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P R O C E E D I N G S

DR. HOLMBERG: I'd like to welcome all of you to the 22nd Meeting of the Advisory Committee for Blood Safety and Availability. My name is Jerry Holmberg. I'm the senior blood advisor to the Assistant Secretary of Health and also the Executive Secretary of the Blood Safety and Availability Committee.

We are sort of working against some adverse events today as far as flights being canceled and the ice and snow outside. Some of us that live locally have even stayed downtown last night just so that we could be here. People have asked in the past: Will the committee move forward? Will we have the meeting? And the answer, as far as I'm concerned, will always be yes unless there's really adverse conditions that we cannot meet.

But we're here. The government is open for business, and I can say that there were probably four of us at a meeting yesterday, and when they announced that the government was closed, the four of us wanted to get up and walk out of the room, but we stayed until the end of the meeting. So we are dedicated to making sure that discussions go forward.

Our chairman for today is going to be Dr. Celso Bianco. Dr. Mark Brecher, who is our official chairman, could not get a flight out, and so he sends his regrets. And we will move forward. We have a very jam-packed agenda.

So I would like to take the roll call at the present time. Mark Brecher is absent. Larry Allen, absent. Judy Angelbeck?

DR. ANGELBECK: Present.

DR. HOLMBERG: Celso Bianco?

DR. BIANCO: Present.

DR. HOLMBERG: Gargi Pahuja, absent. John Penner, absent. Dr. Sandler?

DR. SANDLER: Present.

DR. HOLMBERG: Dr. Gomperts?

DR. GOMPERTS: Present.

DR. HOLMBERG: Dr. Haas?

DR. HAAS: Present.

DR. HOLMBERG: Chris Healey?

MR. HEALEY: Present.

DR. HOLMBERG: Dr. Heaton?

DR. HEATON: Present.

DR. HOLMBERG: Dr. Linden, absent. Dr. Sayers, absent. Mark Skinner? Mark is present but not in the room. Okay. John Walsh?

MR. WALSH: Present.

DR. HOLMBERG: Great. Where did that voice come from? Oh, okay. You moved on us, John.

I'll turn the meeting now over to Dr. Bianco.

MS. LIPTON: Could I just list that I'm also present?

DR. HOLMBERG: Oh, I'm sorry.

MS. LIPTON: Unless you don't want me to be.

DR. HOLMBERG: Oh, I guess I didn't--I have to go on down. You have to forgive me. I couldn't take my contacts out last night because I didn't have any solution. So, anyway, Dr. Wong is here being sworn in at the present time. She's a new member. Karen Lipton?

MS. LIPTON: Present.

DR. HOLMBERG: Dr. Epstein?

DR. EPSTEIN: Present.

DR. HOLMBERG: Dr. Klein, absent. Dr. Bowman? Not present. Dr. Kuehnert?

DR. KUEHNERT: Present.

DR. HOLMBERG: And Colonel Sylvester?

COLONEL SYLVESTER: Present.

DR. HOLMBERG: Okay. Thank you.

DR. BIANCO: Well, I think that what I'm going to say expresses the feeling of all members of the committee and Mark. We all want to welcome Jerry as our guide and inspiration here. You mentioned before, Jerry, when we had just a small discussion, that you hit the ground running, and we know why: because you have a long history in transfusion. And it's very nice to have you in our midst. And I think this committee is very, very important, and it's very nice to have you leading it.

I think that the first item that we have is--I think that--what are you planning to do in committee updates?

DR. HOLMBERG: We'll just go forward.

DR. BIANCO: So we go to Don Doddridge, who is going to speak for the Interorganizational Task Force on disasters. Don?

DR. HOLMBERG: Dr. Bianco, if I could just say that I was remiss in not again stressing the ethics, the code of ethics. We all went through that in the first hour that the committee was closed to the public. And so I would also encourage the speakers to identify their affiliation and also the organization that they represent.

MR. DODDRIDGE: My name is Don Doddridge. I am the CEO of Florida Blood Services, and I'm representing the AABB Interorganizational Task Force on Domestic Disasters and Acts of Terrorism.

I would like to thank the committee for allowing me to present the recommendations of the Interorganizational Task Force on Disasters and Acts of Terrorism. We're going to be talking about a national blood reserve today, and we had a working group of the task force which carefully considered a wide range of issues surrounding the establishment of the reserve. Our recommendation will be that this be a private and a public blood reserve. And this

was at the request of this committee that we come forth with a proposal at this time.

Our next slide, please.

I'd like to review the mission of the task force. Our mission is that during times of a disaster, we coordinate the blood inventory management in the U.S., and we also manage donor response and collections in excess of actual need. And at the request of the Blood Safety and Availability Committee, we were tasked to develop a plan for establishing a national blood reserve for disaster response, and that's what our talk will focus on today.

Our task force participants are the Level I members, which are the AABB, the ABC, the ARC, BCA, ASBPO, FDA, CDC, and HHS. And we have our Level II members, and I won't go over all of them. You can read that on the slide. And we had a blood reserve work group, which were organizations whose members have direct experience in the collecting and distributing of blood. And those members were AABB, ABC, ARC, BCA, and the DOD.

What is the purpose of the national blood reserve? A national reserve could serve both the civilian and military needs. On the civilian side, a reserve would be used to augment the decreased supply of blood due to our donor deferrals and product quarantines. It also could be used to meet increased demands related to a health emergency, disasters, or acts of terrorism. On the public--

I mean, on the private side or the governmental side, the reserve could be used to meet military needs for emergencies or so-called short-notice shipments or to reduce reliance on frozen reserves.

When we were looking at what type of reserve is preferable, the task force considered the lessons learned from several real disasters and national exercises, including the embassy bombings in Africa, the Oklahoma bombing, 9/11, local disasters such as floods, hurricanes, and tornadoes, and the recent TOPOFF 2 exercise and military operations.

We also examined several existing models for comparable government-supported reserve operations, and we will be talking about these later on in some later slides, but we looked at the strategic national stockpile for pharmaceuticals, the DOD war reserve materials, vendor-managed inventories, and many other models were also looked at.

We also looked at the major characteristics of our recommended reserves. And the task force recommended that the reserve have these following characteristics: that the reserve be liquid; that it be composed of RBCs, A's, B's, and O's. They also looked at the size: that it be approximately 10,000 units; that it be designated storage sites spread across the country, both public and private; that the reserves be available for shipment within four to

six hours of an emergency; that we rotate the reserve every two weeks; that it be a combination of government and private sector control over the 10,000 units.

One of the issues has been whether it would be a frozen or liquid reserve, and I'd like to go over some of the reasons that we did not choose a frozen reserve. The task force believes that there are simply too many problems associated with maintaining a frozen reserve and, therefore, supports the creation of a liquid reserve. The disadvantages of a frozen reserve include:

The difficulty of assuring that frozen units are in compliance with the frequent changes to the FDA and AABB standards, and we've had recent examples of that, such as NAT testing, West Nile virus, and other issues that have changed what our requirements are for screening donors and also for the testing that's required;

The logistical challenges, such as the slow process of thawing the units; the limited post-thaw shelf life, and the more burdensome storage temperature requirements that limit the agility of a frozen blood reserve. And we also looked at the experience that the military has had with the frozen reserve.

There was also the need to keep frozen reserves current, which means that the stock must be rotated for these units and the units must be identified. The high cost of freezing and thawing units was also taken under

consideration. The military figures suggest that it would be approximately $28.7 million to maintain a frozen reserve of 10,000 units, that the end-cost of providing that thawed unit would be approximately $500 per unit. This cost does not reflect the additional cost of hiring and training personnel to freeze, rotate, or thaw those units.

The task force also looked at would we just do liquid red cells, and at this time we would recommend that the reserve only hold RBCs. Platelets are not easily incorporated into the program due to their five-day shelf life. It may be possible in the future to add other components such as FFP, cryo, and plasma for transfusion to the reserve if these products are needed and/or practical. Most blood centers are able to carry ample reserves of the frozen product, so this is not as much of an issue as with the red cells.

How did we come up with 10,000 units? We believe this is a reasonable number based upon the experiences of the TOPOFF 2 exercise and HHS Readiness exercise conducted last year. It is also the approximate number needed to provide two major metropolitan areas with approximately a three-day supply of blood, which is the average amount of time it would take to collect, process, and distribute additional supplies to replace the inventory.

I want to talk about why the designated storage sites and shipment. The reserve should be held in

designated storage sites across the country, and that would be the DOD and regional blood centers. This configuration will assure that blood is available anywhere in the country on four to six hours' notice, which satisfies the military needs for no-notice or short-notice shipments.

We also recognize the need of the rotation of reserves every two weeks because of the limited shelf life of 42 days on a liquid reserve. The RBCs will rotate out of the reserve every two weeks; thus, the units will be approximately two and a half to three weeks old when distributed, which leaves sufficient time to ensure that they are transfused and sufficient time to accommodate the three-day requirement for processing additional units of blood.

The suggested reserve draws on the strengths of both the private and public sectors. Approximately 2,000 units of blood will be controlled by the government while at the DOD's Armed Services whole blood products laboratories. The additional 8,000 units will be controlled by the private sector and housed in designated regional blood centers.

Why government versus private sector control? The blood housed in the reserve is meant to serve the public's need in the event of an emergency so that the public--the need is public in that case. But it's also important to remember that the source of these donations is uniquely private; that is, individual donors. For this reason, it is

appropriate that the regional blood centers who have established relationships with their donors control most of the units. At the same time, the government investment in this or any other blood reserve is absolutely critical to the success of this project.

The task force looked at existing examples for reserve management options. In deciding the best model for control of the reserve between the public and poverties, we considered a range of similar existing programs. For an example, under the first column, Option 1, the strategic national stockpile, which falls under Option 1, is the government maintains control of the pharmaceutical products it buys and stores.

Under Option 2, the federally managed inventory section of the SNS program operates through private storage of goods that CDC purchases and the vendors rotate through the system.

Under Option 3, which is the private, the private sector maintains primary control of the goods and manages those resources through sharing of information. This is the current model which we operate the Interorganizational Task Force.

Ultimately, the subgroup of the task force decided on creating a hybrid of such models, combining what we believe are the best assets of both the private and public sectors.

The slide that you're looking at illustrates the two parts of the reserve, both the private and the public, as well as how the overall program operates depending on the level of response needed. In times of an emergency, when immediate support is needed, both the public and private parts of the reserve will be called upon to serve a community. That is, 2,000 units housed at the DOD and the 8,000 units housed at designated blood centers throughout the country may be called upon. The dotted line and arrows at the top of the pyramid indicate the fact that units will move between the DOD and the regional blood centers if particular circumstances warrant.

For an example, if the threat level is raised in a particular portion of the country, units may be moved to the centers that can most readily serve that region, such as what we had in the TOPOFF 2, where we moved to the Chicago area and the Seattle area. The bottom of the pyramid represents the need to sustain general support for the blood supply through information exchange, as is currently done through the task force. Our goal is to maintain a five- to seven-day supply of RBCs at all times. And I think to emphasize the importance of the need to sustain general public support for donating blood, if you look at what the blood centers for the past month have been able to keep on their shelves, currently there is probably less than a two- to three-day supply of blood on the shelves. And in many

cases across the country in the past couple of weeks, we were even down to a one- to two-day supply of blood. So we were nowhere near the five- to seven-day supply that has been recommended that blood centers have.

Now for our recommendation. The national blood reserves would move through the reserve system, and this is going to show how it moves through the system. The blood would be collected at the regional blood centers, which would be the source of supply. The blood would then be stored at the federal and private processing centers, 2,000 at the DOD facilities and 8,000 at the designated regional blood centers. In the event of a disaster, the blood would then be available to regional blood centers or government facilities, as illustrated on the right.

The recommended reserve would have the benefits of a federal, private, and would involve real units on the shelf, not a visual--or not a frozen reserve, and be ready to be accessed in the event of a disaster.

On the operational side, the designated regional blood centers and federal depots would be under contract with the government to participate in the reserve. The blood rotating through these centers would be available to the reserve. After two weeks, RBCs would be sold to regional blood centers or federal facilities at a discounted price, reflecting the shorter shelf life remaining on these units.

In summary, the national blood reserve is not just an asset--I guess I've got to hit on the--sorry. Skip the slide here. I'm a little bit--I'll go over this slide first, the cost considerations.

Two thousand units would be at the labs of the DOD. The initial purchase price--and this is just an example--is $225 a unit to establish the reserve. There would be start-up costs of $450,000 for this. There would be no capital investment for refrigeration and facility space on this example. The operational cost to rotate the reserve is $520,000. There would be a 10-percent value per unit lost to the shorter life after processed through the reserve. So, again, the total start-up costs would be $450,000, and the annual costs would be $1,560,000 for the DOD portion or the governmental portion.

On the regional blood centers--that would be 8,000 units--there would be start-up costs, using the same $225 would be $1,800,000, and there would be a capital investment for refrigeration and facility space to store of $340,000. Operational costs would be $1,040,000 and, again, your discount to move the units after their two weeks would be $4,160,000. So the start-up costs for the private side would be $2,140,000 and the annual operating cost of $5,200,000.

Additional costs would be--and in the future could be increased to blood due to inflation and new safety

measures as they come about if we do Chagas disease or other tests that are on the horizon. We also will need to discount--to take the discounted value and test it in the marketplace to see if the concept of discounting and what price that will need to be.

The implementation strategy would be a phased-in approach that lessens the full investment requirement in early stages of the program.

The total anticipated cost is the start-up cost of $2,590,000 and annual cost of $6,760,000.

What are the critical success factors that we will be looking at? It requires the federal support of a national awareness campaign, which we have not given you a figure. That will be a figure that's determined and we're basing it--it could be comparable to the HHS organ and tissue donation campaigns.

We feel like it needs to be a national campaign that is not focused on the reserves. We do not want people thinking they are giving strictly for the reserves, and we do not want the sites that are identified as the collection sites across the country. But in order for this program to work, there has to be a public awareness of the ongoing need for blood, and that would include funding the reserve.

Implementation. The government would approve the concept and funds program. We would use existing resources to fill the first 2,000-unit reserve. Then we would have

the national awareness campaign developed. The government and private sector would develop the contracts to fill the 8,000-unit reserve. The task force and the government would develop policies for authorizing the use of the national blood reserve. It couldn't be just accessed because you had--you know, your mobiles didn't collect as much blood as you were expecting this past week. We would have information processes and tools established to manage the national blood reserve.

The benefits of the national blood reserve draws on existing public and private infrastructures and systems. It forces the commitment to a public campaign, which we've all talked about the ongoing need for the public to increase our donor base. We feel like this is a modest cost. We also feel like it supports the critical infrastructure imperatives and homeland security.

Our recommendation would be that the Advisory Committee on Blood Safety and Availability would endorse the concept of the national blood reserve program with the characteristics recommended by the AABB Interorganizational Task Force on Domestic Disaster and Acts of Terrorism. And we also would recommend that the Assistant Secretary for Health further develop, in cooperation with the private sector, details of such a plan and secure federal funding for this program.

This is an additional slide that just shows you the management structure as we perceive it, and I would like to thank you for allowing me to give this presentation today.

DR. BIANCO: Thank you very much, Don.

We are going to have time for discussion later today, but if there are questions to Don Doddridge about immediate issues, please. Dr. Heaton?

DR. HEATON: I have two questions, Don, one technical and one organizational. There's a general truism that most reserves are Type O rather than across the board, and I would like to hear why the committee believes that an across-the-board reserve would be a priority.

The second question relates to the necessity for amending the emergency supply contracts between ARC, AABB, and ABC and the U.S. Government to provide resupply once the immediate ready-use reserve had been used up. Did the committee consider that as well?

MR. DODDRIDGE: Yes, they did, and on the first, we did consider using strictly O's, but O's, to build up a reserve, there are many times that you can't at least get an initial blood type with the techniques that are out there today. And so we felt like it would be better to get type-specific, and I will call on the members of the subgroup, Karen, if there--

MS. LIPTON: I think the other reason that we focused on that was because if you look at where we really think the need will be, it's going to be to replace blood that's either been quarantined or donors that have been--you know, that they can no longer donate. And so we're not really talking--we don't think that the primary need will actually be in terms of actual usage of the units, but more in replacing supply that's been disrupted. And for that reason, we thought really it was A's, B's, and O's that was a better mix than just O's.

MR. DODDRIDGE: And you're talking--again, the second one was about the existing contracts that already exist. I think this just builds upon that existing system that's already there.

Alan, you're in the audience, I think, and you were on the task force.

MR. ROSS: Yes, Alan Ross, Red Cross and a member of the subgroup of the task force on reserves. That's true, we're not looking to necessarily create a whole new system of existing--or modifying existing contracts, but just to supplement what's already in place.

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: Thank you very much, and I'm sure I speak for the whole committee appreciating the effort that AABB exerted on behalf of this charge from the committee.

I have two questions. Do you have a cost estimate for what would be required to develop the excess collections needed to establish a reserve in the face of current use which kind of keeps our supplies marginal? That's the first question.

And the second is: Was there any consideration of a surcharge cost onto the unit of blood? Because it strikes me that 50 cents per unit, you know, 13 million collections, would approximately cover $6.5 million, which is what you need for the annual costs of rotation.

MR. DODDRIDGE: Okay. The first question, yes, there was some consideration what it would take for a public awareness campaign. I believe for the tissue and organ, they're spending approximately $30 million. On the low end, they've talked up to $10 million. And if anybody from the subgroup would like to further elaborate on any of those discussions? Karen?

MS. LIPTON: I think that's right. We didn't really know what the figure was, but we know--we thought that HHS would be in a better position to know what they spend. So when you talk about what would we do for those initial units, that's what we--if you see in the implementation phase, a national awareness campaign was really critical.

With respect to your second question--

MR. DODDRIDGE: It was the 50-cent surcharge.

MS. LIPTON: You know, I mean, I think, until we fix the reimbursement system, that putting a 50-cent charge, which isn't even going to be reflected for two or three years and then may not even be felt, just doesn't help us. I mean, we know it's not a pass-through. And unless you have a reimbursement system that's a pass-through, adding 50 cents to a unit of blood is not going to get back to the people who are actually doing the job.

DR. BIANCO: Well, thank you, Don. Thank you very much, and hopefully you can stay for a while so you'll be part of the discussions.

Is Dr. Bowman here from CMS?

[No response.]

DR. BIANCO: He is committee representative from CMS, and, unfortunately, he cannot make it. So I think that we can move on and have an update on vCJD and BSE, and we have both Dr. Epstein and then Dr. Lisa Ferguson.

DR. EPSTEIN: Thank you very much. I appreciate this opportunity to update the committee on the recent report of a presumptive case of transfusion transmission of variant CJD in the United Kingdom, and then I will comment on FDA's current thinking on TSE safety of blood and blood products. And then Lisa Ferguson I understand will give a companion talk about the recently reported cases of BSE in the State of Washington.

What I'm going to do in the next few minutes is give you a case description. This information is preliminary because the case has not actually yet been published. I will then go over the negative epidemiological evidence for any association of CJD--that is to say, classic CJD--with blood exposure. Then I will review the evidence suggesting that the blood of humans or animals with transmissible spongiform encephalopathies may be infectious and the basis for an increased concern over variant CJD compared with classic CJD. And then I will summarize the current safeguards for blood products and suggest where we're going with this issue.

I apologize for a busy slide, but for those of you who can't read it, don't worry because I'm going to read it through pretty much for you.

As I noted, this is an unpublished case. However, the information was available from an announcement to the Parliament in the United Kingdom that was made by a high official on the 17th of December, and FDA scientists have followed up with personal communications with the experts in the U.K.

So the story in brief is that, in March of 1996, a clinical healthy young blood donor donated whole blood to the United Kingdom National Blood Service. This antedated the policy on universal leukocyte reduction, which was later implemented, I think, in 1998 in the United Kingdom. And

the unit went into an older surgical patient. There was actually a second unit on a second date of donation that went into a patient, but that patient expired within a short period after his hospitalization.

So then about three years after the donation, this relatively young donor developed signs of variant CJD and later expired and had a confirmed diagnosis of vCJD at autopsy. And then the U.K. had already established a lookback program in which they identified prior transfusion recipients from individuals who later went on to develop variant CJD. And the recipient then was one of 15 such recipients under active surveillance.

Then approximately 6.5 years after the transfusion episode, in December of 2003, the recipient also died, and a postmortem diagnosis was made of a characteristic variant CJD following a characteristic clinical course for variant CJD.

So the question then is: Why does this constitute a case? And I will come back to this issue of the odds of a random occurrence being about 1 in 40,000.

So the key insight here is that transfusion transmission cannot be proved in this case. The reason for that is that the recipient, no less than the donor, is presumed to have been at risk for foodborne exposure to BSE. And also there is no agent-specific marker that could tag a particular infection from any other person's infection so as

to establish linkage, such as we do with genetic variation for HIV, for example. So it can't be proven. That needs to be understood.

However, why is transfusion transmission presumed? Well, first of all, it's been estimated now with a declining epidemic in the U.K.--and I'm going to show you a graph later--that the risk of presentation at the present time of a vCJD case is only about 1 in 40,000. So the random odds of any given recipient of a vCJD donor having this from foodborne exposure is low.

The second is that the recipient is the second eldest known case of vCJD out of a field of about, I think, 143 in the U.K. Now, that doesn't rule out that it's just another elderly case, but it vastly reduces the odds because it's less than a percent have age over 55. As you know, variant CJD characteristically has younger median age at onset and death, and I will show you that later, too.

Then, thirdly, the incubation period from transfusion to onset of disease is compatible with our current thinking about the incubation period of variant CJD in humans, at least as it might relate to a transfusion exposure.

And then, finally, though not compelling one way or the other, the recipient did have the expected polymorphism of methionine/methionine at codon 129 of the normal cellular prion protein.

Now, I will turn to reviewing the epidemiological data that have indicated that risk of CJD transmission by transfusion--that is to say, classic CJD--is most unlikely, if it occurs at all. This will occupy a few slides, and I'm going to try to move a little bit quickly.

First is that there have been no documented episodes of an apparent linkage analogous to the case in the U.K. So there's never been a putative case of transmission.

Secondly, there have been a number of national mortality surveillance studies which have showed no progressive increase in the incidence of CJD, which stays approximately constant at 1 per million per year, with some adjustments for age. That's insightful because we know that blood use has increased over a period of decades. So if it were being transmitted and there was more blood transfusion, we should have seen a corresponding rise, at least over a multi-decade period.

Additionally, looking at persons who have a high frequency of transfusion, including hemophilia, thalassemia, sickle cell, there's not a single case where there's a coincident diagnosis of death due to vCJD--I'm sorry, to classic CJD and a coincident diagnosis of a condition requiring high levels of transfusion. And, in addition, there are no CJD cases reported under age 19, which is significant because we know that a lot of transfusion goes to neonates. And so, you know, based on credible incubation

periods in man, we ought to have seen some younger cases if, in fact, it was being transmitted. Of course, there are caveats for all these things.

Now, in addition, there has been in place a survey conducted through the Hemophilia Treatment Centers, which are nationwide. There has been on clinical diagnosis of CJD in over 12,000 patients through 1998, and an autopsy study was done particularly focusing on hemophilia patients who died with diagnoses of dementia. And, once again, there is not a single histopathological confirmed CJD in over 30 such targeted autopsies.

Additionally, there have been case-control studies which have been negative. A case-control study basically is designed to answer the question whether a history of transfusion is more likely in a CJD case compared to cohort controls.

Now, there's a certain amount of variability in how you select the controls. Should they be hospital controls, for example? And the different studies have used different types of controls--community controls, hospital controls.

However, there are six studies. Several of them were quite large, involving hundreds of patients. They used different methods to reduce bias. They were done in different countries, quite independent of each other, and all of them were negative, showing no apparent increase. In

fact, in some of those studies, as I recollect, there was, in fact, higher point estimates for risk if you did not get transfused than if you did. But, of course, none of the differences was statistically significant.

Additionally, there have been lookback studies similar to those that were done in the U.K. for variant CJD, but on a much larger scale over a period of years for sporadic CJD. And in the U.S., the studies involved, I think, 196 recipients; worldwide, I think it's up to about 600 recipients. And there's no CJD diagnosis in any of these blood components compared with the 15 variant--from 15 CJD donors, and that's in comparison to the report of one out of 15 for vCJD.

And one caveat about these studies, the question is always asked: Well, did the recipients live long enough to get their disease? And so it's noteworthy that in the U.S. study that was conducted jointly by the Red Cross and the CDC in cooperation with the National Blood Donor Resource Center of the AABB, 42 donors lived more than five years after their transfusion without CJD. And then in a similar European study, 13 recipients lived more than ten years and eight lived more than 15 years after their transfusion. There's another variable, which is the duration of time between the donation and the illness in the donor, and that leads to another stratification. But some of these were fairly proximate, within months of onset of

illness in the donor. And as most of you know, I think the progression of disease is much more rapid in classic CJD than variant CJD.

Then a last piece of evidence is that recipients of vaccines who have been followed, more than 38 million children who received the vaccine under five years of age between 1967 and 1986 are now between age 11 and 19, and there was albumin, human albumin in these vaccines. And at least through the end of January '98, which is the last report of the study, there have been no CJD cases in any of these recipients under age 19, as remarked earlier. So it's a second piece of evidence that at least albumin was not transmitting classic CJD.

So that's all the negative evidence. What's the other side of the ledger? And, of course, this is now the basis of concern, which is that some studies in animals and now the first presumptive human case of transfusion-transmitted vCJD have suggested that blood may transmit transmissible spongiform encephalopathies, both in animals and in man. So, as I said, there's the presumptive case in the U.K. and then the experimental data.

Well, first of all, what happens if you take the blood of humans who have classic CJD and you put it into animals? Well, you have mixed results. Studies that were done in primates, including transfusion of whole units into chimpanzees, have all been negative. When blood was put

into rodents generally by the intraperitoneal or the CNS inoculation route, the data are equivocal. Some studies have been positive, some studies have been negative, and they've been fraught with methodological concerns. However, quite definitively, when other human tissue--spleen, liver, lymph nodes--have been put into primates, some of these have been positive and have established our current concept for the distribution of infectivity in the infected human.

What about the animal experimentation, animal to animal? Well, there have been negative experiments in which blood was taken from cows with BSE, sheep with scrapie, and goats with TSE, and where the inoculations were done into rodents. Now, there's a species barrier, and it's thought to represent about 3 logs. So you have to take this with a caveat. Also, when you inoculate a rodent, obviously you can only put in a very small volume, either that or use very, very large numbers of animals, which has sometimes been done. But be that as it may, all those experiments were negative. Similarly, when mink encephalopathy was put into mink, it was negative.

However, when experiments were done in which model TSE agents, including rodent-adapted CJD, scrapie agent, and BSE agent, were put into rodents including transgenic rodents, a number of these models have been positive and consistently so, apparently demonstrating a low TSE-

infective titer in the blood of the order of one to two logs of infectious dose 50 per ml of the original blood.

Additionally, and more recently, the experiment which is now well known done in the U.K. where sheep were fed orally the BSE agent and then blood from those inoculated sheep was transfused into target sheep. There was about a 40-percent transmission rate by transfusion, implying that the BSE agent is blood transmissible, at least in the course of an infection in sheep. That experiment, unfortunately, was never done bovine to bovine. But it does raise the concern of transmissibility of BSE also by transfusions in man, and it's noteworthy that the experiment was also done with natural scrapie sheep, looking at target unaffected sheep, and transfusion also transmitted scrapie by transfusion.

Now, there are a number of arguments that have led to the concept that there may be greater concern over the blood risk from variant CJD compared to classical CJD, and these arguments, of course, were made prior to the presumptive transfusion-transmitted case which we now know.

First of all, it's been established that lymphoid tissues of patients with vCJD contain much more protease-resistant prion protein, which is thought to correlate with infectivity, than do those of patients with the classic forms of CJD, although the infectivity of these various tissues is less clear.

Most recently, Paul Brown at the NIH has shown that there is, in fact, infectivity in lymphoid tissue in classic CJD. Of course, it was well established for spleen, but now we're talking about other lymphatic tissue. However, it's at a much lower level than in variant CJD. And in variant CJD, as I think some of you probably know, there's now surveillance going on with tonsil and appendix because it has been shown that in cases of variant CJD, those tissues are routinely affected, and indeed, some of that has been demonstrated pre-mortem and at least one case out of about a thousand has been found in a routine surveillance in the U.K.

So the implication is that because blood contains lymphoid cells, namely, leukocytes, that blood might be more infectious in variant CJD compared with other forms of CJD. And there was an experiment in rodents on pathogenesis of TSE in which a leukocyte association was shown. Additionally, partition experiments have suggested that in a unit of whole blood half of what infectivity may be there is present in the buffy coat, again confirming a lymphoid association.

Additionally, we know that variant CJD differs from sporadic CJD in its clinical and histopathological features, that the distribution of infectivity, therefore, being different, cannot be--makes us think that the

epidemiology of classic CJD may not be predictive for variant CJD.

And then, ultimately, there's the issue that we've had a lot of experience with classic CJD; there's been a lot of excellent epidemiological work, which I've already summarized for you; but that for variant CJD, we're dealing with a new epidemic where we simply have had less time and there has been less study.

So this is just to highlight for you some of these differences that I've been describing. This shows the florid plaque--a pointer would be great. I don't seem to have one here. Oh, thank you. I should have asked earlier. I'm sorry.

But this shows the florid plaque. These are the large amyloid plaques of transmissible spongiform encephalopathy, and then a high density of surrounding vacuoles which constitute the spongiform change. And pathologic features of this sort are florid in the brains of patients with variant CJD, whereas they are very infrequently seen in other forms of CJD.

And then the clinical course, as you know, is quite different: older mean age in sporadic CJD compared to variant; the presentation of classic CJD is fairly brief, a four-month course to mortality versus 12 months or higher; presentation here with confusion and ataxia versus abnormal behavior or psychiatric presentation as well as early

abnormal sensations; a specific EEG finding in sporadic CJD not seen in variant CJD. They share the consistent feature of methionine/methionine, homozygosity at this codon 129. I've already pointed out the difference with florid amyloid plaques in variant CJD, and there is a very reproducible and highly characteristic difference when biochemical studies are done on the abnormal prion protein, and their glycosylation patterns are quite distinct.

In terms of the worldwide experience with variant CJD, there are currently 143 cases in the United Kingdom. The bulk of remaining cases are in France, with six cases, and then the cases in France and Italy are important to distinguish because they're indigenous. They're not in people who spent any significant time in the U.K. Indeed, those people never left the U.K. That doesn't mean that they didn't get their disease by exposure to U.K. beef because we know that for a significant period of time before 1996, between 5 and 10 percent of the beef in France was sourced from the U.K. So this is a related exposure.

And then there have been several countries--Ireland, U.S., and Canada--that have had cases, but those were all in people who had spent significant time in the U.K.

And this just shows the epidemic curve. This is by date of onset or year of onset. These are just the U.K. cases, but you can see the early indication now of a

declining epidemic, which would be consistent with, we believe, the successful program for control of BSE in animals, coupled with rigorous measures to control safety of the food chain. So hopefully this trend will continue.

The most recent published estimate in 2003 for the ultimate scope of the epidemic is an expectation for only between 183 to 416 ultimate cases, consistent with the concept of a current risk of about 1 in 40,000.

So most of that was really background so that you can now understand the discussion of current safeguards. So I'm going to talk about the safeguards for blood components, and then I'm going to talk about the safeguards for plasma derivatives.

The blood safeguards are based on the concept of minimizing BSE exposure days in the donors, and the effectiveness of these interventions through donor deferral are estimated based on a risk-weighted model, the idea being that if you arbitrarily assign a relative risk of one to the U.K., you can then stratify other BSE exposure based on its magnitude relative to the amount of contaminated beef products in the U.K.

So on that argument, for example, we assigned the risk in France as about 5 percent of the risk in the U.K. based on the estimated relative consumption of U.K. beef in France as well as the relative proportion of variant CJD cases, which has held up over time at about 5 to 6 percent.

