DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY

Twenty-Second Meeting

Volume II

9:05 a.m.

Thursday, January 29, 2004

Grand Hyatt Washington
1000 H Street, N.W.
Washington, D.C.

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P R O C E E D I N G S

DR. BIANCO: Good morning. I want to welcome everybody this morning. I hope you're rested, thought a lot about what we discussed yesterday.

Unfortunately, Dr. Mark Brecher will not make it to the meeting, so I'll try to fill in his shoes in the best way I can.

Before we start this session, the committee members received from Captain McMurtry a training sheet. If those that were here yesterday morning would please sign it and return it to him.

I also want to thank Renee Wilson, who is our assistant that supports a lot of the activities in the committee, and she's standing all the way in the back.

[Applause.]

DR. BIANCO: She did a lot of work, but she asked us in the committee for one more favor, if on our way out we could drop our business card with her or something. She wants to update her address and e-mail list.

I think that we can go directly to our first presentation of the morning. That is Mr. Brian O'Mahony from the World Federation of Hemophilia. He is the president of the World Federation of Hemophilia, and he is going to talk to us about the global impact of U.S. blood safety and availability.

Welcome, Mr. O'Mahony.

MR. O'MAHONY: Thank you very much. Good morning. Like a true politician, I'm not going to speak on the topic that's on your program.

[Laughter.]

MR. O'MAHONY: I'm going to speak on "Hemophilia Treatment: A Global Perspective." And I guess what I want to touch on really here is to try to give you some perspective on hemophilia care in developing as well as developed countries and where we see the role of government in both those situations.

How do I move this forward? Okay.

Just if we look at the prevalence of hemophilia worldwide, we extrapolate from the U.S. prevalence figures globally, and if you look at an instance of 105 with hemophilia A per million males and 28 with hemophilia B per million males, you're looking at approximately 400,000 people with hemophilia A and B. Yet, despite this, we collect global data every year from all of our member countries, and the cumulative data that we have is on 105,000 people. So there are only 105,000 of those 400,000 actually diagnosed.

Again, we estimate that there are approximately 600,000 people with Von Willebrands who would require treatment globally. We have data on only 38,000.

The global reality is that 75 percent of those with hemophilia are not diagnosed. Many die in childhood.

In fact, I am convinced that if you could magically tomorrow morning diagnose every person with hemophilia, you would find a much higher proportion with mild or moderate hemophilia in many developing countries because many with severe hemophilia will already have died in childhood.

Hemophilia is not a priority with government. It is seen by governments as rare and expensive. There's often a lack of infrastructure, there's a lack of specific training and education of health care professionals for dealing with hemophilia. And the cost of treatment is certainly prohibitive for individuals, and, again, individuals paying for treatment is the only option in many countries, especially developing and emerging countries.

Therefore, a safe supply of affordable replacement therapy is currently only a reality in developed countries.

I just want to briefly show you this. This is basically from our global survey data for the year 2002. If you look at the percent--these are developed countries: Australia, the U.S.A., and Germany. If you look at the percentage of people with hemophilia diagnosed in relation to observed over expected numbers, you see the vast majority are diagnosed, and the per capita use of Factor VIII, 3.0 units, 3.4 in the USA, 5.5 in Germany. So there's good per capita use of Factor VIII. The vast majority are diagnosed. Treatment is either on demand or used in prophylaxis. And

treatment, I guess the objective of treatment is full integration into society in these countries.

If you look at emerging countries such as Iran, Russia, Egypt, South Africa, you'll see that a high proportion are still diagnosed. These are countries with national systems, and these are countries where a large number are diagnosed. But if you look at the per capita usage of Factor VIII, it's quite low: 0.5, 0.6, down to 0.1 in Egypt. And here you may see, you know, survival, but you're certainly not seeing any sort of quality of life. You're not seeing functional independence. You're not seeing joint integrity.

Then if you go to the developing countries--India, China, Indonesia, Bangladesh--the percentage diagnosed is very small: 2 percent in Bangladesh, 4 percent in Indonesia, 12 percent in India--and this is actually a reflection of the fact that they have a good network of treatment centers and a strong national hemophilia organization. But look at the per capita usage of Factor VIII. It's minuscule, tiny amounts of Factor VIII used. And here you do not see survival for many people with hemophilia into adulthood. Many die in childhood.

Again, it's interesting to note that these four countries between them constitute 46 percent of the world's population. Yet less than 10 percent of the world's hemophilia population have been diagnosed in these

countries, and less than 2 percent of the factor concentrates used globally are used in these countries.

And one of the main barriers, of course, for many countries is the cost of replacement therapy. If you look at the cost in developed countries--and this is U.K. data from last year where the average use was 120,000 international units per person with severe hemophilia. At an average cost of 83 cents per unit, that's approximately US$100,000 per patient per year.

Now, if you were to look at individuals paying for that, which is not the case in the U.K., then, for example, that amount of $100,000 would be five years' income for the average person in Australia, three and a third years' income for the average person in the USA. So if they had to pay for treatment, they'd have to pay three to five years' income for one year's treatment.

Now, if you look at developing countries and you look at a minimum amount of on-demand therapy, 30,000 units, that's about 1.5 units per capita, that's really a minimum amount of on-demand therapy to ensure survival and some sort of functional independence. And even at a low cost of 25 U.S. cents per unit, the cost per person would be $7,500.

Now, to those of us who live in developed countries, that looks a very reasonable cost. But for a person in India, that one year's minimum treatment would be 20 years' salary, 20 years in Bangladesh, 13 years in

Indonesia, 9 years in China. So, clearly, it's impossible for individuals to pay for treatment for hemophilia. And, in fact, that is borne out by the fact that about three-quarters of Factor VIII, both plasma-derived and recombinant, which is used globally, is used in Europe and North America and about one-quarter in the rest of the world combined.

So the reality that we see is reflected in this slide, which, again, is extrapolated from our global data. This is the comparison of the proportion of children and adults with hemophilia in countries stratified by their economies. And if you look at the wealthier countries with a GNP of greater than $10,000, you'll see a high proportion of adults to the proportion of children. But in the countries with a GNP per capita of less than $2,000, what you will see very clearly is the adults don't survive--they don't survive into adulthood. Many of them do not live beyond the age of 19. So this is the current reality in many countries.

You can say, Is this just the way the world is, that can't be changed, that hemophilia treatment is expensive, that you can't do anything about this? I don't believe that's the case, and I think we've demonstrated that.

If you put in place a hemophilia program within the national health care system, if you have a network of

hemophilia treatment centers where at least people with hemophilia are going to a center where they're able to adequately diagnose hemophilia and intervene when they can and not intervene when they shouldn't intervene, if you can provide basic blood products such as cryoprecipitate or plasma, and if you can provide concentrates at least for life- or limb-threatening bleeding episodes or surgery or perhaps in childhood, and if you can pay for that treatment by government, by social security, by insurance, but certainly not by the individuals, then you can change that reality without incurring the sort of costs that we have to incur in the Western world.

And if you remember the graph of the countries with less than $2,000 GNP per capita, this is the same graph, except it's stratified into countries where they have put in place a network of hemophilia treatment centers and a plan for provision of basic blood products and some concentrate. So a national program has been thought out. And you can see that the survival into adulthood in the latter countries where they have this program has increased five-fold. And this is a powerful argument, I think, for governments that you don't need to start off spending $100,000 per person per year. You can't start with organization, and by optimally using the limited resources that you're willing to put into this area, you can make a big difference.

I think the real issue for all countries is the provision of safe, efficacious, and affordable replacement therapy in adequate amounts as part of a sustainable national hemophilia program. The need for safety is obvious, but I think there has been a growing acceptance over the last several years, when we've seen many shortages, that there's no point in having a very safe product if you actually can't get it. So you need a supply. You need the availability of that product. And you need affordability, you need to be able to afford that product.

Now, if we take a step beyond survival and we look at improving the quality of life for people with hemophilia, and perhaps getting towards functional independence, getting towards maintaining joint integrity, getting towards--giving them a normal quality of life, you're really then looking at having a network of treatment centers. And here when you are treated in a comprehensive care center, that does decrease morbidity and mortality. I think a CDC study in the USA showed that there's a 60 percent higher morbidity and mortality in a situation where you're not attending a hemophilia treatment center.

You need access to concentrate for all, for all people with hemophilia in the country. You need clinical monitoring of your home therapy because people can undertreat, overtreat, inappropriately treat, and I think in a situation where you are treated at home--and home

treatment is the ideal treatment for hemophilia because you can treat early. But that does need to be clinically monitored on a regular basis.

I also think you need government support to ensure that the high users of concentrate, those who require surgery, those with inhibitors who require immune-tolerant therapy, are included in the system and are not left out of the system. And there is a situation, a situation has occurred where you do not have government support that individuals who are going to cost a lot of money, there's a tendency not to include them. They can run up a lifetime insurance ceiling. Even in countries with national health systems where a government doesn't look at this issue centrally, there can be problems.

A couple of years ago, in the U.K. they had what they called treatment by post code. So if you wanted, for example, recombinant product, it helped if you lived in one part of England rather than another, because some trusts would pay for it, others would not. I'm aware of cases where somebody with hemophilia with a high titer inhibitor--who developed a high titer inhibitor and who needed expensive immune-tolerant therapy would go to their hospital and they'd be told, well, listen, the best thing you can do is go to the comprehensive care center in London, they'll take really good care of you. And, of course, the budget didn't travel with them. So what they were doing was they

were saving their own hospital's budget and they were adding costs to the hospital in London. And, therefore, what you were doing under that was you were punishing the good centers.

In Germany, I've certainly heard of cases where people with hemophilia were encouraged by their insurance company to move from one city to another in order to--that they would fall under the remit of a different insurance company if they were a high-cost individual.

So I think in a situation where you've got one of high users, you certainly need government support to look at ensuring that these people have coverage.

You also have a wide variation in distribution and reimbursement mechanisms, and, again, with government support, looking at this in a centralized and cohesive manner, you can at least identify these problems. I'll give you one example.

In Ireland, where we have government support and treatment is paid for by the government, if you look at the cost of replacement therapy to the hospitals, it's actually made up of three elements. There's the purchase cost from the pharmaceutical companies. Then there is the fee added on by the contract holder, the blood transfusion service. And then there's value-added tax at 21 percent, which adds quite a lump onto the end. So if the government talks about the high cost of hemophilia treatment, you have to point out

that they're actually taxing it and getting 21 percent back into their coffers.

So the role of government, what should the role of government be? Obviously it varies from country to country, but I think there should be a national treatment strategy. Governments should ensure adequate provision of replacement therapy on a national basis, not on a piecemeal basis.

Again, if you have the government taking a national role, then you can predict the demand; you can predict the supply you require. Expensive cases, I believe, should be covered by a central fund so that you're not punishing particular hospitals or particular trusts or particular individuals or particular employers because they happen to develop an inhibitor, because they happen to require joint replacement. So expensive cases covered by a central fund would look at that.

I think the government should be planning for emergencies, not just, you know, disasters but also shortages similar to that which occurred a couple of years ago with the recombinant products, where a lot of countries had severe shortage problems.

I think a national tender or a central purchasing mechanism is something that should be looked at. And I think also in terms of the shortages, without a national system, without looking at this in a centralized way, you can have a situation where in a shortage some people with

hemophilia could potentially continue to take prophylaxis while others are actually dying for want of any replacement therapy for a life-threatening bleeding episode. So a national system helps to deal with that.

On national tenders, what are the advantages of national tenders? I believe there are a number of advantages. They bring together the appropriate expertise, and this is particularly useful in countries where there is not an enormous amount of clinical expertise in relation to hemophilia. At least you're getting all the expertise together to make the decisions.

You tend to get improved selection criteria because it's made by a group of people. Improved assessment of products. They tend to be very methodological in the way that this is done. And, in fact, under EU procurement rules, they're very onerous in relation to the criteria, how you set these out, how you assess these, and it does help.

You get a national assessment of demand and use, and it allows you to plan the cost of the treatment and also the use of the treatment.

They tend to have built-in contingency planning for emergencies. They tend to be cost-effective. You get more uniform care nationally, and also it tends to optimize care.

Let me give two examples. Brazil is a country where they have a national tender, and the use of Factor

VIII has increased from 0.25 to 1 unit per capita over the past five years.

In Ireland, where we have a national tender, the standards of care now tend to gravitate towards the best standard as opposed to hoping that you get the best standard in the capital and not elsewhere. So use of factor concentrate has increased from 1.9 to 5.7 units per capita over the past five years. It also allows manufacturers to predict demand and ensure supply, especially in areas where there could be shortages.

The disadvantages, I've heard people say, it limits clinical freedom and it limits the availability of different products in countries. I don't agree that these are disadvantages. I think that--I don't believe it limits clinical freedom. I think that the tender tends to purchase certain products, but not exclusively those products are those which can be used. You tend to get a wider list of products for which licenses are maintained.

For example, in Canada, the tender covers 90 to 95 percent of the Factor VIII and Factor IX used, but other products can be used once they're licensed.

In Ireland, it tends to cover all of the Factor VIII and Factor IX, for example, but you can use other Factor VIII or Factor IX products as a clinician if you so desire. Mind you, you have to have a good reason for not

using those which have been selected under the national tender, but it's not prohibited.

In England, only some of the products are tendered for and others are purchased by the individual centers. So you get a--there is certainly a degree of flexibility there.

So I don't believe it limits clinical freedom, and I don't believe it limits the availability of different products.

Just looking briefly at Canada, you have ten provinces. They have one national tender where all the provinces come together. They tender for recombinant Factor VIII and IX, plasma-derived Factor VIII and IX, IVIG and albumin, and they also tender for the total fractionation of their plasma. The participants include the CBS and Hema-Quebec, two clinicians, and two consumers, and they have a three-year tender period. There are some similarities here. I think in Ireland we also tender for the recombinant Factor VIII and Factor IX, for the plasma-derived products for the treatment of Von Willebrands. The participants in Ireland would also include not only the consumers and the clinicians but the government officials, the blood transfusion service, a virologist, and two outside experts, and it's a two-year tender period. Brazil I think currently has a one-year tender period. So the tender periods tend to vary between one and three years.

In Canada, the products have to be licensed by Health Canada, and you have to have at least two products in each category, where possible. I think this was a point that was made yesterday by another speaker, that the security of supply is an expense and it should be looked at. And certainly in Ireland, also, we stipulate in the tender that we want at least two suppliers, where possible. Now, that is more expensive, but it does mean that you have a greater assurance of security of supply.

The other point that was made by Martin Gorham yesterday I agree with, that in that situation where you decide--the people deciding on the products and the fact that you want more than one product in each category are also those who pay. So you're not getting a disconnect. You're not getting somebody else saying, well, why don't you just pick the cheapest product and not these two or these three. So you're selecting on the basis of safety and efficacy and supply, but also you're looking at a cost, the same people looking at cost.

And I think Canada, again, at least two products, clinical freedom is maintained. And, interestingly, I think the national tender system in Canada and the contingency planning and distribution mechanisms greatly assisted them with minimizing the impact of product shortages in 2001. And, you know, Canada is a country comparable in size to the USA. They didn't have the same problems in relation to

distribution of product when they had a major shortage. We didn't have the same problems either in Ireland, but I was reflecting yesterday when you were talking about the reserve and four hours, you know, the four-hour time period, in less than four hours you can drive from one part of the Irish coast right across the country to the other side. So the size of the country is a huge factor. But Canada, certainly the national tender system and the national health system in Canada and the way they distribute product and deal with it centrally greatly assisted them when there was a shortage back in 2001.

Again, an issue that's very important is the influence of key regulators, and I think that it's--the FDA and the EMEA play a vital role globally, not just in the USA and Europe, respectively, but the fact is that if a product is licensed by the FDA or the EMEA, it is saying to the world that this product has gone through a fairly rigorous process of licensing, and it adds a lot of validity to the product. And the decisions of the FDA and the EMEA are monitoring by many countries. I know from speaking to colleagues in Canada, for example, that Health Canada, after the Krever Report, does not want any safety measure introduced in another country which exceeds--you know, Canada has to be up right at the top level. So they look very carefully at what FDA does in relation to introduction of safety measures.

And if you look at countries where they have tenders, if you look at where they're selecting products, then they will very often ask us: Is this product licensed by the FDA or the EMEA? So the standards set by FDA and EMEA are very much followed globally.

We've had a situation where we've had to try and guide countries where they contact us and say: Listen, we've got this product that our government is looking at and it's not licensed by the FDA or EMEA, so how do we actually assess this product? And we can't really give them the answers, but what we're trying to do is help them to form the questions they should be asking the manufacturers. So to this end, we publish this "Guide for the Assessment of Clotting Factor Concentrates for the Treatment of Hemophilia." It's available on our website, wfh.org. And this is a training tool that we've used, training regulators from Eastern Europe and from Latin America, and next year we'll be using it for regulators from the Middle East. So this is really designed to help regulators where they have to select products which may not be licensed by the FDA or EMEA.

And, finally, I think, in terms of consultation, I think there's a need for more and more consultation on a global basis. I think the decision criteria in terms of hemophilia when you're selecting products, the criteria should be safety, efficacy, supply, cost-effectiveness;

evidence data and science should be used and clinical reality, and decisions should not be made on nationalism--we're going to use our own plasma and not any from abroad; we must build our own fractionation plant--unrealistic timelines or aspirations, and sometimes I feel that some of the EU directives have unrealistic timelines. The aspirations there can be good, but the timelines for implementing them could really have the potential to cause serious shortages of supply. And emotion is an issue, and that should not be an issue when you're making decisions in this area.

The World Federation is currently in the process of setting up a global consultation mechanism with all of the key stakeholders to reach a consensus of understanding on major issues, if not a consensus on policy. We do not expect to reach a consensus on policy. The players you get in the room will have different views and opinions, and that's fine. But it's good if everybody can at least understand the opinions of the others on these major issues.

We'd like to see an early warning system where we're appraised of legislation or directives or guidelines earlier than the week before they're being passed into law. And that frequently happens in Europe where, you know, you're getting a call saying the European Parliament is debating amendments to the blood directive next week, and there were 68 amendments put down in 11 languages, and can

you look at these and get back to us by close of business tomorrow to see what your view is? So an early warning system would be appreciated. It could help to optimize communication by regular contact, and the global ramifications of regulatory issues and decisions can be discussed and understood.

We're going to have the first global consultation meeting in March in Brussels, and the participants will include many acronyms: WFH, the FDA, EMEA, the World Health Organization, Health and Human Services, DG SANCO, the PPTA, EPFA, and IPOPI. And we have a longer list of participants who could be invited for specific issues or discussions, and we will be having a competition with a prize for anybody who can tell us what all the initials stand for later on.

We'll also be looking at setting up a European network because, clearly, with the European Community expanding from 15 to 25 countries and EU law affecting all those countries, there's a need for the European countries to look at this together and to plan together what their views on these directives are. And I think there is a U.S. network already in place which works effectively.

Standard agenda we would see as discussing legislation, safety issues, availability issues, economic issues, and then global perspectives.

Thank you very much.

DR. BIANCO: Thank you very much, Mr. O'Mahony.

Are there any questions from the committee? Dr. Sandler?

DR. SANDLER: Thank you very much. This is a comprehensive perspective and a real eye opener on the global problem.

I'm interested in learning a little bit more about where the undiagnosed cases are in developing countries, and specifically, just to make an example, I picked Bangladesh where 2 percent are diagnosed and 98 percent aren't.

I've done just a quick calculation using the figures on your slides. If the prevalence rate of hemophilia A is 105 per million people, and if there are 128 million people in Bangladesh, then the prevalence would indicate that there's something around 13,000 people who would have hemophilia A in Bangladesh; 2 percent diagnosed gives us 200. So we've got 13,000 that have it, 200 that are being diagnosed.

My question is: That 12,000-odd group that's being missed, are they people who are out in the population who are bleeding and medical access is such a problem that in order to get to this, there's going to have to be an influx of money as well in medical access? Or are these people who--children who die very, very early, in childbirth, and the number is really the spontaneous mutation rate that is just causing children to be born and children die and that the money that's going to be needed to

address the problem really has to be focused on obstetrical care?

