new technologies. So, you know, what we've copied here is the original list, but we did add those two items yesterday.

DR. BRECHER: Funding for new technologies.

DR. EPSTEIN: It was funding for promising new technologies.

PARTICIPANT: Oh, here. I'm sorry. Here it is.

DR. EPSTEIN: Ah, there they are.

DR. BRECHER: Okay. We're ahead of you. Let's go up to the paragraph.

DR. EPSTEIN: Yeah. They're there.

DR. LINDEN: And the thought was just that the second list of items is going to parallel and order the first list?

DR. BRECHER: It could or it could not. I don't--personally, I don't feel strongly that it needs to parallel it. I think more importantly is addressing the openness of the--how this will be done. So, Mark, what would you propose we change to this paragraph?

MR. SKINNER: I mean this is saying that the Department should develop, and I guess these are--either they need to, you know, commission the development or the Department needs to develop in collaboration with or something that indicates that I mean this is an external--this is a process that includes all of the external stakeholders or an

alternative would be to ask that some of this be tasked back or that we have a, you know, an oversight or a monitoring role or some kind of, you know, we provide feedback for the strategic planning process. But I'm not comfortable leaving it all to an internal government process.

I mean that's the way it reads now is the Department is going to do it.

DR. LINDEN: Should you just say should develop comma in collaboration with stakeholders or, you know.

MR. SKINNER: That would be fine.

DR. LINDEN: Interested parties or affected parties, whatever comma.

DR. BIANCO: Or even with this committee. In essence, that's how we see ourselves.

DR. BRECHER: Stakeholders.

MR. SKINNER: I don't want us to make a recommendation putting ourselves out of business.

DR. BRECHER: And interested parties. Yeah. Does that work? All right. To go back to the motion. We had a motion. It was seconded, and

we've tweaked it just a bit. Is everybody comfortable with this? All those in favor?

[Show of hands.]

DR. BRECHER: Thirteen in favor. All those opposed? None. This resolution carries, and I will forward it to the Acting Assistant Secretary. Jerry?

DR. SANDLER: I'd like to suggest that when Jerry Holmberg writes the cover letter that it is going to say something to this effect: one, that, of course, you're transmitting two recommendations that were developed at the Committee meeting the 19th and 20th of September; but the second one is to highlight that one of these recommendations includes a guidance for an emergency plan or an emergency action for a highly urgent problem that requires immediate attention.

I think if we just leave it as it stands, that we're sending two recommendations, we don't get the sense in that communication that's going to really direct his attention to what we did yesterday, which was something very, very urgent

that has to be taken seriously and has been I think not appreciated at the highest levels for its urgency. I can work that into my letter, as well as capital letters, bold, underlined, urgent.

All right. In terms of other business. Are there any other business we need to address other than when our next meeting is? Do you have the date?

DR. HOLMBERG: Captain, do you have--Captain McMurtrey, do you have the dates for the next meeting please?

DR. BRECHER: You know, we're breaking new ground for this committee. We've never finished this early before, and we're going to go out with a bang.

CAPTAIN MCMURTREY: I have a pretty definite date for the January meeting, which will be the 5th and 6th of January. That's the first Thursday and Friday of the month. The other dates I don't have finalized yet.

I'm sorry. The meeting will be in Virginia at the Crystal City Marriott, and I'll

provide you all with the address. I just don't have it with me right this minute.

DR. BRECHER: Jeanne?

DR. LINDEN: Jerry, when will we find out if we're being replaced or need to plan on attending that meeting for those us scheduled to rotate off?

DR. HOLMBERG: I hope within the next two months, we'll be able to get you some definitive information.

DR. BRECHER: It's possible that some members may be re-upped for a second term. But I don't know that it's clear who will be. I'm sorry. Paul?

DR. HAAS: I'm--much, much in the same regard, I had planned coming in today to either individually or do it collectively saying that I've really enjoyed being part of this process since the beginning, and I think this group has done a lot. But yet, during today's meeting, especially given that we had some time to talk with other members of the Committee, I guess as one that knows he is

rotating off officially at the end of this meeting, but who knows what happens in January, I'm really concerned about what appears or what we're hearing via the rumor mill, I guess, that there's going to be a rather massive change of personnel in the Committee. We have just spent a lot of time talking about trying to set a direction for the future, and if those rumors are correct, who of this group is going to be sitting around the table? What's causing this rather significant change in the composition of the group?

And I guess, as I'm leaving, that's a concern.

DR. BRECHER: Well, I guess part of the question is because two charters ago--or one charter ago--the term of office was a four-year term. And then the most recent charter, it went to three years, and so it happens that two waves now come together, and so a large percentage of the Committee is coming to the end of term, and so--it's a question of HHS whether they want to re-up some of those people to enhance continuity at

their discretion.

DR. HAAS: And I guess it's in that spirit that at least if the information I'm getting is accurate--and I don't know--that a lot of folks who could be re-upped apparently are not going to be. And that's much more of a concern. Someone like myself, it's time for me to rotate off.

DR. BRECHER: Any comments, Jerry? None?

DR. HOLMBERG: Well, the process is not just one person's decision. And the slate that is put forward has to go through several offices to get final approval. So, you know, I wish I could say that, you know, my office made all the decisions on it, but my office doesn't make all of the decisions. My office is an office with a small "O," so--

DR. HAAS: Jerry, let me interject. In the spirit of a comment you made last night at the PPTA meeting, I'm not making this comment as a direct hit on you. It's a general systemic thing that I'm concerned about.

DR. HOLMBERG: Sure. And I appreciate

that, and that's one of the things that we are very concerned about is the continuity and making sure that we do have continuity of members already--I mean the people that have joined--committee members that joined this--Art and Susan, this is your second time. And for Pearl, this is her first time. It is a learning curve, and there's a lot to take in, and so we're very much aware of that, and we are considering that very issue is that we need to have the consistency on that. It's just at this point in time, I cannot say anything really.

DR. BRECHER: And I guess in my role as Chairman, I'd like to thank all of those members who will be departing. I think, while we may not have accomplished all that we wanted to accomplish, I think over the last couple of years, we have accomplished quite a bit. Thank you. With that, this meeting is adjourned.

[Whereupon, at 1:35 p.m., the meeting was adjourned.]

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