So we've undertaken deferrals since 1999, and those were done concurrent with a commitment, well familiar to this committee and to the department representatives, a commitment to monitor the blood supply. That's because this single intervention was estimated to cause a 2-percent donor loss, which at that time was the largest single expected donor loss from any single safety intervention. And we were very concerned about it and could the system handle it.

The donor deferrals initially were focused solely on the U.K., with travel or residence history of more than or equal to six months in a risk period of 1980 through 1996 and/or receipt of bovine insulin sourced in the U.K. after 1980. We also had recommendations for product retrieval if the donor was later discovered to have variant CJD.

Now, we updated this guidance in January of 2002 by adding donor deferrals for exposure to BSE in all parts of Europe. That was based on the emerging knowledge of a wider BSE epidemic consistent with the known fact that contaminated meat and bone meal as animal feed was distributed widely throughout the world, but in particular in countries of Europe.

Additionally, as a further measure to lower risk, we tightened the period of exposure that leads to deferral for persons who were in the U.K. as residents or travelers, moving it from six months to three months. Because of the complexity and expected large impact of these widened

deferrals, we put this forward as a two-phase program which was fully implemented, first phase May of '02, second phase October of '02, and is now, of course, fully implemented.

We estimated that based on risk-weighted exposure days in donors that the risk reduction would be approximately 90 percent and that the estimated cumulative loss would be 7 percent of donors, that representing the 2-percent loss from the 1999 recommendations with an additional estimated 5-percent loss from the 2002 recommendations. And follow-up studies have suggested that those figures probably were roughly correct.

So what are the current deferral recommendations? They are for donors both of whole blood and source plasma: greater than or equal to three months of residence or travel in the U.K. between 1980 through 1996; greater than or equal to five years of residence or travel in any part of Europe; however, for donors of source plasma, this criterion applies only to greater than or equal to five years' residence or travel in France.

Additionally, deferral for greater than or equal to six months exposure on certain U.S. military bases in Europe, those being north of the Alps from 1980 through 1990, or south of the Alps from 1980 through 1996, because at those bases the commissaries and PXs and messes were providing about 35 percent of the beef from sources in the U.K.

We continued the recommendation for deferral for transfusion in the U.K. since 1980, and for history of receipt of bovine insulin sourced in the U.K. after 1980.

Now, the possibility exists of additional safeguards for plasma derivatives based on removal, clearance, or inactivation--although there's really not much inactivation; it's mainly removal--of TSE agents during the course of fractionation and purification. Several plasma derivative manufacturers have demonstrated significant clearance of model TSE agents at a number of steps used in the manufacture of different products. However, there are caveats and questions.

Questions remain how to assess the significance of these data above and beyond the methodological questions which I'll address in a moment. First of all, how should clearance be assayed? Is it sufficient to follow reduction of prion protein, or must one do in vivo assays, such as bioassays in animal models, which are necessarily less sensitive than immunoassays?

How much reduction of infectivity, or prion protein, is "enough" to assume that the products are then safe?

What clearance steps are additive and what clearance steps are not additive? And how much demonstration is required to show that?

And then, even if we can demonstrate independent or so-called orthogonal, perpendicular, non-overlapping steps, how many orthogonal steps should be implemented in a process to call it safe?

Now, that sort of is a tier above methodological challenges--and I don't know why the text is lost. I'll just read that. Some of these questions: First of all, what sources of infectivity should be used? In the animal models, there is the question of different properties of the animals. We know that the distribution of infectivity is not the same, that there are species barriers, and there are precedents where it's hard to find a suitable model, such as hepatitis C. Of course, the ultimate issue is whether there's enough human infectious material to do experiments with a human agent.

Secondly, there's the question of what form of the infectious agent is most relevant to study for blood transmission? It's easiest to get high-titer inocula from brain homogenates of infected animals, but yet the form of the infectivity in the brain homogenate may not be the form of the infectivity that exists in blood.

Now, one can make other preparations: subcellular membrane fragments, purified acellular fibrils, or blood itself, which has very low infectivity. So you could use a natural form of the infectivity, as has been done in some models in rodents and mice, but then you're stuck with the

problem of working with very low titer material when you try to do clearance experiments.

Conversely, you could use an artificial material. You're faced with the caveat of how relevant is that form of infectivity, but then you can do high-level spiking experiments.

And then underneath it all, there's the issue of how sensitive are the assays, and I've mentioned that the bioassays, generally speaking, are insensitive, either because of species barriers or because of other features of the model.

Now, the issue also arises of risk communication because risk communication is a fundamental element of any risk management program. And FDA has been sensitive to this and, therefore, has required that manufacturers have boilerplate labeling regarding the risk of CJD agents, and the concept here is that it will encourage clinicians and patients to focus on balancing the relative risks and benefits of product use and, therefore, to encourage the most appropriate possible use of products.

And the current recommended labeling, which was put forth in our January '02 guidance, states as follows: "Because this product is made from human blood, it may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease agent."

Now, I've also noted that for plasma derivatives, we now have a very substantial body of data on clearance, and in February of last year, we asked our TSE Advisory Committee whether it concurred with FDA considering labeling claims for TSE clearance in plasma derivatives based on specific demonstration of TSE removal during manufacturing of specific products. And the committee has endorsed such a consideration by the FDA, which is now ongoing.

Now, there are a few other cautionary notes. First of all, this is relative risk reduction. It would not be possible to defer all donors who've potentially been exposed to BSE because it would make the supplies of blood and plasma inadequate and unsustainable. So, you know, there's no perfection here. It's relative risk.

Additionally, it needs to be noted that patients with coagulation disorders or primary immune deficiencies have lifelong exposure to their plasma-derived products.

And then in the case of the vCJD epidemic, which we think is diminishing, at least in the U.K., it's not known whether additional presumptive or perhaps someday proven cases will arise. Also, all the known cases to date have only been in people with the methionine/methionine polymorphism in their cellular native prion protein. However, we don't know whether people who are heterozygotes, methionine/valine, or homozygotes, valine/valine, will still develop variant CJD, but with other characteristics. Will

they develop a disease that looks different, or will they simply develop this disease but with a longer incubation period? And bear in mind that kuru, for example, where the neuropathology resembles variant CJD, has had proven incubation periods as long as 40 years. No comments about polymorphisms because they weren't studied in victims of kuru.

DR. EPSTEIN: Now, the FDA also does a number of other things to try to reduce product risks from BSE, we maintain updated lists of bovine materials that are used to make medical products. We encourage manufacturers to eliminate the use of bovine-derived materials in products wherever possible. We have ongoing research on methods to remove and/or inactivate TSE on surfaces. That's focused on the decontamination problem. And we did review what is known about TSE decontamination at the July '03 meeting of the TSE Advisory Committee. And we plan to examine all of our current policies with FDA's TSE Advisory Committee in light of the recent case of presumptive transfusion transmission and the first reported U.S. case of bovine spongiform encephalopathy. That meeting will be taking place February 12th and 13th of this year.

Just to give you a quick tour, the agenda for that meeting will include informational presentations on risk of TSE transmission, particularly the vCJD case in the UK, a comprehensive update on BSE in the U.S. We will then

discuss models for risk-based sourcing of bovine materials and FDA-regulated medical products, and we will discuss current methods to minimize risks of TSE agents in FDA-regulated medical products, not limited to blood products. That will be a broader discussion including vaccines, recombinant therapeutic proteins, tissues, et cetera.

I know that I have run way over my time, but put it this way, Celso, we're just about back on schedule.

[Laughter.]

DR. BIANCO: Thank you, Jay. Thank you very much.

And I didn't mention before that Dr. Epstein is the Director of the Office of Blood Research and Review of CBER, FDA.

His presentation will be followed by one by Dr. Lisa Ferguson. Dr. Ferguson is a Senior Staff Veterinarian from the USDA, and she has been following the BSE epidemic around the world for a good while, and now she's going to look at our own case in Washington. Thank you very much, Dr. Ferguson.

DR. FERGUSON: Yes, thank you. I'm just trying to sort out the technology up here.

I'm glad to be here this morning. It's been an interesting commute for the past few days, but I actually did make it here this morning.

I'm going to go through things fairly quickly, so hopefully I can catch you back up even a bit more on time,

because I'm just going to try and hit the highlights of what we have done with our ongoing investigation in regards to the finding of BSE in the U.S., summarize what actions our colleagues in FSIS have taken, and then a real brief update of perhaps where we see things going in the future.

Let's just run through a pretty quick timeline, and a lot of--if you're looking for a lot more detail on some of these things, you can check on our APHIS website and we do have a lot more detail both in background and in the ongoing investigation.

But all of this started on the 9th of December of last year when what we're now calling the index cow arrived at a slaughter plant in the State of Washington. An error in this slide. It should actually say "sampled" rather than "tested." But we did obtain a sample of the brain stem from this animal as part of our routine ongoing surveillance. She presented as a non-ambulatory animal or a downer animal. That sample was sent to our National Veterinary Services Laboratory in Ames, Iowa.

And on the 23rd of December we announced that we had a presumptive positive BSE result from that sample. We did immediately start an epidemiological investigation and kicked into play our BSE response plan on the 23rd, thereby ruining the Christmas holidays for many of us for forever.

Anyway, on the 25th, Christmas morning, we had confirmation that this actually was BSE positive. That

confirmation was from one of the world reference laboratories for BSE in the United Kingdom.

On the 30th of December our Secretary announced a set of additional safeguards that would be either immediately initiated or would shortly be published as interim rules.

Then on the 12th of January, we did actually publish a declaration of extraordinary emergency. For those of you who aren't familiar with some of the ways we do things at USDA, we did that primarily to release additional quarantine or control authorities if we needed them, also to release some additional funding. We need to do that to get access to additional sources of emergency funds.

So let's go back and provide a bit more meat on that skeleton there. The index cow. This presumptive positive--we called it presumptive based primarily on two tests done at our National Veterinary Services Lab. First of all immunohistochemistry and then also just classic lesions on a histopath slide. This just looked like all of the early cases that they had seen in the UK. I did have a slide that actually showed the immuno test results and this is one of those slides that for those of you who run them, you know, you can hold it up to the light, you don't even have to put it under the scope to see the staining on there. It really was very significant.

However, our response plan did call for confirmation at one of the BSE reference laboratories. So we sent one of our pathologists, on Christmas Eve, to fly over to the UK. Their pathologist very graciously agreed to meet us on Christmas morning, and they looked at the slides and said, "Yes, this is what you've got." So we did announce then that it was confirmed.

This cow was a Holstein cow. Initially we thought she was about 4-1/2-years-old. In the ongoing investigation it's actually confirmed she was about 6-1/2-years-old at the time of slaughter. She was sent to slaughter due to assumed calving complications. She had calved at the end of November and then went down with posterior weakness. As I mentioned earlier, we obtained a sample as part of our routine surveillance because she was non-ambulatory. There were no central nervous system signs observed in this animal. She was what we would call a routine downer.

Trace-back investigation actually determined the cow was born in a herd in Alberta, Canada. Initially we had that inclination, through the investigation of the identification in the records, and that was confirmed by DNA testing, working with our Canadian colleagues. She came into the U.S. as part of a herd dispersal sale in 2001, initially went into a dairy finishing herd in September of 2001, and then had been in that dairy herd since October 2001.

We were then looking for, as part of our epi investigation, animals that could have also possibly been exposed. So based on what we know about BSE, obviously animals that would have been in the same herd as this animal and could have been exposed to the same contaminated feed, but we also cannot completely rule out the possibility of maternal transmission. So we wanted to find the progeny of this animal.

As it turns out she has had four calves over her lifetime, three of these calves born since she came into the U.S. One was a stillborn calf in 2001. She had a heifer calf in 2002. That was still in that index herd in Washington, and then she had had a bull calf, this one that was born right in November, right before she went down.

Now, a very busy slide that gets busier as we go along. This is a graphic representation kind of where we are in the ongoing investigation, also where our Canadian colleagues are in their end of the ongoing investigation, because at this point in time we're running our epidemiological traces on the animals on this side of the border and the Canadians are also running a concurrent investigation, especially on trying to pinpoint is there a known infective feed source and were other animals possibly exposed?

So this would be the 49th parallel here, so the slides in red are the Canadian side of the border, and the

little blue boxes are the American side of the border. This is the birth herd in Calmar, Alberta. This herd was dispersed in August of 2001. The herd owner, due to health issues, decided to just get out of the business and completely disperse their herd. We are in luck that this man maintained very accurate records and kept those even after he dispersed his herd. So we do have access to a significant number of records.

There were 82 animals out of this dispersal sale that were certified for export to the U.S. One of these animals did not come in, so there are 81 animals that came into the U.S. in September 2001. These are the animals that we are trying to track down.

I won't go through all of this detail here. It's become a very complicated web of investigations with cattle dealers and animals moving through sales and entertaining records. So it's been quite a challenge. I will give our field people a significant amount of credit that they have been able to find as many animals as they have.

This is a summary of the animals that we have found, what we are terming "at-risk" animals. The assumption is "at-risk" means just one of these 81 animals from the herd in Canada. We recognize that scientifically, if we had some more information on feed exposure, perhaps we could narrow that down and further define some animals that

might be higher risk, but we're just going after all of the 81.

So one of the 81 obviously was the positive cow, the index case. 9 were in the herd, the index herd in Mabton, Washington. You can see these numbers of other herds where we have confirmed that some of these animals are.

Now, if you notice over here, obviously 131 animals euthanized is a much higher number than 9 confirmed as part of the 81, and this is due to the fact that as part of this investigation some of these animals have either lost identification or identification methods have been replaced. You remove one tag, you put in another tag, and not all of the identification is always recorded on all the records. So it's sometimes a challenge to say, yes, I know that that cow is the one. So if we cannot completely rule out the possibility that an animal in this herd could not be one of the 81 that we're looking for, we're just going ahead and paying for those, euthanizing them and disposing of them appropriately. So that's why you see sometimes these higher numbers. That's because although we knew that in this 131 there were definitely 9 of them that were part of the Canadian index herd, we couldn't pinpoint specifically which ones they were.

Then the little asterisk out here just means those are the herds where we have taken the animals that we

needed, we have done some clean-up, we have gotten negative test results back on these animals and we have released the hold order on these facilities.

Our colleagues in FSIS have taken some actions. On Christmas Eve they actually announced a Class II voluntary recall of meat produced at this slaughter facility. Class II voluntarily recall essentially means that they do not believe that there is a significant public health risk, but they are taking this as a precautionary--or out of an abundance of caution is the term that we've overused at the Department.

They went for meat from all of the animals that were slaughtered at that facility on the same day. This is a very small slaughterhouse which only involved about 20 animals, so a little bit more than 10,000 pounds. This product actually went--wasn't distributed directly from the slaughterhouse--went to a couple of intermediate places and actually then even some more sort of tertiary places beyond then, but had been distributed to several states.

On the 30th of December we did announce a set of safeguards that would go into place. A significant number of these were for our colleagues in Food Safety Inspection Service. All of these were published as interim rules on the 12th of January. What these are, we immediately--and this actually went into effect upon the Secretary's announcement. It prohibited non-ambulatory, disabled cattle

from being used in the human food chain. In the interim rule actually we've also then prohibited specific risk materials or SRMs. Those are also prohibited in human food.

We have instituted additional process controls on advanced meat recovery processes to help prevent nervous system tissue from being incorporated into product that could be labeled as meat, and you cannot use AMR processes on skull or vertebral column of animals greater than 30 months of age.

Another interim rule prohibited the air-injected stunning of cattle. This is actually a rule that's been in the works for quite some time, and we finally got the go-ahead to publish this. This is not to say that this type of a process has actually been in use in the U.S. over the past couple of years. Most of the industry has stopped using air-injected stunning, but we've gone ahead and published that rule to formally prohibit it. Then we have also formally prohibited mechanically-separated meat from the human food chain.

FSIS also published a notice that if for some reason we at APHIS take a sample from an animal that is presented for human consumption, the carcass of that animal will not receive an "inspected and passed" stamp until negative test results come back.

Also for APHIS we made a commitment to implement a verifiable system of national animal identification.

Let me talk a bit about safeguards that we have done in the past and also our surveillance program and some challenges that we might see in our surveillance in the future. I apologize that I lost the numbers on my slide here, but these are the total numbers of samples that we have examined in our surveillance program since 1990. These are actually on a fiscal year basis. If you're just looking for numbers, in 2002 that was 19,990 sample. Last year in FY 2003 slightly more than 20,500 samples. During the first quarter of FY 2004 we've looked at about 8,150 samples.

Our surveillance has continued to be targeted at the high risk population where we think we would be most likely to find the disease if it is present. And if you look at both this case that we found and the case that the Canadians found in May of 2003, both of these were in downer or non-ambulatory animals. So this is a significant population. Experience in Europe also shows this is a good population to sample. So we've been targeting those animals since 1994. This is one of the challenges that we will face. We had easy access to those animals as they were presented at slaughter plants. We are working with the industries and the animal disposal industries to maintain access to those animals, to keep that part of our surveillance up.

We're also targeting dead stock. These are animals that die on a farm for unexplained reasons, usually

after some long, drawn-out nonresponsive illness. We do work with field central nervous system cases, on-farm suspects. We work with a series of veterinary diagnostic labs as they examine neurological cases. They have worked with our pathologists through the NBSL, are looking at those samples in the same way, so they'll report their data to us. We work with the public health labs. As they get rabies-negative samples, they will forward those to us.

And then we also work with our colleagues on the inspection floor in a slaughter plant. If they condemn an animal on antemortem inspection for central nervous system signs or other, what we call antemortem condemns. If an animal is moribund, is emaciated, they will go ahead and call us and we will go out and get a sample from those animals.

I did not bring a slide that shows the breakdown of these different categories. I apologize for that. If you think back on that previous slide that I had--let's look at last year's data--with approximately 20,500 samples total, 16,500 of those were from downer animals or non-ambulatory animals, about 3,000 of those were from dead stock, and that leaves about 1,000 more or less that were CNS, all of these other categories. So a significant proportion of our surveillance has been non-ambulatory animals.

We have tried to target our surveillance goals sufficient that we would find one case per one million adult cattle at a 95 percent confidence interval. I'm sure everybody here knows, as you play with statistics a bit more, you can get different goals and different numbers. For the past couple of years our estimate of our targeted high-risk population was based on an estimate of the number of non-ambulatory animals that are out there. We did this through a survey that we did with the American Association of Bovine Practitioners, and came up with an estimate of 195,000 non-ambulatory animals, either on the farm, presented at slaughter, whatever, in the U.S. in a given year. So we use that as our targeted high-risk population for our calculations. When you use that and run that calculation you get a goal of 12,500 samples to do surveillance at this level.

This past fall, especially in response to the first case in North America, the finding in Canada in May, we decided to do a broader estimate of our targeted high-risk population, and came up with a total of 600,000. These would include dead stock on farms, many of these other FSIS condemnation figures. We feel like this is probably a too broad estimate. Folks in Europe generally say about one percent of your adult cattle population will be in this targeted high-risk population, so that would be 450,000.

We came up with 600,000. We recognize there's probably significant overlap, but we'd rather err on the side of caution than on the other side. So when you run that same formula again you come up with a goal of 40,000 samples in a year. Actually, the exact number is 38,600 and some, but we just boosted it up to 40,000. So that's the goal that we were looking at going into the start of a fiscal year. That is at least still our goal for now. There are a lot of ongoing discussions about surveillance approaches, what we feel like surveillance should do and also what access we're going to have to different parts of the population. But I think at the very least our surveillance will at least stick at that level.

I believe I've probably run over my time, so that's all the high points of our ongoing BSE investigation. Thank you.

DR. BIANCO: Thank you very much, Dr. Ferguson. We are on time, but I think we have time for one or two question from the Committee for clarification.

Dr. Heaton?

DR. HEATON: Since the original precipitating cause is most likely to be contaminated feed, I have two specific questions. Has the Agency taken steps to assure the application of import controls on feed material that does not conform to U.S. regulations, and to recall material

that has already been imported that may not conform to U.S. regulations?

DR. FERGUSON: I could go on for quite some time about our previous import standards, but I'll try and really be to the point. We have had import restrictions in place since 1989 that prohibited the import of live ruminants, and most ruminant products including any type of rendered protein product or anything that might contain a rendered protein product from countries that either identified native cases of BSE or that we assume to be at high risk for BSE. We have not been significant importers of rendered product with a couple of exceptions. Actually, we're net exporters.

Now, there has been a significant amount of trade both in cattle and in feed throughout North America. When Canada identified their case in May, we did impose those same restrictions on Canada. We are working with the Canadians as they're trying to really do a fine pinpoint on was there a specific feed lot that got contaminated and how in Alberta? As they come up with more information on that investigation, we'll take that info from there and do what we need to do, either tracing other animals--it's obviously very difficult to go back and trace feed from 8 years ago, but if that can be done, we would at least attempt to do it.

DR. HEATON: Was any of the material from this animal rendered and transferred into the U.S. feed supply?

DR. FERGUSON: Yes, actually, that's a good point, and I unfortunately dropped that slide out. Our colleagues in FDA did a significant part of this investigation, looking for feed and any type of rendered material. There was product from this animal's carcass that did go into the rendering supply. FDA was able to find that. None of that product went into either domestic or international distribution. On the West Coast a lot of those renderers, their primary distribution is through the export market to Asia. But all of that product was stopped. It was held and is in the process of being destroyed.

DR. BIANCO: Dr. Gomperts.

DR. GOMPERTS: What are the current policies, regulations and proposed thinking around the animal feed situation and the potential for incorporate of rendering materials into the feed supply?

DR. FERGUSON: Let me make sure I understand your question. Are you asking was there potential for anything from this specific animal to get into the animal feed supply?

DR. GOMPERTS: No. The general policies around rendering animal material into the feed supply.

DR. FERGUSON: Okay. I make one big caveat her and clarify a significant point. The feed regulations in the U.S. are done under FDA's authority, not under USDA's

authority, so I'll be speaking on behalf of my FDA colleagues.

We have had a mammalian to ruminant feed ban in place in the U.S. since August of 1997. That feed ban did have certain exemptions in it. FDA has worked very hard, and the compliance figures that they report actually are very good. They have done increasing numbers of inspections over the past several years. At this point in time, as they report it, they have a greater than 99 percent compliance figure based on those inspections.

Earlier this week, actually Monday evening, they did make an announcement that there would be some changes done to that feed ban, primarily removing some of the existing exemptions, and one of those probably of interest to this Committee, would be the feeding of blood products. Previously there was an exemption in the feed ban that would allow blood products to be fed back to ruminants, so that will be removed; also the plate waste exemption.

They will also prohibit the feeding of poultry litter to ruminants, and then will require the use of dedicated facilities. So if you're using--if a facility is producing feed that contains nonprohibited material, they can only use nonprohibited material. If they're using prohibited material, that's all they can do.

DR. BIANCO: Mark? That will be the last question.

DR. SKINNER: I think it's a simple question. Which agency, the FDA or the USDA, has regulatory authority over and would to the surveillance testing for herds that are used for source material that go into plasma products?

DR. FERGUSON: There's no such thing as a simple quick question, is there?

Well, I don't know that there's a good answer for that question. We as APHIS have authority over animal health issues, and if there are disease control, disease eradication programs, that's generally done under our authority.

Now, if that is a specific herd that wants to provide product for a specific market or under specific guidance from--let's say FDA established a set of guidelines to define a free herd, would probably be done under a combination, but that would have to be worked out. It would most likely be FDA that would set up those guidelines, but we'd have to work with them, and I'm going to get Jay to help me out.

DR. EPSTEIN: In the review of license applications, we do require that the manufacturers tell us where the sourcing goes on. What we currently requires is that they meet the USDA defined criteria for an acceptable material for import, which as Lisa explained, is based on defining and BSE country and defining all sorts of bovine materials that are barred from import. There are certain

exceptions to things that can be imported. I think tallow and blood, milk, a few others.

DR. FERGUSON: Yeah, hides and skins, those types of things.

DR. EPSTEIN: Hides and skins, right. So, the current standard then is that sourcing must be done in compliance with USDA import policies. Now, part of the issue that we'll be discussing with the TSE Advisory Committee is what other models should we consider in regard to safe sourcing? But there is not currently a model of specific pathogen-free herd that is applied to TSE. The authorities in Europe, recognizing the spread of BSE, the attempts of many countries to control it, and the fact that good surveillance in some countries have shown presence of BSE only at very low levels, as is true in the U.S., there's an emerging concept, not yet policy anywhere, that perhaps one could move to a set of criteria establishing a safe herd.

So, for example, you know, records of the feeds that were used, no history of use of potentially contaminated feed, full identification and traceability of animals, absence of BSE with adequate surveillance, et cetera.

But we aren't there yet in terms of a policy. So the current policy is that they can only source in compliance with the USDA import policy.

DR. BIANCO: Thank you very much, Dr. Ferguson. Thank you, Dr. Epstein.

I think this is an introduction and an invitation for an interested party to attend the TSE meeting on February 12 and 13.

We now will move into the major topic of our 22nd meeting of the Committee, that is, the role of government in the national blood supply, (whole blood and plasma/plasma fraction) both in daily medical/surgical use and local/national disaster.

I have the pleasure to invite our keynote speaker, Dr. Sidney Wolfe, that is Director of Public Citizen's Health Research Group, to give his presentation.

Dr. Wolfe is a researcher and an activist. He graduated from the Case-Western Medical School, and he has been with the National Institutes of Health, and in recent years has academic appointments both at Case-Western and at Johns Hopkins.

Dr. Wolfe, thank you for coming.

DR. WOLFE: Thank you. A short, three-stop subway trip for me as opposed to Lisa and other people had to struggle much more, including many of you.

I'm very pleased to be asked to talk about this. Unlike Dr. Ferguson and Dr. Epstein, I will not be speaking about transmissible spongiform encephalopathy, not because I'm not interested in it. I've been on FDA's Advisory

Committee for I guess most of the last 6 or 7 years on this topic, and I'm a consultant at the meeting coming up in a couple weeks.

But I'm going to just talk more broadly about the issue of blood safety, blood product safety, and supply from the perspective of someone who has done research. Actually, the part of NIH I was in, we took care of patients with classic hemophilia and I remember having to transfuse large numbers of units of cryoprecipitated Factor VIII and so forth, so I've done some of those kinds of things.

But our group for the last 32 years since I started with Mr. Nader, has really attempted to monitor the FDA from the standpoint of the public, and this has become our view of the relationship between the government patients, the public generally, in the case of people who aren't necessarily patients yet but have some possibility of being exposed to blood or food or blood products when they become patients and the industry. And it really has to do with the balance of power between the government on one hand, the industry, and patients. This is portrayed as an equilateral triangle and it really isn't. Sometimes the government is much closer, appropriately so, to the corner of the patients and sometimes inappropriately so, it's much closer to the corner of industry. In those circumstances we have tried, with some success over the years, to get drugs that are too dangerous off the market or other products, to

warn people about hazards of various products, mostly FDA regulated, although we do a certain amount of work in the occupational health area as well.

Industry is sort of half obscured on the bottom, but that is not the intention of this slide. This is an example of circumstances in which we believe the government has properly aligned itself as much as is necessary with patients and has taken on the industry. In this case, the industry of blood and blood products, blood collection and so forth. This is an FDA inspection of the American Red Cross Headquarters completed almost four years ago, and these were the findings: deficient quarantine system to prevent release of unsuitable products; improper release of CMV position blood products; donors being associated with incorrect histories; inadequate oversight of system problems; failure to follow manufacturer's test kit for an HIV antigen test; lack of timeliness in addressing problems. I'll focus on that one because in the case of blood or blood supply, timeliness is a very, very important element.

Now, the history of this, as many of you know, goes back 15 or more years when the FDA was finding the Red Cross not to be complying with laws and regulations. Eventually a consent decree was signed in 1993 and it was being regularly violated, and at one point in the last couple years the FDA asked for the Red Cross to be held in contempt of court for violating a consent decree. I'll just

add anecdotally that there are a large number of companies or organizations such as ARC who have at one point in the last 10 years been involved in consent decrees with the FDA. I think that in many cases those have been very helpful in terms of resolving problems and some of the terms of these have ended for some of these companies or organizations. That is not the case with the Red Cross.

This is later. Now, about a year plus ago, a year and a half ago, inspection of ARC Headquarters failed to do an adequate investigation following the death from hepatitis B of a patient who had received two units of red blood cells manufactured by ARC. 134 suspected post-transfusion hepatitis cases across all of the Red Cross regions for the period mentioned there were not investigated because the cases involved more than 10 donors, the idea being that the policy as established by the Red Cross was that if there were more than 10 donors it was too complicated to go back and figure out what had happened, which really doesn't make any sense. It is more complicated, but lots of things that you've heard this morning are far more complicated than that, and probably have less risk than some of these kinds of circumstances.

The Quality Assurance Officer in the National Testing Laboratory stated there was a culture to hide problems. This is an organization that supplies half of the blood in this country. Another employee, "Reported fearing

retaliation if she was seen reporting the problem to the supervisor." Staff interviewed "verified they found documents which were changed and their initials had been forged in the changed documents."

These are data which I culled from inspections and documents that were filed in the court here in the District of Columbia in the context of this consent decree and the attempt to get a contempt citation against the Red Cross, and these are just the recalls, as in unsuitable blood product recalls, per year starting back in '88, and you can see they've gone up enormously. You can say, well, there is better detection. It may not necessarily be that there are more unsuitable blood products than there were back in '88, but in fact there are more being recalled. This to me is at the very least an example of the government doing its job or pushing the Red Cross in this case to do its job.

This, more recently, a few months ago, is a letter from Lee Bowers, who's been heavily involved in this because the Baltimore District Office is the one that does the inspection of the national headquarters. Consent decree requires that ARC investigate, correct and prevent all--my underlining--problems. Yet ARC's standard operating procedure clearly ignored that requirement, instead only requiring investigation of certain problems. This is again from this letter. "Because of the egregious failure to comply with the decree, FDA is assessing an $8,500 per diem

fine for the period June 6, 2003 through August." Total amount is $518,000.

This is under the terms of the consent decree and now the arrangement worked out to avoid contempt of court was paying $10,000 a day, but because there was a new director of ARC they gave them a 15 percent reduction for those days.

This now is on the side of donation. As you all know as well or better than I, the whole system of blood involves collection, processing, storing, distributing and so forth. And this is a case, very recently--this was adjudicated, this was not settled--a 32-year-old Virginia blood donor suffered an ulnar nerve injury and permanent pain because of negligence by a blood technician. And it turned out that this blood technician had been recently hired by the Red Cross, and with the knowledge of the Red Cross had been fired--I mean the Red Cross knew that the technician had been fired from a previous job that involved phlebotomy because of "inability to follow procedures," not the kind of background that should lead to the hiring of someone to do this kind of thing.

Shifting over to another consent decree involving other products, this is with Abbott in 1999, concerned 300 diagnostic products that Abbott manufactures, ranging from tests used to ensure the safety of donated blood to tests that detect heart attacks. The consent decree to settle the

issue was undertaken because Abbott did not correct the problems, very similar to the familiar over a long period of time of the Red Cross, despite 6 years of government inspections and warnings. There was a $100 million fine.

Here now is the triangle shifted a little bit, in which case the industry and the government are, at least in our view, were acting too close, and it had to do with the shipment of a large amount of Factor VIII contaminated with HIV back in the '80s. And this is a statement attributed to former FDA official, Harry Meyer, who was then head of the Bureau of Biologics, the predecessor agency to CBER, 15 months after the U.S. approval of Cutter's safe heat-treated Factor VIII, and the quote here from this memo: Although the FDA could revoke the approval of non-heat-treated Factor VIII--now, they approved heat-treated Factor VIII but did not revoke the approval of the non-heat-treated. Meyer did not want any attention paid to the fact that the FDA had allowed the situation to continue for so long, and would like the issue quietly solved without alerting the congress, the medical community and the public. In the absence of those kinds of alerts to a number of countries ranging from Asia, I think somewhere in South America as well, shipped out were lots of Factor VIII contaminated with HIV in many cases. The actual number is not known. Probably between 50 and 100 at least cases of HIV occurred. A negligent bit of FDA action. I mean the negligence primarily is on the part

of the companies that continued selling this, but FDA allowed it and tried to keep it quiet.

