

VOLUME II
DEPARTMENT OF HEALTH AND HUMAN SERVICES
U.S. PUBLIC HEALTH SERVICE
ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY
THIRTY-FIFTH MEETING

The above-mentioned meeting was held on
Tuesday, December 17, 2008, commencing at 8:30 a.m., at
the Hilton Hotel & Executive Meeting Center, 1750
Rockville Pike, Rockville, Maryland 20852-1699, before
Louisa B. McIntire Brooks, a Notary Public.

Job No. 117756

REPORTED BY: Louisa B. McIntire-Brooks

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PROCEEDINGS

DR. HOLMBERG: Good morning. Can we have the committee members after they get a cup of coffee come back to the table please?

DR. BRACEY: Welcome back. We'll call the meeting to order, the second day of the 35th meeting of the Advisory Committee of Blood Safety and Availability. Time for roll call.

DR. HOLMBERG: Dr. Bracey. Obviously you're present.

DR. BRACEY: Yes.

DR. HOLMBERG: Dr. Benjamin? Okay. Anne Marie Benzinger, present. Julie Birkofer?

MS. BIRKOFER: Here.

DR. HOLMBERG: Dr. Duffell?

DR. DUFFELL: Here.

DR. HOLMBERG: Ms. Finley.

MS. FINLEY: Here.

DR. HOLMBERG: Dr. Haley.

DR. HALEY: Here.

DR. HOLMBERG: Dr. Ison.

DR. ISON: Here.

DR. HOLMBERG: Dr. Lopez-Plaza?

DR. LOPEZ-PLAZA: Present.

DR. HOLMBERG: Mr. Matyas?

MR. MATYAS: Here.

DR. HOLMBERG: Mr. Nether had to return to
Chicago. Dr. Pierce is absent. Dr. Pomper?

DR. POMPER: Here.

DR. HOLMBERG: Dr. Ramsey.

DR. RAMSEY: Present.

DR. HOLMBERG: Ms. Wade? Dr. Triulzi?

DR. TRIULZI: Here.

DR. HOLMBERG: Dr. Kuehnert? Dr. Epstein?

Dr. Klein?

DR. KLEIN: Here.

DR. HOLMBERG: Dr. Rentas is absent, Dr.
Bowman is absent, under the weather. Dr. St. Martin?

DR. ST. MARTIN: Here.

DR. HOLMBERG: Mr. Durbin?

MR. DURBIN: Here.

DR. HOLMBERG: I think we have a quorum and

I'm sure other people will join us. Dr. Kouides is here?

DR. KOUIDES: Here.

DR. HOLMBERG: We'll identify people as they come in.

DR. BRACEY: Good. As we continue the second day of the meeting, we will hear more on health prevention initiatives from the blood organizations as well as the HHS Healthy People 2010 program. As we hear the presentations, I ask to remember the questions that have been put to us. We have a revised list of questions with one additional question that you all should have in front of you. But, again, the questions are as shown: Is the current status of informed consent for blood and plasma donation adequate to protect donors? What are the ethical responsibilities to follow-up on donor health if medical conditions are detected during the donor selection laboratory selecting process? Adverse -- can be adverse events as a result of donation occur as a result of donation. New is, what role does -- should, does/should the blood

collector have in informing management and following up with donor health? How well does current medical management of blood/plasma donors align with the Department's Healthy People 2020 goals? What is a wider role for blood/plasma centers as a community health provider, IE, sickle cell testing, PSA, CBC iron status, et cetera, and if so, what are the current barriers to establishing that role and how it can be addressed?

To start off today, I'm pleased to present Dr. Rear Admiral Penelope Slade-Sawyer. She is the Deputy Assistant Secretary of Health and Disease Prevention and Health Promotion. She also directs the Office of Disease Prevention and Health Promotion in Office of Public Health in the U.S. Department of Health and Human Services. She will speak to us today on Healthy People 2010 and 2020. So, Rear Admiral Sawyer, welcome.

REAR ADMIRAL SAWYER: Good morning. Is the mike working? Thank you so much for the kind invitation to come to present the Department's Healthy

People initiative to you. I think that there is certainly a place where we can cooperate and improve the health of the American people. I certainly hope so.