MR. O'MAHONY: Well, I think it's probably a mixture. I mean, I think if I can give you the example of India, with the population of India you might expect there to be perhaps up to 100,000 people with hemophilia. More realistically, you may be looking at 50,000 or 60,000.

Now, about four or five years ago, they had diagnosed 4,500 people with hemophilia in India, but they have a pretty good network of treatment centers, and the hemophilia organization became much more active in setting up chapters around the country and going out and proactively trying to find people with hemophilia. And that number of 4,000 to 4,500 has increased to 9,000.

It's still nowhere near 50,000, but there are people out there with undiagnosed hemophilia. There are also many people who know they have hemophilia, who certainly know they have a bleeding disorder, but there was no point in them getting involved in a central registry because if there's no treatment center, there's no incentive to go to a particular hospital.

Again, a couple of years ago, we had a clinic in one hospital in India, and, you know, it was just advertised locally. And about 200 or 300 people turned up by train, some of them traveling several hours from other cities, because there was no incentive to go to a hospital to get

your name on the hemophilia register unless the hospital can actually give you treatment. So it's really the setting--in the setting up of the network of treatment centers, in setting up a national register, and then making outreach efforts to diagnose, you will actually find a lot of them.

In countries like Bangladesh or India, a lot of the people with severe hemophilia will not have survived childhood. But quite a few will have; certainly those with mild or moderate hemophilia will have survived, and they'll possibly have crippling arthritis.

So I think the numbers that you--if you could diagnose them all, you'd possibly find maybe no more than 50 percent of the prevalence you would expect in a similar country in Western Europe or North America.

DR. BIANCO: Thank you. Any other questions? Yes?

MR. WALSH: Yes, I'd just like to make a comment. It was a very nice presentation, Brian.

I'd like to just recognize that Brian is serving his tenth year as the president of the World Hemophilia Federation and has done a superb job setting an example for other plasma-user communities in structuring a logical dialogue with government and really advancing the interests of this patient population.

So I'd like to personally thank you, Brian, for what you're doing.

MR. O'MAHONY: Thank you.

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: Thank you also, Brian, for this very enlightening presentation.

You noted some success even in developing countries in improving hemophilia care through augmentations to the national policy and program. And I'm just wondering whether those were ever achieved in the absence of a more general national blood policy and program, or whether the two really go hand in hand. I'm sure you're fully aware that the WHO has a very active program to try to encourage member states to upgrade and institute sufficient national programs. So could you just comment on that relationship?

MR. O'MAHONY: I think when we go in and we talk to a government, we look for linkage issues. We look for issues, okay, if you're going to improve hemophilia treatment, you improve this as well.

Clearly, the most common one is the national blood transfusion service, and, you know, you might be encouraging them as a first step to at least screen the donors to at least make available plasma or cryoprecipitate or safer cryoprecipitate. So that is very often linked. But it's not always linked, and there are countries where we have achieved success in getting government programs without actually walking on the national transfusion service, because the problem is that the national--effecting change

in the national blood transfusion service is a medium- to long-term goal. You can't do it overnight. With hemophilia, you can actually start a program. We tend to be an impatient organization. We like to see results. We like to see them within a couple of years.

So let me give you one example of Georgia in the former Soviet Union. We went in there, and we have a national program now in place in Georgia. The government are buying concentrate. They're also using cryoprecipitate. They're buying concentrate. They've set up two hemophilia reference centers. There's an outreach program. They're diagnosing more people with hemophilia. And it's not really linked to any developing of a transfusion service. It is linked to the fact that we managed to get access to the health minister, to the finance minister, to the president, thankfully, before he left office, and there's a strong national hemophilia organization there.

It was quite interesting recently that the health minister from Georgia was at a WHO meeting, and he spoke about two programs of which his country are extremely proud. One was on diabetes, and the other was on hemophilia.

So we try to say as well that, look, hemophilia is an example of how you can treat a genetic condition very effectively so use this as a pilot project on how to effectively treat other conditions. You can link it to

thalassemia. You can link it to HIV treatment. You can link it to many things.

DR. BIANCO: Any other questions? Yes, Dr. Penner?

DR. PENNER: I appreciate your comments on the global availability of the medical specialists to treat the condition. In this country, we're facing a crisis in growing new specialists who are going to be interested and involved. We're considering resurrecting Rasputin as a possibility.

MR. O'MAHONY: For center director. I think there is global concern about the next generation of physicians and where they're going to come from to treat hemophilia. From my understanding, it seems to be a particularly acute problem in the USA, possibly due to the career paths or funding mechanisms. It is also a concern in other countries. And I think one of the areas is to link hemophilia with thrombosis and to look at--this is becoming an increasing thing that you see in many countries where the center will treat people with hemophilia and with thrombosis together. And in that way, you can treat a much larger cohort of patients, and you've got enough critical mass, if you like, to actually have a good clinical service and, therefore, get the resources allocated to that.

So that's one way I see of doing this, but we're also constantly looking for other ways to help train younger

doctors, get them interested in hemophilia. That also means starting in medical school and making sure that they get more lectures on hematology and on hemophilia.

DR. BIANCO: Yes, Chris Healey?

MR. HEALEY: Thank you, Brian. That's a great presentation.

Clearly, you're a proponent of the tender process, and I certainly respect that. This committee spent a lot of time in the past discussing how to get new safety advances and new technologies paid for through, whether it be blood products or plasma therapies. I'm wondering if you can comment on the how the tender process might accommodate or provide incentive for advancing safety and quality measures, firstly.

And then, secondly, you are, I am sure, aware that this year there were four new plasma therapies brought to market here in the United States: one IVIG, two F1 protease inhibitors, and a hemophilia recombinant clotting factor. I'm wondering also if you can comment on how the tender process provides that kind of incentive to maintain new product advancements and new product development.

MR. O'MAHONY: Well, I think, first of all, in a developing or emerging country, a tender process is very useful because it actually puts hemophilia on the radar screen. If you don't have a national database, if you don't have a network of treatment centers, if you don't have

national purchase, then you don't tend to have hemophilia care. You might have a sporadic bit of care in the capital city and nothing outside. A national tender means that they have to look at it nationally.

In terms of how that interacts with new products and increasing costs, I think you must try and ensure that there is no disconnect between the people who are looking at the safety, the efficacy, and the quality of the products that they want to purchase. They should be the same people who are deciding which products to purchase. The purchase should not then be left to a separate group of people who just look purely on the basis of cost.

I really don't want to see the guy who buys the paper clips for the government also buying the factor concentrates. You need the people who look at the safety and efficacy and supply issues and decide, okay, this product is worth a premium, this is going to be more expensive but it's worth it, we need a mix of these products for this population.

So I think if you avoid that disconnect--and in some countries there has been a problem where the decision is being taken purely on a cost basis. They look on it simply as what is the lowest tender without really examining the quality of the products. And I think that disconnect should be avoided.

DR. BIANCO: Yes, Dr. Heaton?

DR. HEATON: I'm curious to know if the Hemophilia Foundation supports the provision of genetic counseling. Obviously that's a key element to the management of the hemophilia community. And in the absence of genetic counseling, you tend to have an ever increasing number of hemophiliac patients. Is that part of your program that you recommend?

MR. O'MAHONY: Well, I mean, yes, it is in the sense that if we talk to a government in a country such as India and they want to give people genetic counseling, and clearly they're not going to put a program in place without that. That is certainly something that we have no problem with. And I think giving people choices is important.

But, you know, the ironic thing is that, you know, for example, termination of pregnancy if you're carrying a child with hemophilia is something that was very commonly done in the Nordic countries, for example, 20 or 30 years ago. You don't see that anymore to any great extent, and it's inversely proportional to the quality of the treatment that people can receive. If you can receive good treatment, then the genetic counseling actually recedes as an issue.

DR. BIANCO: Yes, Dr. Gomperts?

DR. GOMPERTS: Brian, thank you for that excellent presentation.

To focus on safety issues for a minute, many countries, Third World and to some extent Second World

countries, rely on fresh frozen plasma cryoprecipitate as a cornerstone of hemophilia care. And many of those countries are also constrained from the point of view of their health care budgets with inevitable impact on blood bank practices, donor screening, plasma, blood screening, et cetera.

From the point of view of transmission of a major blood plasma-borne pathogens, HIV, HCV, HPV, is there an active surveillance in some countries around the potential transmission, actual transmission of these agents?

MR. O'MAHONY: Well, I think that this is part of what we've discussed with governments when we're looking at putting in place a national program. If I can give you the example of Venezuela where the WFH set up a program a number of years ago, we were able to show conclusively through looking at surveillance data and prevalence data that the risk, if you were taking cryoprecipitate twice a week over 20 years, the risk of developing HIV from--and this was cryo made from screened donors--was 11 percent because of the prevalence of HIV in the population.

So that is looked at, and I think in many countries cryoprecipitate is and will continue for some time to be the mainstay of treatment. So where that's the case, we try to work with the blood banks and the government to make sure that the cryo is as safe as possible. But also there are certainly indication, life-threatening, limb-threatening bleeds, surgery, where cryoprecipitate will not

be efficacious in treating the bleed. And that is why we're also working hard to ensure that the WHO do not remove Factor VIII and Factor IX concentrates from the essential medicines list next year. And we've prepared a detailed submission for them with regard to that.

But, yes, that is very much looked at in each country.

DR. BIANCO: Mark?

MR. SKINNER: I just want to ask a question picking up on what Chris was talking about in trying to translate what you've said back to what's kind of the overall theme of this meeting in terms of looking at a national blood policy.

What I heard you say is that the policy in the countries, you know, was to address the four essential elements--safety, efficacy, affordability, and the cost of care--and that it was the integration of that system that was important, and that the national tender process was a way in which those four could easily be wrapped together. But you weren't saying, or at least what I didn't think you were saying was that the WFH's policy was that the tender process is the way to achieve it, but that you have to keep all those four in balance.

So to the extent that that's how countries define their national blood policy with those essential elements, you could address the elements individually as long as they

were integrated, or you could address them through the tender process in a structure that brought them all together from the very beginning.

But it's not the WFH's policy, is it, that the tender process is the only way to achieve comprehensive provision of product for consumers?

MR. O'MAHONY: No. It's one way to achieve it, but it's certainly not the only way. But I think what you must try and achieve is to ensure that there is a safe and adequate supply of product available to people with hemophilia throughout the country, and that you also have a way to deal with contingencies and emergencies and shortages. And that means putting some sort of centralized planning into this, whether it's through a tender process or whether it's through a system whereby you allocate products, you look at costs on a national basis. There are various systems you can use, but clearly it's one way of doing it.

I'll just reflect that if you and I were to switch countries and you were to move to Ireland tomorrow and I was to move here, not only would you get more rain and I'd get more snow, but you would move to a country where, because you have hemophilia, you would know immediately that you have as much factor replacement therapy as you need, and it would not depend on which part of the country you lived in, whether or not you had health insurance, or who your employer was.

So there is a difference. There is an advantage in having a national system. No, there's an advantage if the national system is a good one. There's a disadvantage if it's a bad one and if it's not providing good care.

DR. BIANCO: Dr. Wong?

DR. WONG: Just a quick question on the tender process in Canada. How would it deal with product changes? You have four recombinant products, and the effect of the biology of the product on the patient? I'm looking at inhibitor status and things of that sort.

MR. O'MAHONY: I don't know. I mean, I can talk about the Irish process because I'm involved in that tender process, and certainly the group doesn't just meet to buy the products. They meet every quarter just to review current reports on products and what's happening and they monitor use of the products. So if there are problems, they should be--they should come up very quickly.

DR. WONG: But a lot of these problems are not picked up in a year or two, and your tender is every two years or whatever.

MR. O'MAHONY: I'm not sure I understand the question. You're asking how they deal with post-use surveillance or--

DR. WONG: Well, let's say there are four products, somebody's using Kogenate and somebody's using

Advate. And next year the tender switches to, you know, something else.

MR. O'MAHONY: Right.

DR. WONG: So how do we track, if somebody developed a problem two years down the line, which product it is?

MR. O'MAHONY: I don't know. It's a good question. But I think that there is always serious consideration given to switching a person from one product to another. You certainly don't do it, you know, on an ad hoc basis without careful thought. And I think that was always--that's actually part of the discussion in terms of switching products.

I notice that Graham Sher yesterday talked about the fact that in Canada they have--you know, it's limiting the choice somewhat that they're only buying two recombinant Factor VIIIs. But there are, in fact, only--you know, there are only three manufacturers of recombinant Factor VIII, so it's not limiting them that much. It's not as if they're buying two out of 20. They're buying two out of three.

DR. BIANCO: Karen?

MS. LIPTON: So do I take it that the tender process isn't so much eliminating products as saying is guaranteeing accessibility and the same price for everyone nationwide? It isn't that you're trying to get patients--have patients switch. It's just that you're saying it makes

much more sense in terms of supply and so accessibility and the price and then availability, just to make sure that it's a nationally negotiated process to acquire product as opposed--

MR. O'MAHONY: Yes, I mean, if you look at Canada, they could very easily--each of the ten provinces could purchase their own product. But by doing it all together, obviously you get economies of scale, but also they're able to predict use on a national basis. They're bringing the best people perhaps in the provinces together to make the decision. And also, in a time of shortage, you can then sort of switch product from one province to another. You can move it around. That's a big advantage as well.

MS. LIPTON: Right.

DR. BIANCO: Well, I'll ask the last question. Isn't there a difference in tender processes in developed countries like Canada or Ireland where you have a lot of sophistication, you have regulatory mechanisms? And in countries like India and Brazil where those mechanisms do not always work and cost is the only factor that ultimately works at it, particularly in short-term contracts, like you said, of one year?

MR. O'MAHONY: There is a difference, but, again, actually if you look at countries like Brazil or Uruguay where they have tenders, it actually--you can have a bigger problem without a national tender because what's the basis

then for selecting products? At least with a tender, you're getting a group of clinicians and regulators together in the same room, and they're discussing it, and hopefully the meetings are with ministers, and they're discussing it and they're looking at the reasons for buying products.

As I say, if you can try and avoid a situation where they're deciding it purely on cost, so that the people in that room should be those deciding the tender, they shouldn't recommend the list, and then it goes off and some guy in the government who doesn't know anything about products picks the cheapest one on the list regardless of the discussions. That is certainly where the World Federation have tried to assist some of the countries where they've come to us and said, look, we're very concerned about this product because, or that product, and the government might buy this because it's very cheap but we're concerned about the safety, can you give us some information? And this is why we also use that regulatory guide, and this gives a lot of the questions that they should be asking any manufacturer of products.

So, yes, it's not an ideal situation, but I still think it's better in many of those countries to have a tender rather than not have a tender, because then not only do you get very sporadic systems growing up, but also you don't get sufficient treatment because in some of the areas they're just--the tender process as part of a national

system actually encourages the government to buy sufficient product to start treating people with hemophilia.

DR. BIANCO: Well, I want to thank you very much. You see that you stimulated a lot of discussion.

MR. O'MAHONY: Thank you.

DR. BIANCO: And this was very important.

MR. O'MAHONY: Thank you very much.

DR. BIANCO: I'd like now to invite our next speaker, who is Dr. Louis Katz. He is the president of America's Blood Centers. He's going to talk about the role of government in supporting community-based blood centers.

DR. KATZ: I'll thank the committee in advance for their attention.

This is a simplified version of the national U.S. blood collection system, and I only want to put it up to suggest that the U.S. does not function in the absence of a national system in some sense. We don't have an NBS like the U.K. But as you'll see, 92 percent, plus the armed forces blood program, 93 percent of the blood supply is as tightly a regulated community as there is in U.S. health care under the auspices of FDA. So there's an enormous amount of, for lack of a better words, systemization in what we do. And I think we talk a lot about degrees here as opposed to the reality.

The Red Cross and community-based ABC Centers were formed to meet local needs, but there is substantial

movement of blood around the country. I don't have recent numbers for the Red Cross, but we know excluding our biggest member blood systems which have spread out from San Francisco to Fargo to New Orleans and back to Scottsdale, outside of that enormous sub-national system under a single license, that about 7 percent of the red cells collected by our 75 U.S.-based members move from one region to another. So there's already a number of models out there about how to level blood supplies across the country from excess to shortage areas.

Hospital-based blood programs are a little bit more difficult to cite in terms of that leveling that I think we're all interested in here, particularly Dr. Sandler, who I think has been rather eloquent regarding the difficulties of running a transfusion service in a large urban hospital. These were established to meet a hospital's individual needs. They are largely not self-sufficient. Most are not FDA licensed, so they can't move blood across state lines, and they're substantially in reality and potentially less flexible in terms of getting blood from one place to another when it's needed.

That's kind of a picture of the system very quickly. I think we're here because the blood community has made it abundantly clear at a number of government forums as well as in the media that we're having trouble at times having the kind of cushion in the blood supply that we think

is necessary to allow the Dr. Sandlers and the Dr. Katzes who are actually what I call real doctors, those who have done a rectal exam in the last two weeks, to do the things that we have to do to take care of sick people.

This is kind of a laundry list. I don't think it's exhaustive by any chance, but we have an incredibly safe blood supply in the U.S., and you can see some of the reasons here from surrogate testing to our malaria and medication deferrals; vCJD we've talked about. CGMP I'll come back to. HIV and HCV testing, including nucleic acid testing. West Nile virus deferrals and nucleic acid testing. All add increments of safety to the blood supply, and I think everybody in the system, from the FDA to the individual blood center and the docs that prescribe blood, should be proud of this level of safety. It comes at a cost, and I think you all can anticipate that that's what I'm mainly going to address today.

I wanted to just point out implementation of CGMP, current good manufacturing practices, which is kind of the regulatory framework under which the FDA is helping us be sure not only that we have procedures in place to make the blood supply safe, but that we follow them. And that leads to a very interesting attitude amongst blood center medical directors, including myself, and that is, at the margins, when in doubt, defer the donor. So there's this creeping precautionism amongst medical directors at our 76

independent blood centers that bleeds donors over a long period of time.

And then finally, at the bottom we have a number of members who have traditionally collected at large military installations, two good examples, South Texas Blood and Tissue in San Antonio and Dayton Community in Dayton, Ohio, that have lost thousands of donations over a period of time to the contingencies that the military has to deal with in closure or reduction of access to bases to supplement the community blood supply at times when the military is not using an enormous amount of blood in a conflict.

So this gives you a feeling. It's kind of--I call it the death of a thousand cuts, and I believe it's what's brought us to the number of appeals that we've seen recently.

Blood shortages are increasing. I think this is the bad news. I'll try and give you some good news as well. But before September 11th, we were averaging based on data from our centers a three- to five-day supply in the refrigerators in the blood centers that was available for distribution to wherever in the system it needed to go. And today we're dealing with a two- or three-day supply, and I'll show you some data from this winter a few slides down the line.

FDA deferrals are increasing. We know this. We believe that vCJD really cost us 8 to 10 percent of our

donors, and in some places substantially more than that, both based on the deferrals and the fact that when these deferrals are publicized, people don't come in who would have come in otherwise because they think they're deferrable. And we can't measure that part, but I think it's a couple percent more on top of this.

Obviously, blood demand increases as the U.S. population ages and we do more coronary bypasses and treat more malignancies and that sort of thing. And there's the demographic issue that that cohort that's aging now, certainly older than me but not older than, say, Dr. Bianco, are our best donors. They're really our best donors, and they're the donors that we have traditionally known how to motivate much more effectively than my kids, for example, who are 19 and 20.

And then suboptimal utilization patterns, and I don't want to understress this. I think that we are transfusing 20 to 25 percent of the red cells in this country to people who don't need them. Now, maybe that's because I got bad doctors where I work, or maybe not. I don't know. I actually think that my docs are pretty average and that we're not doing a good job of using a critical product where it needs to be used.

Why don't most hospitals, with due respect to Dr. Sandler, feel the effect? Well, we're working harder and harder and harder, and if you come to meetings of our

association, most of the talk is how do we get the next donor through the door, through screening, into the chair, and a pint of blood into a bag that we can then take back to the lab. It's really what we do. It's what our association is about more than anything.