This is from an article which I will show a couple other quotes from. It's an interesting article from Modern Health Care, which is a magazine mainly for the health industry, for hospitals and lots of others. This article was published in I think July 8th of 2002. And they're really looking at the response of America's Blood Centers on one hand and the Red Cross to September 11th. Two blood suppliers took two radically different strategies.

Within one day of the attacks ABC Blood Centers reported their coffers were full and urged volunteers to make an appointment for a later date. Red Cross Centers refused to turn donors away, insisting whatever was not used would be frozen. Eventually reports circulated that were correct up to a point--they may have been slightly exaggerated but the concept was correct--that the Red Cross was forced to throw away some blood.

These are data from a presentation made at the TSE Advisory Committee in the summer of 2002, and the blips are just total units that were outdated, and you can see, not surprisingly, that there is a big blip around November/December as the period of time that blood can be stored and expired, and there was a lot of outdated blood. This is surveillance from hospitals.

This now is from Peter Page who's the, I guess, medical research director of the Red Cross, and this is a presentation he made at the same meeting that the slide I just showed was put forth. I point this out because in the past, and hopefully not in the future, the Red Cross has pressed the panic button and made it appear that various kinds of efforts such as the quarantine on people who had been in UK or Europe would so undermine the blood supply that there would be a shortage, although ironically, after having said that, they then came up with a policy that was even more restrictive than the FDA's, and I'm not sure there was evidence that it was necessary. But at least at this point Dr. Page is saying, when anticipated and planned for, new donor referral criteria can be accommodated by increased donor recruitment efforts. After the increase in deferrals, there's a culling and the deferral rate drops. Part of that is because of self censorship, as in people who believe they're in these categories and are aware of them will not turn up at the blood donation facilities. More regular volunteer blood donations continue to be needed to prevent seasonal shortages.

One of the topics that we've discussed several times at our TSE Advisory Committee is why there is a summer slump. Every year there's a summer slump. It's not a surprise to anyone, and the question is why isn't something being done about it? And there are some suggestions been

put forth, but I'm not sure that at this point one could say there's not going to be a summer slump. We figured out what to do about it.

This is again a statement from Dr. Page at that meeting in 2002: In Europe the number of volunteer whole blood donations per 100,000 population is much higher than it is in the United States. I think that is generally agreed upon, and that within in the United States it's higher in rural areas than it is in urban. Just doing a little Medline search on this topic, I found this paper published 10 years ago almost. High prevalence of blood donation among Greek citizens. And this is a random sample--I don't know whether it was phone book or what, but a random sample of 809 people in the blood donation age from the Greater Athens area in Greece. 40.8 percent of them donated blood. The figure you hear here is 5 percent per year, but the prevalence is obviously higher, but I don't believe it is anywhere near that high. Blood donation was correlated with gender, place of birth, occupation and knowledge about donation.

So someone has done a multiple regression analysis to figure out there, even though they are doing better than we are, what factors count.

This again is from the same article in Modern Health Care, the title of which is interesting, namely, Blood Rhetoric Exceeds Supply, a slightly nasty title, but

the article really addressed this. And they used as their example to humanize this issue, a bus crash east of Dallas, killing 5 and injuring 36 others. The day afterwards the hometown from which the bus had come found an eager list of people lining up--a group of people lining up to donate blood. 100 people donated blood. But then the word got out that there was a regional shortage necessitating the importation of 140 additional units of blood.

The hospital where many of these children, as it turns out, were taken care of was interviewed by the reporter who did this story in Modern Health Care, and she said, "This is one of the worst accidents we've ever seen, but it had a negligible effect on the hospital's blood supply." This is a smaller version of some of things that happened on September 11th or after September 11th.

This is just referring to the summer slump and this was their way of describing the summer slump. "Every summer assures there are mosquitoes at the New Jersey shore and long lines at Disneyland, blood banks throughout the country experience a severe, albeit predictable, downturn in inventories. The perfunctory pleas for more donors go out."

This is just finally--so hopefully there are some questions I can try and answer--my recommendations. FDA must continue to lead--and I think it's done a very good job, although I have the conflict of interests of being on one of its advisory committees. I think that in this area--

I would not say the same thing in prescription drugs where we have pushed for many to be taken off the market with some success, but in this area FDA has to continue to lead, which it has, the effort towards evidence-based trust in the collection, processing, storing and distribution of blood and blood components. The need for government regulation over both the not-for-profit and for-profit sectors of this industry has never been greater.

In closing, I am unabashedly an optimist. I think things will work out. Thank you.

DR. BIANCO: Thank you very much, Dr. Wolfe.

DR. WOLFE: I'll be glad to try and take any questions on what I've said or other things that you think I might know something about, or whatever.

DR. BIANCO: Any member of the Committee would like to ask Dr. Wolfe a question? Dr. Heaton.

DR. HEATON: Is your committee proposing any changes in the current regulatory oversight in terms of blood safety or availability?

DR. WOLFE: Well, the meeting that Dr. Epstein talked about as in the 12th and 13th, are going to discuss things like that. We have not, I think probably because of the storm and everything, received the package of information that will be read carefully by me and everyone else on the Advisory Committee to see what the situation is. I mean the only comment I can make without having gotten

that information, is that I think that some of the moves or changes announced by FDA a couple days ago, which Dr. Ferguson mentioned briefly, namely not feeding blood, not using scraps and so forth, and other things along those lines are certainly a good beginning, and it may be that nothing else is added.

I think what's going to be revisited, according to the agenda that Dr. Epstein put up, is whether or not the previous decisions that we on that committee have made concerning things that are made out of cows, ranging from gel used in vaccines to a number of other things, whether those still hold. Does the case for--I mean there are two precipitating events. One is the blood transfusion case in the United Kingdom. The other is the Canadian cow that drifted down to this country and became an American cow, without citizenship we think, but--and do these two things change the recommendations?

I mean my general view--and again I have not seen the data--is that when the recommendations were made back a number of years ago for deferring blood donors, they were made in a worst-case, as it should have been, scenario, and I do not think at this point that it will be necessary to change that element of deferring blood donors even more because now someone in the UK has actually gotten variant CJD from a blood transfusion as far as we can tell. And there will be a more detailed presentation of what happened

with that case at the meeting. But I think that the FDA has notched up a few more levels, appropriately, on Monday, and I wait to see what further information we will get. That's not meaning to sound evasive, but as you all know, you have to look at the data first.

Any other questions?

DR. BIANCO: Maybe I'll ask a question, Dr. Wolfe. The theme of our discussion is the role of government in the national blood supply. I heard that you are optimistic, and I also saw your different triangles showing the different relationships between government and industry. Do you think that this relationship has to change? Do you think that the government should act knowing that there will be a summer slump, slumping collections in the summer of 2004?

DR. WOLFE: Yes. I think the--I mean the idea of the triangle, and the more favorable one, the isosceles triangle with the government being close to the patients--and the FDA is indeed part of the public health service--and its primary function is to protect the public health. There are products that it reviews and helps design studies for and so forth, so it does have a approval or at least product consideration process.

But I think that when over and over something like the summer slump comes up, it is incumbent upon the government--I mean I was pleased but not surprised that this Advisory Committee this afternoon is inviting people from

other countries, the countries which as described by the head of the Red Cross, seem to do a better job recruiting blood donors than we do. And it is the role of the government to organize a meeting such as this or to have TSE Advisory Committee meetings, and to push in the area of research if nothing else. I mean I think that if research would yield--which I suspect research is far less expensive than the penalties paid for the dereliction of legal responsibilities by the ARC--research would probably come up if people were serious about doing it, with some ways of avoiding the summer slump, with some ways generally of avoiding the screams that lead unfortunately to not only the bad publicity of throwing blood away, but just sort of having people say, "Well, the next time they call for something I'm going to have to take into consideration that they threw some blood away last time."

So, yes, I think it is the role of the government defined broadly. Your Advisory Committee, certainly the FDA, not just the TSE Advisory Committee, but the issue of blood goes far beyond just TSE, to lead the way in doing the kind of research that will lead to better collection processes. You could sort of say why do blood organizations that have certain amount of resources. They are not-for-profit, as you know, but why aren't they doing some of that? And certainly they are doing some, but whatever has been done hasn't worked because we still have, as sure as

mosquitoes, a summer slump every year, and there's just no reason for it, but it's not the only slump of the year.

There are also some slumps that are associated with other kinds of problems such as bad weather and whatever else. When there is bad weather it is difficult to donate blood. That is not a big surprise to anyone. It's sort of the winter, or at least winter storm slump. So, yes, I think there is a very strong role for the government to fund, research and then assist in whatever way it can, that the organizations that it is regulating carry it out. I mean there is no reason why as part of the oversight by the Department of HHS, FDA in this case, over the blood industry, whether it's blood or blood products, they can't put in some kind of guidance, if not regulation having to do with avoiding the slumps.

Jay, you want to respond to that at all?

DR. EPSTEIN: Reserves might be one answer.

No, I think that the government has been involved under the Blood Action Plan. Since November '99 there has been an element to monitor and increase the blood supply, and that's been a multi-faceted effort which led to workshops on best practices in donor recruitment. It led to workshops on best use and appropriate use of donor incentives. There have been some efforts to reexamine the donor standards to see if we couldn't remove any outdated standards. That's sort of a long-term effort. There's also

been the initiative to streamline the donor interview process, which certainly facilitates recruitment and retention of particularly repeat donors, and that is an activity that is coming to fruition.

But I think that what you're asking for is sort of more of a global look and a bird's eye view and to see if we can't be more strategic than we have been, and I think that's part of what's open for discussion at this meeting of the Advisory Committee.

But I think it is important to recognize that government has been aware of this problem, that we have been regarding availability as a safety concern for public health, and that we have been attempting actions that could improve the situation.

DR. WOLFE: I read the summary of the meeting in 2000 that you referred to where a number of people from around the country came and sort of said, this is what worked for us to improve. And then also, I guess, a year, year and a half ago, at one of out Transmissible Spongiform Encephalopathy Advisory Committee meetings, someone from New York City Health Department--I think you were at this meeting--pointed out that they had found very successful the issue of tying in driver registration, driver license re-registration with--not you can't get your license renewed unless you give blood--but at least encouraging people, using that predictable, again, encounter between people, a

large proportion of the population, to stimulate blood donation. And it worked.

Again, I don't know if anyone else has done it, so there are a number of best practices, and I was not saying that the FDA hasn't done anything. I think that once some of the best practice are delineated and some of the variables as delineated in Greece, and I'm sure that some work has been done in this country, then it's time to say, these are the kinds of things that you really need to do rather than just sort of talking about the predictable repetitive summer slump and so forth. I mean there's no reason why, if the data are as good as the physician from the New York Health Department told us they were, this connection with driver licensing re-registration couldn't be done other places.

So part of my optimism comes from the idea that there are lots of good examples of things that work, and I'm always unhappily surprised why they don't get disseminated more quickly and more completely.

Thank you again very much for inviting me.

DR. BIANCO: Thank you very much.

And this is an opportunity for a 12-minute break, and we are going to reassemble here at 11:25.

[Recess.]

DR. BIANCO: All right. I would ask that everybody take their seats so we can proceed.

Well, first, I'm pleased to say that some more of our members have arrived, despite the weather. I see Dr. Penner, I see Dr. Sayers, and I know that Dr. Bowman is here too.

Our next presentation will be from the official historian of blood banking, Dr. Paul Schmidt, who has been in this field for many, many years and is going to try to enlighten us in relation to the historical review of the U.S. blood policy and lessons learned from the American Blood Commission that happened in the '70s.

Welcome, Dr. Schmidt. Thank you.

DR. SCHMIDT: Thank you, Celso. I am affiliated with Florida Blood Services, but I don't represent anybody here but myself. So I can speak like it is, as I see it anyway.

I'll be starting at a time when--because my presentation is on, really on politics and not on science. When blood was big time on the national political scene, the Secretary of Health was Elliott Richardson, who you may remember was involved in the Nixon legal things as Attorney General.

Casper Weinberger succeeded him, who is still remembered by many people, and we got the president of the United States involved. And it was, it was big time, and I'm afraid to say, honestly, as a private citizen that it was different from nowadays, when you don't even have an

assistant secretary for Health. In fact, you've only had one for about seven months out of this term, and you're not likely to get one before the election.

So we're talking about a different political time. And the background was, at this time, the Red Cross had a little less of the national supply. The CCBC used to be called--I'm sorry--America's Blood Centers used to be called the Centers for Community--the Council of Community Blood Centers, but essentially it's the same outfit. They were still using some paid donors, and then you had about 15 percent in commercial blood.

We go on through an episode that people seem to have forgotten when the Free Trade Commission ruled against the voluntary blood banks and said you can't conspire against the commercial people at the hospitals, and the state has passed things called blood shield laws that we'll come back to. And federal licensing was by NIH, in its old laboratories, the Division of Biologic Standards, and the FDA was not involved. In fact, when I came to NIH, in 1954, I was taught to learn over and over again, "Blood is not a drug, blood is not a drug. Keep it that way. Don't let the FDA in because blood is us."

It was the founding laboratory for NIH was the original laboratory that had the licensing authority years earlier. Well, the situation in the 1960s was this. At NIH, we got blood from the lowest bidder because you had

open-heart surgery beginning, and there was a sudden need in the country for a lot of blood. The average usage was 20 units per case. And the incidence after commercial blood this time, if you survived your open-heart surgery, you had a 51-percent chance of getting hepatitis. Now, this was, you know, a pretty good hospital, and you can imagine how it was in the recent of the country.

Then, the HBSAG studies came along, and if you got hepatitis B-positive blood in that period, and you survived your surgery, you had a 61-percent chance of getting hepatitis. It finally came down to studies of what could happen if you got rid of this, and that was driven down to 7 percent, even with the early studies. So, obviously, hepatitis was a at least partially soluble problem. And think ahead about something we'll come back to called HIV later on.

It was obvious the Red Cross blood was from volunteers. So, in the overall picture, it had to be better. And there was an action plan put together by the AFL and the CIO. They called it the action plan, and presented it, and they were going to--this is just one of the many enmities over the year, but it's sort of typical of what we're talking about. They offered to recruit blood for the non-AABB community blood centers, and they involved the CIO-AFL, and the hookers were they wanted to have the local community blood centers release all of their finances, and

they wanted to have them pay the Red Cross for recruiting the donors for them. Well, that didn't go very well.

But then there was a book published by a man by the name of Titmus called, "A Gift Relationship." Titmus was an Englishman, and he blasted the U.S. system, and he was criticized in the U.K. as being a poor sociologist and a poor economist. Nevertheless, this is the sort of book that was reviewed in the New York Times and every major thing in the country.

There was a program at the time, something like "60 Minutes," which showed Red Cross blood being poured down the drain, and then there was a California Congressman, who introduced the National Blood Bank Act in Congress, jumped onto this. There were 40 bills produced, put into current session. At the same time, something else was happening, get more involvement, and that is the Apollo Space program was winding down and the White House was saying we've got to find jobs for all of these people. That's happened again since then.

And the, without getting into that, let me say that, internally in NIH, the National Heart and Lung Institute decided it would like to be the National Heart, and Lung and Blood Institute. So they came up with initiatives. And I guess what's currently the rest of what we call DHEW, which is now HHS--I have to deal with two sets of initials, and I have to translate them, in my mind--but,

anyway, they had an idea for National Blood Demonstration Centers.

The response at NIH was a meeting in the NIH Director's Office--I have my notes--December 16, 1971, how are we going to keep out the FDA, retain authority of the biologics and save our Division of Biologic Standards, which was in trouble because of the Cutter vaccine, et cetera, and a task force was formed to write the national blood policy, which is what I'm coming to.

There were five people. I was NIH. There were two from the licensing agency, the Division of Biologic Standards, and two interns, and the direction from NIH was don't write a national blood program, write a policy. And by January, the task force had already produced a document calling for a policy which eventually became the national blood policy, based on supply, quality, cost, demand. We prepared option papers for the President. And in Nixon's health message, the beginning of '72, the New York Times said the only thing he said in it that was important was blood is a unique national resource, and we ought to do something about it.

Well, DHHS already knew what to do about it. The problem was how to do something about it at that time. And they got into big difficulties. A few months later, Secretary Richardson took the regulatory authority away from NIH and gave it to the FDA. In a compromise before a Senate

committee, the only person at NIH who knew about it was the Director of NIH, who had been told the day before--it was news to him--and that's why this whole story is, this is Washington politics in the most, but that's what happened.

Now, not too long after that, the Director of NIH resigned over political interference, not just this, but the fact that Senator Fritz Mondale got blood put in, it now became the National Heart, Lung and Blood Institute, and Senator Kennedy had gotten Congress to say the Director of NCI is a presidential appointment. And Marston said, "Hey, wait a minute. I thought I was running NIH, and now I'm out of it," and I guess the Director has been out of it since then. But this was all background stuff.

By this time, we were into Secretary Weinberger, who hadn't moved yet onto Defense or the Iran-Contra scandal. He was still dealing with our health. And he announced that there would be a government policy, and what he stated was the four original ideas: Supply, quality, accessibility and efficiency was what was going to be or they had--downtown, as we used to call it, changed our term of costs to accessibility, which bears a relationship.

So he called a conference which was held the same year.

That's already done this. Some kind person put this together for me much beyond my electronic capability.

[Laughter.]

DR. SCHMIDT: But he called a conference, and I'm sorry Sid Wolfe is gone because I did go down to him a little after this time and tried to get him involved, but he had many other things on his mind. And the representative at that conference was the Consumer Federation of America, and she said, "We've got a lot of health care problems in this country, and let's start with blood, and if you don't solve it, then we'll get legislation from Congress to fix it."

There was a very good assistant secretary of Health at the same conference who said, "Wait a minute. I hear what you're saying, but we'll fix it. Don't go to Congress."

The AMA was there, a very good blood banker, pathologist was president-elect, and he said, "Wait a minute. Wait a minute. Neither of you fix it. We will fix it." And out of this comes what I'm going to talk about the next step, which is the American Blood Commission. Let's see, it came soon after.

One of my electronic problems is the next one because I have listed here the 10 points that were in the Federal Register for the national blood policy, and, oh, it did come out right. I had a disk which--okay.

So the 10 points were this. And I've put up above the source of the national blood policy. There's been a lot of talk about it. I don't know how many people have ever

read it, but it's available, like all federal documents. If you're considering doing something, you ought to make it available to your Committee here and fiddle around with it and not take somebody else's word as to what's in the national blood policy. Certainly, don't take my word.

But it was to eliminate commercial;

Get data on plasma pheresis, which was just beginning then;

Get data on blood banking;

Support something called resource sharing, which came out finally as regionalization, which I'm going to come back to later;

There should be public accounting of charges;

We should support professional training;

And apply the full regulatory authority of the U.S. Government to controlling what's going on, meaning, "Hey, NIH, tough. Give it to the FDA--we gave it to the FDA, and they're going to really straighten things out";

We should support basic and applied research. That's always good. Nobody ever complains about that except when it comes down to money;

And at the time, there was big talk about something called national health insurance for all blood service costs;

And then, finally, we're going to implement this national blood policy by we're going to do it or legislation

is going to do it or regulation if you fail. So you guys better get along and do this otherwise the government will do it for you.

And it took some months, of course, but the following year, they published an implementation plan for comment in, again, in the Federal Register, and that plan has been put together by the AMA and everybody else in hurried meetings in Chicago, and this was to establish the American Blood Commission. So the ABC, from here on in, is the American Blood Commission, which only died about 10 years ago, and not America's Blood Centers.

And some very unusual language, which I'm hearing some more of today. It said in there that this was going to be a partnership, a federal government partnership with the private sector. I think that's very favorable. And remember this was also a Republican administration, and you had partnerships with the private sector. Instead of just telling go out and do it, you did it in a partnership.

Well, what were the goals of the American Blood Commission? For this part, I relied very heavily on John Millan, who eventually became president of the ABC and watched the ship sink and still believes that it shouldn't have sunk, and we have communicated on this recently. But just getting these actually from the Federal Register, this was their basic goal, which sort of incorporates the 10 items: efficient, safe, high quality, from voluntary donors,

is to be a private organization of 40 organizations. Trouble, trouble, trouble, trouble. And the major idea was to bring consumer groups together with blood collection agencies, and they could sit and talk, and nobody could kind of do anything about it.

They're supposed to meet regularly and sit and talk, and of course that will solve all problems.

You see I have sort of a biased view on some of these things, having sat on the ABC for some while.

They did establish these four task forces: Commonality, which did work out, this is, hey, let's get something similar among all of these organizations about bags, and how much you're going to collect, is it 450 or 480, and all of this stuff;

And Blood Data, which was a very usable task force and which existed in different forms, even after the American Blood Commission died;

And Regionalization, which was a disaster because I was on a little group that went around the country, and we'd go to some place in Tennessee, Wyoming, et cetera, and try and get everybody together and say, "Hey, you guys out here, you've got to have a region of your own and change the system. Change your business practices, and do it for the good of the country, and do it for the good of the whole region, and we kind of don't care if your bottom line goes out because that's the thing you should do."

In Florida, we had the Florida Regional Association of Blood Service Units. And we're nice guys who can get along with everybody else, but we didn't regionalize anything any more than it already was, which were local geography, economics, et cetera. The problem was they were all financed, at this time--I have an error there--the National Heart, Lung and Blood Institute, but they didn't finance the Task Force on Donor Recruitment, so that area was kind of left out.

Then, this is kind of what happened. And what happened was the, as I said, the Task Force on Blood Data worked very well. Donor Recruitment sat around and talked. There wasn't anything to do more than talk. You all should give blood. And Regionalization failed, and there weren't any consumers involved in the Regionalization Task Force. Commonality worked very well. It really did work very well.

But meanwhile there was the usual infighting going on between the ARC and the ARB, ABB, voluntary replacement donors, voluntary, et cetera, et cetera, et cetera. We've been doing this for 30 years. Why should we change now? And actually the commercial blood banks filed lawsuits to attempt to dissolve the ABC, which could not get a congressional charter.

And at least one big piece of the whole picture was solved not by the ABC, but it was solved very simply by the FDA, which came in there, and it said, because it

couldn't control many other things, but it could control the labels on the blood, and it said you must label the blood as either paid or voluntary. You can't ban it or anything like that, but you've got to label it. And once that label is on there, then, because health care is a function of the states, almost all of the states came along with some of the things they already have, and that is they put in laws, the so-called blood shield laws, which pointed out again that they could pass laws saying, "Doctor, you can't use blood in this state that says `paid' on it unless nothing else is available."

And so it was up to the doctor to say, "I don't want to use that blood," because that's the way health care is delivered, and that's what really put the paid blood almost out of business. It persisted for many years after that, when there wasn't something else, but the so-called blood shield laws worked, and part of those things, which got America, this country, through the AIDS crisis was many took the attitude in the states, which was in the national blood policy, that the provision of blood is not the sale, but a service.

And I was unhappy to hear you talk before, Don, about selling the blood in the reserve. And the difference is, if you sell a bag of blood which contains a virus or a mouse, just like if Coca-Cola sells a can with a mouse in it, there's an implied warrantee for products you sell.

Well, almost all of the states, without exception--it's worded differently--have a blood shield law. So, if you provide a unit of blood which has the virus of HIV in it, you're not subject to implied warrantee. Now, this is what, in my view, enabled American to do as best as it could and get--we still have the same system which works--I'll come back to that later--after the AIDS crisis, which other countries don't have.

You know, the Red Cross went bankrupt in Canada, paying things off all over the country. The French director of the national blood program went to jail for two years, and the Prime Minister was indicted. I hope you will hear some of the true stories later on today from people from other countries. They've all been written up and documented, but the problem was a national blood program, and essentially you didn't do right by us. Now, I'm not saying that we've got a big loophole out of implied warrantee, but that's why most of the HIV suits fail.

By 1989, nobody was paying attention to the American Blood Commission, and it was a very expensive place to go talk. I mean, it was big dues to join this thing, which had a budget of $120,000 a year just for talking. And I have an error here, and I wanted to separate out the last three: AABB, ARC and CCBC left.

What I wanted to say was the consumer groups, well, like all other consumer groups, I'm sorry, as a former

member of the bureaucracy, but all other consumer groups--I'm sorry Sid is not here--you know, hey, it's our issue. We've got two groups in this American--representing kidney patients. They're interested in blood for kidney patients, and there are two of them, and they don't talk to each other. There were two groups in there who take care of hemophilia patients. They weren't talking to each other, but they were only interested in hemophilia.

You had the Cooley's anemia group, which was the strongest and most intelligent one. Well, Cooley's anemia is a sort of an ethnic disease, and they had a few Congressmen. And NHLBI did a national study to find out how many patients the United States really needed transfusions for thalassemia. There weren't enough for the heart-bloodests to get interested. They got very interested in sickle cell, but Cooley's was not a big problem. But this was one of the big consumer groups, you see, that the various blood organizations were coming to talk to.

Well, just about that time, and I'll go into the tough details of what happened, but the AABB, the ARC and the CCBC left this group, and so who was talking to who, and, without funding, the ABC really just became inactive in 1992. John Millan told me some years back it's still a corporation someplace, but who knows.

I'm down to the point of personal opinions. All of the others really were facts, and they've been written,

and documented, and I'll give you a reference for that. My thesis is--and this is in direct opposition to I'm sure several, maybe many, people in the room and some on your Committee here--is that a national blood policy worked, and the American Blood Commission failed. And the policy worked because it did not operate a national blood program.

Obviously, the Red Cross wanted it to be a national blood program and to be put in charge, and all of these individual community blood centers had themselves grown up, many, during World War II, and they weren't going to give up the very good job that they did.

So this was not a single national blood program, as crashed in many countries, certainly with the AIDS problem, but it was a national blood policy. And this policy was carried out locally in pluralistic society. The citizens of Seattle or Fort Worth or Tampa-St. Petersburg had established something years ago, and they were not under central control out of Washington, and they decided they had to do it right.

But really the Commission failed because, as I said before, the consumers they were talking to, there was no Consumer Federation of America, there was no Sid's, you know, overall look. It was, hey, we're in this for us, and the government is supposed to take care of everybody else, I guess. There were no cancer society, but that's too complex. Anyway.

But, of course, cost issues were never resolved. It got worse with zero tolerance for risk. Now, I know that we're working in a different economy, but what we published on this in the mid '70s were figures which were about--for the cost of blood--which were about 10 percent of what they are now, not just doubled, but--

Now, as I said before, the U.S. blood system survived AIDS because of the blood shield laws. It could have viruses in the bag or even mice, I guess, without breaking the law, and so they survived. Now, what's now, and this is the dangerous part because I was invited to make comments on the future, not just the history.

Voluntary blood donation succeeds when it's encouraged, and I suggested something for years something nobody seems to like, which is an income tax credit. It gets the right people to donate blood, but it's got all of the problems of everybody is entitled to every credit, whether they are healthy enough or too old or too young, but it certainly would be a solution to much voluntary blood donation.

And then finally this last point. You could regulate the blood service, but you can't utilize, you can't regulate the practice of medicine. Now, here's a great point I disagree with some of the members of the Committee who tell me about the problems in their city, where they never have enough blood. They have to cancel surgery at

times, and they have to reschedule everything, and what is the problem? It's a problem that nobody has ever looked at, nobody has any control of, and I've never heard discussed before a group like this.

And the problem is the hospitals, which are the retail outlets for this and, of course, like everybody else in the retail business, if you hear you have to have your knee surgery done, and somebody tells you, well, don't go to that hospital, they never have enough blood, it's very bad for business. And so each hospital, like each supermarket, loaded with all of the vegetables you might want, which are also perishable, and you never go out back and look at the garbage trucks as they go by, I'm not saying blood gets thrown out, but I'm saying the distribution system, each hospital has the responsibility to the hospital administrator to make sure there's enough of everything, and all you've got to do is get enough blood to have enough blood.

Well, if there isn't enough blood in the system, then there's Hospital A, send it to Hospital B--wait a minute--not if there's going to be a shortage coming up. Does the blood supplier move it from Hospital A to Hospital B? Maybe, if they could control it.

Does the blood supplier take it from Hospital A back and move it to Hospital B themselves? Well, sometimes, but maybe the Hospital A won't get full credit for it or if

it outdates maybe they'll get full credit for it or if there are several blood suppliers, and they're competing with each other, and there are several hospitals in town, and they're all partially supplied, then those hospitals don't get much attention to what's available nationally as if we're your sole supplier, we'll take better care of you if you stop getting stuff from those people.

Now, that's the true world out there. I mean, there has to be a nonprofit. They have to have boards of directors who themselves run companies, and know it's competition--not competition for profit, but competition for doing a good job. Now, let me assure you that America's Blood Centers does not know what's going on out there because you don't get this information from your members, and the American Red Cross doesn't know what those chapter managers are doing and how they are keeping things working pretty well. Do they really take it back and give it full credit? Do they really move it back and forth? And who knows? I don't think we know here.

Now, what's the involvement of the federal government in this? Zero.

What can the FDA do about this? Zero.

Where are the hospital representatives here of the whole organization who care? Do they ever come to these meetings? No. The answer, you know, to a wonderful supply

is we got to regulate properly those blood suppliers and make sure that everything is all right.

Does anybody worry about the retailers? Again, I'm not saying it outdates this way, but it very often isn't in the right place at the right time. So, if there is some sort of national business that can be moved around, you might be moving it around into a place where they're trying to put somebody else out of business, and maybe they're trying to get new hospitals and things like that.

So it's this distribution business which is the problem of your supply, your hospital. As I say, I don't see anybody here who can talk back to that point in the whole big area, to talk back to that point in your city, but who knows what the whole big area is.

The last point I want to make is a little plug, and I asked Don Doddridge if I could do this. And I came to Tampa 30 years ago, and they had this great system where Southwest Florida Blood Bank, it did what we then called the cross-matching for all of the hospitals. There were no hospital pathologists involved. You dealt with the patient.

They sent us the blood sample, we typed it, et cetera, and provided the blood to the hospital which billed the patient and paid us. So there was no, there's no middle man. There was no, you know, we were a multiple retailer. And I didn't put that system in. It existed for 30 years, and I kept it going for 60 years, and it's still going now

in a huge area of the West Coast of Florida, which has all of the problems that you hear why we have shortages.

There's large ethnic populations. It's got many, many, many older people. It's got some of the largest cardiac surgery centers in the country, and these people are coming down and spending the winter, but their loyalties are still in Wisconsin and New Jersey, and they and their families donate blood up there. They're just visiting us for their health. I mean, all of the problems are there.

And I checked with John--I don't know if I asked if I could quote you--but in his recollection--first of all, when I was involved, we never cancelled surgery, and we never had to reschedule surgery. That was 16 years. And Don tells me it's been two years since they had to fiddle a little with schedules--no cancellations. The blood is, there are people involved centrally. It's much easier now because of computerization, and the stuff goes out, and the blood belongs to the central collector of the blood. It deals with the patients.

And I know this has been picked up in different parts of the country. It's existed in a different way in a centralized system in Seattle for years. We're now, it's just not so much centralized as regionalized, which you can do better with computers, but you see it's going to do a lot of hospital--hospital pathologists out of jobs, and what are they going to do? And hospital administrators don't believe

it. They don't believe it's going to work, and they haven't heard from the American Hospital Association that it might work.

So, as I said, I took opportunity of the fact that I don't represent anybody, I don't represent Florida Blood Services, and I just have knowledge of how that works and some of the other things. I hope you will accept the fact that these are personal opinions, but I've seen systems evolve. I think the national blood policy did its job, and the problem was it, again, didn't address, as nobody still is all of these years later, the question of distribution.

Now, can this Committee do something about it? I don't know. You don't have an assistant secretary for Health. So you have the FDA, and you have the people who deal with Medicare, Medicaid, et cetera, and they all report to one man up there who seems to be pretty busy, and as long as we don't get into too much trouble and never get invited back, he says, "You know, I've had enough of this job. I'm quitting next November." It's not his field, and if you think about the disaster of distribution that happened after September 11th, in which the first party that said anything that morning was the American Red Cross, which said, "We have 50,000 units of blood available to send to New York." That was their press release. It came out in less than an hour. "You don't have to collect a lot of blood. There's no need for this. We can send it." I mean, they didn't put

it that strongly, but don't panic, which was followed an hour later by the Secretary of HHS, who essentially said, "Everybody go out and donate blood."