To start with, I'm going to -- I think, I'm having a little technical difficulty. What I am going to do first is give you a little overview of Healthy People and what's going on now. What is it? It's a comprehensive set of ten year goals for the nation to approve to attain. These are not federal goals to attain, but national goals. In other words, the Department sets these goals as a framework for the nation to look to to improve our health.

The Healthy People 2010, the current iteration of Healthy People, has 28 focus areas developed by leading federal agencies across the government using the most known scientific information to establish these objectives and targets.

One of the most important things that I want you to know about Healthy People is that it is data driven. We do not choose objectives for Healthy

People just because someone thinks that they are a good idea. We have to have a science based data driven objective. They need to be specific and they need to be time tested. This is to give the nation a roadmap for the decade.

We are, of course, working on the next decade's iteration of Healthy People and that will be released in two stages. I'll tell you about that in a little bit. But, it is a roadmap pointing the nation toward the health issues that the country needs to address in order to improve the health of its population. Yogi Berra at one time said, "if you don't know where you are going, you're probably going to end up somewhere else." And that's just about the way we feel at Healthy People. We have got to know where we're going. We need a roadmap to point our nation in the right direction.

Healthy People has grown over the years. The first iteration was in 1990 up until today where we have 467 objectives. For three decades, it has grown and changed as the nation's health priorities have

grown and changed. Healthy People has tremendous strengths. It is a collaborative and consensus process. If any of you have ever been involved in trying to get all of the agencies of HHS to agree on something, and including other federal agencies, like agriculture and labor and energy, et cetera, all of us to agree, and then to put it out to the public and have a public comment period where public health professionals all over the nations come in.

When we put out Healthy People 2010 in January of 2000, we had 11,000 comments to consider before we got to the final. So, there is a huge amount of input. And that makes it -- that makes it a document initiative that people can feel they are a part of. It takes a lot of time to do that, but we think it's worth it.

There are some challenges also. For several years now, we have heard that Healthy People is too big. You can imagine with 467 objectives and many sub objectives leading to a totality of nearly 1,000 objectives and targets, some people are saying, we

can't get our arms around this. It's too big. You need to make it smaller.

We also have had some questions about the methods we use to set targets. In Healthy People 2010, for instance, the target setting method was better than the best. That means in the objectives, it had population based data. The best population group was chosen and the target then was for everyone to exceed the best population targets. Quite challenging as you may imagine.

Technical assistance is another challenge. As the department puts together this very large document and puts it out there, gives it to the states, the counties, localities, it says, here it is. And we have been told, you know, we would appreciate a little help trying to implement a plan on this. So, we're trying to address some of these things. As we address these things, we are doing it with the help of some very smart people. We have a federal advisory committee for Healthy People, very similar to you smart people who advised Jerry in his office on important

issues in blood safety and availability.

This is the time line. We had an independent assessment that began in 2005. We have also had public and stakeholder input along the way. The advisory committee was chartered and has met all this year, and as a matter of fact, this afternoon, we have a meeting of our federal advisory committee on Healthy People 2020. So, we are moving along the path. We hope to launch phase one in either late December or early January of 2009 with the full release of Healthy People with all its objectives and targets in January 2010.

This is the two phased release that I just mentioned to you. With the release coming up, we're hoping to put out the framework in overarching goals of Healthy People 2020. We want to give people the skeleton so they know where we are headed for 2020 and they can begin to think about their own plans. A great majority of the states look to Healthy People to set their own priorities for the decade.

This is the draft organizing framework for

Healthy People 2020. We have changed from a focus or focus areas primarily on diseases and disorders to one where we are hoping to move upstream to address risk factors and determinants of health. This is a big change for Healthy People, and yet we feel as most people in prevention do, that it is too late when we address the outcomes of the social determinants of health, the outcomes being diseases and conditions. So, we want to move our focus upstream and work on risk factors and determinants of health.

This is sort of the idea there. The doctor says to his patient, the knife there has to come out. But, that doesn't address the deeper problems. So, that's just what we're trying to do with Healthy People now, is address the people problems or the upstream problems.