Also, blood center inventories have been shifted to the hospitals. Now, when that happens, I promise you that Jerry's not giving us back a unit of O neg when we say it needs to go someplace else. So it reduces the flexibility in the system, and I think you need to understand that.

Successful collections depend on investment of bucks, and at the end of the day, what I'm going to tell you, this is about money. It costs money to recruit the next donor, and it's as simple as that. You give us the money, and we will recruit the donors. I promise. I'll stand here and say it in public. You give us the money, and we will recruit the donors. And the problems that we're obsessing about will go away. And, you know, it's personnel, mobile and fixed collection units, paid and pro bono advertising, pens, T-shirts, cholesterol tests, PSAs, whatever it is that we use to get that marginal donor through the door.

This is just to give you a laundry list of some of the stuff that ABC is supporting in order to do this. Now, remember that ABC gets its bucks from the member centers who

are providing blood for a service fee to their consumer hospitals. So always remember that. "My Blood, Your Blood" is actually a set of two early donor education programs for primary school and secondary high school kids that introduce the next generations of donors to what blood is about and what blood donation is about. Very, very hard to measure the impact of this program, but we believe that priming the next generation of donors is critical, so that when my center calls, after they've turned 16 in the State of Iowa, and says we want you to be a blood donor, they know what we're talking about. Okay?

Member donor initiative is an effort by ABC to produce print and electronic media tools so that our member centers don't have to pay for the production costs and can spend their resources on placement in the most appropriate media.

The Ad Council campaign is extraordinarily exciting. This is an effort by ABC, the American Red Cross, and the American Association of Blood Banks to take $1.8 million, functionally $2 million, in cooperation with the Ad Council, and leverage that into between $30 and $40 million of media placements around the country. And these are not the three-in-the-morning public service announcements. These are the Ad Council placing the blood donor message in prime time where it belongs, so once again, we can prime the population so that when the local blood center does its job,

which is to ask--donors give if they're asked--that they're primed, that they're ready for the message.

We do national blood drives with corporations, unions, associations, and we're promoting Internet-based approaches to bring donors into the blood center because that's the way communications happens in the United States now. And we can talk about that off-line if anybody is interested.

The Stoplight is the first national public real-time supply monitor, and I'm going to show you some of that data in a couple of slides. And at ABC, we're trying to promote resource sharing. We're trying to promote the movement of blood from areas that have plenty to areas that have less than plenty. The big part of that is to convince people who are in areas where they could have plenty but only have enough for their local needs to recruit for New York City, for Richmond, for Memphis, for San Francisco. It's a big commitment in a small community, which is where most of the surplus exists. It's a big commitment and a big educational effort in your community to say we're going to overcollect here because they're bleeding in New York City. It's a long-term goal.

We have an Internet system so that members with surpluses can post them. We have "blast e-mail" so that we can get to all 76 members immediately when emergency blood needs exist in one of the member communities.

This is our website, and you can see that the top two things are really recruitment messages: how to give blood and how to get involved. And if you go to our website, upper right-hand corner and want to check the blood supply, there's the Stoplight. You'd click on it and you'll see it.

This is data from the Stoplight, and the left hand of each pair are the winter of '02-'03 and the right hand of each pair the winter of '03-'04. And I want you to focus on the green portion of the bars. You'll see that in the week after New Year's, 24 percent of our reporting centers, which was 90 percent of the ABC membership, 24 percent had what we would call euphemistically an adequately supply. That's three days or more. We're talking in this meeting about getting to five to seven days as a national inventory, and we're accepting three days or more.

The red bars are less than a day's supply, one day or less, and you can see that we were at 40 percent compared to 30 percent the year before.

Now, what makes that? Well, is it the weather? Is it the holidays? It's all kinds of things. But as we look over time, we see that the cushion that we depend upon to allow elective surgery to occur and to have Level 1 trauma centers has been decreasing.

Why does this happen? And why do we have localized shortages? You guys are probably all familiar

with this, so I won't spend much time. But the large tertiary centers and particularly in the urban area and university communities do more things that require more blood, tend to have a disadvantageous case mix, poor people and trauma in large urban areas and very complicated cases in many of our university settings, even in relatively rural areas like Iowa. These places with shortages are located in areas with complex economic and demographic constraints, again, poverty in particular.

The number of appeals to altruism in New York City is arguably more complex than out in the cornfields of Iowa where I get my blood. And so it is in some certain sense easier for us to get our donor base focused. That rural versus urban sense of community and priorities I won't get into for fear of upsetting somebody from an urban community.

There are disproportionate impacts, local impacts and new restrictions, and I think the best example that we have of that is that the vCJD deferrals resulted in an immediate 25-percent loss of the red cell supply in New York City, related both to the deferrals and to their historic dependence on imported red cells from the European Union countries. And I've already talked about military and former military donors on military bases.

Well, here's what's causing all the trouble. This is data from the National Blood Donor Resource Center, and it looks '89 through 2001, collected versus transfused.

Now, this is based on a sample, so there should be 95-percent confidence intervals, but they weren't--I don't think they were calculated, or if they did, I didn't pay for the full report to get the 95-percent confidence intervals.

At any rate, what you see is where we used to have a cushion between what was collected and what was used--that was two million plus or minus--that's down to about a million these days. And when you count the ABs and other difficult-to-use components that are in the system, it's just not enough at a local level to prevent shortages that result in medical outcomes of one sort or another that we want to avoid.

So why don't we just charge more, and spend more and recruit more donors? This--and I'm sure Dr. Bowman is listening very carefully--it's about where the money is in the system. We're convinced of that at ABC. I believe this is one thing that there is consensus amongst the 76 kittens that we attempt to herd in our association.

Reimbursement through CMS is glacial in reflecting mandated increases in the cost for safety, glacial. Last year, despite West Nile virus NATs and deferrals and white particulate matter and vCJD, et cetera, there was actually on the table for a substantial period of time a proposal to cut reimbursement for blood in the outpatient setting and some blood intensive DRGs in the inpatient setting where most blood is transfused. Now, I think that that did not

happen because good sense prevailed, but there's a disconnect here. Regulatory costs mandated by one branch of the public health service, HHS, are not considered adequately by another branch of HHS, Center for Medicare and Medicaid Services.

Now, the third-party payers, the Blue Crosses of the world, use CMS as a benchmark, so we're trapped for essentially all the reimbursement that goes on in hospitals. And there is enormous pressure from hospitals to restrain increases in component cost.

So we have absorbed these multiple hits associated with producing a safer product, and that means we have less for capital investment and capital investment plus innovative donor recruitment. We need to figure out how to get the Gen-X, Gen-Y and whatever the next one's going to be called, but we don't really have the resources to do it in the timeframe and with the speed that is necessary to protect Jerry Sandler and his patients.

The future depends on this Committee, we believe, tying reimbursement to safety and availability, as its name implies, and that means pressure on CMS and the Secretary to quickly and accurately determine the true cost of blood products and to adjust reimbursement so that we can reinvest in future donors.

This is--I'm stealing a term that Jerry Sandler uses with some frequency. This needs to be new money

because if all you do is add a hundred bucks to the corner rate bypass DRG, the hospital's got no clue what that's about, they'll go out and put striping in the parking lot or buy lunch for the doctors in the surgeons' lounge, and it never translates back to what comes into the blood system. So that CMS and the blood community need to figure out a way, if we're going to adjust reimbursement, that that reimbursement gets where it needs to, to donor recruitment. The devil's in the details. We don't need to decide that today but it's a critical part of the message.

This is charges, charges for red cells average in the ABC system since 1984. You can see that in recent years--I want to thank James Starkey; he's here somewhere; James Starkey put this together from the ABC staff. You can see a rather steep increase in past years as to pressure on us has finally exploded and we've just--we have to increase costs, and the havoc that this creates at our customer hospitals is very, very substantial. This is what we charge, and the hospitals aren't getting any more as we raise our prices. The bottom line is that the hospital's responsible for getting these patients in and out the door, are absorbing what we have been told to do by our best people, what we are regulated to do by FDA, what the standards of ABB tell us is important to do is not being paid for, period, end of story.

The good news is, largely the system works. The disaster that we're all worried about hasn't yet occurred. We're able to transfuse 4 or 5 million people annually and we're saving an enormous number of lives and enhancing the care of an enormous number of people on a daily basis. We do see cancellation of elective surgery to assure a local emergency blood supply, and that's a triage function that many people in medicine are familiar with.

The local and regional shortages occur. There hasn't been a national crisis. We are not throwing away organs with a measurable frequency. We are not getting reports from our system that people are dying in emergency rooms because we couldn't find enough blood to stabilize them after trauma and get them to the OR. Is that going to happen? I think it depends on decisions that are made over the next two or three years, whether we get into that system.

Does the government have a role? Yes, we absolutely believe that. At the top of the list we put "Promoting the will to give is a civic responsibility." The number of people impacted by the need for blood and blood products in a year enormously exceeds the number of organ transplants. We want to see blood donation and blood transfusion on a par with organ donation as a priority of HHS. We think, not only do we support the organ transplanters, but we support the surgeons and the

oncologists and the AIDS clinics like mine, that we're saving lives every day.

We want the government to ensure adequate reimbursement and timely adjustments. I want to apologize to people from the FDA because the blood community has spent the last 15 plus years hammering at the Blood Products Advisory Committee about this problem. It's not the FDA's problem. It really isn't. They're largely prohibited from discussing costs in their deliberations, and this is the other side of HHS that has to address this problem and decide how much safety do we want to pay for? And I think that's really the message. We need funding initiatives necessary for the appropriate regulation of a safe and adequate blood supply, and this includes things like validating proposed donor screening approaches before they appear in regulations or documents so that we don't lose donors we don't need to over white particulate matter and vaccinia and other things.

We need to evaluate changes in eligibility criteria and have that effort funded before implementation, so that if we can't afford a deferral, at least know what we think is the impact before it happens.

Rapid open assessment and new threats to the blood supply, research on appropriate use of blood components, I personally believe that if we write the grants and clinical trials networks at the NIH and elsewhere support the

research, we'll find that there's 20 percent of the blood supply or over the period that that data is collected, a 20 percent increase in the available supply of red blood cells. I think that one of my system hospitals gives red cells to 93 percent of the elective coronary bypass patients and the VA gives red blood cells to 43 percent, I believe, was a recent publication.

That kind of variation, if we document it well, across health care in the United States tells us where the opportunities are, and we need to fund that research. After we fund that research, we need to pay attention to it. CMS and AHQR and other agencies within HHS are beginning to bring Medicare reimbursement into the 21st century with regards to tying some aspects of reimbursement to some measurements of quality in other areas. Perhaps transfusion medicine is another one.

Just to address disaster response, I think you've heard from Sidney Wolfe and others, that I think we know that adequacy per se is not the issue, and we're not taking a position one way or the other on the reserve until the details are worked out. I think that's appropriate. But we do know from September 11th and TOPOFF that while there may be blood on the shelves and in the donors, it's very difficult under emergency conditions to get it from Point A to Point B and feel that this is an extremely important priority to look at.

So in summary, I think that we are saving millions of lives currently and have over 60 years. The government's job is to protect the safety of donors and recipients and promote a culture of donation as a civic responsibility. Reimbursement must reflect the cost of safety. We cannot continue with unfunded mandates from one side of HHS that are not being addressed by the other side of HHS.

Rapid and open assessment of risks, promotion of appropriate blood use are very important components. And I think our message is: give us the bucks; we'll take care of it. We've been doing it for a long time. We do it very, very well. We need the resources to do it. Leave the management and collection processing and distribution to those of us who do it as a career.

Thank you.

DR. BIANCO: Thank you, Dr. Katz.

Any questions for Dr. Katz from the Committee? Yes, Jeanne.

DR. LINDEN: Thank you. There were some very interesting ideas.

One quick question. The graph that you showed with the disparity between the collections and the transfusions, is that difference all truly a cushion of usable units or does that also include units that may not be usable because of testing losses?

DR. KATZ: That's after testing.

DR. LINDEN: After testing.

DR. KATZ: I think there are some manufacturing losses that might not have been captured, but that's after testing.

DR. LINDEN: So those are true usable units, okay.

DR. KATZ: Almost all of them. Karen, am I wrong? Those are usable.

MS. LIPTON: No, you're right, and it actually did also take into effect manufacturing losses, so that's actually what's on the shelves.

To your question, yes, it was--the statistical methodology is explained and it's I think pretty secure.

DR. BIANCO: Any other questions? Dr. Sandler.

DR. SANDLER: I didn't ask a question. I'm being called on, but I would very much support the theme of new money. The question that's being asked to us today is what can the government do? And I agree with you very much, Dr. Katz. The infrastructure of blood collection in the United States, including the American Red Cross in this community where we're short blood and in your community, knows how to do it and can do it if given, through the system, new money. And it's only two words, but we must get that as the conclusion of today's meeting.

DR. KATZ: There's a lot of detail that goes into new money and probably the only third word that I would add to new money is accountability. But in fact, our 990s are

on the IRS website, so the accountability can be built into it fairly simply. But I know of no members of our association who would be unwilling to invest what we would consider appropriate reimbursement for what we do through the hospitals into new collections.

DR. BIANCO: Thank you, Dr. Katz. Dr. Sayers?

DR. SAYERS: Have you closed comments on Dr. Katz's presentation?

DR. BIANCO: I'll take your comment.

DR. SAYERS: You're so gracious, Celso.

I'd like to reinforce what Dr. Katz had to say about money. And it's not just a question of putting money into advertising. It's not as simple as that.

You know, we heard mention of Titmus yesterday, and what Titmus did was ask why individuals donate, and we've got good ideas as to what the motivations are. We're getting to a point though that we're having to put money in reversing that question and asking why individuals do not donate. It might not be commonly realized, but when you look at the deferral rates now and compare them with deferral rates as recently as 5 or 10 years ago. Blood programs have to recognize that close to 20 percent of individuals in the community who by self assessment regard themselves as good candidates for donation, find at the time that they register that they are not good candidates and they're deferred. And those are certainly not the

individuals who are positive in test results. Those are the individuals who don't get through the mini physical or they don't get through the health history questions.

It really appears, at least in our limited experience of trying to put some money into investigating what happens to that group, it really looks as if they are becoming a significant disincentive to the message that blood donation is important and the civic responsibility. They're a disincentive because their incredulity at the outcome of their own self assessment that they were good candidates to donate. Their incredulity becomes a message to their friends, family and the community in which they participate.

So certainly we need the money for the advertising, and for developing the public relations, but we also need the money for understanding what it is that is indeed making donor recruitment less efficient than it was relatively recently.

DR. BIANCO: I see one more question, but I'm going to leave those for the period of discussion. I'd like to go on with the program if you don't mind.

Now, we open a period of public comments, and the first person that is scheduled to speak is Dr. Jonathan Goldsmith from the Immune Deficiency Foundation. Dr. Goldsmith.

DR. GOLDSMITH: I have no fancy slides.

Good morning to Dr. Bianco and the esteemed members of the Committee. I would like to thank the Committee for this opportunity to present our remarks from the Immune Deficiency Foundation this morning.

There are three areas I would like to address on behalf of the foundation and the nearly 50,000 patients and families that we represent. First, access to care, including reimbursement and supply; second, classification of immune globulin intravenous or IGIV; and third is establishment of new research initiatives that we've been instrumental in creating that may actually help with new therapies in the future.

First, access to care. Based on information from the IDF's 2002 survey of patients and families, nearly 70 percent of those affected by primary immune deficiency disease are treated with IGIV on an ongoing basis. Recent language in the Medicare law provides for a home infusion benefit and for product choice due to the fact that there are differences in manufacture and formulation of IGIV products and that individual patients experience differences in efficacy, adverse events and tolerability with some products and not others.

Despite this, the CMS has implemented a policy of reimbursement for IGIV products as if they were generic, and as authorized payment for these products at just over 45 percent of the average wholesale price in the hospital

outpatient setting which is substantially less than the 80 percent that is specified in the Medicare law. This decision reduces a patient's access to their life-saving treatment.

We have already begun to receive reports of individuals who have been denied further treatments by their health care providers because of this decision about reimbursement.

Corporate mergers and acquisitions continue to change the landscape of the plasma derivative industry. This includes the production and the distribution of IGIV. IDF is concerned that there could be negative impacts on the supply of raw material, plasma and finished goods, IGIV and other plasma derivatives, as the number of manufacturers is reduced. For example, U.S. plasma could be exported to other countries for further manufacture and reduce the availability of this critical starting material for the production of biologics manufactured in the United States for U.S. consumption.

In addition, manufacturers may decide to export the finished goods themselves, reducing the supply available to U.S. consumers. Also with a reduced number of manufacturers the supply impact of regulatory actions, such as plant closings for regulatory reasons, will be magnified.

Second, classification of IGIV. Under Medicare legislation IGIV is not classified as a blood product. As a

result, decisions made regarding this lifesaving plasma derivative are sometimes out of step with the needs of patients and families. We would strongly support the reclassification of IGIV as a blood product, because that is what it is, and the change would facilitate access for those with primary immune deficiency diseases by supporting a damping provision regarding reimbursement.

Third, some new research initiatives by way of information to you. On the 28th of September of 2003 a consortium of investigators devoted to the study of the primary immune deficiency diseases was created with fiscal support from NIAID and NICHD. The consortium was named the U.S. Immunodeficiency Network or USIDNET. The research objectives of the USIDNET are to study the clinical, molecular and cellular characteristics of genetically determined immunodeficiency diseases; to identify the molecular basis of newly defined primary immune deficiency diseases; to discover improved diagnostic tools for primary immune deficiency diseases; to advance novel therapeutic approaches for primary immune deficiency diseases; and to encourage the utilization of the USIDNET's Primary Immune Deficiency Diseases' Registries and DNA and Cell Repository.

The USIDNET is directed by a steering committee of eminent immunologists and is administered by the Immune Deficiency Foundation. We anticipate that projects funded by the USIDNET will lead to significant progress in the

management and the treatment of the primary immune deficiency diseases.

Thank you for your attention. I'd be pleased to respond to any questions.

DR. BIANCO: Thank you, Dr. Goldsmith.

Are there any questions? Yes, Dr. Penner?

DR. PENNER: Jonathan, a big problem we always have is diagnostic laboratories that are capable of assessing this condition, and there are just a very few that are trustworthy or even available. What's your approach on that end?

DR. GOLDSMITH: Well, the IDF itself does support at least one laboratory in the U.S. that's involved in the diagnosis of these primary immune deficiency diseases, but there's clearly a need to expand the availability.

There had been moves afoot to try and catalog laboratories around the world that have capabilities, although not all are approved by things like CLIA and other kinds of authorities. But we're trying to create a cataloging procedure, if you will, so that people can find a way to get their patients diagnosed. That's been our initiative.

DR. PENNER: Are those procedures reimbursable from third-party carriers, because that's a big issue? And then the last issue on that is the third-party carriers have a very defined level of reimbursement for a condition, and

if it just goes outside of that a little bit, they quickly block it because obviously this is a big cost.

DR. GOLDSMITH: Right. I think at least one of the laboratories has had some luck in terms of getting some payments for third parties because they have a CLIA certificate. And if the laboratory goes to the extent of being in compliance with state and federal laws, then they can bill for some of these services. I don't think they collect at the level that they would like to collect, which is what you said in the third part. And I don't really have any good ideas about how to effect that change.

DR. BIANCO: Any other questions?

Well, thank you very much, Dr. Goldsmith.

DR. GOLDSMITH: Thank you.

DR. BIANCO: Our next scheduled speaker is Christopher Healey from the Plasma Protein Therapeutics Association, PPTA.

MR. HEALEY: Thank you, Dr. Bianco, and fellow Committee members.

I do have just a couple of slides. You'll be happy to hear only 10 and the first one is a title slide, so it won't take long at all I promise you.

For those of you who don't know, PPTA actually stands for Powerpoint therapeutics association. Everything we do has to be documented on Powerpoint.

[Laughter.]