So we collected a half-a-million units of blood, and in those two cities, we used 69 units, for those patients, all of which was on the shelf before we did it.

So you need a system, and if I can comment later on the national blood reserve, who's going to control it? Who's going to decide what comes out of that system? Is it going to be DOD? Is it going to be HHS? Is it going to be the Red Cross, which after September 11th said, "Well, we got involved because we're responsible for the national blood supply." I mean, who is going to be responsible for that reserve?

So I snuck in some comments that didn't belong, but thank you very much.

DR. BIANCO: Thank you very much, Paul, for all the challenges. We are going to hold the questions for a discussion period, and one of the reasons is that Dr. Graham Sher from Canada has a kind of a tight flight schedule. So we are going to hear Dr. Sher, who is the CEO of Canadian Blood Services. They are responsible for about 75 percent of the blood supply, and he's going to tell us about Canada. And then we'll go to our schedule.

DR. SHER: Thank you very much, Dr. Bianco. And, first, thank you to the Committee for the invitation to

present here to give you some perspectives of managing the blood supply system in Canada and also thank you to Karen Lipton for letting me hijack the agenda marginally so I can make my flight out of here.

So what I'm going to do in the time allotted to me is give you a brief overview of the blood supply system in Canada and try to focus, to the extent possible, on the questions that the Committee has set before itself and to give you perhaps the perspective of another jurisdiction and a somewhat different type of operating the blood system from the system or systems you have in the U.S.

So, firstly, to give you a little bit of background in terms of Canadian blood services, we are a national independent not-for-profit charitable organization, and I will use the word "national" even though we don't operate in the Province of Quebec because those of you who are familiar with Canadian politics know that we have national outside of Quebec, national within Quebec and national including everybody, but we are national, excluding the Province of Quebec.

The mandate given to Canadian Blood Services is fairly simple--to manage a safe, secure and accessible supply of blood and blood products for all Canadians, and I stress the words there "secure" and "accessible" because that is very much the discussion before the Committee today.

The core functions given to us as an organization are obviously everything to do with donor recruitment, collection, manufacturing, testing and distribution, and I'm going to come to the discussion on distribution in a minute to pick up on the former speaker's comments around distribution. And we also have a very clear mandate in related functions of research, education, utilization, management and diagnostic services, in addition to which we manage the unrelated bone marrow donor registry for the country.

That shows you the distribution of the blood centers that make up Canadian Blood Services. Again, the Province of Quebec is in gray, and that shows you where Hema-Quebec operates as an independent blood system. But for the rest of the country, we are a sole monopoly provider of all services, and we meet all of the needs of the hospitals in that part of the country.

CBS or Canadian Blood Services is funded through the provincial and territorial governments who are responsible for the administration of health care in the country. Our annual operating budget for the fiscal year just ending is about 830 million Canadian dollars or about 650 million U.S. dollars. But as I'll show you in a minute, that includes the acquisition of all plasma derivatives, recombinant proteins and related products, in addition to operating the fresh blood component supply.

There are about 4,700 employees, and I will come back to the sort of point around being arm's length from government, but we are not a government agency, although funded out of provincial and territorial government coffers.

We have a donor base of about 1.4 million donors, of whom we regard about 450,000 as being active, meaning they donated at least twice in the last year. We collect about 900,000 units annually, and we provide blood to every single institution in the country outside of Quebec, which has 855 hospitals or health care facilities.

That's a very quick snapshot of the whole blood collection pattern in Canada over the last five-and-a-half years that CBS has been operating the system, and the important point to reflect on this slide is, when we took over from the Canadian Red Cross, we inherited a decade-long decline in blood collections as a consequence of the tainted blood scandal in Canada.

A little bit of historical background to sort of lead up to the existence of a blood policy in Canada today. Between 1947 and 1998, ownership and operation of the blood system was under the jurisdiction of the Canadian Red Cross Society, operating in a truly national manner, including Quebec.

Initially, in the early years, it was entirely funded out of Red Cross funds. Charitable funds raised by the Canadian Red Cross Society went to operate the blood

supply system, but from the mid '70s on, government began to assume a greater contribution to the financial operation of the blood system because it became far more expensive than could be managed by charitable donations alone, and by the early 1980s, it was fully funded by provincial and territorial governments through a variety of interfering bureaucratic institutions known as the Canadian Blood Committee, and subsequently the Canadian Blood Agency.

It's well-known to everyone in this room, I'm sure, what happened in Canada in the early to mid '90s, culminating in the Krever Commission of Inquiry on the blood system in Canada, which was struck in late 1993, and Justice Krever spent about four years doing a very thorough and detailed exploration about what was going wrong and what had gone wrong in terms of decisionmaking in the Canadian blood system, and he issued his report in November of 1997, almost immediately following which both the federal as well as the provincial and territorial governments got together and declared that they needed to create a new national blood authority and no longer would entrust the operation of the blood system to the Canadian Red Cross Society, feeling that the damage done had been too far and too extensive, and that as an organization, the Red Cross did not have the wherewithal to extricate itself from the legacy that is really shown by a selection of many, many hundreds, if not thousands, of editorial cartoons and other material which

characterized the years of scandal and failure in Canada, as I say, culminating in the Krever Commission of Inquiry.

And so when the ministers who are responsible for managing all aspects of health care in the country got together, and I will use the term F/P/T, meaning both the federal level as well as the provincial and territorial level of governments in Canada, they got together in an unusual display of cooperation between multiple levels of government and signed what is called a Memorandum of Understanding in late 1997, essentially outlining very clearly the roles and responsibilities for what would become the new national blood system in Canada, including the functions and structure of a national blood authority and providing the governance framework for all aspects of the system.

And, again, to just point out the peccadilloes of Canadian politics at this point, it was contemplated in late '97 that Quebec would be part of that, but Quebec seized the opportunity to add to their secessionist war chest and decided to go their own way.

So the issue of a national blood policy in Canada, well, if one really takes it to its strictest definition, there is no national blood policy per se. The Parliament in Canada has tried, but failed, on several occasions to enact a federal act in which blood would be incorporated for a

national blood policy, but has failed repeatedly to pull that through.

However, the MOU that I will refer to--the Memorandum of Understanding--signed by all levels of government in 1997, has become the de facto national blood policy for that part of the country, excluding Quebec, which is not bound by the MOU. And so I would say that we have a national blood policy inasmuch as we have to operate under it, even though it is not enshrined in an act of Parliament.

The principles of the policy are shown on this slide here, and they are somewhat "motherhood," but essentially are the framework in which we have to operate: The safety of the blood supply is paramount; a fully integrated approach is essential; accountabilities must be clear; and the renewed blood system must be transparent. Again, a lot of this deriving from the reports of Krever and some of the failings of the previous blood system.

There had been, in 1989, again, an attempt to create a national blood policy, a series of what are now called ministerial principles put together, and these have essentially been incorporated into the MOU that still acts as our guiding framework, and some of these are repetitive of the previous four. But just quickly to speak to them:

The system must be voluntary. There was no contemplation and never has been a paid system in Canada;

National self-sufficiency in blood and plasma collection should be encouraged, and I'll come back to that point;

Adequacy and security of supply should be encouraged;

Safety should be paramount;

Here is an important distinction from the U.S.--gratuity of blood, blood components and plasma fractions to recipients must be maintained. In other words, all recipients of blood products and derivatives receive them free of charge--hence, our global operating budget;

The system should be cost efficient and cost effective;

And it should be a national system.

So, in the MOU, the specific functions ascribed to the operator are spelled out in some detail. As I said earlier, it has to be a fully integrated system, responsible for all aspects from donor recruitment and management through to collection testing, processing, storage, distribution and managing the inventory.

In support of those core functions that are obviously common to all blood operators, we were given a clear mandate in terms of guideline setting, policy determination, coordinating a national program of research and development, surveillance, monitoring, public education,

professional education, health risk management related to the practice of transfusion medicine.

So, in that framework, then, of a quasi-national blood policy in Canada, I want to begin to answer some of the specific questions that the Committee has addressed and try to give you a perspective of what happens in Canada.

The role of governments really are split across two levels. In Canada, the federal government has a singular role with respect to the blood system through the federal Minister of Health, assuming, essentially, regulatory oversight over the blood system. The regulator is part of the Department of Health at the federal government, and their responsibility is for inspection, compliance, regulation, auditing, et cetera. Aside from that, they have no function with respect to the operation of the blood supply, and I'll come back to that in a little bit more detail.

The provincial and territorial governments, though, are responsible as corporate members or shareholders of the blood system for fully funding it, and again I'll spell out their details in a little bit more detail in the next couple of slides.

So we viewed the Ministers of Health in the provinces and territories as--the term that is legally used in Canada--the corporate members of the blood system, but essentially the "shareholders" of the corporation. But it's

very important to stress again here that the MOU does articulate quite clearly that CBS is not an agency of government and must operate at arm's length from its corporate members. And this, of course, gets us into some fascinating debates at budget time, since our budgets derive from government, that the day before budget approval, it's a thalidomide arm; the day after budget approval, it becomes a rubber arm again, and it sort of varies throughout the year.

But we are essentially arm's length from government and not bound by government practices and government bureaucracy.

They are, as ministers, responsible for the overall expenditure of public funds by CBS in delivering the blood program. They do have a role in appointing the board of directors, but once the board is appointed, it is independent and autonomous of government. And as I say, governments do approve our annual budget and flow us the budget at the beginning of the fiscal year, after which we are free to operate the blood system.

In addition to acting as corporate members of the blood system, they are responsible for the administration of the rest of health care in the provinces and territories. All health care is a provincial jurisdiction in Canada, not a federal jurisdiction. They have a role, therefore, in public health, in disease surveillance and monitoring, not

only related to blood-borne pathogens, but to general disease monitoring and surveillance as well.

There is a role for the federal government in surveillance and epidemiology, but the rest foundation health care, as I say, is delivered at the provincial level.

The federal government, as I said earlier, acts as the regulator of the blood system. The mandate for that derives out of the Food and Drugs Act, in which blood is classified as a drug, under Schedule D of the Food and Drugs Act in Canada, and so we are regulated, as a pharmaceutical manufacturer, under the Food and Drugs Act, and the Minister of Health derives his or her power from that federal act there.

And as I said, there is a small role for the federal government with respect to the blood supply system in only as much as they provide us an annual grant of $5 million every year for research and development, but outside of that, they have absolutely no funding or operational responsibility for the blood system.

So I would, then, characterize that in Canada as saying there is no direct role--and I stress the word "direct role"--played by either the federal or provincial levels of government in managing the supply of fresh components or plasma derivatives in the country.

That being said, certainly, the federal government, through Health Canada, does have ongoing

dialogue with us as the operator of the blood system in terms of the impact of the blood supply of any directives under review, and obviously there are many examples one could cite here, but perhaps the one that others have talked to and is the most recent in many people's minds is, as contemplation was being put to the evolution of the variant CJD deferral policies, very clearly the regulator had significant concerns around supply issues and relied on the operator to provide them with an understanding of the impact on supply.

The provincial and territorial governments, while not having a direct influence over how we manage the supply, have an indirect, but rather large, influence through the delivery of health care services.

And the example I cite here is, if a provincial government is going to invest in a new health care institution, as has been their bent over the last many years, for example, new cancer treatment centers or cardiac surgery centers, they frequently do so without any understanding of or consultation with the blood supply or understanding of the implications of meeting the blood supply in that region. And we're continuing to work with the provincial governments for them to recognize that investments in health care have implications on the need for blood to meet those delivery of health care services.

The distinction I want to draw to the Committee's attention in Canada, with respect to fresh components and plasma derivatives, is an important one for us in Canada. We are, and have always been, 100-percent self-sufficient in terms of cellular components, but have not, for the longest time, been self-sufficient in terms of plasma for fractionation into plasma derivatives.

Today, in Canada, only about 20 percent of the needs of intravenous immune globulin are met by plasma collected in Canada, either source plasma or recovered plasma from our whole blood collections. About 100 percent of albumin needs are met from Canadian plasma. And in Canada, Factor VIII for hemophilia care has been 100-percent recombinant for the better part of a decade now.

So, essentially, our needs for plasma for fractionation are driven by the utilization of IVIG in Canada. So about 80 percent of our IVIG distributed in the country comes from the commercial market and is not custom fractionated out of plasma collected in Canada.

And this is one of the stark ironies of the Canadian blood system today, in that it has been a ministerial principle in the country for close to 20 years now that there should be plasma self-sufficiency. Canada should be fully self-sufficient in terms of sourcing its plasma for contract fractionation or custom fractionation,

but there has been a reluctance on the part of government to invest in that plasma acquisition.

I also put the last point on the slide just to point out to the Committee that in Canada we don't have a large-scale fractionation facility.

There is a company well-known to many of you, I'm sure, by the name of Cangene, which is one of the largest manufacturers of rhesus immune globulin in the world and makes some other niche products, but outside of Cangene, there is no fractionation facility in Canada either for profit or not-for-profit. There had been in the past, in the early 1980s.

So what, then, is the role of the operator in managing the supply of both cellular components and plasma derivatives? Essentially, the full responsibility then falls on the operators, Canadian Blood Services or in the Province of Quebec, Hema-Quebec.

Just to focus on the data from CBS, we target a minimum of four days of red cell inventory across the country. In fact, for the last couple of years, we have run closer to a 6- to 7-day inventory of all blood groups, but our minimum is 4 days is our target.

As the agency responsible for the acquisition and distribution of all plasma derivatives and recombinant proteins for the country, we target to keep somewhere between an 11- and 12-week inventory in our warehouse of

most plasma derivatives and recombinant proteins. And that number has been derived from a lot of experience over many years, in terms of understanding the ability to obtain supplies from the international market and meet hospital needs at all times.

And because we've had that capacity to do that for many years, Canada, in fact, has been one of the few countries in the world that did not suffer adversely in terms of both the IVIG's shortage in the early '90s and more recently the recombinant Factor VIII shortage experienced in the late '90s, early 2000s.

Hospitals obviously run their own blood banks and transfusion services. We are not a centralized transfusion service, save and except in the Province of Manitoba. But in the rest of the country, hospitals operate their blood banks and transfusion services and carry their own inventory of cellular components that they derive from us as well as their recombinant material and plasma derivatives. But I'm just focusing on the inventories that we operate on a national basis.

There are no formal supply agreements between hospitals in Canada and the operator, but we do share on a regular basis our inventories. On a biweekly basis, hospitals receive a detailed report of the plasma derivative inventory in our system. They also get weekly reports of our cellular component inventory by blood group as well as

by component type, plasma, platelets, and red cells. And hospitals share with us as well their outdating information on red cells and platelets so we are aware of what is happening at the user level. And all of this is happening, as I say, absent formal supply agreements.

I wanted to just throw one additional comment in here, although it's not directly related to the questions before the committee, but I think it is important and it has to do with the whole issue of demand forecasting, and give you a sense of what we're trying to do in Canada and why I think running a national system, in fact, provides a very substantial advantage over a decentralized system. I wanted to just draw the distinction between forecasting in terms of stochastic forecasting and causal forecasting.

Stochastic forecasting is a very short-term method of predicting needs. It's the method that all of us have used up until now. It's the method on which the National Blood Data Resource Center relied until the end of 2003. Obviously, it does extrapolate into the future based on blood use patterns from the recent past. Stochastic forecasting is useful, but only useful for a short time frame, probably six to 12 months, and becomes much less accurate when trying to predict further out into the future. And it works reasonably well, provided changes in patterns of use are kept to a minimum. The advantage of stochastic

forecasting obviously is that data requirements are generally very modest and, therefore, reasonably easy to do.

Causal forecasting, on the other hand, is a much more complicated process to undertake. It has the predictive capacity of stochastic forecasting. It has all those values. But it can incorporate changes that are going to occur in the delivery of a particular health care service, in this case the utilization of blood or blood products.

For example, you can build into a causal forecasting model increases in blood use that may be expected to arise as a consequence of changing demographic patterns or changing treatment patterns. And it is, therefore, much more useful over the longer term than is stochastic forecasting, and a well-built causal forecasting model can, in fact, predict with a reasonable degree of accuracy, as long as five to ten years into the future, recognizing, of course, there are going to be many caveats to these models as well.

The difficulty with causal forecasting is that in order to achieve that degree of precision and predictive capacity, the data requirements are a lot more intensive, and you have to have the capacity to understand the changing practices in the delivery of health care.

The advantage that we have in Canada and one that we're attempting to build on is, in fact, that we have

accurate data on actual collections from the entire country, which does distinguish us from how the National Blood Data Resource Center operated, for example, where they had to estimate blood collections because they were only sampling collections from admittedly some large and key blood centers, but it was an estimate of U.S. blood collections as opposed to actual for the whole national system.

In addition, we're working very closely--and this is perhaps the most important point on this slide here. We are working very closely with the provinces in Canada where health care is delivered to understand patient use of blood at the every-patient level. We have most successfully achieved this in the Province of British Columbia where we have a centralized transfusion registry on utilization of blood and blood products in every recipient. We've just achieved the same in the Province of Nova Scotia, which is a much smaller province on the east coast, and are working with other provincial governments to get these centralized transfusion registries built into their information system networks across the country. As a consequence, we have some rather ambitious plans in Canada to undertake detailed causal forecasting models for both cellular components as well as plasma derivatives in the future.

Switching back, then, as I wrap up, to some of the other questions that the committee asked us to address from the perspective of other countries, I thought I'd give you

an understanding of the role of governments in managing or impacting the blood supply during disasters.

Disaster planning for the blood supply is, again, the responsibility of the operators in Canada. There is no direct responsibility given to government here. As an operator, we are intimately linked to both federal and provincial emergency response organizations. These linkages have been in place for a long time, but like all of you, and like this and other committees have addressed before, we all reviewed our experience post-9/11 because it was very clear that we all learned a number of factors post-9/11. And while it was obviously a U.S. incident, the skies in North America were shut down, and as you all know, most of the flights were, in fact, originally diverted to Canada, which obstructed our airports for a couple of days. And as a consequence, we had some major impacts in terms of logistics, in terms of moving samples and components around the country.

So as a consequence of 9/11, we have strengthened our linkages with emergency response organizations and have built in a mechanism whereby blood inventory is incorporated in those data requirements that these EROs have ongoing at all times.

We do not have a national reserve in Canada. Unlike the very interesting earlier discussion from the interagency task force, there are currently no plans to

build a national reserve in Canada. Although there have been contemplations on this between ourselves and the federal government in the not too distant past, at this point there are no plans to build a national reserve.

Adequacy, as I say--and we're all well aware of this--is not the issue post-disasters, be they manmade or natural disasters, and we all have lots of experience in terms of being able to meet supply immediately post-disaster. The issue is much more one of transportation, logistics, and coordination of emergency response measures.

I wanted, though, to reflect on the inventory management in Canada and perhaps provide a little bit of insight on why we place such heavy focus on managing the inventory in a truly national manner. And here the national, in fact, go so far as to include a relationship between CBS and Hema-Quebec.

But when we inherited the blood system from the Red Cross in '98, although it was a national system, it operated very much on a decentralized regional model. Blood collected in Toronto was possessively held in Toronto, and they wouldn't let go for dear life of a unit of blood for anywhere else in the country and vice versa. And we have very intensely and purposefully sought to operate a national inventory across the country and put in place a series of systems and mechanisms to allow that to happen.

So on a routine basis, we move blood across the country from city to city, across provincial and territorial borders, without any restrictions. We have standing import-export patterns between blood centers, particularly those cities where we have the larger tertiary care facilities that are the larger users of products, for example, the Torontos and Vancouvers of the world, and have routine import patterns from the smaller rural parts of the country where we have a greater ability to collect blood with a lower utilization rate.

In addition to those standing import-export patterns, we have a national inventory manager and a national inventory system that allows us to direct blood at the push of a button from one location to another when and as required.

In addition, for cellular components we manage the plasma derivative inventory on a similar national basis, with one single large warehouse in Ottawa and smaller distribution warehouses regionally located across the country.

And the advantage that we've had since focusing on a national inventory management system is that we have never had a canceled or postponed surgery in Canada in five years. We have managed to meet all blood supplies of all hospitals at all times, despite a number of major issues. We've had a number of labor disruptions in Canada. We're a very highly

unionized workforce. We actually have a strike going on in one of our blood centers at the moment that is entering its 12th week. We are collecting virtually no blood in the entire city of Halifax and have met 100 percent of needs of all hospitals in the Province of Nova Scotia because of the national inventory system. For example, the August 2003 blackout, when there are occasional regional shortages because of weather or SARS, for example, in Ontario, hit very badly by SARS, we've been able to meet 100 percent of hospital needs because the inventory is viewed as a national system.

The needs of the military, I guess one could say embarrassedly, in Canada are very small. We have a reasonably small or a very small--compared to the U.S.--military. The Canadian Armed Forces do not have an independent blood supply. All needs for the military are provided through us, or those military bases in Quebec are served by Hema-Quebec.

We do have a number of very active programs with the military where we partner with the Canadian Armed Forces in blood drives, and, in fact, they're one of our largest partners in terms of promoting blood collections.

The largest deployment of Canadian troops outside of Canada is in Afghanistan. That's where we're in active combat. We have a very large deployment in Europe as well. And all the needs are provided through CBS by routine

shipments to those areas, as well as any other needs as required, and this is both for cellular components as well as plasma derivatives and plasma for transfusion.

The role of government in monitoring and tracking the blood supply in essence, therefore, is somewhat limited. No specific role in tracking or monitoring the blood supply. As I said earlier, we do provide on a regular basis the inventory information on both plasma derivatives and cellular components to the federal government. We also share with all our hospitals, as I said, all our information on our inventory of cellular components. And the regulator does request on a regular basis an impact analysis of inventory issues when there has been a disruption to inventory, for example, post the blackout, post the SARS period, during labor disruptions, et cetera. And there are formal and well-tested supply agreements between CBS and Hema-Quebec that we have occasionally had to move blood across Quebec, the rest of Canada borders, to make sure that either agency can meet needs if there are local or regional issues for a particular blood group.

So, in summary, Mr. Chairman, and for the committee, I hope I've given you a sense that CBS operates a truly national blood supply system responsible for all aspects of collection, manufacturing, testing, and distribution, and is responsible for meeting all needs in the entire country, and Hema-Quebec essentially with a

duplicate mandate. We are also responsible for acquisition and distribution of all plasma derivatives and recombinant proteins, either through custom fractionation contracts or commercial purchasing contracts.

There is no national blood policy per se but a quasi-national blood policy as given to us through this federal, provincial, and territorial Memorandum of Understanding.

In the five years that we have been operating the blood supply system in Canada, we've managed to increase collections by about 26 percent over the five years, but we have a very, very long way to go in Canada in terms of being self-sufficient in terms of plasma for custom fractionation.

The way we manage the inventory on a national basis has greatly minimized shortages and has permitted stable supply during disasters of a variety of types.

I thought I would just end up with reflecting what the Canadian public views of its blood supply system are since the major challenges we faced at the height of the Krever Commission. This slide is some recent data done by an independent polling firm looking at the views of what people believe about the safety of receiving blood and the safety of donating blood, perhaps the red bars being the most important, and you can see that there's been dramatic increases in public trust and confidence in the five years since we assumed operation from the Red Cross. And some of

the comments that were made as a consequence of this most recent public opinion polling, something we do on a biannual basis, some of the comments here that the last five years have seen blood collection in Canada move from being a front-page disaster to a mid-page success story, and that's how we hope to keep it, certainly for a long time into the future.

That all being said, I don't want to leave you with the impression that it's all roses in Canada. It's not. We face many of the same challenges that you do here in the U.S. in terms of ensuring an adequacy of supply. Despite a reasonably stable and healthy inventory, we nonetheless face regional challenges from time to time, and some of the public view on the supplies is a very interesting paradox from time to time.

In the most recent public opinion polling data shown in the yellow bars here, over 80 percent of Canadians still believe that enough blood is being donated, and yet 78 percent of them--the comment at the bottom--when asked, believed that blood will be there if they need it. And I find that a fascinating paradox, and something we're trying to do some social sciences research on is to understand why the same proportion of people who believe there's not enough blood and yet the same proportion believe it will be there when they need it, and yet they're not running out of their chairs to become active, committed blood donors.

So, in conclusion, then, absent a more formal role of government in the supply of blood components and plasma derivatives, I believe, like some of the other previous speakers have said, that governments should assume an active position in promoting the need for blood and the importance of blood donations, more than they even do today, and obviously ensuring that regulatory requirements address appropriately the balance of supply and demand issues, and that there needs to be an adequate funding in our system, given that it is a government-funded system, perhaps different from the remuneration system you have the U.S., but an adequate system of funding to ensure that we can meet the challenges of both safety as well as security of supply.

Thank you very much.

DR. BIANCO: Well, thank you very much, Graham. That was comprehensive and very informative.

Since Dr. Sher has to leave, we will allow a few questions. Do you want to start, Alan? Alan Williams from CBER.

DR. WILLIAMS: Yes, thanks, Celso.

Graham, shortly after the transition and contiguous with the first BSE donor deferral, CBS undertook a multi-million-dollar donor recruitment campaign at the national level, and I just wondered, five years later do you have any lessons learned from the national campaign?

DR. SHER: Yes, that's a very good question, Alan. We invested very heavily at the time of the first variant CJD deferral in paid advertising. We continue to do that today. We've become much more adept at focusing our marketing activities and spending fewer dollars than we did in the initial years.

In terms of focusing on not so much the initial recruitment activities now as much as the retention activities, our focus has shifted very much to keeping those donors that we have in the system. We some very targeted campaigns focused at young donors. We have our marketing campaigns that become regionally based as opposed to simply having one sort of blanket strategy across the country. We're working with a large number of the visible minorities and ethnic communities in Canada who, not dissimilar from the U.S., traditionally donate in smaller proportions to their representation in the population.

We've got many lessons that we've learned from our initial foray into paid advertising. We do believe it is a necessary way to go. We continue to see an increase in first-time donors. We've seen our donor frequency rate rise as a consequence from about 1.6 when we started to over 2.1 now. So we're beginning to see that retention there.

We lost a greater proportion of donors as a consequence of the vCJD deferrals. We lost close to 5 percent in the first go-round, the first U.K. deferral

policy, and probably another 4 or 5 percent subsequently, and yet we've seen our collections rise, as I showed you there.

So it is true, we invested quite heavily into donor recruitment activities, both in terms of the marketing campaign and local strategies to work with various community groups and social groups. And we continue to do that. We felt it was absolutely necessary at the time, given that we had an abysmal collection system at the beginning of '98. So we're spending fewer dollars now, but I think we're still seeing the yield come in.

DR. BIANCO: Thank you, Graham.

I want to recognize the audience, but first I'd like to recognize the committee. Judy?

DR. ANGELBECK: Graham, you noted in a slide early on in your presentation that, in support of core operational functions, the NBA would provide a number of key functions, one of which was health risk management. And I wondered if you could define or delineate the role of an organization like CBS versus Health Canada versus the provincial ministries in health risk management.

DR. SHER: That's a very good question, Judy. In fact, when we sort of reflected on what that mandate meant, we wondered exactly how does an organization such as ours go about doing that without, one, treading on the toes of the operator and, two, given that at the end of the day the

decision to approve our budget is made at the provincial and territorial government level.

We have a very rigorous risk management framework. It is a framework that we have shared with both the regulator through Health Canada as well as with our funding governments. While it doesn't require their approval, we developed it in consultation with Health Canada and in consultation with the funding governments. And it incorporates all the elements of cost, benefit, and risk, so it does incorporate the issues of cost.

We attempt to do cost-effectiveness studies prior to interventions, and we engage with both the regulatory and the funding levels of government in that.

Our risk management framework is quite similar to the one that Health Canada uses and has developed, obviously in conjunction with other regulators worldwide, in terms of health risk management with respect to blood policy.

But all that being said, it's a very loose application of health risk management activities. The precautionary principle, as you know well, swept broad and wide into Canada as a consequence of Krever. It still drives a large part of our decisionmaking now.

I think as we move more and more away from the legacy of Krever, we are seeing a greater involvement of the cost component in that, if you want, triad of cost, benefit, and risk; whereas, some of the decisions we made--and this

sort of gets to Alan's question around it was relatively easy to invest multi-million dollars in donor recruitment in '98, '99 because governments were not going to say now. Now it's becoming a much more rigorous analysis, and, you know, cost is becoming--as it should be--a legitimate part of that equation, more so than it was in our early years. And I see that shift happening quite realistically, and it's true for West Nile and other technologies and interventions we're considering.

DR. BIANCO: Dr. Gomperts?

DR. GOMPERTS: Dr. Sher, I have two questions. The one relates to the decisionmaking around the introduction of new technologies such as NAT testing and who pays for it once a decision is made to incorporate such testing.

The second issue is: Does CBS evaluate physician/surgeon utilization practices? And if so, is there any attempt to modify and impact that?

DR. SHER: I'll take them separately.

The first question on who is responsible, if you want, for implementing new technologies or safety initiatives, it is entirely the mandate of the operator. At the end of the day, though, our funding derives from government.

And there is something that I didn't point out on the slide, though, that is a very important tool that we

have in our armamentarium to facilitate that decisionmaking, and that is, we have a contingency fund outside of our annual operating budget on which the organization can draw without any approval from government. So we have a well-funded contingency fund that in the event that CBS wishes to implement, let's say, NAT testing or West Nile virus testing or some other technology that is not approved in an annual budget, we can implement that by drawing out of the contingency fund, and then government is obliged to replenish those funds.

So that was one of the almost cardinal cornerstones of giving us that arm's-length relationship from government and eliminate, to the extent possible--and I stress to the extent possible--to eliminate government decisionmaking in funding initiatives. But at the end of the day, they then have to replenish that, so there's always that relationship back to funding government.

In terms of the second question, our relationship with, if you want, prescribers of blood products, surgeons or physicians, again I stress the fact that we don't have formal agreements in terms of utilization practices. We are not in the business of the practice of medicine, and we simply cannot influence that at the hospital level.

We do develop and distribute guidelines for a variety of transfusion products and components. We sit on the transfusion committees of all of the large hospitals.

We have the CBS staff sitting on those committees as well. And at the provincial level, where a lot of sort of policy decisions for health care are made, provincial governments have sponsored transfusion programs at a provincial level that include both blood operators and hospital transfusion committees.

So it's more, I would say, influenced by involvement than any mandate given to us, and obviously we have a long way to go there.

DR. BIANCO: Thank you.

Dr. Sayers?

DR. SAYERS: Thanks, Celso.

Graham, you've only got to put a group of people interested in collection and recruitment together, and somebody's going to make mention of the 5 or 6 percent of the population, the eligible population that donates. So I was looking at that figure of yours of 1.4 million donors. Any idea how that relates in Canada to the size of the accessible group?

DR. SHER: Absolutely. We're currently--you know, again, it all depends on how one determines that, but the metric that we have used consistently at CBS is percentage of eligible donors, and in our case eligible is between the ages of 17 and your 71st birthday, after which you're bumped out. And by using that denominator, eligible population in the regions of the country that we are responsible for

collecting, and the numerator of the equation being the number of donors in that given year, we have moved in the five years that CBS has been at this from a 3-percent donation rate to a 3.8 percent donation rate.

So we're still far below a target of 5 or 6 percent that many of the European countries seem to report, but it's always important, Merlyn, as you well know, to add into that equation the donor frequency rate, because it is not just an issue of the percentage of eligible population that donates but what frequency do they donate, and that will give you, if you want, your collection volumes in a year. And as I say, we've also moved our retention rate or our donor frequent rate from 1.6 times per year to 2.1 times per year. So, in my mind, it's really a combination of both of those factors.

DR. BIANCO: Thank you.

Matt?

DR. KUEHNERT: Yes, it looks like you have pretty good data on collection, and you mentioned that you were going to try to get patient-level blood use, and that was started, at least in one province. But I just wondered if you could describe what the impetus for that is. It doesn't sound like it's for targeted education for utilization. And is it for improved forecasting? Because it seemed like your forecasting was pretty good. You said you haven't had any

major shortages. So I wondered what the purpose of it was and whether it seemed to be giving you data that was useful.