MR. HEALEY: Hence the slides. The presentation briefly goes into the role of government and plasma therapies, and I think Brian made the point earlier that different governments and different levels of governmental oversight are appropriate for different types of governments, different types of national development. So you might have a development country that needs a certain type of government oversight and a well-developed country that needs a different level of oversight. So this focus is really on the U.S. Government and what the role should be for U.S. Government and plasma therapies.

Just to start with a few conclusions here. Safety and availability is obviously what this Committee's all about, and that's the first and foremost responsibility of any government in the regulation of any therapeutic entity, whether it be blood, plasma or traditional pharmaceuticals.

Preserving access and choice is really I think where the debate is today, access to new therapies, access to developing therapies and existing therapies and then choice among therapies. And that's really where PPTA and our member companies are focusing our energies, trying to assure that there is access and choice. That's been largely through appropriate payment systems, you can see here, that recognize the unique nature of plasma therapies.

One of the things that is unique about plasma therapies is trying to figure out where they fit in. We

heard earlier that the National Blood Policy was developed because blood was viewed as a national resource, and that's sort of on one end of the spectrum there. And you can see blood, tissues and organs and some of the characteristics of any national resource that have to be acknowledged that might give rise to a higher level of government involvement or government vigilance if you like.

On the other end of the spectrum is traditional pharmaceuticals which typically follow more free market principles. And some example there, obviously, different safety profile, generics are rampant in the pharmaceutical industry, and it's make more-sell more. That's the watch word of the pharmaceutical sector, more free market principles, as I said.

So where do plasma therapies fit in in this spectrum? I'd posit that they fit somewhere in the middle. They're really neither a traditional national resource, nor a traditional pharmaceutical, and that's what we grapple with as an industry, and I think part of what the Committee grapples with in defining a role for the government in the regulation of plasma therapies.

A number of countries have taken the approach that plasma therapies are a national resource and a few examples are listed here, and various other speakers have talked about it. BPL, obviously is the fractionator for the UK. Holland has a fractionation facility. CBS, Graham Sher

talked at length about the distribution system there for Canada. The bottom line I see here is that national resource approach doesn't quite fit for plasma therapies. It's effective in ensuring safety and availability, that's true, but when it comes to access and choice, this level of government oversight is not a good fit for plasma therapies.

When I say "this level of government oversight," what I mean is the government taking an active role in plasma collection, actually performing plasma pheresis, having a national plasma collection system, or having a national fractionation system or a national distribution system. Clearly, every country has a payor system, and in the U.S. there is a robust payor system with CMS, but it's not all patients. It does not provide payment for all patients, as Medicare and Medicaid, which make up only a percentage of the total payments for plasma therapies.

Of course the traditional health and safety authorities is a must and most national organizations, most national governments have some level of regulatory oversight, whether it be a national authority such as FDA or a supernational authority such as the EMEA.

So again the theme here is plasma therapies don't fit the traditional model of a national resource, but they're not a pharmaceutical either. This colorful slide is really just to try and contrast some of the costs associated with plasma therapies versus traditional pharmaceuticals.

You can see here by depiction that the raw materials for plasma therapies absorb a much greater percentage of the cost than they do for pharmaceuticals. Raw materials for pharmaceuticals are relatively cheap compared the cost that goes into the starting material for plasma therapies.

Direct manufacturing costs are perhaps a little bit higher for plasma therapies. That's largely due to the advancing technologies and safety initiatives, NAT testing and the like. Marketing is another area of big contrast. You can see in traditional pharmaceuticals probably north of 30 percent of the cost of any pharmaceutical is taken up in sales and marketing efforts, whereas for plasma therapies that's more on the order of 10 to 15 percent.

R&D tends to be greater for traditional pharmaceuticals largely because there is a higher return on investment, a higher revenue base for traditional pharmaceuticals than for plasma therapies. Fixed-cost equipment, facilities, things like that, relatively stable and overhead's relatively incidental to the cost. But again, the cost base for plasma therapies versus pharmaceuticals are very different, as is the return on investment that I alluded to.

Here you can see based on some data from the Market Research Bureau, the cost of source plasma depicted in red along the bottom there and the sales per liter through the blue line. This is adjusted for inflation, you

can see from 1992 to 2003. And this tells an unfortunate story, and that is that the sales per liter have declined relative to the cost of the starting material since 1992. That means that the fractionation companies aren't making the types of revenues that they have traditionally made off of these therapies. That's why you heard Dr. Goldsmith allude to mergers and consolidations and narrowing of the field. That's not a sign of a healthy industry. That's the sign of an ailing industry, and I think in terms of assuring access and choice, the U.S. needs to remain an attractive market place for plasma therapies and blood products, obviously, to show that there is access and choice.

So what we do about plasma therapies? Well, I'd suggest that we need something of a paradigm shift. We need to focus on end product safety. Clearly there's been tremendous strides in the safety of the starting material, and that's depicted at least in part in the cost of that starting material. Those strides in safety are absolutely appropriate, absolutely necessary, many of them driven by FDA, many of them driven by industry itself. And we can't back away from that.

But as we go forward we need to consider new ways to assure end product safety, and we've seen discussions about this such as West Nile virus, where industry has used a model virus concept to provide assurance that the therapies are safe from West Nile virus.

Further, we need to start planning for emerging pathogens, rather than reacting to them. We need to start doing some advance work in thinking about how we're going to manage things going forward so that we can start planning for those costs today and not have to absorb them as each one comes.

Thirdly, facilitate R&D through clinical trial requirements. Currently, IVIGs really carry the plasma industry. The IVIG preparations are really bearing the cost of production for the entire plasma industry. And there are relatively few labeled indications, and the populations for which they are indicated are relatively small. There are vast numbers of additional indications that they could reasonably use for and enjoy clinical support through research of esteemed institutions around the country. We need to work with the agency to get our hands around ways to get those indications on the label in a reasonable manner that appreciates both the unique therapies, unique nature of the therapies as well as the small populations that they're intended to treat.

And finally and most importantly, you heard Jonathan Goldsmith speak about this, but establishing appropriate payment methods, and that's really where today's focus I think needs to be.

So a couple of topics there on payment methods. Medicare Part B, Jonathan again alluded to IVIG is listed as

a generic product. Clearly that's a disconnect with FDA's regulations and laws on generics. There is no such thing as a generic biologic. So we need to make sure that CMS is using the same language that FDA is and that that's reflected in the cost and payment methods for the therapies.

Under this Medicare Part B rule that came out as a result of the Medicare Prescription Drug Law that provides payment in average sales price, plus 6 percent in 2005, 2006. We consider that woefully inadequate. We don't agree that the current system of average wholesale price is appropriate, and we acknowledge that that needs to be changed, but average sales price plus 6 percent is inadequate when you factor in all the administrative fees and the carrying costs and the storage costs associated with maintaining the therapies.

Also through the prescription drug legislation is the Hospital Outpatient Prospective Payment System, and these, again, these plasma therapies were listed in this rule as non-innovator multi-source products, effectively a generic product again. This is again something that needs to be harmonized with FDA regulations. Each plasma therapy is an innovator single source therapy. One IVIG is not equal to another IVIG. Each is unique.

And as a result of this erroneous listing by CMS, the current payment rate is 46 percent of AWP. Clearly where we need to be is at the innovator multi-source rate of

at least 95 percent of AWP--excuse me--the single source rate of 95 percent of AWP and we'll be commenting to CMS on that, and look to the Committee for support of that.

So Medicaid limitations on access and choice. This is--Medicaid, for those of you who, unlike me, prior to this presentation were uninitiated, Medicaid is of course the state laws that apply to reimbursement and access and choice. A number of states have some form of prior authorization which means physicians have to get approval before they treat. Clearly that doesn't work for hemophilia, nor does it work for a number of indications which IVIG may be supported through clinical literature.

Reference pricing and mat pricing is another way of clustering or treating plasma therapies as generics. Again, each therapy needs to be reimbursed based on its own unique characteristics.

And single-source provider contracts effectively are a state run supply program much like the Canadian Blood Services or other national programs, where there's a single contract with one provider to provide one therapy throughout the state, and again, access and choice to the multitude of therapies, we need to make sure that states offer the full range of therapies to all the patients in the state and not just one price, one therapy, because they can get it at a better price.

So conclusions again and wrap-up. Plasma therapies are unique. They're neither a national resource nor a pharmaceutical. They are somewhere in the middle, and today's urgent issue is payment systems. Tomorrow's urgent issue is going to be assuring reasonable clinical trial requirements to make sure that the marketplace remains robust and attractive to the fractionators and the other parties involved in ensuring access and choice.

Thank you.

DR. BIANCO: Thank you, Chris. Are there questions from the Committee to Chris Healey? Oh, Jay.

DR. EPSTEIN: Chris, thank you for those comments. Could you expand a little bit? When you say that you don't see plasma as a national resource, on the one hand, many countries have affirmed policies of self sufficiency in plasma. I know there's a big international debate over that. But on the other hand, there's no denying that because plasma must be donated by the population, there are no products if there are no plasma donations. And so there's the sense that it's at least a resource. So what does PPTA mean when they say it shouldn't be seen as a national resource? If it's not a national resource, where does plasma come from?

MR. HEALEY: Good question, and thank you for that. I think really what we're saying is that it should not be treated exclusively as a national resource. In other

words, plasma definitely has some characteristics of a national resource. There's no doubt. It comes from the people in the country. It comes from a national body of citizens. But it has other characteristics as well, and that is, it is further manufactured. It undergoes significant processing, and in those respects it is more like a pharmaceutical. So again, it's a spectrum issue. How much of it is characterized as a national resource and treated as such versus how much of it is treated more along the lines of a traditional pharmaceutical. It is somewhere in the middle there.

DR. BIANCO: Dr. Sandler.

DR. SANDLER: Does PPTA have a category for recombinant coagulation factor concentrates? Is it seen as a plasma therapy, or would you see it sliding closer to a pharmaceutical since it's not derived from a plasma collection?

MR. HEALEY: I think it would definitely shift closer to the pharmaceutical end of the spectrum than the traditional plasma drive therapies, absolutely. We, of course, represent those companies and advocate on those issues. We consider them plasma-derived analog therapies. They're analogs to plasma therapies.

DR. BIANCO: Thank you very much, Chris.

MR. HEALEY: Thank you.

DR. BIANCO: Our next scheduled speaker is Teresa Lee from AdvaMed. Teresa.

MS. LEE: Good morning. I'm here to represent AdvaMed, the Advanced Medical Technology Association, but I have a distinctively low technology presentation and do not have Powerpoint slides today.

On behalf of AdvaMed and the AdvaMed blood sector companies, I'm thankful for the opportunity to provide comments to you today. My name is Teresa Lee and I'm Associate Vice President for payment and policy at AdvaMed. AdvaMed represents more than 1,100 medical technology innovators and manufacturers worldwide, including manufacturers of blood-related hardware, software, disposables, testing equipment and reagents and other technology processes.

We have two points to share with you today. First, we recommend that the Committee re-emphasize its comment to ensuring adequate Medicare reimbursement for blood, and that the Committee include reimbursement as a component of any recommendation involving national blood policy.

We live in a time of rapid technological innovation that offers the potential to reduce morbidity and mortality in the United States. However, the reality is that poor Medicare reimbursement provides a disincentive for

companies to stay in the business of creating technologies for the blood community.

As Dr. Paul Ness said in his editorial to the August 2003 Supplement to the Journal Transfusion, "The number of technology vendors has diminished and the lack of reasonable profits will force companies now working in the blood arena to turn to other markets. Without a fair return on their research investments, they may have little choice. Inadequate reimbursement is clearly a malevolent force leading to the fragility of the blood procurement industry and transfusion practice." As Dr. Ness eloquently states, "Reimbursement plays a crucial role in the safety of the national blood supply, and therefore should be a major component in national blood policy."

To improve reimbursement for blood, AdvaMed's blood sector has been actively supporting the efforts of AABB, Red Cross and ABC members to sponsor seminars nationwide that educate hospital employees on how Medicare pays for blood and the importance of billing appropriately for blood products and administration procedures. However, without CMS's exercise of its power to improve payment levels and to consolidate and clarify its procedures for blood billing, these educational efforts will be limited in effect at best.

We appreciate the Committee's attention to this issue in the past, in its May 2003 recommendation to the

Secretary to consolidate and clarify the blood reimbursement rules and guidance. In addition, we note that congress recently spoke clearly on this issue and has directed the Secretary to do the same in conference report language issued last year in conjunction with the Medicare Prescription Drug legislation.

We also greatly appreciate the CMS' representative's update on the agency's continuing commitment to clarify and consolidate the billing rules for blood, which confirmed their earlier statement in the 2004 Outpatient PPS Regulation.

AdvaMed looks forward to working with CMS, the blood collection community and the hospital community to ensure that these rules are clarified appropriately. Notwithstanding, we point out that CMS had committed to clarify its rules last year, and we are concerned that blood reimbursement may yet again fall through the cracks.

In an environment of competing priorities at CMS, we believe that this Committee's role is significant in ensuring the CMS keeps its commitment. We urge the Committee to continuously obtain updates from CMS on its progress, and if necessary, formally redirect the Secretary to take action to improve reimbursement for blood products and services.

Second, we applaud the Committee's efforts to improve the critical infrastructure needed to react in times

of disaster. AdvaMed stands ready to collaborate with this Committee and the blood community to ensure that manufacturers are able to deliver much needed products and supplies in times of disaster.

In the wake of September 11th, AdvaMed is keenly aware of its role in representing manufacturers of medical supplies and has established a Medical Technology Preparedness Council. In addition, we have been actively involved in the task force organized by the AABB to identify critical areas for local and national emergency preparedness for the blood supply. Accordingly, AdvaMed has completed a formulary that informs suppliers of what products to send in an emergency, and has developed an emergency planning guide that has been distributed to thousands of local and national emergency management personnel.

We believe that the formularies and the guides lay the foundation to facilitate supply chains that were previously undefined during times of disaster. We applaud the Committee's efforts to address preparedness through its discussion on the National Blood Reserve, and we urge the Committee to be aware of the involvement of the medical technology and supply manufacturers as it develops its overall policy for the critical infrastructure to prepare for disasters.

AdvaMed looks forward to working with the members of this Committee, the AABB and other key members of the

blood collection and provider community to develop public policy to safeguard the nation's blood supply.

Thank you again for the opportunity to share the views of the medical technology industry.

DR. BIANCO: Thank you very much, Ms. Lee.

Any questions from the Committee? Dr. Sandler.

DR. SANDLER: Thank you very much for those comments, but I in particular want you to bring back a message of gratitude from me at least for the publication that AdvaMed was responsible for, "Ensuring Blood Safety and Availability in the United States." This is an extremely valuable and reliable document. It's required reading for graduate trainees in transfusion medicine at Georgetown University Medical Center because of its quality and the information that it gives. It's a terrific job. Thank you.

MS. LEE: I'm pleased to hear that, and we were pleased to provide it to the Committee as information.

DR. BIANCO: Well, it's time for a well deserved--Teresa? Could you come to the microphone and identify yourself?

MS. WIGMAN: Teresa Wigman, AABB. I just wanted--

DR. BIANCO: I'm sorry. It was my fault. Before we break, we have a statement from AABB.

MS. WIGMAN: I can go after the break too.

DR. BIANCO: No, no. I think we should it now. I'm sorry. It was my fault. I had it here.

MS. WIGMAN: Thank you. I'll try to be brief. I'm Teresa Wigman, Director of Public Policy and Counsel to the American Association of Blood Banks.

I think we'd probably all agree that the goals of the national blood policy established in 1974, that is, a safe, available and accessible blood supply provided through an efficient delivery system, hold true today. I would just like to highlight on behalf of the AABB, a few areas where we think the government should focus in advancing these goals again today.

In relation to the first of the goals, safety, considerable progress has clearly been made since 1974. Working together the government and the transfusion medicine committee have achieved a volunteer blood supply, and introduced new generations of screening tests for infectious agents.

A notable example has been the recent introduction in record time of a West Nile screening test. The public and private sectors collaborated to speed the introduction of this test, which likely prevented more than 1,000 individual transfusion recipients from being infected with this potentially deadly virus last year.

The AABB supports ongoing research to identify transfusion transmissible diseases and develop effective screening tests to protect patients from these agents. The

government and the transfusion medicine community should continue to focus on these areas.

In addition, the AABB strongly believes that far greater attention needs to be paid to noninfectious risks of transfusion. The greatest risk to an individual receiving a transfusion today is not that they will be infected with HIV, West Nile virus or any other infectious disease, it's that they will receive the wrong unit of blood. This problem has been identified and highlighted in the press recently, but unfortunately, we believe that this deadly problem has not been sufficiently highlighted either at the government or at this Committee.

Therefore, AABB urges that the reduction of the risk of mis-transfusion through the introduction of new technologies such as promising technologies to improve patient and sample identification, and through efforts to improve processes within hospitals must be a priority for the Department of Health and Human Services, as well as this Committee and the entire transfusion medicine community. AABB urges the Committee to focus on the risk of noninfectious--excuse me--the noninfectious transfusion risk in the future.

Now, when it comes to assessing the availability and the accessibility of the blood supply, AABB is concerned that more progress has not been made. As the Committee heard earlier during the meeting yesterday, five years ago

the AABB's National Blood Foundation convened a forum to look at the national blood policy that was established in 1974. During that meeting, as has been the case for the last 30 years probably, two themes have been highlighted repeatedly. That is the need to educate the public about the importance of donating blood, as well as the need to ensure fair Medicare and other reimbursement payments for blood products and services.

Unfortunately, these problems do not seem to go away. For years the AABB and others in the transfusion medicine community have called for a federally supported public education campaign. yet the Federal Government has failed to support this effort. If we are to ensure that the blood supply is sufficient to meet the increasing need for transfusions, the Federal Government, in collaboration with the transfusion medicine community, must dedicate significant resources to promoting blood donations.

Lastly, again, as this Committee has heard repeatedly, Medicare policies and payments lag far behind blood safety advances. If this trend continues patient access to the safest possible blood products and services will be threatened. Any overall national blood policy must focus on reimbursement and ensure that hospitals receive fair payments to account for valuable safety advances.

Both the government and the transfusion medicine community play an important role in promoting the safety,

availability and accessibility of the nation's blood supply. The transfusion medicine community must use its expertise and experience in fostering improved patient care. In addition, the Federal Government must support, through both funding and actions, initiatives such as the public education campaign, improved Medicare policies, and ongoing transfusion medicine research.

This support--and I would highlight this following point--must come today. We've heard for now it seems 30 years these repeated calls for action. If another 5, 10 or more years pass where we once again note that such efforts are needed but nothing happens, it is the patients who will suffer. We must work together to serve these individuals who depend every day on receiving quality transfusion care.

Thank you.

DR. BIANCO: Thank you very much, Teresa.

Any questions for Teresa Wigman from AABB? Dr. Penner.

DR. PENNER: There was a recent article, some three pages in the Kansas City Star, on hepatitis C, deriding the government's failure to respond to the crisis. Does AABB have a policy or a stand in this issue?

MS. WIGMAN: On the specific hepatitis--

DR. PENNER: The issue of hepatitis C and the problems developed?

MS. WIGMAN: Well, we have--in relationship at least to Look Back, the AABB has worked in collaboration with this Committee and others on making sure that our members move forward with Look Back in conjunction with what the FDA has been directing us to do. So years ago we sent out materials to our members trying to inform them as best as possible about how to proceed with Look Back. Unfortunately, to complete that process, it's difficult without final guidance from the agency. I think that some of our members would have concern that they would do one system of Look Back and then if the ultimate guidance is different, that they would have to go back and repeat it.

So, I think if there are any members out there, hospitals that have not completed the Look Back, that would be why, but AABB at least has tried to inform and urge our members to do as much as they can in this area.

DR. PENNER: You're saying that you feel there's a lack of direction from the FDA in this respect?

MS. WIGMAN: We have, you know, been looking for the agency to complete and issue final guidance on this area, yes.

DR. BIANCO: Any other questions? Yes, Dr. Sandler.