DR. SHER: The model that I referred to in the Province of British Columbia and the development of a centralized transfusion registry in that province grew directly as a consequence of the rapidly rising budget that the provinces were having to pay every year. Remember, there's a global budget for, if you want, the operation of the fresh component as well as the plasma derivatives. And, you know, government saw the budget of CBS rise somewhat dramatically in the first five years, and very quickly they said, well, a large part of that is we're responsible for using the material, and, you know, it's fine if you're collecting it and meeting our needs; but if we're not putting in some form of monitoring at the utilization level, that's going to have an impact on our budget. So the centralized transfusion registries in many ways have been driven by financial imperatives that the governments face.

That being said, I think it was best championed in BC because there are a number of blood bank groups and physicians there who are particularly interested in outcomes and good patient care. So, you know, I think it's a combination of events, but, you know, when all is said and done, it was driven initially by financial issues and will continue to probably be the driver for most of the governments.

DR. KUEHNERT: Just a quick follow-up. Is it also tied to monitoring patient events after transfusion, or is it simply to look at use?

DR. SHER: That has sort of grown as a corollary of that. We do not have, unlike in the U.K., for example, serious hazards of transfusion event monitoring system. The federal and provincial governments in Canada have invested small sums of money in a surveillance system for adverse events. It's only operating currently in three of the 12 provinces. It's voluntary, and we just know by the numbers of data and events reported on a monthly and annual basis that we really are only hitting the tip of the iceberg at this point.

So there is no mandatory or even widespread voluntary adverse event reporting system at this point.

DR. BIANCO: Chris?

MR. HEALEY: Thank you, Celso.

Graham, just with respect to the plasma derivatives, a couple of things. I know that you use a tender process in Canada to obtain your products, and for quite a while there was a single-source arrangement where you just had one supply of product. What do you do to assure product choice, first of all, the full range of products? And then, secondly, through that tender process, if your supplies run low, for example, are you then forced to go out on the spot market?

DR. SHER: Yes, that's a very good question, Chris. As you know, when we inherited the system, we inherited in place a multi-year, very long-term single-supply contract for all plasma derivatives and recombinant proteins for Canada, which one, certainly from a supplier's perspective, would argue served them financially extremely well for many years.

I think there are some benefits in those very, very large contracts in that we were able to leverage obviously significant cost savings for the country. But there were some very significant down sides, particularly if that manufacturer experienced recalls or product shortages, as they did. And in those days, we found ourselves landing up on the spot market paying huge premiums in the absence of any contracts because we were caught up in the web of sole suppliers.

So we have intentionally made policy decisions now to move away from sole suppliers of key components to try to split our eggs in more baskets.

We have some constraints in Canada in terms of the number of licensed products available from which we can choose, and, unfortunately, we don't have quite the array of licensed products that you have, for example, in the U.S. So even in using, let's say, the recombinant Factor VIII market, there are currently only two, a third waiting, licensed products in Canada, so that's all we could go for.

We've done that in a contractual manner now in an attempt to avoid that spot market penalty.

The issue of product choice is still a controversial one in Canada inasmuch as currently it still falls to the operator to make those decisions, although there are very significant stakeholder pressures both from the user community as well as the funding governments to sort of say, hang on, you know, is this a really free-for-all and will you get any product for anyone if they wish it and at what financial premium.

So we have a lot of work still to do on the acquisition of which products will be available on the marketplace.

DR. BIANCO: And the last question will be from Dr. Katz.

DR. KATZ: Graham, you already dealt with part of it regarding utilization review in terms of product utilization. We think in this country the number that gets thrown out is 20, 25 percent of what gets transfused in terms of red cells. Some of the more conservative of us in the audience might not have transfused.

The best way that we get at that data in the U.S. is to look at variation, the same procedure at a number of different places, and we see a heart program here, and 97 percent of the coronary bypass patients are exposed to red

cells, but the VA system it's 43 percent, or something of that nature.

Do you have any handle on that in Canada? And can you give us any feeling for whether, as some of us believe, you guys transfuse less than we do and how that impacts adequacy?

DR. SHER: We have some data in that regard, Louis. For example, there was a study done by Joanne Kebetter [ph]--it's now a number of years ago--which did look at utilization patterns in a number of locations across the there. We did see a variation. We saw it to a much lesser degree than some of the data appear to be the case in the U.S. And when sort of there have been some of the larger institutions have done utilization audits based on commonly accepted criteria and guidelines for use, we certainly don't see in the red-cell arena anywhere near as high as 25 percent deemed to be inappropriate by the criteria applied.

I guess the strongest evidence we have in terms of less red cells used per patient or per procedure are on the national averages. We're using 37 units per 1,000 population in Canada, which is considerably lower than you're seeing in the U.S. I'm not convinced that we have any worse patient outcomes as a consequence. Some of the large studies recently published, for example, the TRICK trial, in fact, showed reasonably good patient outcomes with

lower transfusion levels, and that has influenced care in Canada.

So, you know, I think the data, as you well know, is scant at the best of times, but I think there is some evidence to the fact that we use per capita less red cells than appears to be the case in the U.S.

DR. BIANCO: Well, thank you very much, Graham.

DR. SHER: And I thank the committee for the agenda.

DR. BIANCO: Hope you have a nice flight back.

Our next presentation, in the schedule it says Dr. Kathleen Sazama, but Karen Shoos Lipton is going to make that presentation, and she promised that she's going to help us catch up a little bit on our schedule. Thank you, Karen.

MS. SHOOS LIPTON: Thank you. I actually will be quite quick.

I'm sort of picking up I think where Dr. Schmidt left off in terms of what has happened with the national blood policy in this country. And in May of 1999, which actually was the 25th anniversary of the national blood policy, the AABB's National Blood Foundation convened a forum to discuss the policy to discuss its relevance to operations then and actually, I suppose, to now.

We engaged in organization out of the Harvard School of Public Health to help us do this so that we could have a recorder who had I think a more objective way of

looking at this, and we had quite a good attendance. I just wanted to let you know that. It had one objective, and that is to establish a dialogue between the blood banking and transfusion medicine community, government, patients and other interested parties to review the 1974 national blood policy and discuss the need for an appropriate scope of an updated national blood policy.

The forum participants, there were 50. We had representatives from I think just about every sector: blood banks, hospital transfusion services, consumer organizations, medical societies, government agencies. And it was very interesting, at the end of the day--we started really with a review of the '74 policy, and I think that in general the participants' conclusion was that the policy itself, as opposed to any kind of program around it, really had been a success. It had, in fact, promoted an all volunteer blood supply.

There had been improvements in blood safety. Notable decreases, particularly in hepatitis transmission, were due in large part to the move to a volunteer supply, which probably was really a result though of the labeling efforts by the FDA. We had also developed a significant number of new screening tests, and participants also said that the national blood policy and the collaborative efforts it encouraged had helped to even out the blood supply and reduce shortages.

Interestingly enough, though, after a day of deliberations, we did have some conclusions, one of which was there was absolutely no consensus reached regarding the need to update the national blood policy. The vast majority of participants said that the United States should have a national blood policy, but that the private sector should take the lead in implementing and the government should oversee implementation.

The group specifically looked at the goals of the 1974 national blood policy, and they said they did believe that those four principal goals remained consistent: safety, availability, accessibility, and efficiency. What's interesting to note is I think in 1974, in the last bullet, when we talk about efficiency, there was about a 25-percent outdating rate, and now we've been pretty consistently at about under 5 percent for about almost the last 10 years.

The particular issues that needed to be addressed had changed between 1974 and '99, I think both due to the successes we had achieved, the volunteer supply, and changing circumstances, and particularly those changing circumstances where technological advances and probably most significant was the implementation of DRGs in this country.

Participants identified some priority issues that needed addressing in order to achieve those four principal goals.

First, was supply. The need to ensure a safe, adequate blood supply, particularly at a time when data showed that demand was increasing and donations were decreasing.

Data collection. The lack of sufficient data to identify problems and potential solutions. This was highlighted both in terms of collection and utilization. And as this committee has heard time and time again, we cannot fully evaluate the scope of the problems we face or develop appropriate solutions without underlying reliable data. At the time, in 1999, it was specifically noted that there was insufficient government commitment to collecting such data.

Education was also seen as a remaining issue or something that was needed to make sure that the national blood policy was fulfilled; public education regarding the need to donate and blood safety, physician education regarding appropriate use of blood and transfusion therapies.

There was also a significant amount of discussion around research. Participants agreed that additional research was needed to promote the appropriate use of blood components and the ongoing improved safety of the blood supply. For example, one specific thing that was raised was government support for research into evolving potentially transfusion-transmissible infectious agents.

The last priority issue is one that I just mentioned before, and that's adequate reimbursement for blood. CMS, which was then HCFA, and other third-party payers should pay for blood safety advances, particularly those required by FDA. And there was a strong sentiment at the meeting that inadequate reimbursement is a disincentive to invest in future generations of blood safety technology.

Another priority issue was cooperation and coordination of blood donation. There was a specific recommendation that blood centers give consistent messages to donors. It was also a recommendation that blood centers start to work cooperatively, and not competitively, in promoting blood donation; that blood centers should not be trying to take blood donors groups away from each other, but in each community, if they chose to enter a community, there should be an effort to get new donors to the table. I think the feeling I expressed at the meeting was that a rising tide lifts all boats.

I did want to make sure that you understand that even though this was a consensus, it was a consensus in the true sense of the word; that is, most people probably believe this, but there really wasn't a vote. And there were some strong minority opinions and reservations about the national blood policy. A few participants said not only did we not need a new blood policy, but we didn't need one

at all. And there was a question of the role of big government in this plan.

There were also some consumer groups who weighed in relatively heavily about the failures of the national blood policy in that it failed to focus on plasma derivative issues. There were several hemophilia patient advocates who said that the national blood policy was a failure, and industry representatives said the challenges of the plasma industry have largely been met and questions the role of government policy. So I think I can say that there really wasn't significant consensus around the role of the plasma supply in the national blood policy.

Most of the day's discussion, though, if we looked, really focused on blood and blood components, and so I think it's unfair to, I mean, even though we said it didn't include in the national blood policy, I think if we had focused the discussion a little bit differently in the beginning, in terms of who we invited to the table, we might have had a different outcome there.

So general conclusion was, although they are different today, in 1999--that was 1999--many blood issues merit examination at the national level, with the recommitment to a safe and adequate blood supply for all Americans.

I do want to make one comment, and that is the availability of the text of the national blood policy, which

is not as easy as you might imagine. I think the Committee all has a Xeroxed copy, but if you actually want to find it, you have to go back to microfiche. You can't pull it off-line or anything. So I think that there's really a question as to whether there is a remaining commitment on the part of the government to a national blood policy.

Any questions I could answer, I'd be happy to.

DR. BIANCO: Thank you, Karen.

Any questions from the Committee?

[No response.]

DR. BIANCO: So, Karen, was the conference worth it?

MS. SHOOS LIPTON: I actually thought it was. I mean, I was actually an attendee there, and I thought it was interesting that, remember, even though we said some of the issues were different and needed to be addressed, that everyone supported the goals. Whether it was a national blood policy or not, we all seemed to be on the same page, and still on the same page as to what the priorities were. Whether there was a role for government in this, wasn't really clear, but I believe everybody agreed safety, availability, accessibility and efficiency remained important, and there was consensus around the issues that were problems that we needed to address, which I would say are still on our table today, not having progressed much further.

DR. BIANCO: Any other questions?

DR. KUEHNERT: I guess I just wondered where the recommendations went after the forum.

MS. SHOOS LIPTON: Well, I will be honest with you. We tried to get this Committee interested, and not this Committee directly, but we did bring it to HHS and at the time there was not a particular interest in discussing the issue, and I think that, you know, Jerry is a new person in this mix, and I think he thought that maybe this was something that should actually be brought before the Committee. It never really made it that far.

DR. BIANCO: Jay?

DR. EPSTEIN: Karen, I was present at the 1999 meeting, and it's my recollection that part of the driver for having that forum in the first place was the sense that there was a lot of economic discord in the blood system--in fact, the press called it blood wars--and that one of the central questions was that the agreements over regionalization and the agreements over sharing, in order to deal with shortages, had unraveled, and whether the system was capable of addressing such short-term problems as spot shortages.

And I don't really see reflected in the summary the whole dialogue that happened about the structure of the industry and the economic forces, and I just wonder if you have any recollections or could otherwise comment.

MS. SHOOS LIPTON: No. I must say we're somewhat handicapped because we were relying on write-ups. I recall some discussion about regionalization and getting back to the whole issue of was the problem really one of distribution, but I think that in the end there wasn't any consensus around that, to be honest with you. I do think that right after this there was a significant activity on the part of the blood organizations, if you will, to renew their commitments to work together.

And right where we are right now, I mean, I know that was five years ago, but I think that we are in an excellent position, in terms of understanding from the private blood organizations, you know, the nongovernment sector, that we do indeed need to work all together, and I absolutely believe that there's a firm commitment on the part of all of the organizations to do that: I think the interorganizational task force, the way we're working there; I think there are a lot of private initiatives to try to deal with some of these competitive issues and get people talking at the table; and as you all have heard before, for the very first time, we're all cooperating on putting together a national appeal that will appeal to kids about the ages of 19 to 25, and we've put a significant amount of resources--we could use more from the federal government on this.

But I think maybe we've kind of grown up, if you will, and figured out that we do need to work together if this is going to change.

DR. BIANCO: Thank you, Karen.

I think that we are going to reap the rewards of an excellent morning session, and we are going to get a lunch break. And we should reassemble here at 2:15, and we are going to start promptly.

Thank you.

[Whereupon, at 1:15 p.m., the proceedings were recessed, to reconvene at 2:15 p.m. the same day.]

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

2:24 p.m.

DR. BIANCO: Well, I welcome you back, now that you are well-fed and calmer.

Our program this afternoon, we are going to make a few slight changes. The first one is that Dr. Bowman, from CMS, wasn't able to come here early in the morning, and so we are going to start having a presentation by him.

The second thing is that we probably will transfer the discussion period to after we hear from our national blood programs in developed countries. Many of us felt that their contributions may be important to that discussion.

And so, first, I would like to invite Dr. Bowman to make a report from CMS and help us understand how it works.

DR. BOWMAN: I'm not sure if I can help you understand how it works, but I'll have a very brief report.

In follow-up to the recommendations of the Committee in August, CMS has obviously received the letter that communicated those recommendations, and somewhere in the system there is a response being generated to that letter. But on a more practical basis, the parties involved and responsible for the payment processes within CMS for the blood and blood products has arranged to follow up very specifically on those recommendations, and Dr. Jerry Holmberg is going to be visiting in early February with the

various staff members and divisions to go over those recommendations in detail.

It has taken us or taken me a little bit of time to assemble this sort of a meeting, primarily because the last three months of the calendar year 2003 were fairly hectic for the payment group folks at CMS because that is their busiest time of the year for implementing and finalizing the physician payment rule, the inpatient hospital payment rule and outpatient payment rules. And because of that, it was difficult to put the right people together at the right place to address these issues.

In addition, of course, toward the 1st of December, the new Medicare bill was passed, and there were quite a few action items that had to be addressed and implemented by January 1st, and that put some further constraints on things.

There are some changes that are involved with the payment of drugs and biologics in the new bill, and they're fairly complex, needless to say, so I'm not going to address those at this point. The good news is that the payment for the blood and blood products in that bill remains unchanged from the current way those products are being paid for, and so, going forward, those payment processes will remain the same.

As you know, from the news of the bill, the drugs and biologics payment mechanisms are going to be

transitioned eventually to a competitive bidding-type process on the physician side and to average acquisition costs on the outpatient side. These should be in place by 2006, according to the legislation.

Finally, the rules for the physician payment and also for the outpatient payment systems had to be updated because of the passage of that bill, and those rules are in the Federal Registers for January 6th and January 7th, respectively, of this year.

I'll certainly be available to help answer questions later on today or tomorrow.

DR. BIANCO: Thank you very much, Dr. Bowman.

First, I want to thank Dr. Bowman for coming to the Committee, for opening the doors to Dr. Holmberg. I think that we're all very happy with this new level of interaction and hopeful that this is going to address many of the problems that we have around.

Now, Dr. Heaton, you are welcome to ask your question.

DR. HEATON: Yes, I indeed have a question.

I have a copy in front of me of the January 2004 OPPS payment rates and also for the physician office payment rates, and I notice that the January 2004 reimbursement rate is 85 percent or less than 85 percent of the May 2003 Red Book rate. Is this already implemented? Could you give me a bit more background on the basis for this? Because I

thought we were stabilizing these rates pending an analysis of reimbursement of the cost of purchase rather than reducing the rates to 85 percent or less of previously reimbursed rates.

DR. BOWMAN: Are you referring to the outpatient rule?

DR. HEATON: Absolutely.

DR. BOWMAN: The outpatient rule for the Federal Register was January 6. Those rates should be in effect effective January 1st and, for the most part, those are 85-percent AWP for certain pass-through status drugs and biologics. I presume that's what you're referring to, the drugs and biologics.

There are some drugs and biologics that do not have HCPCS codes and were not available on April 1st, 2003. Those will be at 95-percent AWP. And then there were some-- I believe those are the only two categories that are applicable in the drugs and biologics.

Now, those should be published not only in the Federal Register, but on the CMS website, those are available by HCPCS code number with the reimbursement rate. So that should be accurate. It's a fairly large Excel spreadsheet file that's zipped for the computer folks here.

Does that answer your question, Dr. Heaton, or did I not completely understand the question?

DR. HEATON: It does, insofar as it goes, but I notice certain reimbursement rates, not that I'm a special advocate of the American Red Cross, but I notice that their reimbursement rate for Gammagard went down 13.67 percent this year over the previous year. And given the linkage that we've discussed in the past between additional regulatory requirements associated with improved product quality and declining reimbursement rates for certain top-line blood derivative products, I'm just concerned that this will place pressure on the blood bank industry and make it very difficult for them to maintain levels of service and to support new safety initiatives. The HCPCS number is J1563, for your reference.

DR. BIANCO: Christopher Healey?

MR. HEALEY: Thank you, Celso.

Thank you, Dr. Bowman, for being here and giving us the opportunity to ask a few questions.

With regard to the new rules, and on behalf of I guess the plasma users in industry, we're pleased to note that IVIG was exempt from the competitive bid process for Medicare Part B. There's a lot of concern, however, and some confusion about the fact that the hemophilia clotting factors were not exempt from that. We believe it was a technical error that's been acknowledged by committee staff, congressional committee staff, and we'd like to see that

corrected, obviously. That should cover all blood and blood products.

With regard to the OPPS, things are a little more concerning because I understand that, as of '06, they're going to be paid at ASP plus 6 percent. And given the unique nature of these therapies, the 6 percent simply does not adequately account for all of the ancillary costs, including administration fees, and storage and so forth. So I feel those rates are very inadequate, and you'll be hearing from us on that as well.

DR. BIANCO: Do you want to comment?

DR. BOWMAN: I don't have a comment. Did you have a question?

MR. HEALEY: No.

DR. BIANCO: Any other comments or questions for Dr. Bowman?

DR. PENNER: Just a question. We had some discussion in some of these sessions about DRG and costs and an attempt maybe to pull out some of the costs--the additional costs--that are built in now because of some of the increasing costs of the blood products, and apparently that has not been addressed. The DRG situation is being maintained as is; is that what you're telling us?

DR. BOWMAN: From the inpatient payment perspective, your comment is correct. There is a comment in what was the final rule, prior to the passage of the drug

bill, on November 7th, for the outpatient payment system that made the comment that CMS plans to address the issue of billing, filing claims and the complexity of that process going forward.

And of course I think that will carry over to the inpatient side also, from the perspective of filing the claims for those particular and various and sundry processes that are involved with those services, because it is fairly complex, and it uses a number of HCPCS codes that gets bogged down in a lot of minutia, quite frankly. And the CMS staff recognizes that, and I think that was the intent of that statement in the outpatient rule in the November 7th, 2003, Federal Register.

So they're aware of your concerns and hopefully will be addressing these going forward this year.

DR. HOLMBERG: Dr. Bowman, would you care to comment on the Federal Register from last Friday, I believe, the 23rd, for the call for nominations on the panel?

DR. BOWMAN: Well, I hate to admit this, but I'm not aware of that statement in the Federal Register.

DR. HOLMBERG: I was just aware that the APC panel was looking for nominations, and I thought it would be a good opportunity to express that to the panel here and also to the audience, that if they want to put forward a nomination, that that is a possibility.

DR. BOWMAN: Yes, I'm sorry. I thought that was earlier. Was that just the 23rd? It's been a long four days or so.

It was in the Federal Register on January 23rd. The APC panel--which is, I'm not sure of the technical name, but that is an advisory group on the ambulatory payment classifications for the outpatient payment system--meets regularly during the year to consider concerns from various parties and individuals regarding the payment system of the outpatient payment system for Medicare, and this panel, in turn, makes recommendations, as you're aware, because some of you have made presentations to this panel.

There are some vacancies on this panel, and the process for applying for vacancies to be a member of this panel for nongovernmental employees is listed in the January 23rd Federal Register, and it is open to otherwise individuals who are interested in this issue. So it might be of interest to some of the people who have concerns within this community to look into that possibility.

DR. BIANCO: Thank you very much.

So, Jerry, we move to the presentations? So we are going to move to the presentations, and then we come back to the Committee discussion, with a series of questions that are posed here, because we feel that those presentations will contribute to the discussion.

And we'll start with Dr. McCullough. He is going to review national blood programs in developed countries. He is from the University of Minnesota.

DR. McCULLOUGH: This isn't something ordinarily I've been involved with, but during the late 1980s and early 1990s, with all of the changes and turmoil that we all remember from those times, and after a couple of particular personal experiences of serving as fodder for a John Dingell subcommittee hearing, and also a "60 Minutes" story, that contributed to the feeling at the time that in countries where there was a so-called national blood program, somehow they could do it better than we could in the United States.

So, after I survived Washington and went back to Minnesota, I determined to try to look into this to learn what I could about the nature of blood programs in some other countries, and that led to a study that I think you have a reprint of and that was kindly partially supported by a contribution to the Minnesota Medical Foundation by Ortho Diagnostics.

The issues that I determined to try to learn more about are illustrated here, and that is, first of all, in countries that contended that they had a national blood program, the extent to which this really was operated as a single national system, the span of authority of the person responsible for that system, the nature of the relationship of this national blood program to the government, the

sources of funding for such national programs and the structure of governance and establishment of policy.

Actually, let me back up. I selected 17 countries to contact mostly because these were countries where I was pretty familiar with or knew key people in national leadership positions and thought that I could probably get the kind of information that I sought. There was no other structure to the selection of these countries. As you know from this discussion, this intentionally focused on developed countries. It did not focus on the less-developed parts of the world. The issues there are different than the issues that we're talking about here.

So this is the list of countries who responded to my inquiries. Three countries did not respond. Those are Germany, Spain and Mexico. So you see here the list of the 14 countries that I was able to study, shown here in alphabetical order.

Those countries collected a total of about 18 million units of blood. And I want to emphasize this study was carried out in 1992 and '93. So the information that you have, except for some things that I've been able to update, really is about 10 years old, but I think the concepts that I'm going to share with you are still valid.

For comparative purposes, I've put the approximate blood supply of the United States--12 to 13 million at the time--and a figure of 75 million was developed by Professor

Licola [ph], from Finland, as an estimate of the world blood supply in the late 1980s. As you can see here, the collections per 1,000 population in these countries were all in the 40 to 50 range, similar to the United States. For some comparative purposes, the figures at that time for Europe were considered to be about 37 to 40 and for all industrialized countries about 50.

So the blood production in these countries probably is pretty representative of what was happening in the world at the time. And I would emphasize this figure of about 18 million units would represent about a fourth of the world's blood supply if Professor Licola's statistics are close.

So, first of all, I would draw your attention to this column. When these 14 countries, the leaders of blood activity in these 14 countries were asked whether they had a national blood program, these are the responses: Essentially, 11 of the 14 indicated that they did have a national blood policy. As you see, Austria, Italy and Sweden were the countries who said they did not. I've put a couple of question marks here also by France and Switzerland because of the nature of the structure in those countries which we'll talk more about in a few minutes.

Because the Red Cross, on a worldwide basis, was involved in blood in many countries, I did ask of these countries whether there was involvement from the Red Cross,

and I emphasize involvement. That wasn't intended to identify whether the Red Cross actually operated the blood program in these countries.

Again, you see here the mixture of yeses and noes. For the most part, 7, I guess, of the 14, indicated the Red Cross was involved in some way. And then in Israel, of course, it's the Magen David Adom--did I get that right, Jerry?--Society, Red Star of David, that's involved with the blood program there. So that would be 8 of the 14 that had involvement from the Red Cross.

Now, I didn't have a chance, and some of the participants have changed since that time, so the data here under '04 are not a formal resurvey. They are what I think I know, and some of you in the room may know things that would correct this.

But, first of all, to look at whether the national blood program situation has changed in any of these countries, and it really hasn't. Italy did not have a national blood program in '93, and I really don't think they do now. The reason I put some question marks here by the Netherlands and Switzerland, and I still have the question mark by France, is that the structure in those countries has changed a bit and focused somewhat of a separation of the donor recruitment activity from the more technologic side of blood operations.

The other thing that has changed some is, in this column, the involvement of the Red Cross in some of these countries is not as extensive as it was at the time I did that survey. As you heard earlier from Graham Sher, that certainly is the case in Canada.

Another example of the shifting nature of the Red Cross relationship in some of these countries is the change in the Red Cross Blood Office at the Federation of Red Cross and Red Crescent Societies in Geneva. As many of you know, they did have a nice nucleus of people there for a number of years, and now the staff has one person whose focus is on donor recruitment and assisting Red Cross societies around the world with donor recruitment. So that probably is the major change on this slide.

Now, this isn't as busy as it looks because I want to make just two or three points from this slide.

First of all, the reason for getting this kind of data is, if there's a national blood program, to what extent does the leader of that national blood program have the ability to manage various aspects of the program that enable them to succeed with their responsibilities?

And the first grouping here is different aspects that I think of as more operational: donor recruitment, nursing and blood collection, laboratories and inventory management. This column is the same column as you saw in the previous slides, and so what I'm trying to do is to

show, for instance, that in Australia at the time, 1993, the people responsible for the national blood program did not have direct operational authority over the people who carried out these functions.

And there are some other countries here where there are some of these disconnects: England and Wales at the time, France. I don't need to go through all of these.

Now, the situation has changed in England since that time, but it was interesting that at least a decade ago, there were a number of these countries in which they considered that they did have a national blood program, but the person responsible for that national blood program did not have authority over donor recruitment, laboratory testing or blood collection. I would think that would be kind of a challenge to accomplish one's responsibilities.

So, even if one has that sort of responsibility, what about what I would refer to as the management authority for things like finance and accounting, public relations, human resources, computer systems, building of facilities? Now, on the one hand, you might say, "Why do we want to bother with that? It's an administrative hassle."

On the other hand, as many of you in the room know who have responsibility for operating blood centers, if you're responsible to generate the adequate blood supply, but you have no control over finance and accounting, personnel policies that allow you to hire the kind of people

you need to succeed, the building of facilities that allow you to create the facilities in which you have to function, it's very difficult to really succeed.

So this is the reason I was also interested in this kind of information. Again, you see there are some important disconnects here. Australia, I'll just use as the example because it's at the top of the list, where at that time the head of the national blood program did not have authority over these kind of management and supportive functions. So you may begin to pick up a theme here.

Another important part of a blood system is the use of computers. As we all know, computers long ago moved out of being used just to provide management information, and they're now an important part of the control of operations and product quality control. So one of the things that we were interested in is the use of computers in these national blood programs and the number of different computer systems they used.

Eleven of the fourteen countries used computers, which means, in 1993, three of these did not. Six of the fourteen countries had a single computer system, which means that the other five had multiple computer systems, and three didn't have computers at all.

The reason that I was interested in this is the ability to manage the program, first of all, using aggregate data, but also the ability to move blood around. There have

been a number of comments this morning about the importance of an inventory management system and being able to shift blood around the system, depending on where it's needed. And, clearly, if one doesn't have a single computer system, these kinds of issues become far more difficult, if you're looking on a countrywide basis.

So it was pretty clear in 1993 a number of these countries who felt they had a national blood system did not have the computer systems to support the way we probably would think that a national system should work.

This also isn't as bad as it looks. This deals with sources of funding, and the numbers on here are the approximate percentages of the total cost of operating the blood program and the different sources. I just arbitrarily divided this into government, patients, donations, and nonblood product sales. For the most part, this represents income from plasma derivatives.

As you can see, there are several countries here where essentially all of the funding came from the government. We'll get, in a minute, to what that means, however. And a couple of these countries--France, Israel and Sweden--the difference was made up by the sale of plasma. In this case, that's the same thing down here, plasma derivatives, and France and Israel--I wasn't able to get all of the breakdown of this, and we may be able to hear

a little bit more about the present mechanisms of funding from our next speaker.

As you can see, there are also several countries--Taiwan, Switzerland, the Netherlands, Japan--where most of the funding of the national blood program comes from patient charges, and nonblood product sales, plasma derivatives, primarily, are an important source of revenue in several other countries. There is essentially no meaningful support from donated funds here.

And the information here for the United States is I made estimates. I don't want to say I made it up. I didn't get that from anywhere except a guesstimate on my part. But what I'd like to emphasize about this is--actually, let me back up.

Let's just use Canada as an example from what you heard from Graham Sher earlier this morning. I've listed this as 100-percent government funding. But as he said, the funding comes from each of the provinces, and so the Health Minister of each of those provinces develops the projected budget for blood, and the national budget, then, is an aggregate of the funding from all of these provinces.

So it does come together as one total amount of money that the Canadian blood system is able to manage in order to carry out their national activity, but they are kind of at the mercy of trying to negotiate, then, with each

province for the amount of money that that province is going to contribute.

The same thing is true in some of these other areas. The National Health Service in the U.K., much of that comes through different individual regional portions of the National Health Service, and the amount of money that is directly budgeted to operate the national program is a relatively small amount that covers only the operation of the central office.

And so even in most of these that look like they are heavily government funded, it isn't one allocation that comes to the blood service in a single pot. Their challenge is to negotiate with a large number of people and different agencies for the amount of money that agency will provide, and then aggregate this and try to figure out how to operate this as a single national program.

So this is kind of a summary of the way in which these different funds come together. You might have government funding, a total national allocation which I'm not sure there's any country that really has it that way. Most of it is either a national and regional government funding or a national funding and then income from hospitals to which the blood is provided.

I put this under government because, in the case of countries that have a national health system, the funding of those hospitals is government funds that is provided

through the health system, but those hospitals then use that money to buy the blood from the National Blood Service. So it's almost as if the national blood program sells blood to individual hospitals, as occurs in the U.S. The difference is that the funding for those hospitals is government money.

Now, also, there are some countries where this is mixed. There may be some national funding, but then some funding from the sale of blood to private hospitals or to insurance--coverage through insurance--and I'm not sure there were any of these countries that considered that they were all privately funded.

Well, the next piece of thinking about the funding is the ability of the national head to develop a budget based on their projections of what they think the national program would do in the following year and submit that budget to some rational, hopefully, just a single place, and try to negotiate that and determine whether the budget would be approved.

So I've consolidated a fair amount of data on this slide, and this is the same column that we've used all along to show those countries that said they had a national blood program. This is from the previous slide, funding from the government, and this shows the mixture of the group, different groups that would make the final budgeting authorization decision. And you can see this ranged, in 1993, from the Red Cross to different regions of the

government, provincial Ministers of Health, regional health authorities, Red Cross, Minister of Health, the Red Star of David, and so on.

So there really wasn't anything that was relatively consistent. Actually, in all of the narrative and the communications I had with the people who so kindly provided this data, the rather surprising part of it was that--I'm looking for my notes here. I think it's four--the budget was developed and proposed by the national head in only 8 of these 14 countries.

Another interesting thing was that in 6 of these countries, the national director of the blood program was not even required to approve the final budget. So sometimes they had no ability to really develop the budget; in other cases, the budget could be developed and approved without their necessarily buying into the budget or approving it.

To summarize this, the final budget decisions were made in five countries by the Health Ministry, four countries by regional governments and another four countries by the Red Cross.

Well, to pause just a minute to summarize what I call two kind of different structures, I've called these Type A and AA because I didn't them to be 1 and 2 or A and B, to imply that one is necessarily better than the other. But the Type A is a somewhat more unified structure, in which there would be a unified plan for national blood

production, and the head of that blood program would have a fair amount of authority over operations, although often this is somewhat limited, and there would be central management of the administration and finance activities, and relatively close at least to a single source of funding.

And the other thing I haven't mentioned is what I mean by single report here is that the head of the blood program would have one place that they would report, as opposed to being responsible to multiple different constituencies that would make it difficult to have a cohesive plan for a program.

This is really more what most of these countries really illustrated, which is that the decisions about the annual blood production really generated from the ground up. In other words, different regions would decide what they thought they could produce in the coming year, and that would be aggregated, and that became the blood production plan for the subsequent year, which is a little different than we heard Graham Sher talking about different ways of projecting the nation's needs.

Coordination of operations is different from control of the operation. This is probably more common, where the operations are carried out in different regions, and the head of each of those regions might report to a regional board, as well as to the national head, which opens up a lot of opportunity for confusion as to priorities and

ability to really assure that the national program is truly functioning in a unified manner.

There may be separate management systems for the administration and finance activities, multiple sources of funding and multiple reporting mechanisms into higher levels of government.

This also isn't as bad as it looks. Another issue then is the nature of the regulatory environment in these different countries. Here again is our listing of those who believe they had a national blood program. And as you can see, virtually every government had written standards. It's hard for me to believe that this is really true, but Pim van Akin responded to my inquiries that this did seem to be the case.

Most of these countries also had some sort of a government inspection program, and I was kind of surprised at the number of the countries who had some kind of a voluntary inspection program. I am sure that these voluntary inspection programs would not have nearly the quality or the extent of the kind of inspection accreditation programs that are operated by the AABB here in the U.S., but I didn't have time to go into this further in this project.

So, to summarize, most of these programs are not really what I would call a "total" program at all, and many of them had no national usage data, and so it was almost

impossible for them to project their blood production for subsequent years because often they didn't even--they had trouble gathering the data to identify the total blood use in the country.

The production goals were fragmented. By that I mean they were based more on the ability of different regions to produce than looking at a national need, and I want to pause on that for just a minute because it's an example of one of the shortcomings from a system like this.

As we know, and as has been discussed here already today, there are many parts of the United States that are not self-sufficient, and there are other parts of the United States that are fortunate to be able to collect quite a bit of extra blood. We never have a blood shortage at the University of Minnesota because our blood supplier ships 100,000 units of blood out of Minnesota to the rest of the United States. So it's hard for me to understand, to relate to blood shortages that occur in other parts of the country.

But if you are trying to operate a national system and you have each region deciding how much they're going to produce, you don't have the ability to look, on a national basis, at where you can get blood effectively and where you can't and to collect the maximum amount of blood, on a national basis, and then move it to where it needs to go.

In many of these countries, the national organization really functioned more as a coordinated

function rather than a truly management operational function. So their ability to move quickly in response to a crisis or to implement change or to assure that they're doing things in a standardized way throughout the country was limited.

There was little inventory sharing. There were, I think in 1993, very few of these countries had a single national inventory sharing system where they could move blood around. There is quite a bit of difference in the mechanisms for approval of the budget and governance, multiple sources of funds and so on.

So I think that I would stop there and answer any questions that you might have or provide this to the Committee for your discussion.

DR. BIANCO: Yes, Karen?

MS. SHOOS LIPTON: Thanks, Jeff. I just had a question because you really did have a little--last slide here--sort of on the characteristics of an ideal program.

DR. McCULLOUGH: Oh, you've seen that?

MS. SHOOS LIPTON: And I was wondering, you know, it intuitively makes sense that those would be what you're looking for, but did you have any criteria, in terms of did they report shortages, did they--a transfusion rate in any of these countries to kind of sort of get your arms around really the patient care issue related to the blood programs in these countries?

DR. McCULLOUGH: Actually, the short answer is, no. I couldn't really figure out exactly how to do that, and I was focusing more on the structure of--and you went through a lot of this with me at the time. It was a pretty vocal, and often unspoken, concept, I think, through a lot of parts of the health care and public system, that a number of these other countries, because they had national programs, could do a lot of things quicker, faster, better, maybe cheaper than we could, and I was never very convinced about that. So I was really trying to focus on the structure of how they would operate the program, and it would have been nice to have some patient-related data, but I don't.

DR. PENNER: Jeff, you've had a lot of experience in this area. What did you think of these programs? What appealed to you most, of the group that you looked at, that you thought might have had the most effective or efficient, recognizing the fact that we're talking about whole different concepts of size of country and all of the rest of it.

DR. McCULLOUGH: I guess I think they illustrated that there's more than one way to do a good job of it, and a lot of it had to do with the quality of the people. An example may be the Netherlands. If you look back through some of these slides, they don't have the kind of nice, tight system that might have been ideal. On the other hand,

I think, those of us who know, that they ran a first-class program.

And so I think there's more than one way to structure this to make it work right. I don't have any magic answer, but the people, the relationships, the structures that they operate in could be different, but good people--maybe good people make things work regardless, I don't know.

DR. BIANCO: Dr. Sayers?

DR. SAYERS: Jeff, I suppose all of these programs were volunteer programs, but--

DR. McCULLOUGH: Yes.

DR. SAYERS: They were?

DR. McCULLOUGH: Well--

DR. SAYERS: I'm just wondering if there were some unusual incentives in some of those programs.

DR. McCULLOUGH: You know, I can't--I think I asked about that and didn't put it on here. There might have been a small amount of payment in a couple of these countries. I think Italy, at the time, had some payment for donors. I'm not sure if any of the other countries did.

Of the 18 million units on that second slide, I think very, very few of those would have been paid. And I don't think paying donors was any meaningful part of the activity of any of these countries.

DR. SAYERS: Just as an aside, it looks as if Canada is collecting 20-percent less blood now than it was in 1993, just comparing Graham's figures with Jeff's.

DR. McCULLOUGH: Yeah, I was interested to hear him say the 900,000 earlier, also. I don't know--

MS. SHOOS LIPTON: That might also not--Quebec was probably included as part of that at the time.

DR. McCULLOUGH: Yes, it was. Yeah, right.

DR. SAYERS: Quebec then sounds like a lot more fertile ground than any of us had imagined.

DR. BIANCO: Jay?

DR. EPSTEIN: I have two questions, Jeff.

Is there any value in pursuing the notion of a national policy as opposed to a national program? That was a distinction that Dr. Schmidt made for us earlier in the day and could underlie part of the apparent success of countries that lack programs. Maybe they have well-articulated, well-followed policies.

And then, second, is a more technical question. You've correctly said that government is not the direct source of funding for our blood system, but, on the other hand, we all know that at least a large chunk is through reimbursement through hospitals by Medicare and Medicaid, and I wonder if there's an estimate for the amount of funding of our blood system that does come through that

route. That may be a question as much to Dr. Bowman as it is to you, but I just wondered if you've thought about that.

DR. McCULLOUGH: Let me take the first one first. It is an important distinction that this deals with programs rather than the policy. And I wish I had thought more about your question, John. I'm going to think about it some more. It's a good one. But you may be right, that that may very well be an important part of the success of some of these programs regardless of the crispness of their structure and reporting relationships.

I don't recall at the time whether I asked to see the national blood policies of these countries. I don't think I did. I think I asked them whether they had one, but I don't think I asked to see it or that I didn't ask questions surrounding how meaningful it is, but it could very well be that that is an important factor in the success.

Your second question, I think you're right, Dr. Bowman is probably a better source of that. I didn't really look into it at the time I did this.

DR. BOWMAN: I apologize. I don't have that information off the top of my head right now, but I can certainly find out for you.

DR. BIANCO: Thank you. Thank you very much, Jeff, and I hope you're going to stay for our discussion.

Our next speaker is Dr. Eilat Shinar from Israel. She came the furthest to talk to us and to discuss the national blood program in Israel.

DR. SHINAR: Good afternoon. I wish to thank very much the Advisory Committee for inviting me to tell you a little bit about the national blood program of Israel, and also share with you the experience we had in the last three and some years about supplying blood under, I would say, constant acts of terrorism.

So as Jeff McCullough already said, the blood services of Israel is a part of a division of Magen David Adom. Magen David Adom, the Red Star of David or the Red Shield of David, and MDA for short.

We are a civil not-for-profit organization. It was founded by volunteers in the 1930s and the statutory statutes that we got is since 1950. There was an MDA law passed in our parliament, in the Knesset, giving us the responsibility to provide first aid and pre-hospital emergency medical services for the population, to operate the national blood program. We are the Israeli national society that works under the Red Cross, Red Crescent principles, and to do whatever the organization feels it needs to do.

I'm just showing you actually the two operating divisions of MDA. One is the emergency medical system, ambulance services, and the other is the blood services,

because the relation has a lot to do. Then the other division would be finance, personnel, logistics, and that actually are supposed to supply us the operational divisions we need to do our jobs.

In total in MDA we are 1,400 employees and about 6,500 volunteers, adult and youth volunteers, mostly in the ambulance services. The blood services is not attractive enough. We don't have sirens. We don't go to rescue people on the field, so it's hard to recruit volunteers. And we try also to recruit adult volunteers to the blood services, less of the young people.

And you can see we're about less than 10 percent FTEs. The EMS has one national operational center at headquarters that gets reports from 11 regional dispatch centers and some (?) for the ambulances, and we have the national center, two component laboratories and repositories, and donor room that are actually situated in MDA first aid station in the city so people can walk in and donate blood.

The issues I was asked to address is the national blood program, the management of the national inventory during peace and during disasters, the requirement of blood units and components in multi-casualty events, and to talk a little bit about the government role, and I'll try to put it in whenever it will be applicable.

So the MDA Blood Services, we actually collect I would say 95 percent of all the blood units needed nationwide, all from volunteer blood donors. In the year 2003 we collected about 276,000 units. We are a population of 6 million, so if we aim to the 50,000 units per million, we are pretty close.

We do the preparation of routine and modified blood components, and by modified I mean leuko-depleted, irradiated, baby bags, whatever the hospitals would like. We do testing of the units for blood groups, antibody screening and infectious disease marker. We store and maintain the country's inventory. We do daily shipments to the hospital blood banks and clinics of blood, and we supply all the needs of the military in Israel. The IDF, the Israeli Defense Force does not have their own blood bank. We supply them with whatever they need whenever they need.

The cherries on our cake are listed here. We have the National Blood Group Laboratory. We got that from the Ministry of Health in '94, and actually every blood bank in the country, whenever they need help, just doing antibody screening or if they want to do phenotype, and of course if they need units they'll refer to us.

We do like to do some R&D projects. Some of them I think you know. One of the systems that we developed, sampling, I know have been used in this country for some time. We have a small project of macrophages for chronic

wounds. We try to do as much research as we can with our limited resources. And I pointed up this specific grant because this is a grant that we do with our Palestinian counterpart in Gaza. The unrelated marrow program was actually stolen from us, so we started the National Whole Blood Bank about a year and a half ago, and we try to do as much international collaboration as we can.

The system works as follows. We have an advisory committee for the Ministry of Health, like yourself, which has a representative of blood banks from the major hospitals, small hospitals, and myself as the head of the national blood program of MDA. We write the national standards. We try to adhere to either the ABB and the European guidelines, and they apply to the hospitals and to us.

We are the major supplier of the blood to the hospitals, and here I would say, as Jeff mentioned, we are reimbursed--we hate the word sell or paid--we are reimbursed by the hospitals for the units they take or they get or they purchase. Being a monopoly in Israel, we are not allowed to put whatever price we like. This is dictated to us by the Ministry of Health and Finance, and something that I really wouldn't recommend, but that's the situation by monopolies in Israel.

I would say this keeps us--about 80 percent of our budget would come from there. As Jeff said, about 10

percent come from providing plasma to the local fractionator. I'll tell you a little bit about it. And about 5 percent comes from donation of MDA friends around the world.

The relations with the IDF, with the military are interesting. In the past whenever there was a war or a disaster, the army was supposed to take over and we were supposed to work under the army orders. However, people realized that in Israel in general whoever does the work on peacetime would do it best on emergencies. So right now we are actually reporting to the emergency division of the Ministry of Health, which is a civil body, and we help the army and they help us, in that they allow us to collect blood in the camps. We would provide them with whatever they need, and we would also train their reserve phlebotomists, reserve medics, that in case we need to upgrade our force of blood collection, we have about 150 medics that are trained by us and are kept fresh, and they can come and help us if we need.

The responsibilities and operation in the vein-to-vein chain are very well defined. It's our role to go from the vein of the donor till the unit is ready to go. It's the hospital blood bank responsibility to use the units and infuse them into the patient, and the pre-hospital system, meaning the army or whatever emergency system, would use "O"

(?) only, double-typed, that they'll get from us in the field.

This is the scheme of blood donation. We have data from 55 almost from the beginning, so you can see that we are still ramping up. Of course in case of wars there's no problem in recruiting donors. The hard work--I don't have to tell the people here; you know it very well--is to get it higher every year. And so far we've managed to increase 2 to 3 percent every year our blood donation.

85 of the blood is collected by mobile units all over the country, and we conduct around--you can see the force that we can send out--we conduct around 20 to 30 mobile drives a day. The 2 here stands for bulletproof armed vehicles that we had to add to the staff because we do collect blood all over, and some places you need to go in these vehicles.

Another 15 percent are collected in our donor room, fixed-site donor room, located at MDA First Station. And when we're talking about what do our donors get, the only thing we give them is what we call the MDA Future Credit Program. That means if a blood donor has donated a unit, then he and his immediate family, spouse, children to the age of 18 and then parents of both sides, if they would need blood, they won't have to go for a placement. So the donors get what we call peace of mind and this drives the

system. This is why people would come and donate blood, and we'll go on doing that.

For characteristics of our donor you would see that the donors are pretty young. You can donate blood in Israel from the age of 17 to 65. I heard that in Canada it's 71, and I just like it, and I think we'll recommend to do the change. 75 percent of the donors are male, very embarrassing for a woman standing in the head of the program, so we have to do something about it. And you can see that about 73 percent are repeat donors, and the first-time donors are actually the young people. These are the senior high school and the new recruitees to the army who are in this group. And you that the army does give a lot of blood as a solid body, but actually it's only 25 percent of the collection, so 75 of the collection comes from the civilians.

What do we do with the blood? So from the 280,000 units we collect annually, we provide everything, from platelet, random platelets we make out of about 45 percent of the unit. Fresh frozen plasma for transfusion is still needed. 25 percent of the unit, about 70,000 units a year and some cryo, and all the rest is going for fractionation. It is done in our own facility, operated by a local manufacturer, and they would make out of the Israel plasma, albumin, Factor VIII, gamma globulin, some biological glue, but most of their operation would be biological glue made

out of American cryo, and I think you know that it's going to be supplied here under the name of CryoSeal.

So for plasma products, it's regulated by the Ministry of Health, and we don't really have a lot to say about what's going on there apart from cases that we need them to do something for the country. And this was a case about a year ago when we decided that--I mean the government decided, or whoever decided, that we need to have some VIG in Israel because of bioterrorism threat. So 21,000 health care workers were vaccinated in Israel. We got the mission to collect 2,500 liters of plasma to produce the VIG, and it was done in the Fractionation Institute, and we ended up with IV-IG which is high titer of anti-VIG antibodies.

What about the national blood inventory management? The Ministry of Health Advisory Committee recommended that we would--I mean the MDA Blood Center would maintain an inventory of three days worth. That's about 3,000 units on the shelves. We receive the early report from the hospital when they place their order for blood, so they don't get anything before they tell us how much they have. We coordinate and supply the blood units in components to all these hospitals. As we say, we provide the needs of the medical corps, and we will conduct public appeals when shortage is expected.

The hospital was recommended to have 3 or 5 days worth of inventory, and the 5 goes actually for the small

hospitals, remote places, or those that are in more than a 2-hour distance from an MDA repository.

The way the inventory is controlled is they report either to a regional--I forgot to mention that in Israel we had actually--I think I said two component laboratories, two repositories, not because we need size-wise, but because we are very nervous about the middle part of the country that can be very easily cut into two, so we would like not to have all the eggs in one basket.

The hospitals get the blood from the regional inventory repositories that we have in the north report to them. We in the central get the report from the hospitals we provide and from the region, so we know at all times, at every minute, how much is there at the hospitals and in MDA repositories. And then, as was said earlier, with the push of a button we can send this report to whoever wants it, the Ministry, the army, the home front command. Whoever wants to know how much blood is there now, we can do it very easily.

And this is how the daily reports look like. These are the MDA repositories. It all goes by type, blood type, and this is only red cells. The country's divided to the north, the central and the southern part, and this is the important table where you get the total in MDA in the two facilities, "O's" and the total number, total in the hospital and the grand total, and this page goes with me.

It's like an American Express. I don't leave work without it. It's in my pocket every minute.

There's some interesting data that was collected by Barbara Silverman that was actually working with some of you guys in the past, and this is what we had from the year 2002, and you can see that this is the number of red cells we supplied, and this is the number of beds. This was our daily supply. This is our inventory, national inventory. This is in the blood services and this is in the hospitals. So you see, despite the fact that they were recommended to have 3 to 5 days, they actually have 2. We compared it to the data from here on the center monitoring study, and it in some things looks quite similar.

How do we operate during multi-casualty events and other emergencies? The issues that come immediately in mind is that we'll have to have an immediate increased demand for the blood units and components. We would need, depending on the size of the disaster, to decide about collection, production, testing and supply. We'll need to organize our personnel, our work schedule. We usually work in two shifts in the lab, and immediately in a disaster one consideration would be to divide it into two 12-hour shifts to make things easier. And in the last year of course we had to take into consideration to work in sheltered facilities because of bioterrorism and other kinds of terrorism.

A typical suicide terrorist attack would look like this. This is a bus in Tel Aviv. And immediately, I think in one minute to two, the MDA ambulance system is notified by the public. Your 9-1-1 is our 1-0-1. People would dial immediately. So regional dispatch and central dispatch immediately will know what happens, and we set up a system that once they know, they notify us.

So our SOP in a nutshell would be to receive the information as soon as possible from the EMS system regarding the extent and type of the event. We need to know the data including the number, the gender--and this is for the O-negs, mostly women and small children--severity score of the casualties and their admitting medical centers. We can evaluate the national blood inventory in no time. We do calculate 2 to 3 units of blood--but I'll show you that the data is a little different--or 7 units for the severely or moderately injured. We contact the receiving hospital, and we need them and we want them to update their need. So we don't wait for them to call us and tell us what they need. Whenever we get the notification, our person in the dispatch would call the receiving hospitals, will tell them what's on the way to them as we know it from the emergency system, a medical system, and what's the situation.

And of course we'll supply the needed blood, either by ground or air transportation, and we again will conduct the appeal if severe shortage is expected.

Now, we had to do that because in the beginning whenever there was a disaster and a terrorist attack, all the hospitals in the whole country would call in for blood and for a lot of blood. Then we realized that it's better that we manage what's going on. We'll find out. We'll tell them how much we think they need. They come up with they have, and we'll kind of negotiate.

So what are the statistics? The El-Aktza Intifada started in the end of September 2000, and it is still continuing. Not only people are damaged, ambulances are getting hurt too of course. We had about 1,300 multi-casualty events in which about 6,000 casualties--this is 0.1 percent of our population. If you think of your population of 200 million, we're talking about 200,000 individuals. 800 were dead on the scene, about 30 percent. About 66 percent are mildly injured, and this is something you have to take into consideration when you're talking about disasters in civilian setup as opposed to wars and other disasters.

So the patients that we are really interested in are the civilian moderately wounded because these are the patients that will require blood. Out of these 1,300 MCEs blood was only requested in '92 at 7 percent, and we provided a total of 15,000 units in blood components, about 8,000 units and 6,000 components. It's really not a lot if you think about what you do annually. It's only a lot when

you have to supply 20, 30 percent of your inventory now and immediately.

We're talking about these figures with Mike Fitzpatrick I think for the last year or more, and this is how much blood would you need per casualty? So what I did here, the full bars would be if you take the total number of casualties, and this is red cells and this is components. And these bars would be for the severely and moderately wounded, and again for components--and we have data from 1982. This is the Lebanon War. We have data from the late '90s. There was a time of some riots in Jerusalem. And this is the intifada that we're talking now, 3 years, and you would see that if you take the total number of casualties, and say 66 percent are really mildly injured, you get a number of 1-1/2 units and 1 unit of component per casualty. But if you take the moderately and severely injured you would end up with 7 units or 5 components units per casualty.

What does the public do? How do they respond to what's going on in Israel? In the last three years with 85 of the casualty being civilians and--they act pretty nice. What I want to say is that we actually increase from 20,000 units per month, let's say 3, 4 years ago, to about 23, 24, and it is maintained.

April, for example, is a holiday season, so we'll have a drop in April despite the fact that we know that

April is a holiday season, and the same would happen probably in September. This is a little bit changed because of your September 11th event. But what I plotted here are the MCEs, the terrorist attack that we had each month in 2001, and we actually called the public only twice. This was actually a civilian thing. It wasn't a terrorist attack--I'll tell you about it--and this is September 11. Other than that we would not have called the public.

The civilian event was the collapse of a wedding hall floor. You can see here is the party and here is the hole in the floor. And actually when we knew about the casualties and we knew about our inventory, we didn't have to have the public in. But as mentioned before, the Minister first actually was on television. People asked him, "What should we do?" He said, "Go donate blood." And we have to open the donor room and collect blood, and very quickly I managed to get on the radio and the television, and asked the people not to come any more because we are okay, everything is taken care of. Please stay home. Come next week.

The other event was September 11th, of course, and the public appeal was conducted at the request of the Minister of Health. We didn't know what's going to happen in Israel. We didn't know what may happen in American facilities in Europe. I called Mike that night, and they wanted us to start collecting blood, which we did. The

public really poured in. You can see that we doubled the collection. And again, after 3 days, when we figure out what is going on, we again told the public not to come any more. We promised that every unit is going to be used in Israel, which that was the case. So these are the only two times that we called the public in 2001. Actually, we did not need to do that at all.

The only time that we did call the public and we needed to do that was on this event. This was March 2002. It was really a horrible month for us. And this happened in Saturday after a holiday. shortage was--O was really low, so you see that inventory was low, so we called the public in, and of course they came. And after 2, 3 hours of O collection, we told them not to come any more.

Barbara Silverman helps us to find out what does these MCEs do the inventory in the hospital and the national inventory. And you can see that the hospital stay on 2 days inventory whatever happens. It's us that actually absorb all the changes. We were talking about what government can do. We would like very much in times like that when the inventory drops down, we would like hear their support, and the financing of a big campaign to recruit the donors.

So in summary, our system is a model of a national blood program operated by a civil central organization. We are responsible for the national blood collection and supply for both civilian and military at all times. We have

routine daily reporting of blood units inventory by all the holders, meaning the hospitals, the regional blood center and the national blood services to the health authority, and the reporting is mandatory.

The central control of the national inventory and distribution facilitates the closed monitoring and adequate response to unexpected events. We manage a live national inventory rather than a national reserve. And I think one of the most important experiences that we have is that real-time reports by an EMS system, being it is your own organization, all the EMS system that provide it to the population, enable immediate response of the blood supply during emergency situation.

I want to finish with thanks, of course, first of all to MDA volunteer blood donors, and then to our employees and volunteers--this is just the lab personnel in the center--phlebotomists who are out there working, to you for inviting me, and to the rest of you for your attention.

Thank you very much.

DR. BIANCO: Thank you very much.

Questions from the Committee? Oh, Jeanne.

DR. LINDEN: Thank you very much for the excellent informative presentation. On your nonreplacement system what type of penalty is there if the person has not been a donor, if there hasn't been a donor in their family, and how long has that--which I guess is a national policy--been in

place? Do you have evidence that that has been an effective incentive in your setting?

DR. SHINAR: I would start from the end. To make it effective you really need to collaboration of the hospitals. There's no actual penalty. Everybody who needs blood will get it, and will be transfused of course. The only thing is, would the hospital then tell them that they need to bring anything back? Most of the hospitals collaborate on that because they understand the importance of the national inventory. So they would ask them. If they are an MDA donor, they would be excused of bringing in donor.

If not, they could either bring replacement to the blood bank of the hospital where they were to transfused, or they can do it in any MDA station in the country and just bring a certificate that they did that. So the system works on a voluntary basis, but providing everybody understands the importance of having enough blood. This is the only initiative or incentive for the donors.

DR. LINDEN: So you mean they have to recruit a donor?

DR. SHINAR: Yes. They would be asked for. I mean the family or the patient would be asked to either recruit a donor or show that there are MDA donors. Now, the donors can be recruited that came to make the blood either at the hospital or at any MDA station.

DR. LINDEN: What if they aren't medically eligible and they don't--

DR. SHINAR: Then we support them. Then they'll get a special support from MDA. So it's just a question of goodwill.

DR. BIANCO: Yes?

DR. HEATON: I have a question relative to how you set policy for blood bank testing in Israel. I noticed you have an advisory committee to the Ministry of Health. So if, for example, a new issue comes up that's raised by the physician community like bacterial contamination, for example, would that committee review it spontaneously? Would it have to be asked to review it, and if it did review the question, would it make a formal recommendation to the Ministry or would it be a matter of discussion between your organization and this Advisory Committee before you would make a policy decision?

DR. SHINAR: What we do is usually we and the Advisory Committee would come up with the needs. We usually would do a feasibility testing at the blood services to show that we can do that, and then we'll appeal to the Ministry of Health to make it mandatory, but making it mandatory, of course, makes them responsible to either increase the price of a unit or find a budget or whatever they do, and it is of course a problem because then it goes to who has the responsibility of not doing a test. Is it the professionals

that really recommended to do that? Is it the Minister that didn't find the money to do it? So it is a problem ongoing.

DR. BIANCO: Dr. Penner?

DR. PENNER: Certainly Israel has a very unique situation. Do the Arab population donate in the program? And then secondly, in the occupied areas do you provide blood for the Palestinian population there, or is it broader than that?

DR. SHINAR: The Arab population will need blood, and we conduct a lot of drives in Arab villages and cities. We do not agree, of course, to guarantee that blood collected in Arab villages would be given to our patients. Of course, this is unaccepted. The Palestinian or the Gaza Strip in the West Bank used to get all the blood supply from Israel before the Oslo Agreement, because they were depending on the Israeli health system. Since the Oslo Agreement they are independent so they take care of their own needs. The only time that they would apply to us is if they have a rare blood type, and then we have, either from our liquid inventory or our frozen inventory of rare blood, we'll provide the unit and then we'll find ways to bring it over or send it over to them.

DR. BIANCO: Yes, Mark?

DR. SKINNER: Shifting just a moment, you did have one brief slide that talked about the plasma derivatives, and I noted that you produced Factor VIII and provide other

plasma components. Are those products distributed through the same network, and do you import products as well, or is that the supply for the country?

Then in terms of--I guess I was going to ask a similar kind of reimbursement question--obviously those would be ineligible donors, and is that just provided by the government at no cost?

DR. SHINAR: Our role in the plasma derivative is actually providing the Institute with all the surplus plasma that we have. From there it's taken by them. Factor VIII from Israeli plasma would be, I would say, would answer to about 30 percent of the needs in Israel. All the rest is imported mainly from the States, I guess. Albumin, we have more than enough, and the gamma globulin is about 90 percent of the Israeli needs are provided by gamma globulin made out of Israeli plasma and the rest is imported.

Again, I think every patient is covered by what would you say--something like your Medicare system. And blood and blood component are part of the DRG or part of this, so we don't bill with patients. When they're in the hospital, their insurance companies would deal with that.

DR. BIANCO: Dr. Sayers.

DR. SAYERS: Thanks, Celso.

Do you have an information system which links you to the hospitals? I'm just wondering how you know what the

hospital inventories are, or do you just rely on reports from the hospitals?

DR. SHINAR: Right now we rely on reports. And I need to say that they report the free units, not the cross-match and not the outdated, just real inventory. We hope that with a new system that we are introducing now, we'll be able to contact them or put them on the same system. They need to want to do that, and I'm not sure they want to do that.

[Laughter.]

DR. BIANCO: Well, thank you very much, Eilat.

DR. SHINAR: You're welcome.

DR. BIANCO: We are going to take a 15-minute break, and your encouragement to be back here on time is an exciting presentation by Dr. Martin Gorham.

[Recess.]

DR. BIANCO: It's a great pleasure for me to introduce Martin Gorham from the United Kingdom. He is the head of the National Blood Service. He has interacted a lot with all of us in the United States. We have learned a lot from him. We also enjoy his sharp sense of humor.

Martin, enlighten us.

MR. GORHAM: Thank you, Celso. You're obviously trying to kill me today. I mean first you give me a doctorate I don't have. Then you promise that I'm going to be exciting, and then you said I'm going to be witty.

[Laughter.]

MR. GORHAM: Nonetheless, thank you very much indeed for the invitation. Not least because it's caused me to think about the issues that you raise. I'll start at the beginning. I do promise to answer Jerry's questions at the end, but I've chosen a slightly different route through there. The reasons which I have will become clear.

The overview of my presentation is that I want to say a bit about what blood services is for--and that's really a substitute for is it a blood policy in England--something about the ownership and organization of blood services, then something about the NBS as a nationalized service, something about the NBS as a national service, then the way we've approached, developed our approach to contingency, emergency and disaster, fortunately, mainly learning from others, a little bit about plasma products and then the answers to Jerry's questions.

What are blood services for? The definition I use is to provide a safe, sufficient, secure blood supply at an acceptable price. There isn't a written down blood policy in England that I've been able to find, but that's my interpretation of the demands that are actually made on me. And we need to do that to meet routine demand, which I've defined as known knowns. And I think you'll recognize where these come from. Predictable contingencies, the known unknowns. And unpredictable contingencies, which I think

it's taking us into the territory of unknown unknowns, and I won't try to say the whole of the quotation.

There's some key words in my first slide. The first one is "safe," and of course the question there is how safe? Those of us in the blood world live with that all the time.

The second one is "sufficient." Sufficient for what? And I think that's changed quite significantly over the last 2 or 3 years.

Secure. How secure? Does that mean you never run out? You're sometimes short or what?

Of course, the bottom line is the acceptable price, and the key question is who decides what the acceptable price is? My general thesis would be whoever determines what is safe, what is sufficient and what is secure, also needs to be the person who pays the acceptable price.

Which takes me neatly into the issue of ownership and organization. The reason I wanted to spend a little bit of time on this was that it is evident to everybody in the United States that the English system is totally nationalized. I suppose in some times we'd have said it was a socialist system, but that word no longer exists in the UK.

[Laughter.]

MR. GORHAM: I can get away with that here.

The reason I want to talk to you about ownership is because I think there are some significant benefits that we've got out of being a national organization, and it would be very easy to write them off as being benefits from being a nationalized organization. I don't think you can totally unpick the two, but I do think there are some important distinctions there.

So I came up with this very sophisticated graph, and on the horizontal axis I've got a line running from private to government, and that's the ownership. And on the vertical axis I've got a line running from local to national, and that's the organization.

If you look back at the National Blood Service in the early 1990s--an I think it's the National Blood Service that Jerry was describing I his talk in fact--you would have found the NBS was very much a local service, though very clearly government owned. If you look at the NBS now it is an extremely nationalized service, and it is to exactly the same extent government owned. I have moved it slightly to the right because I think the reality of the situation is the government pays a greater interest to the detailed running of health services in England now than it did 15 years ago. So I just try to reflect that a little bit.

So a bit about the NBS as a nationalized service. Well, I say it's 99 percent tax funded. That means not 100 percent. It's no more scientific than that. We do get some

of our income from supplying blood to private hospitals and that's always been the case, but the bulk of the funding of the NBS or the blood services that make it up, has always been tax funding.