DR. SANDLER: I very much welcome the comments about blood safety with regard to mis-transfusion and misidentification of patients and blood samples. Based on

the pioneer work that was done by Dr. Jeanne Linden on this Committee, we have put a bar code identification system for blood samples for patients and for the units in the outpatient department at Georgetown, and we have that there.

The problem is going forward from the outpatient limited number of transfusions we have there to a 500-bed hospital will cost us $1 million. So there's a lot of opportunity for the Committee and the government and others to find ways to move this forward because this is an increment in the cost of blood that exceeds anything that we've looked at prior to this date.

MS. WIGMAN: Right. I think it is notable that you can't look at each of our issues in a vacuum. They obviously go together, and this is just another example of where we need to make sure there is adequate funding in the system to pay for this important patient safety advance, and we would join with you in that thought.

DR. BIANCO: Well, anybody else in the audience? Thank you very much, Teresa.

MS. WIGMAN: Did you have a question?

DR. BIANCO: Oh, there is a question?

DR. HEATON: Andrew Heaton, Chiron. I believe from Chiron's perspective, we'd like to go on record that Chiron is developing with our alliance partner ZymeQuest, a novel system for enzyme treatment of red cells to convert all red cells to a common blood type, type O, which might

render cross-matching much less necessary and the risk of mismatching in the hospital much less of a risk to patients.

So industry is working on some new technology developments which will greatly reduce probably the single greatest remaining risk in transfusion today.

DR. BIANCO: Thank you, Andrew. But you expect to be paid for it, right?

[Laughter.]

DR. HEATON: I wouldn't wish to say. There is a conflict of interest. I'm merely reporting on an upcoming technology development.

[Laughter.]

DR. HEATON: Which would allow the elimination of a significant risk that we were just discussing. Thank you.

DR. BIANCO: Thank you, Teresa.

Anybody else from the audience that would like to make a statement during this public comment period?

[No response.]

DR. BIANCO: If not, we are going to take a break of 15 minutes. At 11:15 we start.

[Recess.]

DR. BIANCO: We are going to restart our deliberations. We now come to certainly the most difficult part of our job. We have heard from a lot of people with a lot of very good information. But now we have a charge to answer a number of questions.

Dr. Holmberg is going to give us a general view of the expectations that HHS has in terms of those questions, as he formulated them with Dr. Brecher.

And so, Jerry, if you could help us?

DR. HOLMBERG: I think as I mentioned yesterday--it bears repeating--and that is, what we are doing today is basically looking at developing a road map of where we should be going in the next couple years. We've heard a lot of comments from the community saying that we can't wait another 5 years for a lot of things to change. We have to start moving. We've been sitting around for 30 years with a national blood policy. Especially since 9/11 we have seen blood shortages, and we need to identify exactly as a Committee what should be the next steps, what do we need to do, what does this Committee need to do? What kind of material or what issues do we need to address so that this Committee can make recommendations to the Assistant Secretary of Health?

One of the things, in going back over the recommendations over the last couple years, I've noticed that there are certain things that jump out, and all of these things actually hover around a national blood policy. There have been recommendations on the supply issue, of beefing up recruitment. Definitely we have almost every meeting--I think it has been probably every meeting--reimbursement has been an issue. And we're glad that Dr.

Bowman has joined us, and I commented during the break that I glanced over and he was frantically taking notes. I really appreciate his attentiveness to these issues.

I think we can--we will improve the relationship with CMS and I think that clearly the recommendations that have come out of this Committee and also the wording in the various congressional hearings, or I should say the conference over the Medicare bill, clearly states that we have to make sure that things are in harmony. And so reimbursement has been an issue that has jumped out, definitely supply and safety, Look Back.

The whole purpose of this Committee getting started in the '90s was the Look Back issue, the safety issues as far as even the hepatitis C, and more recently since 9/11, the first advisory committee after 9/11 looked at blood reserves, how do we handle emergency issues?

And along with that, even as far back as 1999, there were recommendations on monitoring, and HHS does have a sentinel system that was reported in the Transfusion of last year, and we all know that the monitoring needs to be a lot better. And not only for being able to see shortages but to predict shortages, not only for the supply but also the potential of what are the effects of different policies that are being anticipated.

So I wanted to start here because I got the impression with talking, hearing the discussion yesterday

afternoon and reconfirming that with various members of the Committee, that really we jumped right into the National Blood Reserve, and that there were other issues that we really needed to look at first. The National Blood Reserve was just one element of a bigger process or a bigger picture, and the bigger picture really is do we need--are we looking at a policy or a program? Are we looking at a national blood policy or a national blood program?

If we are looking at a policy, I would like to ask you what are the core values that need to be addressed in that policy? Some of the specific questions that were addressed--and I'll refer to those in just a few minutes as I move to my next slide--but are the values, the core values that were identified in 1974, are they still the same core values that we want to concentrate on today?

My English there is not the best. What programs and activities do the Committee need to address for an effective blood policy? So I guess, keeping that in mind, we can go back to that graphic in a little bit, but I would say what have we learned--I guess the first question I'd like to ask is what have we learned over the last 30 years regarding our national blood policy and our national blood supply and open that up for discussion.

There is really no order that we have to do this in. If you want to comment on that, in conjunction with the national blood policy, whether it's obsolete; if not, what

is missing and what needs to be addressed; and also, learning from our colleagues from other countries, what can we learn from other countries and what needs to be considered within the U.S.

DR. BIANCO: Yes, Karen?

MS. SHOOS LIPTON: Just to take a stab at it, I mean, I think this is going to be very difficult, and this is purely my personal opinion, I think that in terms of putting together an entire program, I just don't think we could get there. I think we need to start with policy, and I just have two observations.

If you look at the goals of the national blood policy from 1974, supply, quality, accessibility, efficiency, there's one interesting change to me, and I just want to point it out because it didn't strike me until I wrote it down. It used to be quality, and now it's safety. And so somewhere in this transition, we lost the best possible care which, to me, is more patient oriented, if you will, than blood safety. If we get to quality, it's that we expect every patient in this country to have access to the best care, to the best technology, the best physicians. It's more encompassing, if you will, to me. It was just something that struck me that safety, in some funny way, is just a very narrowing focus that maybe hasn't been entirely helpful to our country--just to comment.

But I think the one thing that we can say that has changed in the 30 years, when you look at it, and it just sits in there like that 800-pound gorilla is the introduction of DRGs. And somehow I think when we address this policy, I think the policy goals are fine. I think the backdrop has changed, and I think DRG and the DRG system has totally turned on its head how we practice transfusion medicine in this country, and somehow, in some sort of policy, it needs to be addressed.

I think the other thing is that we had this policy that's out there and it's not out there. There has to be some ownership by the federal government of this policy. Somebody, some brain at the top of HHS has to say this is the policy, and it must be communicated to all of the agencies. HHS has a number of different agencies, and they all have their particular mandate, but there isn't, you know, I think to the general public or to the people--and maybe it's more to the people who operate in this field--there is no sense that there is a discussion of direction and a balancing of these interests, and at the end of the day that they're all pulling out this national blood policy and saying, "Did our decision fit these criteria? Have we done service to the patients who this policy is supposed to serve?"

DR. BIANCO: Thank you, Karen. I think I want to follow a little bit on what Jerry said and what Karen said.

Maybe I'm overstepping the boundaries as an acting chair, but you'll allow me to do that.

When we are talking about blood policy, actually there were big words in that document, and most of it is still very true, and there was the heart of the people there.

What many countries had that led them to radically change their systems--Canada, France or even England--were national tragedies of such an extent, in terms of the management of the systems and all of that, that forced the systems to reorganize and forced people and governments to make a commitment to blood. It's not just having a blood policy. What we need is a national commitment to blood. And we had our tragedies. We had many mistakes made, but none of them was, in itself, sufficient to cause that radical change that reorganized everything. We had much more enforcement by the regulatory authorities, particularly by FDA.

We had a tremendous focus on safety, but that was in detriment of everything else. Safety seems to have taken over even quality, as Karen mentioned, but it seems to have taken over everything, and the product became the focus, not the whole system, not the entire process of collecting blood from a donor and having it reach a recipient appropriately to safe the recipient's life.

So, if you were to ask me should the U.S. have a national blood policy, I would say, definitely, yes, but it's not just a policy that is on paper or even like the one we had 30 years ago that was voted by Congress. We need a commitment that is much bigger than just a policy, a commitment that maybe we will have to extract from government, from politicians and from the people to say we want it, and that's how we want it.

I think that the first slide that Jerry showed show a number of elements that should be part of that blood policy and that blood commitment. All the major areas are there in those circles.

So I invite people to challenge me.

Judy?

DR. ANGELBECK: Celso, I'm not going to challenge you, but I want to follow up on a comment that Karen made about DRGs, with the introduction of DRGs.

Repeatedly, with every topic, with every presentation, one of the major issues that must be dealt with by a country is money. How are you going to pay for what you're going to do? And the larger proportion of blood is used inside the hospital, and that's what's impacted by the DRG. I think that with the DRG payment and system, blood is lost, essentially. Blood is lost to the diagnosis of the patient, and it's grouped in with all of the various services and treatment that the patient receives. So,

essentially, with that policy fiscally, there is no commitment to blood. It's just another service out there that the patient utilizes. So that's a pretty dramatic kind of change based on the current type of reimbursement system that we have.

In the outpatient side, there was at least an opportunity, and certainly many people in this room fought very hard to get a carveout essentially for blood, to recognize blood as something that should come out of that shadow, and dollars are what's at the bottom of being able to do a lot of things, to create what Dr. Katz talked about the culture of blood donation as a civic responsibility, for example, dealing with safety issues, dealing with availability. So I don't know how, to what extent and what depth the Committee wants to wrestle with that topic, but my personal view is that blood is really completely lost in the DRG system.

DR. BIANCO: So how do we fix it?

DR. ANGELBECK: Well, I suppose one option is to have a carveout for blood on the inpatient side as you do on the outpatient side. That's certainly one option. If blood is a national resource, why is it in the same market basket with aspirin?

DR. BIANCO: So Paul is going to come with his economic view of the world.

DR. HAAS: You're right, Celso. How did you know that?

[Laughter.]

DR. HAAS: I'm not going to disagree with the three of you either, but I'd put just a little different slant on it, and I'll come back to some words that you used, Celso, in the sense that you used the word "commitment," and part of what I want to say is how do we get a commitment in a society where, as a society, we want the so-called marketplace to be driving most of what we want, but we're trying to drive it within the context of saying a national resource of blood which we want the best possible care possible.

The economist sits there with that and says, Wait a minute. There's a disconnect between what's going on, similar to the statement made yesterday about you've got to know who the payer is. So let me see if I can run through something here fairly quickly. If we follow the economist model of competition, that says, when something new comes out, the market does allow for prices to rise and reward the innovator, but the nature of competition is supposed to be driving that price down. We see that in the computer market all the time right now.

But we also are talking about the societal concern, the best product, access to product, R&D. Those are things that benefit more than just the maker or the

manufacturer of whether it's a product, it's a plasma product or whatever. And when we talk about the societal benefit, that's something that then dumps into what the economists call the public sector or what we're just simply saying, government, and now we have tension.

If we have government that simply does everything, economists have a language for that, too. They talk about the creation of a moral hazard, a moral hazard being something that says, well, gee, to the end user, the price is free, so overuse it. And so we lose some of the discipline of the marketplace which drives efficiency. So we're saying now to those who make things that we want them to do it efficiently, but if we have government in some way paying, that takes away that discipline. I'm not trying to accuse anybody of anything here, but yet the complexity of what's going on--

And my bet is that if I went around the table and asked all of us here, and probably all of us in the audience, what would we want if we were getting care? We want the best product, the latest technology, and we want to pay for it at the lowest possible price, which again is another disconnect in terms of what we have.

So is there a solution? I'm going to try and answer this before you ask me back, and I'm not going to have a good answer, but I think when we're talking about the combination of the private sector and the public sector to

get to what we will maybe call a blood policy or I think agree a blood program is down the road quite away, I think we constantly have to remember the tension that exists between what we as individuals want for ourselves, and our families and those we treat and what society wants.

I doubt if anybody in this room would stand up right now and say we want the health care costs of the United States to run from 15 percent up to 20, 25 percent. No one is going to advocate that. Yet, if we simply talk about the best possible product, period, that's what will happen. And maybe that's okay, but it's only okay in the context if society itself says this is a really high priority. It's your commitment type of comment that you're making, Celso, and we here are a very small part of trying to get that commitment out of society. We need to be I think putting a lot of effort on working with the government folks to think in terms of the whole blood health care sector in a much, much bigger way than I think it has done.

That's too long. I'll stop.

DR. BIANCO: Dr. Penner?

DR. PENNER: I agree. I think we have a national policy in hand already. We have common standards, and FDA has applied things I think very effectively there. We have common labeling, as far as I know. We also have common suppliers for our testing kits and things of this sort. So,

if we look at it from that standpoint, those things have already been pulled together as policy.

What we're asked to do I thought today is consider the possibility of an emergency reserve. And if there is going to be an emergency reserve, we need some central governmental depository for the data so it can be quickly applied and blood moved where needed. And that has been discussed before, but I don't know if we have anything implemented, but I think that should be under FDA and not under the auspices of some other agency in government.

And, lastly, if we're going to support that, we have to support the donor level to maintain what we've been discussing as perhaps a 5-day supply for the country, and that means that we'll have to have it paid for, and you can pay for it, as we've been doing it, by increasing the price through the DRG or we can add money from the government which seems to be allowing it to flow readily these days, but there are two ways of going at it, and I think that was the approach that I'd see for handling the problem that we have now.

DR. KUEHNERT: Celso?

DR. BIANCO: Matt?

DR. KUEHNERT: I just wanted to come back to one of Karen's comments on quality. I actually looked at the 1974 Federal Register and looked at their definition, which is "the attainment of the highest standards of blood

transfusion therapies through full application of currently available scientific knowledge, as well as through advancement of the scientific base."

And then later they say--somewhere--"Particularly troublesome is the lack of information on the fate of each unit of blood drawn," and then they say a bunch of things about post-transfusion hepatitis, which I think has been addressed, but particularly about the outcomes of transfusion therapy. And Jerry had some nice ideas about possible components of a national blood policy which included monitoring and safety, and then he had something on look-back, which I think is important to know when you have not optimally delivered quality.

But also I think we need to look forward. And so I think outcomes is a very important element of this, to be able to look at outcomes, not only immediate adverse events, but also outcomes concerning both infectious and noninfectious events and to try to optimize therapy I think is very important. I think having sort of a clinical component of this I think is important.

The other thing which hasn't been addressed, and I'm just going to comment on, and it is another passage in this original policy was that the basic principles of the policy, although not necessarily the specific details, are appropriate to a broader system, which it says here, back

then, "must soon be developed to encompass all transplantable human tissues."

I think I know we've got enough of a Pandora's Box with blood, but I think we just need to consider other tissues, including solid organs and other tissues which I think have changed quite a bit. The technology and the industry has changed quite a bit since 1974, and I think we just need to consider how that also can be integrated in a broad, comprehensive policy.

DR. BIANCO: Ruth Sylvester?

COLONEL SYLVESTER: I want to, after listening for the last two days, I never heard anybody say that the original policy from 1974 was bad or that there was anything wrong with it or even in today's environment that we work that we would change it very much. And so I think, as I was reminded last night at another briefing, that having a policy is good, but it's the execution piece that you have to watch.

And I think what's happened is the policy is probably still very valid, and the desires and the goals of that policy are still very valid. We've come a long way, as Dr. Penner has said, improving the state of the program that we have that supports that policy, but I think we probably just need to make modifications for the current state of affairs as we're at and not say we need to throw the policy out and start all over again. We just need probably to

improve it and then better support for the execution piece in the pieces where we need that support, but I have not heard anything that says that the policy was ever bad or wrong.

DR. BIANCO: Dr. Sayers?

DR. SAYERS: Thanks, Celso.

In support of those remarks, if we are going to agree that the policy is a good policy, maybe we could consider augmenting it with really some of the excellent ambitions of the FDA's Blood Action Plan. One of those elements is monitoring and increasing the blood supply, and the necessary steps that were listed to achieve that goal included monitoring, encouraging more donations, improving donor relationships, removing restrictions to safe donation and addressing economic issues facing the blood industry. I think that's a pretty all-embracing potential supplement to the existing and ancient blood policy.

DR. BIANCO: So you are advocating revision of the document or supplementing with another document that reflects the 30 years.

DR. SAYERS: When I read the Blood Action Plan, it's almost as if some of the work of the Committee has been done. This is a good document with what looks like an extension of some of the messages or at least a mirror image of some of the messages that we've heard here.

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: Thank you, Merlyn. We thought it was appropriate when we wrote it, and I would point out that it's already endorsed by the Department because the Department did accept FDA's proposal for a Blood Action Plan as a plan owned by the Department. So, to that extent, it's already national policy.

That said, there's a lot of question that could be raised about implementation and funding of initiatives, which I think deserves more open hearing. I wanted to come back to two frameworks. I think that Paul Schmidt laid out for us the 10-point program of the national blood policy, and my own sense is that some of that does need dusting off and updating, even though the four policy areas I think remain sound as goal statements.

And the second point is that I want to just quickly review what Lou Katz said about the opinions of ABC in regard to the government role and focus on what I think the tension is.

So, first of all, with respect to the 10-point program that was published in the Federal Register in 1974:

Eliminate commercial collections. Well, we're there, in essence. We didn't make them illegal, but labeling effectively eliminated almost all remunerated collection for transfusable components, and at least in this country we're not still fighting the battle about paid apheresis for the fractionation of plasma.

Obtain data on apheresis practices. Well, we can always use more data, but we have a reasonable understanding of the system.

Obtain data on blood banking. Well, I think we've all heard that there are a lot of dimensions where we could use more data. Inventories is part of it. Use patterns is part of it. Current practice standards is part of it. That could go on.

Support resource sharing. Well, I think what we've been hearing is that that's been endorsed by different organizations in the private sector, but that it doesn't function optimally, and I think that it comes back to highlighting a question that hangs in the air. It's been said, and this then is the point made by Lou Katz, leave management of collection, and processing and distribution to the industry. But the core question here is whether more intervention is needed by the government because resource sharing and the regionalization model have not worked as well as we might have wanted.

Support professional training. I think we heard remarks that more should be done through educational programs with government support.

Apply full regulatory authority. Well, I haven't heard anybody complain of lack of regulatory authority.

[Laughter.]

DR. EPSTEIN: Support basic and applied research. Again, Lou stated that he felt this was a major function of government.

Insurance for all blood service costs. I think that we could easily package the whole debate about Medicare and Medicaid funding over the problem of reimbursement, not just looking at insurance, but looking at the change in Medicare or I should say in CMS-mediated funding.

And then the last point was implement a national blood program through legislation or regulation if the private sector fails in this mission. And I think that's always been the veiled threat that has brought people back to line is that if the system deteriorates badly enough, we do see it as a national charge, and there would be intervention of government at some level. I don't know what that needs to be, short of nationalizing a part of the medical system which I'm sure would meet great resistance.

So I think then that this conforms very well with the list that Lou put forward. He felt that the appropriate government role is donor and recipient safety, that is to say, standards;

To support or enhance the culture of donation. Well, that's funding education, and a lot has been said about wanting to fund programs targeted to young people to make sure that we renew the donor base;

That reimbursement must reflect costs of safety. Well, that has to do with the whole issue of interagency coordination and to find mechanisms not just to fund, but to fund in a timely way safety mandates;

Assess risks. Well, I think government already accepts that it has that role. We do this at our various advisory committees. We assess risks, and we have engaged I think in a very public process of risk communication;

Promote innovation and research. Well, that's again coming down to targeted budgeting;

And promote appropriate use of blood. Largely, that's been left to professional societies, but, on the other hand, consensus conferences that government funds are steps in that direction, as well as statements and guidelines that come out from federal bodies, for example, CDC guidelines.

So I guess that I find that there's a general agreement between most people's current thinking about the goals of the national blood policy. I think that we probably are not in a position to redesign a program, that if we were to move down that path, it would not be identical to what it was in 1974 because of structural changes in our system. And I think that the question that we're really dancing around is not just the issue of money, but whether a federal role needs to be changed in terms of collection processing and distribution.