It is an integral part of the NHS, which as you know is a tax-based system which covers the whole of the population, and we do report directly into the Department of Health, which is our Health Ministry, and I'll say a little bit about that. We do have what's called a statutory instrument which defines the duties of the National Blood Service, and this dates from the mid 1990s. And it sets out there--I'm sorry, the slide is quite busy. The interesting thing about that is it says we do those things. The reality is we do virtually all of some of them with the dominant provision for some of them, and we're just one of the people who does it for some of them, and it's not defined. We are effectively the monopoly supplier of labile products. It doesn't actually say that there, but nobody else is authorized to do it.

I thought it was worth pointing out that, although I'm from the UK, I don't run the UK blood services. There are four countries in the UK and each has their own blood service. In reality the Scottish Blood Service provides quite a lot of support in Northern Ireland and we provide quite a lot of support to Wales. And I also made the point that of course we've got the Irish Blood Transfusion Service

operating effectively in the same geography, although not part of the UK.

This is not insignificant. There has been a degree of devolution in the UK, and the response of the blood services has been to work much more closely together as a result because we actually find it much more helpful if we cooperate and try and provide a UK blood service.

Just to give you a sense of the scale, the population being just under 50 million, Scotland around 5 million, Wales around 3 million, Northern Ireland about 1-3/4 million, a total of about 60 million population.

This is a highly-simplified diagram of our relationship with the Department of Health.

[Laughter.]

MR. GORHAM: You should see the unsimplified one.

[Laughter.]

MR. GORHAM: S of S is the Secretary of State, who's the senior political appointment in the Department, the cabinet minister. There's a Junior Health Minister, who actually takes state-of-area responsibility for the blood service. NHS is a single organization, albeit of many component parts. There's a chief executive of the NHS, Chief Medical Officer, and somewhere within the Chief Medical Officer's empire there's something called the Blood Policy Unit.

The National Blood Authority technically is a special health authority. It has a board, and there's a chairman of the board. I report on a day-to-day basis to the chairman of the board, and I'm supported by a group of executives. And then you see there some crossing relationships. In reality we deal mainly on a day-to-day basis with the Blood Policy Unit.

The role of the Department of Health is to determine policy, and they receive expert advice. Some of that expert advice comes from something we call the MSBT, the Microbiology Safety of Blood and Tissues. That is made up of experts which includes experts from the Blood Services. I suppose the other major advisory committee of the SEAC was Spongiform Encephalography Advisory Committee, which is jointly owned by the Department of Health, and the Department that's responsible for food safety. It approves strategic and business plans. It approves the funding, and it does monitor our performance, and I did say to Karen Lipton during the interval the extent to which they monitor our performance is in inverse relationship to how well they think we are doing.

That is a fairly simplified description of the NIHS. It gets reorganized quite regularly. The current arrangement is that there are 28 strategic health authorities who are responsible for geographical groups of population. The major health service providers are the

Primary Care Trust, who provide general practitioner and community services, and the NHS Trust, who run the hospital services. Our major relationship is with the NHS Trust who provide blood transfusion services, and without using a verb to describe the relationship, they give us money and we given them blood. And then there's another set of central services which report to Department of Health.

Who pays? We have a body called the National Commissioning Group, and they meet three times or four times a year, and that is the negotiating body by which the price of blood for the following year is determined. It's chaired by a senior person in the Department of Health, who's actually the person who looks after us. It includes representatives of the NHS Trust and of the blood services. I have long argued with the Department that they need to be clear what the role of this organization is. The great benefit is that it's a single organization. We have the price negotiations once a year and we have one set of national prices.

In reality, the Department of Health determines the policies and therefore largely drives the amount, the overall cost of blood, but the trusts then become involved in some of the detailed negotiations.

Effectively and very crudely, what is determined through that group is the projected amount of blood that is going to be required for the following year, the overall

projected cost of the service, and you can derive the prices from that, and you don't have to be a terribly good mathematician to do it. And then we have a system for basically if we over provide in the year, we pay back our service profits, and if demand falls more than we expected, there is a system for ensuring that we don't go into a negative balance.

I thought it was worth saying something about the role of the regulator, because it's actually very different from the position here. They've changed their name recently, which is why I've had to write it down. They're now known as the Medicines and Health Corps, Medicines and Health Care Products Regulatory Authority. The significant difference is the regulators do not determine the standards in the UK. They enforce the standards. The standards are actually determined by machinery which is--of which they are a part, but is mainly blood service and transfusionists, and it's heavily derived from the Council of Europe Guidelines.

Regulatory is part of the Department of Health. Quite clearly the European Blood Safety Directive, which came into European law last year and has to become international law next year, will have an impact because that's the system that is more driven by setting regulatory standards.

That's the NBS as a nationalized service. So the NBS is a national service. Well, Jerry did this bit for me.

The different colors represent the 14 different regions in England. There's a bit of North Wales as well on the left-hand side. It was a completely regional structure pre-1994, and it was actually--well, the people who were around at the time say, well, the most obvious thing about it being a national service was in the name.

There was a restructure in 1995 which took it into three zones. That was the time when the National Blood Authority was set up. The zonal system didn't work well because it really didn't get into the provision of the national service. The boundaries, then zones, became very prominent and got in the way of a national service. As a result a vacancy occurred at the Chief Executive Level, and I joined the National Blood Service.

Since then we've worked very hard at developing what we call a truly national service. We don't have any zones any more. We actually try to run a single national operation.

The red dots are the traditional blood centers, and if you remember the first map, they do fall mainly one in each of the regions. No two centers now provide the same service. There are still 10 centers that do processing and 11 that do testing. There's only 3 that do NAT testing, that you couldn't actually go into any two NBS centers and discover exactly the same service, and we do talk about a network of centers. And in common with a lot of European

services, we're thinking about whether we've still got too many things in too many places. We need to make a major investment in our state, and it is highly unlikely that we can move forward to make that investment in so many places.

Again, just to give you a sense of the scale of the NBS, our turnover is 400 million pounds per annum I think on the latest exchange rate. That's about 720 million U.S. dollars, of which 80 percent is the traditional blood service, and the remainder is BPL Bioproducts laboratory, which is our fractionation plant. 5-1/2 thousand staff, 2.33 million red cells, which I think is remarkably similar to the number Jerry was quoting for the early '90s. Issued 2.19 million FFP platelets. Served just over 300 hospitals. And we've got an active donor base of just under 1.7 million. That is falling. Like everybody else, we struggle to attract and retain donors.

The discussion we are now having is whether we should be trying to actively manage it down, but to increase our ability to retain donors, and we're doing a lot of work in that direction.

Just to prove that things have changed since 1993, that is the structure. It is totally a national structure. So we have a single director for Services to Donors, a single director in charge of all of the Processing and Testing and Issue. And if you go over to the right-hand side, we've got a single director for each of the support

functions. The gibberish in the middle, Public and Customer Services, would be called marketing anywhere else, and we are very clear that the management protection and enhancement of the brand very much lies with the national organization.

Nonetheless we do have an organization objective which is to provide local services in a national framework. I suspect just as everywhere else, most of the population identify much more readily with their local community than they do with some mysterious place a long way away, and a lot of our donor marketing we obviously do locally.

Our second objective is resilience, and I'll say more about that as I go on. And out third objective is responsiveness. Clearly, if you set up a national organization like we have, maintaining the local links with the NHS in responding to individual hospitals within that context is extremely important, and as a result we have quite a significant hospital liaison function dealing directly with the hospitals.

So in providing national services, the first actually I want to talk to you about is the routine demand which I've defined as the known unknowns. I think it should have been known knowns, actually. I think that's probably a misprint. There's two areas I want to talk about there. One is demand planning, and the second is supply and stock

management, and there will be some quite significant similarities with what Graham Sher was saying this morning.

We've put a lot of work into predicting total demand, and we can do that pretty accurately now on a year-to-year basis to the point where we actually do end-year adjustments of really quite small numbers. We also think we're quite good at predicting the fluctuations. We have seasonal trends. We don't get good collections in holiday periods any more or in bad weather periods any more than anybody else. So we've planned to increase our collections before those periods, and set up appeals once those periods have passed.

We have to respond to changing practice. The UK is behind the States in terms of ambulatory care and noninvasive surgery, and those changes are coming through quite quickly. There's also national priorities for cancer treatment and cardiac treatment, and there's an increasing demand for blood. And then the overall NHS demand can vary quite a bit, and you've probably picked up there's been a lot of pressure on waiting lists in the UK, and we have to be able to respond to that. I would not wish to be Chief Executive of the National Blood Service when the Waiting List Initiative came to a halt because we ran out of blood. I wouldn't be Chief for very long.

Supply and stock management. I think we've taken quite a through-the-system approach to this. So we do see

attracting and retaining donors as the first step in our supply and stock management. We have gone over completely to the national stock management scheme. We move blood around a lot within the service. Because we've adopted a policy of keeping relatively high stocks, which means there's a bigger risk of blood out-dating, we run a first-in, first-out system, and to run that effectively we actually move blood between centers to equalize the date profile of the blood.

We have something called the Blood Stocks Management Scheme, which is a collaborative work between ourselves and the hospitals that use blood, which essentially has been a system for monitoring stocks, and then on another basis, being able to compare your stock management with other similar hospitals. So it's not as developed as in Israel, but it's a distinct encouragement towards appropriate use. And we've been putting an increasing amount of effort into appropriate use, and that's the terminology we use, only transfusing blood where it's really necessary.

We see that both as a supply issue and as a safety issue. We're clear that the less blood we need to collect, the less we compromise the quality of the donors, and particularly as we get under pressure for more and more exclusions, being able to keep up the quality of the donor stock seems to us to be very important, and clearly there's

a safety issue for the patient in terms of the safest blood transfusion you had was the one you never got if you didn't need it.

I then split the contingencies into two categories. What I describe as the predictable, the known unknowns and then the less predictable--I suppose they're not completely unpredictable--the unknown unknowns. And we tend to describe this as an insurance policy because even in the UK if you want an insurance policy, you have to pay premiums, and what we're trying to get across to the users of the service is that if they want this level of resilience and this level of security of supply, it's going to cost more.

We heavily developed our emergency plan in response to the millennium, and having done all that work, we realized actually we could use our emergency plan for lots of other things as well. It puts us into a more command and control mode through the system.

So we now operate our emergency plan for any range of incidents, so internal incidents such as equipment failures. Interesting that we now describe in the external category major incidents as routine. Public utility failures: for example, we lost a blood center for 24 hours 18 months ago because the telephone system went down, and we suffer from these sorts of weather conditions as well, which can easily put us into serious problems.

So we've established a whole set of resilient strategies. We've standardized our practices. We've got common quality standards. We've got common labeling standards. That means that we can lose a major blood center and still provide normal services. We have got the capacity to respond to that and continue to supply the hospitals. Part of our resilience has actually been to give up some of the potential economies of scale. We do not by choice rely on a single supplier of any of our essential components, so we've got more than one blood bank supplier. We diversified our NAT testing, for example. That has a cost, but it means we're more resilient. We put quite a lot of effort into auditing external supplies. We don't embrace suppliers unless we're pretty sure they can do that job. And all of our decision-making tries to make a judgment about a balance of safety, sufficiency and cost.

Since we went over to using the emergency plan in a fairly routine way--and which of course is good we're practicing it regularly--we realized there was also the need to extend it for contingencies that we hadn't previously thought about, and clearly 9/11 was a considerable factor in this. So we now have developed the plan so that it will cope with massive loss of NBS service, and significant loss of the donor supply. That has meant we've had to build more resilience into the system and that has meant that we've had to have discussions with our funders about the consequences

of that. Clearly, we've had to think about the potential impact of terrorism. We have to think about our response in the event of war, and of course we're all having to think about new threats to blood safety. West Nile virus hasn't become a problem in the UK yet, but clearly we've been watching that very closely, and we watched SARS very closely, and of course we live with the unpredictabilities of variant CJD all the time.

What we've done subsequently is developed different scenarios which are even more extreme, so the level of mass casualty incident that we now think about has got some very big numbers in it, and we're having to start to think about much more radical solutions to how we would respond in those circumstances.

I put the last point on because, well, I suppose in the sense that I was congratulating the organizers of this meeting. A lot of these things that we're now starting to think about are global and if the blood services internationally don't talk to each other, then we're losing enormous learning opportunities. So we do need to do that.

A bit about plasma fractionation, as we were asked to talk about this. I have to say this is really very different in England. We do have a plasma fractionation plant. It was originally built to a size that it could have supplied all of the UK market. It's fully owned by the UK Government. In practice it operates in a competitive

market. The plasma fractionation market in England is open. The defined objective is to assure security of supply, and the problem with that defined objective is it's difficult to be clear precisely what that means and I suspect it changes from time to time, does not meet all the England demand, on most products essentially meeting about 40 percent. I know in the case of albumin it's about 80 percent.

The surplus product is exported. Does try to respond to UK market shortfalls when they occur and when an existing supplier drops out of the market for whatever reason, and it primarily does that by restricting its exports. I think you all know that pre 1999 it was based on UK plasma. Post 1999 it's been based on imported U.S. plasma, and that was a decision taken on the basis of a greatly reduced risk of the donors and being exposed to variant CJD, and I don't think anything's happened to change that view.

In 2003, as a result of advice given by us in 2002, as the plasma collection market in the United States was being rationalized, the government purchased a U.S. plasma collector, and that will become the dominant--well, it will ultimately become the sole supplier to BPL. That is not run by the National Blood Service. We take no part in that organization.

So in conclusion, and trying to answer Jerry's questions if I can remember them without having them in

front of me, effectively there is a national blood policy, and I think it would be described like that. But in terms of is there a sort of statement you can look up and read, no, there isn't. The government role in peacetime, well, I've described our relationship with the Department of Health and with the NHS, and obviously the government does have a role in that. I don't describe myself as a government employee. You probably would, but clearly our relationship is into the Ministry of Health, and the government is the source of funding, albeit the money actually goes through the hospital providers.

I think I had a problem with the first one here in the sense that my English and your English is slightly different. Our stock levels are set such that there would be sufficient of a reserve to meet any foreseeable event that might occur, so the stock levels are higher than they would need to be if we were merely meeting routine hospital demand. So there is quite explicitly a contingency factor in there. The UK Government has taken very active steps in planning for terrorist activity, and we are totally plugged into that machinery. And we are the provider to the military. The military has no separate source of blood these days, and we work very closely with them.

I found this the trickiest one to answer in some ways, because I do think this is where our different status really does confuse the issue. We actually make our stocks

public anyway, so they're readily available. And we include the Department of Health in our daily stock reports, and really to stop them from asking for them.

[Laughter.]

MR. GORHAM: I'm told the current minister actually does look at them on a weekly basis. It was said to me by one of the civil servants that she didn't want to be the minister when the NHS ran short of blood. So I said, you can reassure her, I don't wish to be the Chief Executive of the National Blood Service when the NHS runs short of blood.

But I think my final point--and I think it really is very important--security of supply in the way that we're talking about now is expensive. It only occurred to me on the plane coming across that I might have tried to calculate how expensive, but I didn't think of it beforehand, and it's quite difficult to do in an airplane. And making those sorts of policy decisions does require informed consent from the paymasters. They have to understand what the consequences of the policy decisions are if we're going to get a match between the policy and delivery.

I think that's all I really want to say. Thanks, Celso.

DR. BIANCO: Thank you very much, Martin. Does anybody from the Committee want to ask questions? Paul.

DR. HAAS: Throughout the day, especially this afternoon, of course we're looking at these different countries, and for me I'm trying to say to myself how might we fit something that I'm hearing into our society. In looking at your presentations, you've walked us through the history of the local emphasis, to the regional to finally the national scene. On slides that looks like it happened so smoothly. What were some of the barriers that were there as you were trying to make those changes?

MR. GORHAM: A very heavy commitment to the local services. And I have to say as the architect of the National Service--no, that's too strong because a lot of people had realized that we actually had to go down the road to the National Service and they really just needed somebody to give them permission to do it.

But I think it's been terribly important in treading that route that we haven't destroyed local commitment, and I have to say that in the future we might actually try to reinstate some of the local things that we've taken out at the moment. It's very difficult--well, I mean we've got all the senior staff who actually used to run their own blood centers and don't like the fact they can't do that any more. And it's--I think it's difficult for people with strongly-held views, who have been able to implement those views, to accept that they have to reach

agreements with other people and sometimes compromise on what in their view is the best practice.

I think explaining and demonstrating the advantage of going down that route has been very important. I do have an advantage in that I'm neither a scientist nor a doctor, nor a career blood banker, so I'm not actually sitting there knowing the answers. My role has been much more facilitative in terms of helping people to come up with the answers. I think ultimately when we're really sort of totally confident the National Service is working, we probably would like to see whether there should be a bit more local variation than we'd encourage at the moment.

DR. BIANCO: Yes, Andrew?

DR. HEATON: You described the Blood Policy Group. Could you give us a bit more detail about the relationship between the Blood Service and the Blood Policy Group? For example, if a new infectious is identified, take CJD, how does Blood Policy Group decide that it needs to be tested for or precautions taken? And then once it's implemented, what's your role and responsibility to the Blood Policy Group to show whether it worked and was effective?

MR. GORHAM: Usually we would be the source that recognizes that something needs to be done. So in making our input to that group--and I did make the point, but I will reiterate it--that some of the members are actually Blood Service people. In making that input we would then

work with other people as appropriate to develop effectively a business case and a risk assessment as to whether or not a particular initiative was the right one to proceed with. And we would advise on the likely implementation time scale.

In practice the policy group would like to see things implemented quicker than we say it's practical to do. Once an initiative is implemented, then we report back on the effectiveness of the intervention, and clearly that will play into judgments about future interventions, because again, one of the things that we spent a lot of time working on over the last two or three years is trying to assess the relative risk and the relative effectiveness of different interventions because at one point in the UK there was a danger that the only interventions that would be considered would be variant CJD interventions, and we started to worry about whether other important known threats were being lost sight of

DR. HEATON: If they recommend or accept the business case, does that guarantee you funding or is the funding reviewed separately, or does this group independently report to the funding agency that this needs to be funded?

MR. GORHAM: They make recommendations to the Department of Health and Ministers, and the Department of Health and Ministers decide whether a new intervention will be introduced, and if so, we then negotiate the funding. I

mean that was one of the points I was making right at the beginning and again at the end. I think it's very, very difficult to work a system where the people who make the decisions about whether or not something should be done are separate from the people who determine the funding. So, you know, I think there's some sort of ambiguities around the English system, and that's be we don't have written constitution.

It's messier than yours, but the bottom line is that the policy decisions and the money sit in the same place.

DR. BIANCO: Karen, but I'll use my prerogative.

So you believe that we have no unfunded mandates in this country?

MR. GORHAM: We might--well, we might be put under pressure to fund things by efficiencies in other areas, and I mean come with the rest of the NIHS. We find efficiency savings each year, but I find it highly unlikely that we would be asked to introduce something on the scale of NAT testing without there being adequate funding.

DR. BIANCO: Karen.

MS. LIPTON: Actually I was going to go back to your last statement which you just put as being a question of security of supply. But isn't the optimal situation that all of these require informed consent from the paymasters? I mean that really even safety and then--what was your

second--safety, sufficiency, it just seems as soon as you have that--

MR. GORHAM: That's safety, sufficiency and security.

MS. LIPTON: I was just thinking, you know, to Paul's point. He said he's having a hard time understanding sometimes the relevance of these systems, but I think the message we're finding out is that that disconnect which we clearly have here is really one of the fundamental problems in allowing us to have a rational policy.

MR. GORHAM: I think that's absolutely right. I mean we're lucky, additionally lucky in that the Department of Health have operational research and statistical analysts who have done a lot of work on variant CJD, and we took a decision three years ago that we needed similar sort of support, and we actually asked whether we could just buy them some additional staff and work with them, which is what we did and how we now operate. So quite a lot of the risk assessment and statistical work that we do is done jointly with the Department's own specialists anyway.

Now, I suspect that's quite difficult to replicate unless you've got the ownership arrangements we've got. That's certainly worked very well for us, and if you like, takes some of the potential conflict out of the system.

DR. BIANCO: Merlyn, and this will be the last question.

DR. SAYERS: Thanks, Celso.

Martin, I'm wondering about the role of government and I'm looking at your mercifully simplified diagram of the relationship between the NBA and the Department of Health. That board that you report to, are the members of that board political appointees?

MR. GORHAM: No. The appointments to both health authorities now are made via--well, it's a similar body to ourselves--what's called an arms-length body. So the chairman, I think in your terms, is a political appointee, but the other members, normally there would be no political involvement in--the Department of Health's involved in them, but the civil servants, not the politicians.

DR. BIANCO: I think that we are going to get a little bit into the discussion period.

Dr. Fitzpatrick.

COLONEL FITZPATRICK: This may be relative. I just wondered what percent of your budget goes to marketing and recruitment?

MR. GORHAM: Sorry, I didn't catch that.

COLONEL FITZPATRICK: About what percent of your budget goes to marketing and recruitment?

MR. GORHAM: Well, it varies quite a lot year on year. Just wait while I do a sum in my head. You've got to remember this is after 10 o'clock at night for me now.

[Laughter.]

MR. GORHAM: It's peaked out at around 10 million. I suspect it's rather less than that at the moment, so that's 10 million on 320 million, 2, 3 percent I think.

MR. HEALEY: Pounds or dollars?

MR. GORHAM: Sorry?

MR. HEALEY: Pounds of dollars.

MR. GORHAM: I'm doing it all in pounds. I mean I think what's misleading about that figure is it's very much a headline figure, because we've also been investing a lot in improving the quality of the service we offer our donors, which is very much aimed at retention. But I mean like Canada, we do pay television advertising. We do a lot of direct mailing, and we now run a--well, we don't run the call center--we've got a contracted out call center. I mean we invest a lot, certainly against the not much more than zero that it was 6, 7 years ago.

DR. BIANCO: Martin, thank you very, very much. Oh, Jay?

DR. EPSTEIN: Just a quick question. Could you just tell us, if you know, what the target daily inventory for the system as a whole? In other words, at the hospital level what is the daily inventory? At the collector level what is the daily inventory?

MR. GORHAM: We're aiming to collect, it must be about 8-1/2 thousand units a day now. Our midpoint target is 50,000 units an hour stock, which is about 6 days supply,

and our low level is 30,000, which is not far short of 4 days, and we also have a line at 70,000 as probably getting too high. We don't manage the hospital blood banks, and we don't offer them advice on their stock levels. What we do is encourage them to compare themselves with other similar hospitals, because in fact a sensible stockholding varies greatly according to the size of the hospital and the nature of what they do. What they are able to see is their respective wastage rates, and the stock holding is very much driven by trying to keep their wastage rates at a sensible level without obviously damaging their security of supply.

Their stock holding has gone down a lot as we've become a much more reliable supply, and again we're thinking about whether there's ways in which we could actually hold more of the wastage in the NBS, if that would be more efficient in the whole system's terms. Just for clarity, once blood is issued to a hospital, we don't take it back again, and it's not normally moved between hospitals, but we do a lot of moving, as I said earlier, within the service.

DR. BIANCO: I think that now, Martin, we have to move into our discussion period. And I would ask Jerry to help us, as he and Mark planned this meeting with the many questions on how we should conduct this discussion.

DR. HOLMBERG: Well, to all the Committee members, Mark did send you a letter specifying the intent of this meeting, to be able to lay out a road map. I think that if

you have that with you, that would be a very good guiding point to--and it may be in your handout. Yes, it is. It's the first page. The next page was the federal notification.

I think the one thing that we want to do is before it gets too foggy in the day, is that I think that we need to come back to the issue of the National Blood Reserve because clearly I think that there's some decisions and some comments that we have to make on that. But I think the issue that we have before us is that as we heard some of the discussions earlier in the day, for instance from Canada--and I think Dr. Epstein laid this out very nicely to me earlier, was that, you know, Krever had four years, and we're not going to solve all these problems in two days.

And so what we really need to do is to be able to lay out over the next day and an hour, be able to lay out what should be our road map for the future for these meetings. What can we put together as far as discrete chunks that we may be able to put our arms around and make further recommendations?

I think other than the National Blood Reserve, Dr. Brecher's intent was to basically have recommendations for ourselves. Where do we go as a Committee? There are several things that I mean we clearly see, and I think what was just presented to us from the UK, I think that the disconnect that Karen pointed out to us was the informal

consent from the paymaster. I like that expression. I think we have to be able to consider some of those issues.

What I'd like to do is for the next hour, if you would, if we could have some discussion on the National Blood Reserve, the proposal that was put forward today on that. We may have to have those slides put back up to refresh our memory on it. But then as we leave here tonight, I would like you to think about some of the questions that are in Dr. Brecher's e-mail to you, and think this through as far as how can we lay out a road map for us as a Committee?

DR. SANDLER: I'm ready to start on the National Blood Reserve if you are.

DR. BIANCO: Well, we are.

DR. SANDLER: Paul Schmidt asked the question earlier. He says, where's the American Hospital Association? And I guess I should clarify I direct a blood transfusion service here in the nation's capitol, but I'm actually sitting in a seat that the Committee has designated to represent hospitals, and I am here representing the American Hospital Association. And as I heard for the first time--it was really quite a surprise to me, I really hadn't heard much about this National Reserve--from my last couple of weeks of starving for blood, although I've got one of the best Red Cross Centers providing blood to the nation's capitol, we still are very, very short, and I have listened

to this discussion. It sounds like another entity that's going to compete with hospitals for blood. It sounds like someone's going to be recruiting blood from the people that my community blood center is recruiting blood from and doesn't have enough, that it's going to end up in a reserve for a theoretical need when I got bleeding patients last week, this week, and even three phone calls today, that I'm not quite getting enough blood for, that I'm not going to have real good access to at exactly the same dates when this wants to have it. In other words, we go to Code Orange here around the holidays and around the summertime because people are traveling, and that's when we don't have blood in the hospitals.

So I'm wondering if one of the persons who has been sponsoring this in going forward would explain to me how this doesn't compete with the shortage we already have.

DR. BIANCO: I think Karen wants to take the first shot.

MS. LIPTON: And first, we had a discussion this morning, but it wasn't in a public setting, and I do want to say that I have a conflict here because I was one of the people that developed it, and this is--the proposal does include a private and a public section, so I want to get that on the record. We had quite a discussion.

Jerry, can you give me the answer to our question before we go further? Are we allowed to discuss and/or vote on this?

DR. SANDLER: Yes. I think we all agreed that the composition of the Committee is going to include going forward six members who, like I did--I declared what my representation is, and you've got one--and that makes for informed discussion.

MS. LIPTON: Okay. Just wanted to get that on the record.

You know, in terms of it competing, I think one of the things that we have to make clear is that there are really only 2,000 units that are actually going to be held specifically in reserve. The other 8,000 are really what I would call a pass-through. It is planned to approach some of the centers who are exporters and say, "Before you export those, we would like you to hold them for 2 weeks," and then they would go on to their regular--you know, under their normal contracts.

It would only compete if we tried to do it without raising the reserves first, if we tried to tap into it, so that it really just becomes a rotation issue, if you will, rather than being something that we're raising blood to hold someplace, and I think that's why we also said it was so important to focus on this national awareness campaign as not being for the reserve, but in assuring that underneath

those 8,000 units, you have 5 to 7-day inventory in every single place in the country, so that as we move things out, we can move things up.

I think what we want to look at the reserve is literally building supply in every community in the country, and we think we have to do it in a coordinated way with national, federal help.

DR. SANDLER: Karen, how many units of blood are collected every day in the United States?

MS. LIPTON: Collected. Well, let's see, we had 14 million last year, divided by 365, so it's a huge amount. I guess your point is this is a very, very small amount, and that's what we talked about too, that in terms of overall supply and really being a help, if we were take all 2,000 units, Jerry, I guess and direct them to your hospital, it probably would make a difference, but it's really just a tiny drop in the bucket.

DR. SANDLER: Well, the tiny drop in the bucket that we had was we're going to lose a little bit of sickle cell with leukoreduction, we're going to lose a little bit with West Nile virus, we're going to lose a little bit--it got to be 7 percent--with BSE. Every time I come to this particular Committee, we do something that reduces supply. The members of the Committee got this book, and I'd like you to just take a look at the title of it. It says "Ensuring Blood Safety and Availability in the U.S." The mentality of

the person who wrote this put big bold letters on "Blood Safety" and little small white letters on "Availability."

You know, we've got a major responsibility to availability and we don't have enough blood, and the people sitting at this table don't sweat the way I sweat for 3 to 5 units of O-neg. And when someone is shipping blood out from an exporting, they're not throwing it into a refrigerator to sit there, I'm standing at the waiting dock with bleeding patients to try and get that blood. And I hope this Committee will address itself to the importance of availability. If this concept is valid, if it's really valid, then we could phase it in with a provision that says: if a hospital in the community needs the blood, it can get it from the reserve. And then you've solved the problem.

If it's valid that this is needed, that the country doesn't need any more blood and that this is just a drop in the bucket like all the other drops in the bucket that we approved here, then putting a provision in that says we'll phase it in over one year, and if hospitals need the blood, we'll tap it out, and then we can move from there. It's a way to go forward.

MS. LIPTON: Maybe the best thing though is to focus first on the national awareness campaign and get the 5 to 7-day inventories in every blood center as an implementation plan, rather than saying, well, you know, I'm worried about setting this up. I think we have said there

is no reserve without a national campaign. This will not work. We keep trying to say that very, very loudly. I think if we--we've made this recommendation over and over again. We still don't have the money in this. We don't seem to get any reaction. If we do that and build our inventories on a daily basis I think that could give you greater confidence.

DR. BIANCO: Dr. Penner.

DR. PENNER: Thank you.

Karen, I'm a little confused here as to what the reserve is for. My presumption was this was for a catastrophe, and if we had a catastrophe what would happen is we just discontinue all non-emergent surgery? How many units of blood would we have in this country if we had a major catastrophe, wiped out cities and so on and so forth, we would just hold off on non-emergent surgeries? How many units do you think we might be able to produce?

MS. LIPTON: I don't now. We actually had--and I wish--I do have some data back there, but if you look, most of our units right now are related to transplant. I mean that is the single biggest use that we have. And can you postpone a transplant? Well--

DR. PENNER: Yeah.

MS. LIPTON: Well, you might lose the organ.

DR. PENNER: Sure.

MS. LIPTON: So I think we have to be careful. Most of our use isn't for trauma. It really is for transplant and cancer patients, and that's--so if we just postponed what you would call elective surgery?

DR. PENNER: Yeah. The elective surgery, as looking at some of my hospitals, there's still a fair amount of blood--

MS. LIPTON: I could get you that figure tonight, but I don't have it with me right now.

DR. PENNER: That would develop a lot. I don't know if the UK people had any information on that.

MS. LIPTON: Do you know, Teresa?

MS. WIGMAN: No. But I raise another concern that you can't also draw those units and move them within the 4 to 6 hours, which was the goal of this group, to have the units available and ready to get to the place that it's needed within a short period of time, rather than drawing from all over the country in a system that is potentially more chaotic.

DR. PENNER: Now--

DR. BIANCO: Excuse me, Dr. Penner.

Would you identify yourself for the record?

MS. WIGMAN: I'm sorry. Teresa Wigman from the American Association of Blood Banks.

DR. BIANCO: Okay. Dr. Penner.

DR. PENNER: But then those units that would be sent out to the hospitals just wouldn't be sent out. They would be then transferred to the central area where you need it, so all of the blood banking centers that have so many units of blood available, I think could mobilize them, and they're used to handling this, so that might be a possible, even on a regional basis. But I don't know the numbers. But maybe that would be 10 or 20 or 30,000 units in a region that would be readily available in those circumstances.

DR. BIANCO: Dr. Fitzpatrick.

COLONEL FITZPATRICK: Mike Fitzpatrick from ABC. In response to Dr. Sandler, that's about 39,000 units a day that are collected in the U.S. As far as--

MS. LIPTON: I thought that was a transfusion figure, not a collection figure. That's what I was going to say, but it's not a collection figure though.