And I think that that's where the issue of reserves gets complicated. Because, on the one hand, we've heard some members of the Committee say, well, this should just be a function of government, in other words, let government fund it and operate it. I think Dr. Penner said put it at FDA or another part of government. But then we've also heard the private sector say we're the ones that know how to do this best. Just let us do it, but we need financial support. And I really think that that's where the tension lies is over managing operations of the system and whether we need to change the balance of the government role.

DR. BIANCO: Jay, I will ask you to expand a little bit on the intervention side. How would you see that triggered? How would you see that role being played in a more pragmatic way?

DR. EPSTEIN: Well, I don't have the answer, but I think we heard models in other countries. There are models where there are bodies that are either under contract or are quasi-governmental and that have a more direct role in management of inventories, distribution of blood and decisionmaking on reimbursement. In other words, it's sort of the Blood Czar cubed. You actually have somebody that does this full time, that gathers data, that links it on a daily basis to allocation and that does it in a context where it also manages resources. So that's at least one

model. I'm not advocating that we go there mind you. I'm just saying that there are models for doing such things.

DR. BIANCO: Before you go, Chris, I want Paul to comment on that.

DR. HAAS: I don't know if I have a comment that's meaningful, but in the spirit of what Jay is saying, I think it's consistent with what I was trying to say in that no matter what government does, that in some way restricts the freedom of the companies that then have to react to that. So, in a private-sector economy, which ours primarily is, the types of discussion around reimbursement say that as government puts a particular I'll just say burden--a general term--then individual companies aren't just looking at how can they do blood things more efficiently. They have other options. They look at blood versus all of the other types of things that could be done besides.

So I think, as we're trying to work through this, the plea to get better reimbursement from the companies is a very real one, but one that we constantly have to be asking, in terms of the general policy, where are we trying to go. So we're constantly running up against conflicts, which are awfully hard to resolve in this society because of who we are, and our like, on one hand, of government and our total dislike of government, on the other hand.

DR. BIANCO: Chris Healey?

MR. HEALEY: Thank you. I don't disagree with anything that's been said, but I have a different question I guess, and that is I know this topic came to the Committee through the subcommittee that met after I guess it was the last meeting or perhaps the meeting before last. I'm just wondering, you know, we could spend a lot of time and craft a great blood policy presumably and have a wonderful document, and the question then is what happens to it and where does it go, and to what end are resources being put.

So I wonder--maybe now is not the time--but I wonder if it's appropriate to have a discussion at some point about either Dr. Biato's commitment or HHS commitment and whether it might be appropriate to ask, in essence, ask for a mandate to do this so that before we expend too many of our resources we know that there is some level of interest and endorsement for the Committee going down that path. Maybe that's already been done.

DR. BIANCO: Do you want to say anything, John? You don't have to.

Dr. Penner?

DR. PENNER: I'd agree with Jay's assessment, but I think if we'd consider that we have an emergency need for blood, the government I think has to step in, and I think FDA is in that position that they are not to manage blood, but they have to have the data available so in the case of an emergent situation, they have to be able to take over the

transmission of that blood product where it's supposed to go and know exactly where it's available and not leave that up to the private sector, which I think also wouldn't want to do this because of the liability that might be part of that. I think it has to be a government issue.

DR. BIANCO: Ruth?

COLONEL SYLVESTER: I don't know that I necessarily agree that the FDA is the best one to do it. In none of the models that I saw was the regulator also the manager. I think we all have different roles, and the regulator's role is to maintain the safety of the blood product by setting standards, and requirements and stuff, and that's what I see the FDA doing to us. And there are others, and if the government has a role, there are other ways it's being done.

And since September 11th, in my experience, it's been done through the interorganizational task force, which, as I understand it, came about as a result of an HHS request. Am I correct how that came about?

MS. SHOOS LIPTON: No, I think it was called a void.

COLONEL SYLVESTER: But now it is working along with--under HHS's auspices and has been working. So I don't know that the interorganizational task force is just the private industry because there is government participation in that. But I would be concerned, if we start blurring the

lines between the regulators and then the managers. That would be my only concern.

DR. BIANCO: Karen?

MS. SHOOS LIPTON: I agree with Ruth, and I think one of the things we have to understand is we looked at different national blood programs, but we are an entirely different country from a lot of other places, and I find it very interesting that we always seem to get hung up in blood on this public-private relationship which, if you look at any other sector of our economy in the United States, it's just how we operate.

The Department of Homeland Security cannot do everything it needs to do, and in fact most of the things it's doing, it's doing through public-private arrangements, and I think there's an appropriate role for government oversight in this. I think that we need to understand that they need to feel confidence, but I don't even think in the Department of Homeland Security that they think they can do this all.

There simply aren't enough--you can't build up another separate structure. I think Jerry said this earlier, and it is so true, and it's something Dr. Shinar said, too, which is that you have to build your emergency operations into your everyday operations. It can't be something that you suddenly pull out the manual and go, "Oh, my gosh. We're having an emergency today. How do we

function?" It has to be something that you do every single day, and I do think that the blood organizations are the best to handle this.

I also found it--this is just an aside of something that Ruth said--that in most other countries the model is that people who set the standards, those regulators are not the people who are doing the assessments against those standards, and we actually have a very unusual system where we have both in one agency. It's just a comment. I hadn't really thought about the difference, but it struck me that it was different.

DR. BIANCO: Eliat, you wanted to make a comment before. Maybe this is the time.

DR. SHINAR: Thank you, Celso.

It actually has to do with donor recruitment. I just wanted to tell you a story. When I came through Immigration on Tuesday, the agent asked me what I am going to do here, what's my business, why did I come, et cetera, and I told him. And he said, "Would you deliver a message to this Committee? I used to be a long-time donor, and I'm not going to donate any more because, when I needed blood, they charged me $250 for a unit."

So I didn't go into the details. I just had my passport stamped and went away, but--

[Laughter.]

DR. SHINAR: I think that one of the things that when we're talking about donor recruitment and education is that I think we need to think what would the donors get out of it? I think most is fine, but I think we are getting more and more practical, and I think that altruism by itself may not be enough. So I don't know, I was trying to explain yesterday the system that we have with a future credit, whatever system would be suitable for you in this country, but I think that there needs to be something that the donor will feel that it's worthwhile to donate and not only to save lives. I mean, everybody knows that it's saving lives, but why would I get up on a snowy day like today, walk into whatever mobile or place that you have and donate blood? So this was my comment.

On the subject you are talking now, I think it's absolutely necessary that indeed the agencies that do the work every day would do the emergency. I think either the government, and I agree it shouldn't be the regulator, but either the HHS or any other--I don't really know the internal politics here very well--they should know about it. They should be ready to help if you need to ship blood from place to place. But the people, I mean, you have very good experts here--AABB, ABC, ARC--they know how to do the job. They just need to maybe organize together. Forgive me for saying that, but organize together and the government shouldn't have the data, and I think this would help.

Thank you.

DR. BIANCO: Thank you, Eliat.

Dr. Fitzpatrick, you were closely involved in the logistics of the proposal for the reserve. Do you want to add to this discussion? You can pass.

COLONEL FITZPATRICK: I think it's important that I pass.

DR. BIANCO: Okay, Mark, help us.

DR. SKINNER: I may take us in a little bit different direction.

As I was reading the 1974 policy, I mean, it was clear--and this is going back actually to Karen's original comment--some things that have changed since then, and there have been tremendous advances on the plasma-derived side of the equation. And plasma therapies were recognized in the blood policy. And in large part, as I understood what I was reading, they were recognized as uninsurable, along with a lot of the other products. And to the extent that we're focusing on the economic piece, we could look at going back and rewriting and creating a new paradigm, and the political reality of that isn't there.

And we can look at trying to continue to piece together and make work a system which I think almost all of us think is broken and may be beyond repair as we try to patch each individual piece, whether it's 50 percent, 80 percent, in-hospital, out of hospital and all of the

difference in variations or we could actually go back and consider validating what was in the original '74 blood policy and acknowledge that what they forecast was true actually has manifested itself; that blood therapies are a national resource for plasma and components in whole blood and that they are inherently unaffordable, uninsurable and are progressing even more rapidly in that direction, and perhaps we need to look at a time of taking them out of the traditional reimbursement mechanism and consider putting them into some kind of pass-through mechanism which still can be a blend.

It doesn't mean nationalizing insurance. It doesn't mean nationalizing the industries. It can simply be a pass-through for the hospitals to a national fund or it could be a pass-through for third-party payers and insurers for these kinds of items. But I think the core components of what the consumer community is looking for are there. Reality has borne out the prophecy, and the only solutions perhaps are things that we haven't tried because we've been trying to make the current system work for 30 years.

DR. BIANCO: Thank you, Mark.

Larry?

MR. ALLEN: Just a couple of observations here. I wanted to say, first of all, until I came to this Committee, I wasn't aware that there was a national blood policy, and I know I'm not the only one that has a child or children that

goes to the hospital and needs blood that wasn't aware of that. However, I think for us to make recommendations about this policy is one thing; I think for us to try and rewrite the policy is totally a different issue for us. I don't think that that's something that we have the time right now to handle, unless it's mandated that we go after this issue.

However, knowing that there's a blood policy, and then hearing about things like calves being fed slaughtered cow blood in place of milk, tells me that there's some loopholes in this policy that need to be addressed, that some people are taking advantage of, and they're not taking advantage of it for us as a whole. They're taking advantage of it for themselves, and that's a concern. Because, as we all know sitting up here, there's a lot of consumers who believe that this country has forgotten about and certainly doesn't want to hear any more about their issues. And these are just things that I have to be mindful of because I know that this is what people think on a daily basis.

I need to bring one personal observation here, and that is my children go to Georgetown. Prior to meeting Dr. Sandler, we had some of the same fears we had other hospitals our children went to, and that was the type of care that was going to be given with their transfusions. Once Dr. Sandler and I sat down, we came up with that plan. I know every parent doesn't have that opportunity. I know every patient doesn't get the knowledge they need in order

to make sure that they get the proper transfusion. That is a real concern for me as well.

But I think we need to accept the fact that there are some real gaps in this whole system here that need to be addressed so that people like myself certainly feel confident when they take someone to the hospital. I don't even have to worry with that with Dr. Sandler. I don't have to worry about it, but other people do, and I think at some point we need to address those types of issues.

DR. BIANCO: Thank you, Larry. Thank you.

Dr. Sandler?

DR. SANDLER: Some years ago I had a watch that was slow. The watch just didn't keep up with things, and with bad judgment, I tried to take it apart and to fix it. And not only didn't it get back to where it was, it just didn't keep time after that. And the lesson I think that we all know, and we've all done this in one way or another is don't take something apart unless you absolutely have to do it.

What Dr. Katz pointed out to us is we've got a system that's working, and all we need to have is the government pay us what it costs. It's just a matter of money, and we need new money. That's all that's broken. All that's broken is we need some new money in the system, and if we can get Dr. Holmberg to go up and put his face and the face of the people that he is charged with advising and

saying, Look, there's a roomful of people that are ready to take the whole damn thing all apart if you don't pay your bills. You've just got to pay your bills, and you can't wait two years to readjust it and do everything. Just pay the bills, and the United States blood system can do its job.

And I think if we can just focus on that, just getting the new money out of the government and finding out how they're going to let us do it--if we take this whole damn thing apart, we're going to be in a mess.

I'd just like to ask Karen, if I can, one very specific question. I look at the policy. The four goals were supply, quality, accessibility and efficiency. I look at Slide No. 6 that you were asked to present, in the absence of Dr. Sazama, and it's changed to safety, availability, accessibility and efficiency. I am much more happy with what's in there originally because No. 1 is supply--a supply of blood and blood products adequate to meet all of the needs, and then it has quality which you raised. No. 2 is quality, accessibility. And then No. 4 is efficiency, which is includes utilization of the national supply of blood in an efficient way.

So it's all there. How did we get to the slippage with Dr. Sazama's sixth slide?

MS. SHOOS LIPTON: Because what they were looking at was what the Committee, when they got the forum together,

that's what they focused on. They didn't see it was significantly different, but they were tinkering with some of the--they said, "Oh, to us, it's really safety, not quality." And I agree with you. I think that going back to the original language is actually more instructive to us. It leads us in a better direction.

DR. BIANCO: Dr. Katz?

DR. KATZ: I wanted to get something on the public record that I've been trying to figure out all morning. Allen Williams and Sharon Orton write a chapter for a book that was entitled, "There's Something About Blood." And certainly those of us in the blood community recognize there's something about blood, and we intrinsically understand it's different than aspirin or understand, believe. We can play with the words.

We're not stupid, and the comment I'm making is mainly for Dr. Bowman at CMS. We understand very, very clearly the 12,000 priorities that are being hammered at CMS. And I think this Committee needs to be ready to articulate what that something is about blood that's different. I think that the resistance at CMS to carveouts is, if you look at the whole system, is very, very understandable. And if what we're--what one of the main themes here is somehow to carve out blood as different than everything else, this Committee needs to address explicitly

why blood is different than aspirin and coronary stents and take your pick.

DR. BIANCO: So why is it different, Dr. Katz?

DR. KATZ: Well, because our raw material is the good will of the people in our communities that come in and let recent high school graduates take a 16-gauge needle in their antecubital fossa 1.7 times a year for nothing more than reasonable cookies, not great cookies--

[Laughter.]

DR. KATZ: And understanding that at someplace anonymously down the line they've enhanced somebody's life or even saved it. We can't go out and manufacture blood donors, and we consume enormous resources figuring out new ways to ask.

What we know, what I know, is that if you ask, people will donate. It turns out that it's not free to ask. So we're dealing with this resource that Titmus tried to describe, and Jane Pellebon has tried to describe, and we all--it's like pornography, we think we know it when we see it sort of thing. But these are people coming in, laying down, letting people stick 16-gauge needles in their arms for moderately good cookies. That's why we're different.

DR. BIANCO: Dr. Fitzpatrick?

COLONEL FITZPATRICK: I'll take my marker now.

As a former liaison to the Committee, and what I've heard is what Ruth said--and I'm trying not to be

redundant here. There is a point--that the policy exists, a plan existed. Jay told you what the plan was. The Committee has discussed several times over the past several years the fact that something needs to be done.

That resulted in an action of monitoring the supply and being able to present to the Committee with data that said, you know what, in December, supply is short--not probably a great revelation to Dr. Katz. And in July and August, supplies get short again. Oh, gee, another great revelation. Did we ever do anything about it? No.

Did Dr. Epstein's plan get fully funded by the government when they came up with the plan? No. Did and is there an advocate at HHS and in the administration that goes and pounds on a desk and says, "Blood is important"? Probably not because there's lots of other important stuff that may or may not be as important. So we need an advocate.

The other thing is that timing is everything. And in order to get governmental money, timing the requests to whatever is going on currently to get governmental money--and as a 28-year governmental bureaucrat, I think I can speak to some of that--is everything. So you link your request to the current cause du jour, and you say this is important, and you legitimately link that request. You know, say the request is, you know, I need sand for the

playground sandbox because there's going to be a terrorist attack. Okay, well, that's not really very linked.

There is a great deal of interest and legitimate interest in homeland security. I think to go forward with another request that says, you know, we're low on donors in December, we're low on donors in August, and we really need more donors is the same thing that we've said over and over, to link that request to what is a real and legitimate threat, which is that there is a threat of what happens in other countries on a daily basis--Dr. Shinar gave you statistics and showed you on a daily basis what happens in her country--on a daily basis, people in uniform are dying in Iraq, not because there are people in uniform standing up on the hill shooting at them, but because there are terrorists in cars loaded with explosives, blowing them up, hoping they'll kill a few people, not hundreds and thousands of people, not millions of people, just a few people to make their point, make you live in fear every day.

We had a taste of that in 9/11, just a taste. We are fortunate and blessed to live in a country where we don't do that every day, and we're not prepared to deal with it on a daily basis. I think you have the opportunity to link your request to a current cause of concern that is legitimate in this country and get the money to fix some of the problems that we are concerned about, but timing is everything.

And I would ask Dr. Holmberg, and Dr. Epstein, and Mac McMurtry if there is a narrow time window available to you as a Committee to make a legitimate recommendation and actually see some results from that.

DR. BIANCO: Actually, I don't know if it is appropriate for me to review that, but talking to McMurtry, I think you have days to work on days to work on that proposal, not more than that.

DR. HOLMBERG: First of all, I want to address the comment about the commitment. I think that that's very important. The question, as far as whether the policy is still effective and whether we should take it apart is a question. It does not mean that Dr. Biato wants to take the policy apart. But obviously we do have a problem, and Dr. Biato is very concerned about that problem, and that is our supply, running at a 1- to 2-day supply sometimes, how do we react to that, and also how do we meet a disaster situation and respond to that?

We do have days, and the timing is critical, as far as putting together and taking advantage of input into what should be the blood supply or the blood response. That's why it's very critical that I think that this Committee move forward, before we adjourn today, on a resolution on or a recommendation on the national blood supply.

We probably will not get to a point of details, but there are things that encompass that national blood supply, a national emergency reserve, and that is issues not only, first of all--and I agree with Dr. Sandler, and I have to say that his comment yesterday about not having blood on the shelf when he needed it, and the message that was trying to be conveyed also at the same time was that we need to elevate the donations. We need to increase the amount of donations and elevate the level in the pool. That's the first step that I think needs to happen.

In addition to that, there also needs to be monitoring of what is happening across the country in a more comprehensive way, and then there is also the building of a national blood supply. And it depends on the Committee, if they want to endorse what the interorganizational task force has presented.

But all of this--and I agree with Dr. Fitzpatrick--that it must be, we must take advantage of the timing, and we also have to--and I agree with Dr. Sandler--is that it has to be phased in, but we have to stop talking and start doing. And I think that's what we're also trying to get from the Committee here is what are the next steps?

DR. BIANCO: Judy?

DR. ANGELBECK: Jerry, what I also think I hear in what you're saying is that the Committee would have potentially an ongoing role in dealing with aspects. I

mean, you can only deal with so much in the time frame that you have, and you have your first steps, you have your acknowledgement of where we are.

I mean, if I look at what we've discussed, at least as I can summarize it, I think there's some general consensus that we have a policy. We may wish to reinforce that with the FDA's Blood Action Plan. I think most of us feel that the current management of our operations is appropriate, that there is not a role for government there, and the timing that is pointed out is crucial.

We have a challenge with the donor base in building that culture of donation in this country which goes a long way and is a very important part of what was presented to us yesterday as the national blood reserve plan because, as all ships rise, then we have more availability throughout all parts of the country, and sooner or later we have to get around to funding and money that's going to support those efforts.

Jay certainly implied that the HHS endorsed the FDA Blood Action Plan. So where we are is at implementation and funding, it would appear to me, and calling out some of the specifics that you just reviewed.

I would also assume from that that this is so important to what we're doing or why we're here about blood and availability that this is something on an ongoing basis we might continue discussions and programs on to review

because it's not possible. I mean, we're still at the sort of 30,000-feet level on a lot of these topics. For example, what is it and then how do you encourage that culture of donation?

That's a pretty complicated topic because the demographics have changed in our society. So perhaps that's a topic of a later period that the Committee spends a more focused period of time on to further the reason for HHS to be serious about the implementation and funding of what's going on here.

DR. BIANCO: Andrew?

DR. HEATON: I'm big on prioritization. As the discussion is going around, and we look at what the original national blood policy suggested and where we are now, we're really talking about three areas that we'd like to see change in.

One is reimbursement, and the key issue underlying that is linking reimbursement to changes in regulatory standards and changed needs.

The second is prioritization of donation as the role of a citizen and doing something about that so that more people donate.

And third is taking extra steps to assure we have enough blood to meet disaster protection.

I suggest that this Committee prioritize those in the reverse order; that we talk first about the extra steps

needed to ensure disaster protection because that will allow us to propose to the population very strong, logical and self-interested reasons why people should donate more. It also would allow us, following Dr. Fitzpatrick's logic, to secure extra funding, first, for the national stockpile, but secondly to assure that the tide rises.

So I would propose that the Committee prioritize its discussion on disaster preparedness and protection, that it look then at communication of this to the public to raise the tide and, third, look at resources as related to regulatory requirements and as related to the cost to assure disaster preparedness.

DR. BIANCO: Any comments? Dr. Linden, you've been very quiet.

DR. LINDEN: Well, I really only would echo what has been said by others, who I think have articulated the issues: that we have a good policy, parts of it are antiquated, and we can make resolutions or, you know, recommendations for updating. But, you know, I think everybody's in agreement that the fundamental issues are really coming down the money and that we really are able to do what needs to be done. And it's a matter of the funding to do it.

So I don't have anything particularly unique to contribute.

DR. BIANCO: Mark?

MR. SKINNER: I wanted to follow up. I think Andrew's comments about prioritization are good ones, and I think that may be the stickiest wicket that we have to deal with, because I think what the question really comes down to, when you put those in order: Are we here to talk about the crisis that we think may occur at some future point with some disaster or terrorism event, or the crisis that exists today in providing the already available therapies to the communities that depend upon them?

So depending on which one we're asking, you know, I'm not sure if I'm talking from a consumer perspective, a user of these products, that I wouldn't leave them in the order that you first stated them. So I think it's very difficult to set them in an order of priority, but we probably won't reach resolution until we figure out what it is--where we want to commit the government dollars first.

DR. BIANCO: Dr. Sayers?

DR. SAYERS: Thanks, Celso. This has to do with what has changed and that comment about why is blood different. If we look at the national blood policy from the early '70s and compare our conduct today, one of the major differences is that in the early '70s we were testing for hepatitis B and syphilis, and now our scrutiny of individual donors is extensive.

I suspect that the largest public health exercise in the world is reflected in all the testing that is done on

40,000 adult Americans a day. That is a huge public health exercise. And against that background, the national blood policy has become part of the national health policy because, whether we like it or not, blood programs are now public health organizations.

And there seems to be some irony in the fact that we are fulfilling that responsibility essentially for 13 million Americans a year, and we're paying for it through a DRG-based system. I don't want to sound like I'm harping on the money, but this is just another reflection on why for blood programs to be functioning efficiently and effectively and for them to be contributing to national health in the fashion that they do, the money is an important consideration.

DR. BIANCO: Thank you, Merlyn.

Dr. Penner?

DR. PENNER: Since we have to come up with a proposal, I put together a few things. I don't know if this is going to be in the area that we're in agreement on, but which might fall in the category that we've been discussing right now that one has to sell the issue, and we know what is salable now. And, therefore, whatever we request that is going to require funding, it will have to be something that reaches the popularity level that would be acceptable.

And something of this order might be considered:

In view of the critical daily level of blood and blood products and the need to provide these products for catastrophic events that currently threaten the country, the committee recommends the following:

One, the establishment of a private and governmental data collection office that could provide daily information on blood availability in the United States;

Two, identify responsibility for responding to the needs that occur with such events;

And, three, provide funding support for increasing the blood supply to meet the needs of such emergencies.

DR. BIANCO: Thank you, Dr. Penner. We're getting to more concrete suggestions. There is this order of priorities that you did not--that Andrew Heaton just made that he put specifically the national blood reserve. You are looking at more general ways.

I would like to make a suggestion. I think that we matured into, I believe, pretty clear ideas of what the issues are. I want to suggest that we take a one-hour break for lunch, and then we return here. We will have Jerry's set--he's going to put this set of priorities up, and maybe Dr. Penner can help by providing a copy of his writeup.

I think that there was some homework assignment from yesterday that Dr. Epstein was working on, on the preamble to the emergency plan that we have here.

And when we return from lunch, we'll go specifically into those, hoping for an early resolution so many of you can go home at a decent time. Is that acceptable?

So it's almost quarter to 1:00. I'd like us to start precisely at quarter to 2:00. Thank you.

[Whereupon the meeting was recessed, to reconvene at 1:45 p.m., this same day.]

AFTERNOON SESSION

[1:57 p.m.]

DR. BIANCO: Could the members of the committee take their seats?

Thank you for coming back, and I promise early release if we can reach consensus.

We have had a discussion in the last hour or two trying to focus, and we were helped by a suggestion of priorities that maybe Jerry can quickly put on the screen as the previous slide that came from some of these discussions. It was to take extra steps to ensure disaster protections, to increase donation priority--trying to translate what Dr. Katz had said, making it a civic duty and encouraging that, and then reimbursement linked to resources and requirements, regulations.

But if we go to the specific words that are in the next, those were drafted as specific recommendations. I don't know who exactly drafted it, but I understand Dr. Epstein had a touch there.

So the committee specifically recommends that DHHS take steps to enable development of a five- to seven-day inventory of blood components in all collection centers, both to stabilize the blood system and to improve preparedness for disasters.

Two, fully fund the DHHS Blood Action Plan, especially in the area of private and government data supply monitoring and increasing the blood supply.

Three, address unmet funding needs at all levels of the blood system to support safety, quality, availability, and access.

And, fourth, additionally fund the development of a national blood reserve program as a government-private sector partnership.

Karen?

MS. LIPTON: Sorry. Jerry was using this as an IV pole illustration.

[Laughter.]

MS. LIPTON: I just have a quick question. One is that DHHS Blood Action Plan--and I just clarified this with Jerry. It really was an FDA Blood Action Plan and it's now DHHS, and so it is without respect to which agency, right? It is a departmental as opposed to an agency?

DR. HOLMBERG: I'll let Jay address that.

DR. EPSTEIN: FDA developed a plan in, I think it was July of 1997, and then it was officially adopted by the department as a departmental plan in March of 1998, and it has remained a departmental plan, but, of course, it's implemented predominantly through the agencies, although as you well know, the blood supply monitoring function was taken over at a later date by the department itself.

So it is a department-owned plan.

MS. LIPTON: Okay. As long as it's not agency specific.

The other thing is: Are we dropping anything about the characteristics of the national blood reserve--the recommendations of the task force on the characteristics?

DR. EPSTEIN: Well, there was language drafted yesterday which I think the committee will also wish to consider, and my concept in drafting this is that it's a set of specifics that follow the earlier statements that were drafted yesterday. That's what was handed out. Unfortunately, somebody swiped my handout, but I'm sure it's available up at the podium.

DR. HOLMBERG: I may have captured that, Jay. I'll try to get you a copy.

Dr. Bianco thought that this was better if we went to the specifics on this. What I also changed on your proposal, Jay, was that Dr. Penner had suggested that trying to merge his recommendations along with your recommendations. He wanted to be specific about the blood monitoring of the private and the governmental data supply monitoring so that an informed decision could be made.

MS. LIPTON: I'm still not clear, though. So does that mean we're dropping the specifics of this second recommendation or does that come at a different time?

DR. HOLMBERG: I would say no, we're not dropping the specifics.

DR. EPSTEIN: Could I suggest that that text also be shown so people could see how they fit together?

DR. HOLMBERG: That highlighted red was my change. I thought it went smoother.

DR. HEATON: I'm also planning on proposing an extension to that because I'm concerned that the blood reserve program, as developed by the AABB Interorganizational Task Force may not be achievable within a realistic timetable. And I believe that we may want to ask the task force to pursue other interim steps which might ensure the availability of an emergency response pending completion of the first series of recommendations.

DR. BIANCO: Could you help me? I don't remember a timeline in the proposal.

MS. LIPTON: There is no timeline in the proposal. I think you could do it in whatever steps you wanted to. You could decide to start with building five- to seven-day inventory. You could start with the 2,000 in the ASWBPLs. You could start to build up 8,000 in the private. So there's no timeline and there's no priority in terms of where you have to go first. I thought this was sort of suggesting that we want to go first in the direction of raising the tide.

DR. HEATON: Jerry, could you go back to the fourth stage? Because I'd like to speak in favor of it and of the logical sequence. I see this is a very logical step through the issues.

Point one focuses on the development of the five-to seven-day inventory, but hooks into a primary goal here, being improved preparedness for disasters. That's a critical determinant, I believe, in gaining acceptability of this recommendation.

The second recommendation picks up the fact that there already is a DHHS Blood Action Plan. It's already had some level of review. What we're doing here is proposing that it be supported and funded and that it pick up data capture.

I think the third one addresses the issue of reimbursement, unmet funding needs, and then that could pick up the reimbursement requirement to fund regulatory mandates.

And then the last one hooks into the key issue, which is our hot priority right now, which is the development of a national blood reserve program. So I see this as a very logical series of steps with cross-links to other recommendations and current political priorities that should make a very attractive package.

DR. BIANCO: Does anybody want to add to--Dr. Sandler?

DR. SANDLER: It's unclear to me which of the two slides goes first. In other words, are you going to send letter or are you going to send something--which goes first? Because it looks like this is the second one, where I thought this was to--it is the second one. Can you go back to what you call the first one, then?

DR. HOLMBERG: This is a preamble, yes.

DR. SANDLER: I would have seen this for some reason as the second because this is the detail of the national blood reserve. So I would have thought that you--the other one goes first, and it says the committee makes a recommendation, and then this one would begin by saying specifically we recommend consistent and so forth.

DR. BIANCO: So that would be the preamble--

DR. SANDLER: This is the detail.

DR. BIANCO: --to number four.

DR. SANDLER: This is the explanation of the specific details coming out of the first document. If you put this one up first, you're going backwards with the other one.

DR. HEATON: That's how I see it as well.

DR. BIANCO: Dr. Linden?

DR. LINDEN: Yes, I agree. I don't think we want to send the message that our main point and concern is promoting the national blood reserve program. We have many

concerns, and that's just one suggestion. That's not our main and primary concern.

DR. BIANCO: Actually, I think that the word "additionally" in the next slide, in number four, gives the impression that that's an appendix, and it doesn't match what you have in that preamble here.

Dr. Sayers?

DR. SAYERS: Dr. Bianco, if the other slide was reduced to conventional legislative-speak, then each one of those points would start, "Whereas," and there would be a string of five or six whereases, which would then be followed with specifically these are the recommendations which follow out of that preamble.

DR. BIANCO: So Dr. Sayers is suggesting that we--

DR. SAYERS: Can we have that earlier slide again? Whereas, previously we had recommended, and whereas this would add stability, and whereas the committee endorses, then this follows.

DR. BIANCO: Dr. Linden?

DR. LINDEN: It really doesn't follow. I mean, if these were whereases--I mean, all you're saying is because we think a national blood reserve program would help, then one, two, and three don't follow from that. Only four does. I mean, I don't think these two items go along with that list at all. I mean, it's sort of further explanation of four.

MS. LIPTON: I see it as you have one, two, three, four, and if you want to put in a whereas, but my only point was that you're missing the last half. It's the development of a government-private sector partnership, and we endorse the elements, with the elements as developed by the AABB Interorganizational Task Force. I'm just saying that something's missing in funding a private--you say fund it, but you don't say and we endorse the--

DR. BIANCO: Karen, how would it work if number four started with the second paragraph of the previous page? The committee endorses the elements of a national blood reserve program as developed by the task force and recommends that the Secretary consider facilitating development of such a program within the context of improvement to the large blood system.

MS. LIPTON: That's what I--

DR. BIANCO: And additionally recommends that they fund as a government-private sector partnership, or something like that.

MS. LIPTON: Jerry, does that work for you, taking the second paragraph of the recommendation about the blood reserve and really appending that to number four.

DR. HOLMBERG: Sure. Sure.

MS. LIPTON: Okay.

DR. HOLMBERG: So you want the second paragraph, this paragraph here--

MS. LIPTON: I mean, there would have to be a little bit of editing, but essentially cut it and paste it into number four. You might put it after four so we can see what we--make sure we've covered everything. But it's part of four.

DR. BIANCO: Do we have any more contributors? Dr. Epstein?

DR. EPSTEIN: Well, I share the sentiment that the enumerated items need to come first. But I think that what's needed then is a new introductory sentence or two sentences focusing on current instabilities in the system that, you know, threaten day-to-day safety and adequacy and limit preparedness for disasters. Therefore, we recommend one, two, three. And then for item four, I think we should take some of the text that was written yesterday as a preamble, saying that, you know, consistent with previous recommendations, we endorse a national blood reserve. And then we could either continue the language from four or simply revert to the second paragraph from yesterday as the specific recommendation, that, you know, we recommend that the Assistant Secretary consider facilitating development of such a program within the context of improvement, and we could add the word "funding" there.

So I think it's not that hard to merge these, and I do agree that we want the larger context first, as Dr. Linden stated.

DR. BIANCO: I see a lot of people nodding, but what are they nodding to? Dr. Gomperts?

MS. LIPTON: What he said.

[Laughter.]

DR. BIANCO: We'll give you a few minutes to put this on paper. But I'd like to hear more comments, particularly from those that haven't said much, like Ruth Sylvester.

COLONEL SYLVESTER: I agree with what he said. The bigger concept, even in the task force as we worked with it, was that we need to increase the whole supply. And to have a national blood reserve, you have to increase donations across the board, not just as the centers that are going to collect them. And I think we all envision that the national blood reserve is a way of having blood strategically located should we have a need, and I don't know that it was a finite forever thing. It was until we can get our blood industry back up to the five- to seven-day levels, it's critical to have blood set aside for those emergency purposes.

We also discussed HBOCs coming down the line. When H Box, if and when they ever become a reality, again, the need for a national blood reserve would probably, you know, drop off.

DR. BIANCO: Yes, but from what I heard from Dr. Fitzpatrick--and I'd like you to confirm or deny--it's that

the issue was more an issue of logistics, of having those units there easily transported within a matter of four hours.

COLONEL SYLVESTER: And that's key. It's one of the concepts when we were discussing it, that they have to be strategically located. And we tried to--we didn't pick places. We just said that they need to be able to be moved in four hours and they need to be drivable distance to anywhere in the United States. And that way we have the ability--if we lose air, like we did on September 11th, we could still move blood around to wherever it's needed. And those are some of the characteristics, without having to actually pick a location. And you don't put all your eggs in one basket. You know, you could say I want 10,000 units, I'm going to put them in one place, and they're gone with one terrorist event. So by dispersing them out and then putting them where they can be moved and logistically moved, just like we have a national stockpile of pharmaceuticals and those are strategically located, it would be the same kind of concept.

DR. BIANCO: Mark, does this thinking kind of attend your concerns?

MR. SKINNER: In the context of what Jay said, if the whole recommendation is put in the context of addressing the national reserve, then I'm very comfortable. If we were trying to establish of all the things in the world that need

to be done with blood and plasma in this country, this is our number one priority, then I think we'll have a much longer debate. But ordering the things, the order of things that need to be done to achieve a national reserve makes complete sense.

DR. BIANCO: John? John Walsh.

MR. WALSH: I think this is very well articulated, and, you know, this addresses the issue I brought up yesterday. And I think that I totally agree with Jay that we have to have an initial statement, whether it's a preamble or whatever, that ties this with an immediate need and to be strategic with the government that there's monies available and this needs to be addressed now, not three or four years of planning from now.

DR. BIANCO: Dr. Sandler?

DR. SANDLER: Let me just take a couple minutes because my goal is to give Dr. Epstein time to get his work done. But going off-line while he does that, I'd like to point out that the HBOCs, hemoglobin-based oxygen carriers, should be a national reserve in hospitals. They're going to carry the patient over in the hospitals until the national reserve can get to the place where the injured people are. So whoever is going to be involved in planning the national reserve wants to think of a national reserve of HBOCs at the point of care, which will be hospitals, and a blood reserve that can back it up. That would be, you know, the concept.

DR. BIANCO: And that gets there within the 12-hour half-life of the HBOCs.

Larry, how do you feel about it?

MR. ALLEN: I'm fine with where we're going with it right now.

DR. BIANCO: Good. Thanks.

MR. ALLEN: Thank you.

DR. BIANCO: Chris is quiet.

MR. HEALEY: Count your blessings.

I'm fully supportive. I think he's going in the right direction.

DR. BIANCO: Andrew wanted to say something.

DR. HEATON: Yes, could we go to the next statement? I have a concern about the way this is written. This implies that it endorses the elements of the national blood reserve program as developed by the Interorganizational Task Force, in effect, as presented.

I, from a practical perspective, believe that whilst its desirable to have a liquid reserve and I think it's a great goal and I think we might get there in a year or two, I do not believe that we will get there in under one to two years. Therefore, as a result, I believe we need to amend this to reflect the need for an interim plan, which might well involve frozen product, but certainly an interim plan to meet this need more rapidly. I do not believe that

we should endorse the AABB Interorganizational reserve program exactly as presented.

As a general plan, I think it's excellent. As a goal, I think it's excellent. But I don't believe that the liquid program is feasible within a one- to two-year period.

DR. BIANCO: But, Andrew, don't you think talking about the elements you are giving sufficient flexibility to the group that is going to work on it to create timelines, plans, and all that that will ultimately take you to the final product without being bound to how much is frozen, how much is not frozen, how much is liquid, how much time to get there?

DR. HEATON: Well, yes, I guess. There's the element of timeliness. I think we need to come up with a reserve program, a realistic reserve program in a reasonably short period of time; and that if what we're now proposing took two years, I think that would be too long.

DR. BIANCO: Ruth?

COLONEL SYLVESTER: To be quite honest, from my experience with frozen I think it would be quicker and easier to come up with a liquid than to come up with a frozen reserve. It just takes so much time and effort and resources on the frozen side to bring up a frozen program. I think we could accumulate the liquid units faster than we could accumulate the frozen because we wouldn't need any additional equipment, freezers, and people to actually

freeze the blood, so you'd have less manipulation on a liquid than a frozen. And that's just speaking from experience.

DR. HEATON: Well, I've only been in U.S. blood banking for 30 years, but during that time I have never seen or could envisage a period where you would easily accumulate that amount of blood and make it available on a consistent basis. I absolutely understand it's the best way to go. I just don't think it's practical.

DR. BIANCO: Well, I understand your concerns, Andrew, but what I see is that it's a bubble, a wave, that will tax the system on the first several weeks when you are building this inventory. And then those units are being rotated every two weeks. So the effort is just this initial push for the 2,000 units, for the one based on DOD, or for the 8,000 units strategically placed around the country. That is the effort. After that, it's just maintaining and rotating those units.

I believe that if we start at the right time of the year, like in April, May, or in September, October, it's not going to be that painful. If we try to start it now in January, we are not going to be able to do it.

DR. HEATON: Celso, that's like saying the Social Security reserve is fully funded. You know perfectly well the government raids it, constantly borrows against it and overallocates against it. And the needs of Jerry and his

hospitals will raid that reserve constantly unless you have a very successful recruitment program that is guaranteed to back-fill behind it.

DR. BIANCO: I have to agree with you that it's not by itself, without that effort to increase collections, in general it's not going to work. But I'm going to retire before you, so for me Social Security will be fully funded.

Dr. Wong, you have not commented on that as yet.

DR. WONG: Being the only one who will not retire before everybody else, I think I'm stuck with the--but looking at the changes that are being made, I think I fully support what's being said.

DR. BIANCO: Dr. Penner?

DR. PENNER: I was going to ask Jay if this sexy enough to get through and get money, but he's already departed, so presumably he agrees that this will pull it out.

Oh, there he is.

[Laughter.]

DR. BIANCO: Dr. Sayers?

DR. SAYERS: Is there any way of wrapping into this or does anyone even feel enthusiastic about it, a need to have some reporting system so that we know what progress is being made?

DR. BIANCO: Yes, I agree with you, and we can request, as Dr. Penner has requested, have a meeting report

on the HCV look-back. We can request a report back to this Committee on the status of this recommendation.

DR. KUEHNERT: Can I have a clarification on that? Was that a report back on the status of our recommendations or a status of exactly--at first, I thought what the suggestion was is actually evaluating the reserve and at what state it's in at various points, but I think both are probably useful. But concerning the reserve, I think it may be just as difficult to be able to evaluate at what point the reserve is feasible. There have been comments about the feasibility of 10,000 units. What about the feasibility of 2,000 units, 3-, 4- or 5-? And how do you evaluate that and determine what is feasible and what's not?