COLONEL FITZPATRICK: No, but if you took--I mean we looked at that before when we talked about a quote, virtual reserve, meaning there's enough blood collected a day and on the shelves in blood centers a day that the country ought to be able to respond to a disaster, an incident that requires blood with what is on the shelf.

The problem is you would disrupt some things, and that we don't have a system, a logistical system that is able to respond rapidly to that. And that's the problem. So the reserve is a combination--the proposal is a

combination of real units and the system to be able to capture those units quickly and send them somewhere, whether that's for a real incident where that's required or a disruption such as in the exercise, were the inventory in that region was unavailable or the donors in that region were unavailable. So you have to replace the supply to continue normal operations, and that as one of the premises that was considered. Normal operations, in those situations, need to continue. So that as where we got to with that.

But the reserve allows you to build that system to rapidly respond, not to have to call an individual center or centers, find out their inventories, look at the geographic region where they are, and put together that in a short period of time, because right now we can't do that.

And I say that from experience because of the embassy bombings. This country, even though I could have called and gotten the units required to Andrews Air Force Base, and there were units available throughout the country, that wasn't the problem. The problem was we had 4 hours to respond. There wasn't a system to go to. There wasn't a location close enough to Andrews Air Force Base with enough supply on hand to be able to respond within 4 hours. And that was a fact. That was a reality. We don't have a system that can respond.

DR. BIANCO: Dr. Penner.

DR. PENNER: You could collect that. That kind of data we were in hopes of being able to collect on a day-by-day basis as to where the deposits of blood products are in the regions.

COLONEL FITZPATRICK: But the northeast region is a region that--like Blood Bank of Delaware, I could probably have gotten the blood from them. That's not within 4 hours. I mean we don't have--even if we just look at the collection agencies that have blood to export, it's not in geographic regions throughout the country where we could respond anywhere within the country within 4 to 6 hours.

DR. BIANCO: Matt Kuehnert.

DR. KUEHNERT: I think you answered the question. My question was whether the problem was that you could not locate the available blood or was it the latter, that you just couldn't transport it from where it was within that timeframe.

COLONEL FITZPATRICK: Right. I mean the number of units was rather modest. I mean we were looking for initially 400 units of blood, primarily O. Within 8 hours, actually within the 6 hours, we had 200 units. Within 4 hours we had 21 units.

DR. KUEHNERT: You mean you knew where those units were or you had them in hand?

COLONEL FITZPATRICK: They were physically at Andrews Air Force Base, and ready to go within 6 hours. And

possibly--if there had been a system available for immediate transportation of a rapid nature, we probably could have made the 4-hour window, but calling and making arrangements for transportation, getting clearances, figuring out who's going to pay for it, all those factors come into play when you're trying to respond rapidly, and we don't have a system to do that.

MR. WALSH: Mr. Chairman?

DR. BIANCO: Yes.

MR. WALSH: As we're deliberating the creation of a reserve, on the slide this morning it said "respond to civilian need, health emergency or disaster active terrorism." And I think it's inconceivable to me that we can't make certain that we make supply available in reserve for emergencies, and a transplant, an individual waiting for a transplant in that window and that one organ, for an opportunity to survive needs that blood as much as somebody in another emergency situation. So I think if we're planning a reserve, and we're going to ask the government to spend money on promoting an awareness campaign to create that reserve, let's create a reserve that has the capability to support a hospital in need or a local community that doesn't have enough blood in a non-emergent basis, for transplants and shortages.

DR. BIANCO: Dr. Sayers.

DR. SAYERS: Thanks, Celso.

I'm just wondering if this reserve is established and civilian need is recognized and emergencies such as the ones that Jerry has described to us, do in fact occur, then my sense is there's going to have to be some group which is going to decide on where are the priorities, because I think at any one time, Jerry, there are going to be any number of hospitals in the same position as you are, equally deserving patients. We've got--what was it--a few thousand units of blood. I mean is there going to be some panel of arbiters that are going to decide whose civilian need ranks higher than somebody else's?

DR. BIANCO: Karen and then Andrew.

MS. LIPTON: What we had anticipated in the group was not to tap into it for things like transplants, only because we are pretty effective at dealing with that kind of situation. The Inter-organizational Task Force now operates fairly effectively knowing that we have some pretty well established routes of finding out. We have a National Blood Exchange. We have ABC and BCA do resource sharing. In a situation like that, in a real emergency, you can get the blood for a particular patient.

It was our intent to establish this for truly disasters that would be recognized by--in the 8,000 units by the Inter-organizational Task Force. Right now in a disaster we convene within an hour and we talk about is this really a disaster? Do we need to ship things? Who has the

blood and who's responsible? And it's fairly efficient. I think this group, which is the level one responders, so it includes all of the blood organizations, it includes FDA, CDC and HHS, if they could make a determination as to whether it should be tapped into.

I must tell you that there is great reluctance on the part of this group to establish this as a reserve that people who are experiencing periodic or chronic shortages can tap into because then you get into Jerry's problem. You're not fixing the chronic shortages problem, and we don't think that this should be a solution for chronic shortage or regional shortages. We think that that needs to be fixed by really making sure that that supply on the other end is a 5 to 7-day, and that regions who have responsibility for providing blood should have responsibility for making sure that blood's to their hospital every day.

DR. BIANCO: Andrew, then Jerry has the final word.

DR. HEATON: I'd like to make a series of comments related to production supply. My past experience before working Chiron, I worked for the American Red Cross, where I ran one of the largest exporting blood centers in the American Red Cross system. And then I worked in San Francisco in Irwin Blood Bank, which is one of the largest importing blood centers in the American system, and certain

realities stick to you very quickly when you are in that circumstance. The first is that we're running a nearly ready service. We have just enough blood to meet the next two days worth of surgery most of the time. People talk up a storm about 5 or 6 days, but the reality is that most of the U.S. blood supply runs on 48 hours inventory. We've designed it that way. We've costed it that way, and we funded it that way. So that's the system we've set up.

Second issue, point I'd like to make--and Jerry makes a very good point--it's very hard to talk about a strategic reserve when you're worrying about meeting the needs of a patient today and cancelling elective surgery. You think about nothing else. You don't care about national reserves. You think about getting to tomorrow. So when you talk about a national inventory, you've got to think about changing the underlying principles that relate to the supply situation. If you can't do that, you're frozen inventory is the only way to go because it's sequestered and it's not available for local use. So that rolls me down to the fact that you need to support your underlying system.

If you look at what happened in the 0/11 disaster, we were easily able to increase the throughput of testing of blood availability by a factor of three during the one-month period after the 9/11. So the lack of availability of blood has nothing to do with staff or insufficient labs or insufficient blood banks, or insufficient delivery systems.

It's simply due to inadequacy of donors. One of the reasons that blood centers don't get enough donors is they don't have the public priority and they don't have the economic resources to buy an extremely expensive resource which is advertising.

You've heard today two presentations, both of which were very interesting, the first of which was a Canadian presentation which talked about a budget of 850 Canadian dollars for 900,000 units. That's 900 Canadian dollars per collection per year, or about 700 U.S. dollars per collection per year. You've just heard about the UK service which has a budget of 320 million pounds and about 2.3 million. If you calculate that through at today's rate of exchange, that's $240 per collection. The average American blood center gets around 200 to 250 per collection. It simply doesn't have the economic resources to build a basis to support the national inventory that we're now talking about.

So if you want to have a national inventory, either we've got to change the underlying economics, or we've got to design an inventory or an emergency supply situation that doesn't put pressure on the likes of Jerry Sandler and his blood bank because you have the American Hospital Supply opposed to you because you're raiding today's supply to meet a contingency that may never happen. So key prerequisite to our making a recommendation I

believe, is to look at the fundamental underlying issue which is that of donor access and donor recruitment. That's the logic.

DR. BIANCO: Jerry Sandler.

DR. SANDLER: I think I may be repeating a bit what Andy said, but I find it very difficult--maybe it's easy when you're in a room like this to say that the priority of this country should be a theoretical refrigerator out in some airport hangar and not the patients who need it in a hospital. I can't believe I'm hearing what I'm hearing.

Paul Schmidt, who is here, wrote an article in the New England Journal of Medicine. He reviewed the actual disasters that occurred in the United States, and the big problem, Paul, if I got it right, was we had too much blood that was collected. These theoretical disasters are not the disasters that this Committee must look at. You've got to look at the disasters like the transplant patient for whom I didn't have blood and he didn't get his transplant. That's what this Committee has got to focus on. I've given you a very good out. I've said if you've got a valid proposal, just phase it in, and when you phase it in, if there's no need for people in the community whose community fellow citizens donated the blood, then you can lock it up, but don't lock it up till you've given it a trial phase-in.

DR. BIANCO: I'd like to hear more comments from the rest of the Committee. Jay.

DR. EPSTEIN: Well, I think that this discussion that we're having about the tension between the daily inventory and the reserve comes back to a question for the task force. Was the concept of the reserve predicated on current inventories or was it with the concept that the inventories would be built to a level of 5 or 7 days? And are you talking about the collectors' inventory or are you talking about the hospital inventory, making the distinction between Jerry's point and Andy's point, that the hospital runs on a very tight margin of inventory, but on the other hand, if there's ballast or flexibility to collector, then it can keep hospitals even with a small local inventory.

So the question really comes back to what were the assumptions made when the proposal was developed?

MS. LIPTON: Well, the assumption was building--I mean the whole thing is building 5 to 7-day in a blood center, I mean in every community. That's sort of our starting premise. And you know, we don't have to look at this question--and I, more than anybody in the world am acutely sensitive to Jerry's issue--but there was some urgency about talking about building frozen reserves and everything. I think we were trying to go back and find a way that was less costly, less intrusive, really could be built into a system and really was quite modest in terms of

its numbers. The only numbers you're talking about that would be, as you said, held specifically in reserve are 2,000 for the military. And the military is going to do this no matter what. I mean if we don't participate in it, they still have to have this type of reserve, and they will build it one way or the other. They don't have a choice.

DR. BIANCO: Yes, Chris?

MR. HEALEY: I just had a couple of questions about the proposal as it relates to the awareness campaign. Just wondering how much detail was built into that. Was there a business plan created for that? And how feasible would it be to key the reserve off of the success of a federally funded awareness campaign? In other words, if you could somehow link increases and donation to federal funded awareness campaign, could you then earmark that increase for a reserve, tie those things together so you're not drawing from what's there, but rather you're adding to?

DR. BIANCO: Dr. Fitzpatrick.

COLONEL FITZPATRICK: Well, I mean the point of Don's talk was that it has to be linked to an awareness campaign. The awareness campaign that we're aware of is the organ and tissue campaign that HHS has sponsored. We think that blood is at least equal in importance to that and should receive at least the same level of funding. We don't know exactly what that funding level was, although Don gave you an estimate.

In response to Dr.--I don't want you to think of this as a 10,000 that's locked away. It's being delayed for 2 weeks, so the inventory has swollen to 10,000. It's keyed to swelling the inventory. So you're going to get some blood that might be 2 weeks older. It's not never going to reach you. As you saw in Don's proposal, it's rotating every 2 weeks. It's not locked away from you.

DR. SANDLER: But right now if it's out there and I need 5 units of O-neg, the plan would be that I couldn't get it, and it just seems so easy to get everyone on board by saying, well, if you really need it and you don't have it, you could have it during a phase-in.

COLONEL FITZPATRICK: And all it takes is 200 hospitals that need 5 units of O-neg and it's all gone.

DR. SANDLER: Then your plan is premature.

COLONEL FITZPATRICK: No. It's ready.

DR. SANDLER: It's not linked.

COLONEL FITZPATRICK: It has to be linked. You can't do it without swelling the inventory. If you don't swell the inventory you don't have a reserve.

DR. KUEHNERT: Celso?

DR. BIANCO: Yes, Matt.

DR. KUEHNERT: As I hear about this and the back and forth between discussion about surplus and demand between blood collectors and hospitals, it just seems like a nationally representative monitoring system would have to be

implemented at the same time to be able to measure exactly what's happening as you're implementing something like this, and I just wanted to hear comments on what the status of any monitoring would be during the implementation.

MS. LIPTON: One of the slides that Don unfortunately skipped--you know when he said, "I skipped over a slide." We think that data monitoring is extremely important in this. If we don't have a sense, we just don't know. I mean I know that the Department and the Assistant Secretary of Health are right now trying to work on refining and getting that monitoring system down. I know that we're still talking about trying to get money to do the data collection that's retrospective but does give us some predictive value going into the future.

I feel like everybody's saying you have to choose one thing. I think what we're saying here is we're not saying choose one thing. I don't think I'm saying anything that I've ever said differently up here. You have to fix reimbursement. If you don't fix reimbursement, we don't have increased supply. You have to have the federal government committed with their dollars in terms of putting money into data collection and into national awareness campaigns.

Again, if I go back to what we talked about with a national blood policy, we just keep saying the same thing. It's just that nothing ever happens.

DR. BIANCO: Allan Ross, you want to say a word? The Red Cross has been very quiet.

MR. ROSS: Well, I think Dr. Sandler is absolutely correct. This is not going to work. And as Karen has mentioned, as Andrew has pointed out, unless we have a 5 to 7-day underlying ready reserve in every community in this country, we cannot lock up blood when there's patients in need on a daily basis. We have monitoring systems in this country already. We monitor by every location, by every blood type, by every day of the week. I think this country collects about 50,000 units every weekday, and that's how we tend to look at inventories. Collections on Saturday and Sunday are much less in nature, but you know, this is doable but it's not doable without funding. It's not doable without an adequate, safe, consistent supply of blood every day of the year.

And so there's lots of pieces to this puzzle. It's not a simple thing just to establish a 10,000 unit reserve. There are underlying issues that need to be fixed first.

DR. BIANCO: Dr. Epstein and then Judy Angelbeck.

DR. EPSTEIN: I want to come back to the question for the task force, which is if we were to establish a 5 to 7-day reserve in all regions, and in your own terms it was at all collection sites, is the additional reserve

necessary? In other words, what is its independent function if all the local reserves have already been augmented?

Now, I understand from Mike that there may be a special need for forward shipping for the military, but as Dr. Penner has correctly pointed out, whatever's in the region gets mobilized immediately, and the question is how much of the surplus inventory do you need so that you don't have to disrupt normal operations to deal with disasters.

So again, I'm approaching this naively because I wasn't on the task force, and I don't have a bias against reserves. It's just I need to understand better what the role of the described reserve is if it's predicated on the assumption of a prior establishment of a 5 to 7-day inventory throughout the entire collection system, because I think that would make our system more analogous to what we heard from Dr. Shinar, where they simply maintain an adequate base and they only rarely have to go on appeal.

DR. BIANCO: Judy.

DR. ANGELBECK: Thank you, Celso.

My question is just slightly different. In listening to this debate, I can't help but not have my marketing hat on. And when you talk about a national awareness campaign, I mean essentially if I'm understanding the discussion correctly, we're talking about raising the level of inventory in the entire country at all sites to a 5 to 7-day supply.

To me, a national awareness campaign is a discrete event. It has a beginning, a growth period and an end. What you need is a fundamental change in the culture of who donates blood, why they donate blood and why they continue to donate blood. That's much more to me than a national awareness campaign.

I don't know if that was what was intended or if I'm interpreting that incorrectly.

DR. BIANCO: Allan?

MR. ROSS: I wanted to address Jay's comment on if we had a 5 to 7-day reserve throughout the country or base inventory throughout the country, why we would need a reserve. And it gets back to Mike's points that he made. It's really about logistics and it's about getting things to where they're needed in a timely fashion.

I would submit that we have an adequate amount of blood in this country for most any event at any given time, but the point is, can we get it there when it's needed? And that's the whole issue and the underlying assumption that the task force took under consideration when promulgating these recommendations.

MS. LIPTON: If I could just add to that, it was that when we looked at the numbers actually, Jerry, we weren't looking at trauma because we believe, as Paul Schmidt said, that really isn't a situation. What we were looking at was, again, product quarantine and donor

ineligibility because in the TOPOFF 2 exercise, as we watched in one city, in Seattle, where the FDA was saying this cloud is moving over, we're talking about quarantining those units right now. We're talking about this number of donors being unavailable for three weeks. And we were saying if that were the case, what would, you know--and we knew that within 3 days we could replace that supply from the rest of the country. What would we need immediately to get there within 4 to 6 hours to take care of routine needs?

And that's how we came up with the 10,000, which really isn't a very big number, but it was really--as you said, it's a staging issue I think. And with the 5 to 7, then it allows you to fill in that, to backfill that without disrupting and making other people cancel surgeries. We have the blood, as Allan said, everywhere. It's really, it's not always in the right location. So you have to pick a number of locations that are strategically located across the country that you can get to an airplane fast and you can ship fast.

COLONEL FITZPATRICK: Just to add to that, too, remember that we looked at existing reserve products. My comment wasn't specific to the military. It was to an incident that could occur anywhere. The Department of State asked for that blood. The military didn't. The blood was to go to the area, and the embassy bombings are probably the largest casualty-producing event that we've seen in the past

ten years from a terrorist incident. That's an example. It could happen here. It doesn't necessarily mean it will. The TOPOFF example could happen here. It doesn't necessarily mean it will. But we should be prepared to respond.

The discussions that we had were that, you know, the national pharmaceutical stockpile is a large amount of pharmaceuticals that sit in a warehouse, prepackaged, in containers, available and ready to go. It's not on shelves. It's not in a pharmacy. It's not sitting at Upjohn. It is prepackaged, in containers. All it has to do is be loaded on a truck and sent. That's what the national pharmaceutical stockpile is, and it's rotated to help reduce cost, but there is a cost associated with keeping it. There's no marketing campaign. There's no awareness campaign. That's just a cost the government has decided to absorb in the face of being ready to respond to an incident within this country, not outside the country.

So those are the models we looked at, and as far as an awareness campaign, I submit to the expert. You're right. We were talking about that initial awareness campaign, which then needs, as we heard from the U.K., the substance behind it to maintain the marketing and maintain the recruitment. It's not a one-time deal, no.

DR. BIANCO: Dr. Gomperts?

DR. GOMPERTS: Just following on what has just been said, this is clearly not a one-time deal. This is an ongoing program that has to be maintained. There needs to be an infrastructure, there needs to be information systems that are ongoing, that need to be maintained, an ongoing focus on donors, an ongoing infrastructure with costs related to management, as well as coordination and decisionmaking and so on.

Surely, just sitting where I am right now, isn't this part of homeland security? Doesn't that fit in with government? And certainly this is a government-private partnership theoretically. But it does seem to be a strategic issue.

DR. BIANCO: Jerry, can you help us, where in the Federal Government this would land?

DR. HOLMBERG: Well, I have to tell you that Captain McMurtry left this afternoon primarily to deal with this very issue, dealing with what is the mass casualty supporting homeland security and the level of blood inventories, to what level should a geographic location have? You know, these are some of the issues that are being addressed.

Now, as far as the government responsibility, homeland security, yes, it's in their plans. But, again, we're talking, you know, I think the words were, What's the business plan to support something like this? What are the

recommendations? How do the numbers fall out? How do we create an interaction within government and the private sector? How do we make sure that the inventory, first of all, gets boosted to a level, like Dr. Fitzpatrick said, to swell the inventory? I like the idea of it, and I think Karen mentioned this earlier, as far as raising the tide. We need to raise the tide.

And so, you know, all of these are components that we have to consider as far as even getting to a homeland security issue.

DR. BIANCO: Dr. Penner?

DR. PENNER: It seems to me this discussion is hung up on the recruitment of donors, and we've been there before. About every year we kind of come around to the same business that we aren't recruiting enough donors.

And in contrast to what has come up, the awareness program and various sorts of awareness programs have been discussed before, television spots, newspaper articles and so on. And to my way of thinking and my experience with our regional Red Cross programs over the years, it really comes down to a parochial issue of recruitment. Why do you go in and donate, the people who go in and donate? It's because their community needs it or the neighbor next door is on the Red Cross Committee or on some other committee and calls them and says, "Are you coming down?" Or a group is coming down. And we see that all over the country, and they'll

come out very, very nicely if you have people who are on a one-to-one basis.

I don't think I have seen very many people coming out to a newspaper article on it unless there's an acute shortage and some major catastrophe has occurred. So we want to not work on a catastrophe basis. We want this to be a continuing element. And I think we really have to focus our interest in developing this on a local basis to promote more recruitment. And I think it can be done.

DR. BIANCO: Karen? Then Jerry, then Andrew.

MS. LIPTON: I agree with you. I think we would separate--we would make a distinction between national awareness and really public education and recruitment. We don't intend to recruit donors through this program. We are, if you will, softening the market. I mean, right now in this national awareness campaign, we did a lot that we are going out and trying to fund now. We don't have the funding. We can develop great materials. Where we're short is money to put it out into the marketplace where people will actually see it.

But the whole program has been based on focus groups with kids who are, like, 17 to 24, and it tells us they think a little bit differently than we did. They liked to do things, it turns out, in groups. Who knew? So we're trying to develop a campaign around going with a friend and doing this.

Now, we're not going to get them with this campaign to call up their local blood center. But when the local blood center calls, it just might get them there. And if the local blood center knows this information about kids liking to do things in groups and they go with a friend because it's more comfortable and they do it, it can change their recruitment activities.

So I agree with you. I think recruitment has to stay local. I think it's got to be the relationship between the local blood center and its donors. But I think that there's a huge role in terms of role modeling and understanding what gets people to get their attention at a national level. And I think we need to focus on that. I think the Canadian experience has shown us that, yes, they did get more donors when they did that. You can't do it one shot. We have this as an annually recurring cost as we maybe move into different sectors of the donor population.

DR. BIANCO: Dr. Sandler?

DR. SANDLER: Celso, I think you've got a bit of a deadlock here that I'd like to suggest how you might get around it.

The overall topic that we're looking at is the role of the government in the national blood supply and so on and so forth. A big picture. But you've got a small picture up there for a recommendation that I think would

have significant dissent if we took it up before we got the bigger picture in a discussion tomorrow.

Judy's got, I think, the front piece. We need to have an infrastructure built. And Jay suggests if we get that built, we could get up to 5 to 7 percent around, and then it would be a luxury and I'd vote for it to have a national reserve if we had the bigger plan in place.

I'd like to suggest maybe we don't want to look at the end piece--which is up on the board-- first but that we start with the base, work our way up to it, and then this would be a piece of cake.

DR. BIANCO: Dr. Heaton?

DR. HEATON: I'd like to make a couple of comments.

First, I think I've had past experience with the Department of Defense frozen blood program, and I'd like us to revisit that issue for a number of reasons. I believe it's doubtful that we'll be able to increase recruitment fast enough to avoid the problem described by Jerry where you're trying to fill a stockpile at the same time as meeting local needs.

The frozen blood program failed previously for about three key reasons: the first of which, the military didn't keep adequate frozen retention samples to do testing as testing standards changed; secondly, the post-thaw dating after the units were thawed was only 24 hours, so the units

were extremely inconvenient if you needed them; and, lastly, they disappeared to Fort Knox, where coincidentally the gold is kept as well, and, therefore, it was as hard to get the blood out of Fort Knox as it was to get the gold. And as a result, the units were not rotated and, therefore, they weren't current with current donor guidelines.

My strong suggestion is that we re-evaluate the frozen blood option, not because frozen blood is necessarily the best product, but because many of the reasons for the failure of the last program have disappeared; and, secondly, because I believe it's realistic to create a frozen stockpile more quickly without cutting into the immediate blood supply available to hospitals and patients.

DR. BIANCO: Dr. Fitzpatrick--oh, I'm sorry. Can you hold for a second? Mark Skinner asked for...

MR. SKINNER: I've been listening to the conversation and thinking back to what I understood even when we passed the recommendation about a year ago endorsing the concept of the task force and looking at it, we were asking for an answer to the question: If we had a national reserve, what should it look like? And my understanding is that's what they brought back to us, is that if we're to have a national reserve, this is what it would look like. I don't think they've tried to answer the question and weren't necessarily asked to answer the question: How do we go about implementing it? How do we fund it? How does this

compete with all the other priorities? Because there are clearly more priorities here than we can talk about, and it perhaps is unfortunate, perhaps it's fortunate, because it highlights the magnitude of the problem that this has come up in the same meeting where we're trying to talk about an entire national blood program and policy.

I would have to think if we discussed this at a separate stand-alone meeting, some of this discussion wouldn't occur. But I do think the second part of the recommendation that's up on the screen actually goes toward answering part of what we're all struggling with. If we just understand that we're answering the question, the national reserve should be liquid, it should be 10,000, the goal is four to six hours, then we've had a group of experts or interested parties or stakeholders say these are our recommendations that if this is the goal, this is how we do it. But they aren't saying go out and do it tomorrow. They're saying that the Secretary then needs to come up with a plan how to implement this in conjunction with all the other priorities and issues that we need to resolve.

And I think what we're being asked to answer is: Do we want to put this forward as our substantive recommendation on how a national reserve should be? And then we can consider it in context of the big policy.

So based on that understanding, you know, I'm prepared to support and accept the recommendation of the

committee that we're trying to tell them this is our opinion, we bless the concept of what a reserve should look like, and then the how you do it part really comes in the big picture.

DR. BIANCO: Dr. Fitzpatrick?

COLONEL FITZPATRICK: I'm not necessarily speaking for ABC at this point, so I'll just make that clarification and respond back to the some of the problems with the DOD blood program, which I think I have some intimate knowledge of.

Just to clear up a couple things, once the blood was frozen, it was moved overseas. It was placed in Korea and Europe and on board ships to put it at the sites where it was most likely to be used. Rotation back to the States was extremely costly, to rotate units on dry ice, 10 to 15 in a box, and you can't thaw them and send them because of the 24-hour dating.

The samples that were frozen for retention did prove to be inadequate for nucleic acid testing and for HIV P24 antigen testing. However, our crystal ball wasn't good enough to tell us that there would be a special tube that we would have to freeze in that didn't even exist at the time we froze them. And I don't think our crystal ball currently is good enough to tell us what test in the future is going to be necessary and what sample we should retain for those units. And really the only solution is rapid rotation. And

to rapidly rotate, you first have to decide is it two years, three years, four years, five years.

You can rotate given a sequence of events that makes it more costly. The other biggest problem with frozen blood for a large number of units at one time is the fact that even with current automation that provided 14-day dating, it still takes 55 minutes per unit per machine. And so you can get one unit per hour per machine. So however much money you want to spend on machines and techs to run them, you can increase your throughput.

There is a place for frozen blood--and Dr. Snyder has given that, and Dr. Gilcher has reported on that--in a local supply scenario, where if you have a hospital-based system or you have a local system and you want to have, to answer, to meet Dr. Sandler's problem of he needs five units of O, okay, you've got a freezer full of about 200 units of O, you thaw five units out, and you give them to him. That's a very simple solution, and Baltimore ought to be able to do that. No offense.

So there is, I think, a place for some frozen blood within this country as a reserve or a backup for some instances, and it could be proven cost-effective, I think, in a local area for that region. And Jerry and I have talked about that a lot in his previous life.

But as far as a national reserve to marshal a lot of units at once and send them frozen, even with 14-day dating, has problems.

DR. BIANCO: Thank you, Mike.

The hour advances, and I heard two points--one from Jerry Sandler, one from Mark Skinner--saying that fundamental--and Judy Angelbeck--that fundamentally--that's how I heard it, so please help me--that fundamentally the concept is there, and that it's partially represented by this sentence number two in that slide.

There are issues that were raised in terms of infrastructure, continued support, and funding, and how to shape it within everything.

Is that representative of the thinking among members of the committee? I'd like to hear comments.

MR. SKINNER: If you're looking for feedback, I thought it was interesting that we never really discussed or debated until this very last discussion on frozen blood the actual six bullets in terms of what the characteristics ought to be. So there seems to be--I wouldn't say unanimity, but a high degree of agreement over the first bullet up there. So I think the discussion is solely focused on the second bullet.

So to the extent it doesn't provide enough direction to the Secretary of the items that should be explored and then the order in which they should be explored

before it's implemented, then perhaps it could be fleshed out a little bit more. But in terms of the meat of the recommendation, I agree, I was hearing consensus.

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: I haven't heard any dissent with the recommended elements of the reserve. I think that all the debate is really focusing on two things: Do we need a reserve if we establish inventories? And should we be talking about endorsing the reserve if we haven't looked at the larger system by which we stimulate donation and maintain inventories?

And I find myself in agreement with Judy and Jerry that I would be very uncomfortable trying to come to closure on a recommendation on the issue of reserves until we've had our discussion about the system in the large. Because I think even the task force has said that you can't dissociate the two. Well, if you can't dissociate the two, don't we have to talk about both before we recommend anything?

DR. BIANCO: Jay, it would be--I hear you, and I think more people hear you. I just heard Jerry.

However, I think that in order to move these concepts, we should come out with some recommendation. Is there a preamble to those two recommendations that would represent the big picture that we could add that would help us at least come out of this meeting with an idea that, yes, we have to address the big picture; yes, if we address the

big picture in these ways, we should address a national blood reserve?

DR. EPSTEIN: I think the answer is yes. I think that if we say something along the lines that in the context of a general improvement to, you know, donation--to donor management and inventory management in the U.S. blood system, the committee believes that establishment of a liquid reserve would enhance the capability to deal with urgencies, disasters, et cetera; and that in such a context, the committee endorses the principles that have been put forward by the AABB Interorganizational Task Force, something like that. I think placing it in context is key, because I have a lot of trouble with Item 2, to tell you the truth. I think it's premature to recommend that the Assistant Secretary move to development and funding without looking at, you know, feasibility, practicality, and need.

DR. BIANCO: Paul Haas?

DR. HAAS: I agree with Jay, and I want to add that we be very explicit about the costs that are associated--I mean, there is the phrase in that second sentence about federal funding, but there are significant costs associated with doing this. And whether it's dollars up front or moving things around, that's got to be very clear.

DR. BIANCO: Yes, Karen?

MS. LIPTON: In light of the conversation, I guess one of the things that's occurring to me--and Mark is right, we only did--we responded to what the committee had asked us to do. I sense now that there's some concern over whether we should even be considering a national reserve, which is fine.

My concern is that if we don't come out of here looking at the substantive issues relating to the reserve, somebody else is going to do this, and it may not be this committee. And so, you know, even if we don't endorse that there is a reserve, if a reserve is looked at, you know, they should take into consideration these characteristics, because there is a whole other department out here that is right at this moment concerned about blood security and availability and adequacy in the event of an attack on the homeland. And I think that if we don't come out with something, we are in some way ceding authority to that other department to say, well, then, you figure it out.

DR. BIANCO: Karen, I think this is a very good lead-in to a suggestion that I have. Can we work on the wording of a resolution tonight that we could discuss tomorrow that could try to embed these concepts? I'm sure that Dr. Epstein will come with some nice words. I'm sure that Karen will help. Mark has assumed some responsibility there for starting it.

[Laughter.]

DR. BIANCO: And Merlyn can make it florid. And so is that acceptable to the committee? Yes?

DR. SANDLER: Yes, I think that Dr. Epstein's formulation would be good. Ideally, we would have another recommendation that would go before this that would talk about changing the paradigm of blood donation with a platform and set a goal of five to seven days of reserves in community hospitals, and then this would be the third recommendation, and it's fine the way it is, almost.

In other words, we've just got to get the other picture in before we vote on this so that this isn't the only product that comes out.

DR. BIANCO: Karen?

MS. LIPTON: We had that recommendation already that came out of this committee. Perhaps we could resurrect it.

DR. BIANCO: We have a list of all the recommendations in our documents.

Jerry, I think that before we close this session, you wanted to make a statement about starting times and the meeting tomorrow.

DR. HOLMBERG: Yes, several of us that are local are concerned about the traffic tomorrow morning and whether there's going to be a repeat of today. So what we're going to do is we're going to back the meeting up until 9 o'clock and start at 9 o'clock tomorrow morning.

DR. BIANCO: So this session today is adjourned, and we'll resume tomorrow at 9:00 a.m. Thank you.

[Whereupon, at 6:00 p.m., the meeting was recessed, to reconvene at 9:00 a.m., Thursday, January 29, 2004.]