DR. BIANCO: I agree with your perspective, but I think that the feasibility has to be done by the experts, the people that are sitting in the Committee and are trying to, in contact with all of the blood centers and looking at the blood center, to say it.

But I think that you're right in that they could come and tell us where they are, that is, what is the ultimate goal and where they are in relation to that goal, and I agree with that.

Larry?

MR. ALLEN: Well, I just want to jump on with Dr. Penner here. I would love to hear more about some of the updates, some of the recommendations we've inquired about in

the past. I would love to hear more about that. But my question is, from the experts in the room, I've got a concern as to the money that it's going to take to do this, is this going to happen to the detriment of some of the other programs or policies or reimbursement issues that we've been dealing with? Is there some kind of way we can tie this together?

DR. BIANCO: There is, actually, in your package, unfortunately you weren't here yesterday when the presentation was made, but there is in your package a presentation. And the entire program, if I recall, would cost about $5 million a year to maintain. So it's not within the context of homeland security and all of that.

MR. ALLEN: This would cost $5 million?

DR. BIANCO: Maintaining that repository. There is an investment. It's in the pile of papers that you received.

MR. ALLEN: And who is paying for that?

DR. BIANCO: Hopefully, this is going to be presented to Homeland Security as part of their emergency plans.

MR. ALLEN: But we're also aware that there is also a new Department of Homeland Security or bioterrorism through the NIH, and I think about 30 percent of the safety budget is going to that now, where before this new homeland safety was developed, that money was going somewhere else.

Now, 30 percent of that budget is now allocated towards this. So that's what I'm afraid of, that once again we're going to rob Peter to pay Paul. That's all I'm concerned about.

DR. BIANCO: We raised that, and I think it's a legitimate concern, Larry, and we should make sure, and that's why Dr. Sandler the whole time is talking about new money.

MR. ALLEN: New money, exactly.

DR. BIANCO: New money.

MR. ALLEN: But, you know, we asked for certain recommendations or considerations on this panel before only to come back to find out it's been to the detriment of other people. So that's a concern.

DR. BIANCO: Yes, I hear you. And I think that we have to charge Dr. Holmberg to carry the message with all of the energy that he has.

One of the editors left the podium so--

DR. HOLMBERG: Do you want me to read it?

DR. BIANCO: Yes, please.

DR. HOLMBERG: Whereas, the DHHS ACBSA finds that current instabilities in the national blood system pose threats to blood safety and availability and limit national preparedness to address disasters, including potential acts of terrorism, the Committee recommends that DHHS urgently take steps to enable development of a 5- to 7-day inventory

of blood components in all collection centers, both to stabilize the blood system and to improve preparedness for disaster;

Two, fully fund the DHHS blood action plan, especially in the area of private and government data supplying--government data supply--supply, it should be. -- supply, monitoring and increase the blood supply;

Address unmet funding needs at all levels of the blood system to support product safety, quality, availability and access.

Consistent with our previous recommendations of January 2002, the ACBSA further believes that establishing a national blood reserve program would add stability and security to the U.S. blood system if developed in the context of expanded daily collection inventories through an enhanced program to expand and sustain volunteer blood donations.

Additionally, the Committee endorses the elements of the national blood reserve program, as developed by the AABB Interorganizational Task Force. Therefore, the Committee recommends that DHHS fund development of the national blood reserve as a government-private sector partnership.

DR. BIANCO: Could you use the microphone, Dr. Penner.

DR. PENNER: It seems to be a separate element the way you have it set up, which would mean it may be a separate paragraph for the additional.

DR. EPSTEIN: Just to comment, John--Mr. Chairman?

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: We envisioned Item 4 as a fourth specific recommendation. However, it has its own preamble because you'll notice that the rest of the text that antecedes it doesn't contain a recommendation. It's just a statement of findings.

DR. BIANCO: So would you like, instead of "consistent," we will say "or in conclusion" or something like that, that would show this is a summary of--

DR. EPSTEIN: Well, I saw it as sort of a separate "whereas" type statement along the lines that Merlyn suggested; that we make our recommendations only after we state our conclusions or findings.

DR. BIANCO: Dr. Sayers?

DR. SAYERS: Yes, I'd put separation on this "whereas" business. I think that paragraph there where the cursor is could be, "And whereas, consistent with our previous," et cetera. "Therefore, the Committee recommends" or "also recommends for DHHS fund development."

DR. BIANCO: Could you help Dr. Holmberg introduce that?

DR. HOLMBERG: I didn't hear that.

DR. KUEHNERT: Celso?

DR. BIANCO: Matt?

DR. KUEHNERT: I just wanted to make a comment about No. 3, this address unmet funding needs. The understanding seemed to be this was about reimbursement. To me, it just wasn't entirely clear. Maybe that translates to everyone else, I don't know, but I didn't quite understand what encompassed. I just wondered if there were any thoughts on it being more specific.

DR. BIANCO: Dr. Sandler?

DR. SANDLER: What I think it misses is that we want to say "using new money." In other words, what we don't want them to do is to receive this and say, "Let's just take something out of the cardiology budget for stents and shift it over here." And to avoid that, I think you have to build into the structure of this that what we're talking about is not shifting around something that you're already spending for one part of the health care system and just bring it in because that's not going to really get us where we've got to go. I think somewhere into this we have to just put the simple words "using new money."

DR. KUEHNERT: I think this "unmet funding needs," there's also a term, you know, "unfunded mandate," which basically just means what we've been talking about. So I'm just a little bit worried about the language here.

DR. BIANCO: Dr. Linden?

DR. LINDEN: Well, I agree that that's very vague. Although we've mentioned the issue about reimbursement, CMS, Medicare and so forth repeatedly before, we may want to specifically mention appropriate reimbursement for blood products, you know, in there as an example of this--you know, specifically, including appropriate, you know, include reimbursement.

DR. BIANCO: Paul, what would an economist do?

DR. LINDEN: Karen was just agreeing. Not limited to that, but including.

DR. BIANCO: Could you draft a couple of words so when they finish editing the preamble to four, we can focus on--

DR. KUEHNERT: It's almost more a funding inequity, and then you could use that as an "e.g."

DR. BIANCO: Well, inequity, you are blaming somebody for doing the wrong thing. Here, I think that we should be more positive and find--

DR. HEATON: Isn't the key issue here adjusting reimbursement to meet, I mean, there's two key issues. One is new regulatory requirements and the other is new services or quality of services.

DR. BIANCO: Could we focus again now on the preamble to No. 4. Jerry, would you like to read the last version.

I prefer your accent than Dr. Sayers' accent.

DR. HOLMBERG: What accent is that?

[Laughter.]

DR. HOLMBERG: Whereas, consistent with our previous recommendations of January 2002, the ACBSA further believes that establishing a national blood reserve program would add stability and security to the U.S. blood system if developed in the context of increased daily collection inventories through an enhanced program to expand and sustain volunteer blood donations;

And whereas the Committee additionally endorses the elements of the national blood reserve program, as developed by the AABB Interorganizational Task Force, therefore, the Committee also recommends that DHHS fund development of a national blood reserve as a government-private sector partnership.

DR. BIANCO: Could the members of the Committee express the degree of comfort they have?

DR. HEATON: That was very nice, Merlyn.

DR. SAYERS: As far as comfort goes, I feel posturepedic about this.

[Laughter.]

DR. BIANCO: Karen?

MS. SHOOS LIPTON: Then, if we can go back to the three. Can I ask a question? I actually was thinking do we really need "unmet funding needs" or is it just "address funding needs, including inadequate reimbursement for blood,

blood components, plasma"? And I still don't think your concept, though, of "new money," addressed through additional funding or something, I mean, I just don't think that "unmet" necessarily gets us anywhere. It's a funding need.

DR. SANDLER: The simple language is "new money." It's not as elegant as a "whereas," but I think anyone reading "new money" knows what it means. To me, new money is the core of everything we've talked about for two days. We need money to come in addition to what's there. And if we just avoid the words "new money" we obscure the whole message. I would just say, "And using new money," and I would just stick it right in there so any bureaucrat would read it and understand it.

DR. BIANCO: Chris Healey?

DR. HEALEY: On No. 3, what if you changed it, it seems like the "unmet funding needs" is causing a little bit of heartburn, what if you said something like, "address currently inadequate reimbursement systems or payment systems for blah, blah, blah at all levels"?

MS. SHOOS LIPTON: Well, I think it's not just reimbursement. I mean, I think we're talking about all sorts of funding things, some of which may come out of HHS in terms of national awareness campaigns, some of which--I mean, reimbursement is a piece, but it's not the whole problem.

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: I would suggest that Item 3 be continued in the following way. It would say, "Address funding needs at all levels of the blood system to support product safety, quality, availability and access through targeting of additive resources and appropriate reform of the CMS reimbursement system for blood and blood products."

[Applause.]

DR. BIANCO: Jerry--

DR. SANDLER: That's what I meant by "new money," Jay.

[Laughter.]

DR. BIANCO: While Jerry puts the final touches on No. 3, any additional comments or thoughts from the Committee?

DR. KUEHNERT: This is--

DR. BIANCO: Matt?

DR. KUEHNERT: This whole statement, I guess it starts with this preamble and all of that, how does this all sort of fit into what we were discussing overall about the blood policy?

DR. BIANCO: Well, it certainly is not responding directly to the question whether we should have a blood policy. But I think that some of the comments that I heard, and I'm sending them back to you, were that we have a blood policy and that if you add the FDA Blood Action Plan, and

that it, in a certain way, updates it to some of the more current issues, is just that it's a policy that is sitting there without enough attention.

So maybe to make Dr. Brecher happy, we should say that there is a blood policy, and many of the elements of the 1974 blood policy are still applicable today.

DR. KUEHNERT: Yes, I just wondered if we needed any affirmative statement about that. I'm not saying we do or not. I just wonder if we, to tie it all in.

DR. HOLMBERG: The question I have, blood and blood products, does that address the plasma community, plasma fractions? Is that broad enough?

DR. BIANCO: It probably would be better plasma therapeutics, right?

DR. HEALEY: Yes. In the past, we've that language and then included a tag line that says "including plasma-derived therapeutics or therapies," something like that.

DR. SANDLER: How does that language address Factor VIII recombinant and recombinant Factor VII recombinant products?

DR. HEALEY: It needs to address that, it does. So we'll have to capture that.

DR. BIANCO: Dr. Linden?

DR. LINDEN: I think, in the past, we have said, "and their recombinant analogues."

DR. BIANCO: Dr. Epstein?

DR. EPSTEIN: I'd like to come back to I think it was Jerry's point about what are we doing about our charge to comment on the national blood policy or program. And I think that what we need is just a "whereas" statement early on that, "Whereas, the Committee finds that the stated goals of the 1974 national blood policy on supply, quality, accessibility and efficiency remain sound," something along those lines.

It's a finding of fact, that we find the goals of the '74 policy still current or sound. Because that gets us out of the box of needing to go meticulously through the policy and update it. We can just say that its overarching goals are still appropriate.

DR. SHOOS LIPTON: I agree with that. Then, we're just limited to those four pieces that were the goals, and we don't get into the implementation plan or anything else. We just say those goals are our policy. I think that's good.

DR. HOLMBERG: Are you suggesting that up front here?

DR. BIANCO: Dr. Epstein, we need your help. Is that where we would place it, just opening the sentence?

DR. EPSTEIN: My personal preference would be to make it the second "whereas," because I think the urgent need is to deal with the current problem. And we see the

goals of the 1974 national blood policy as a road map to how to fix things, and it's still the right road map.

MS. SHOOS LIPTON: Could we just limit it? It would be so much simpler if we just say, the reference is, "The federal recognizes four principal goals," and if we just state that there are four goals, we don't get into the stuff underneath it. And then when you go back, you can actually tag into the language and the policy that talks about supply, quality, accessibility and efficiency.

DR. BIANCO: Yes, Karen, but how do you suggest that we insert this?

MS. SHOOS LIPTON: I agree with Jay, that just putting it as a second "whereas," leaving the first one, "Whereas, the Committee finds that the four principal goals of the 1974 blood policy are still applicable."

DR. HOLMBERG: And where do you suggest putting that--right before the listing?

DR. BIANCO: Before No. 1.

DR. EPSTEIN: After the word "terrorism," start another "whereas."

DR. HOLMBERG: Is that "And whereas"? Help me.

DR. EPSTEIN: "And whereas the DHHS ACBSA or the Committee finds that the goals of supply, quality, accessibility and efficiency--"

[Pause.]

DR. EPSTEIN: "--supply, quality, accessibility and efficiency--"

DR. HOLMBERG: What was the last one?

DR. EPSTEIN: "--efficiency, as stated in the 1974 national blood policy, remain applicable--or remain appropriate."

I think applicable, "--remain applicable, the Committee recommends."

DR. BIANCO: Jerry?

DR. HOLMBERG: Yes?

DR. BIANCO: Would you be kind enough to read the whole thing so the Committee hears it once more.

DR. HOLMBERG: Whereas, the DHHS ACBSA finds the current instability in the national blood system pose threats to blood safety and availability and limit national preparedness to address disasters, including potential acts of terrorism;

And whereas the DHHS ACBSA finds the goal of supply, quality, accessibility and efficiency, as stated in the 1974 national blood policy remain applicable, the Committee recommends that DHHS urgently, one, take steps to enable development of a 5- to 7-day inventory of blood components in all collection centers, both to stabilize the blood system and to improve preparedness for disasters;

Two, fully fund the DHHS blood action plan, especially in the area of private and government data supply monitoring, and increasing the blood supply;

Address funding needs at all levels of blood system to support product safety, quality, availability and access through targeting of additional resources and appropriate reform of the CMS reimbursement system for blood and blood products, including plasma-derived therapeutics and their recombinant analogues;

And, whereas, consistent with our previous recommendations of January 2002, the ACBSA further believes that establishing a national blood reserve program would add stability and security to the U.S. blood system if developed in the context of expanded daily collection inventories through an enhanced program to expand and sustain volunteer blood donations;

And whereas the Committee additionally endorses the elements of a national blood reserve program, as developed by the AABB Interorganizational Task Force, therefore, the Committee also recommends that DHHS fund development of a national blood reserve as a government-private sector partnership.

DR. HAAS: There is just the one, small change in No. 3, line 3, Jay used--

DR. HOLMBERG: Okay, three?

DR. BIANCO: Paul, what is line 3--

DR. HAAS: No. 3, line 3, "additional" should be "additive."

DR. HOLMBERG: That's not redundant?

DR. EPSTEIN: No, strike "additional." "Additive" is just the government term of art.

DR. BIANCO: Jay?

DR. EPSTEIN: I think just some minor text editing in the paragraph, "Whereas, consistent with previous recommendations," when you come down to the previous "whereas," you probably want a semi-colon and a space.

DR. HOLMBERG: Right here?

DR. EPSTEIN: Yes, make that a semi-colon and add a space--a line space.

DR. BIANCO: Any more comments?

DR. EPSTEIN: No, I was suggesting that you make that its own paragraph. Just hit enter before "and."

And then back up where we talk about "data monitoring," there's a little bit of an awkward construction there that we need to fix. Just back up where you talk about blood action plan.

DR. BIANCO: This is the prior page.

DR. EPSTEIN: "Especially in the area of private and government supply." Just take out "data." Take out the word "data." Just "supply monitoring."

And I think we probably need a comma because supply monitoring is one concept, and then increasing the blood supply is another concept.

Originally, in the blood action plan, they were linked "monitoring" and "increasing," but I think the way it's phrased here it's better off separated as two elements.

DR. BIANCO: Is the Committee happy?

DR. EPSTEIN: And just, again, after the first paragraph, "Whereas," again, make it a semi-colon after terrorism because it's not a sentence, in fact.

DR. BIANCO: Dr. Linden?

DR. LINDEN: If we're going to do nitpicking--

[Laughter.]

DR. LINDEN: --then I think number two needs a comma before "especially." What you're saying is you're making the especially...

DR. EPSTEIN: I wonder if we should delete that word entirely, because there's this ambiguity about fully funding the action plan, and really we're talking about fully funding that element. So--because we haven't talked about the other elements of the action plan. Of course, I'm not against it being fully funded, but isn't our message to fully fund the action plan in this area?

I mean, we haven't discussed whether to fully fund it in the area of updating regulations, for example. You know, there are six elements.

DR. BIANCO: I thought you were funded it already. You're already funded for that.

DR. EPSTEIN: No comment.

DR. BIANCO: Well, I think that we've done our job. Jerry, what would be the procedure here? I think that Dr. Brecher should see these recommendations. I think we should take a vote, but then let the final details of write and rewrite to Dr. Brecher as he prepares his letter to the Assistant Secretary.

DR. HOLMBERG: We need to vote on this, and then what we'll do is forward this to Dr. Brecher, and he can send this to the Secretary.

DR. BIANCO: Do I hear a motion--yes, Dr. Gomperts?

DR. GOMPERTS: I'm not sure that Dr. Brecher should be able to change what we vote on.

DR. BIANCO: I don't believe that he will change the contents, but Dr. Brecher as the chairman is the one that is going to submit the letter.

DR. GOMPERTS: Yes, he clearly needs to submit the letter, and obviously he'll need to see it. But he's not here and he hasn't partaken in the deliberations and the details.

DR. BIANCO: I'm sure that Dr. Holmberg will convey this concern.

DR. HOLMBERG: Yes, I think in the spirit of being transparent in our actions, I think what we decide on here goes forward and that nothing substantive can be changed.

DR. GOMPERTS: Okay. Thank you.

DR. PENNER: Isn't that first--the paragraph before number four redundant or at least very similar to what we have at the beginning? It seems we're expressing the same--

DR. BIANCO: Yes, but--

DR. PENNER: Consistent with the recommendations of--could--

DR. BIANCO: I agree, Dr. Penner, that it's not a literary work, but it reinforces the message, don't you think?

Dr. Epstein?

DR. EPSTEIN: All the whereases could be just lifted up to the top, and then you'd just have all those in all the recommendations. If that would be a little better?

It's just it was framed this way because it reflected the two dimensions of our discussion, which is fixing the system as a whole and then specifically addressing the problem of reserves. So I think there's a logic, but--you know, as an English text it might be better the other way. But I think there's a logic to this.

DR. HAAS: I'm from the private sector. I like it, John.

DR. EPSTEIN: I hope you don't see that as a contradiction in terms, John.

[Laughter.]

DR. BIANCO: So what is the recommendation, Jay?

DR. HOLMBERG: Do you want to cluster all the whereases?

PARTICIPANT: No. As is.

DR. BIANCO: Well, that's the consensus that I hear. Now we have to move from the consensus to a vote. And I'd like to hear a motion.

DR. HEATON: So moved.

DR. BIANCO: Dr. Heaton moved, and I hear--I see Dr. Sandler raising his hand as a second to the motion.

DR. SANDLER: I second. I was thinking of adding that I'd like a highway or a bridge, just to make sure that we get this through with appropriate pork for Washington. But in deference to the hour, I'm going to pass on that.

DR. BIANCO: Yes. And does the committee feel that we should have any further discussion on the motion?

[No response.]

DR. BIANCO: If not, I ask that all those in favor say aye? Those opposed, same sign? Those abstaining?

So from what I see, the decision is unanimous. Thank you, Dr. Holmberg, and thank you, members of the committee.

Yes?

MR. WALSH: Excuse me. I'd just like to express my appreciation, and I'm sure on behalf of the whole committee, to Dr. Epstein for his well-crafted wordsmithing here. Thank you very much, Jay.

[Applause.]

DR. SANDLER: And I'd like to add my appreciation to Dr. Celso Bianco in his surrogate role. Thank you.

DR. BIANCO: Thank you, Merlyn.

[Applause.]

DR. BIANCO: And I thank you. We'll convey our recommendations to Dr. Brecher, and Jerry and Mack will help us carry it upstairs. And so I hope you all have a nice rest of the week and weekend, and thank you.

[Whereupon, at 2:57 p.m., the meeting was adjourned.]