Healthy People 2020 has focused on health IT and preparedness which are new this decade. We often remember September 11th, 2001 that put emergency preparedness, all hazard preparedness on the map. And if you all think back to January 2000, the internet was

perking along a little. But, in the last decade, think how all our lives have changed because of information technology? And Healthy People realizes that it also needs to take part in the health IT continuing revolution and make use of that. Of course, prevention has always been the primary focus of the national health promotion and disease prevention goals.

I think that we would all agree with Dr. Spencer who said that the public health is too important to be left to the health sector. And so we are reaching across. We are looking at other things that determine health and we have gotten this stakeholder input that is a public comment website that I hope you all will make note of. And we have 6 regional meetings across the nation to hear from our stakeholders out in the country about what they thought Healthy People 2020 should look for.

We have created a Healthy People consortium. This being a group of nongovernmental organizations that have joined with us to help us frame the nation's goals for 2020. There is also, as I told

you, the secretary's advisory committee, much like you, out of government experts on the health of the nation and then there is a federal interagency work group that is across the government that is led by HHS, but as I said, we have invited other federal parts to take part in the work on developing 2020.

We have had over 300 public comments that were submitted during our public meetings across the country, and most of them supported this two tier approach, and I have mentioned to you a primary focus on upstream factors with a secondary focus on diseases and conditions. It was very interesting. Those who told us they wanted Healthy People to be smaller, also wanted to make the point that they wanted to decrease the number of Healthy People objectives and targets, but to be sure not to leave them out. And so when you hear that from everyone, you begin to sort of get the picture. No one wants to be left behind, but everyone wants Healthy People to shrink.

So, when we presented the idea that we might then shrink it, there was quite an outcry, and so

we had decided that because of the advances in health information technology and computer based books and documents, that Healthy People's size is not so much an issue as it was in January 2000.

These are the folks that are on the secretary's advisory committee and we will have a meeting with them later today with John Fielding, the county health officer of Los Angeles County, a county of 8 million people, and Shiriki Kumanyika who is on the faculty of University Pennsylvania Medical School in disease prevention and those other outstanding members on this advisory committee. We have got some of the best minds in the world helping us and we're very grateful for all of their great work.

This again is the consortium that I hope that some of your organizations will join. Here is the -- so far, this is, as of the 15th of December, the break out of those organizations who have already joined the consortium.

This is a little slide that I thought sort of kind of might represent the federal government. We

see an oblivious Stuart there about to face disaster because the two sides of his body don't know -- the left hand doesn't know what the right hand is doing. I don't know if that happens in any of your organizations, but I expect so. But, certainly we have to deal with that when we work for Healthy People.

Occasionally the federal family behaves in this way, and Healthy People with its overarching collaborative and cooperative manner has to deal with that. This is the federal collaboration that sometimes is not totally aware of what's going on in other departments.

So, Healthy People 2020, phase one, the vision, mission, over arching goals and determinants organizing framework. We have built up this foundation now on which objectives will be built and targets set. Our next process then is to develop processes for selecting those objectives. That will happen. We will begin to discuss that this afternoon with the federal advisory committee and ask their assistance. How should we pick? Which objectives that were in 2010

should remain? One of the things I can tell you is that we have instructed the federal interagency work group to look at the 28 focus areas, the federalees on each of those 28 focus areas, and begin there. Look at the objectives in the focus area, say, on vision and hearing. Look at the objectives that were present for 2010 and see, are they still relevant? Are they understandable? Are they actionable? And begin there to think about objectives for 2020.

The specific and significant issues that we will work with the federal advisory committee on -- and the federal interagency work group are there on any objectives. What are the specific topics that we should address in 2020? Should the targets be aspirational or should they be achievable? That's another thing we have had lots of discussion about. When you have a target set to be better than the best, you know with population group objectives or population based objectives, there are going to be many that don't make it. And is that a problem? If you are looking at a business model and you have objectives set and you

have your meeting and you say to your board of directors, well, we achieved 20 percent of our targets.

What will their response be there? That is one question, or one way to look at it. It would not be a very good management tool in a business, I think.

On the other hand, those aspirational targets give you a way to shoot for the moon and land among stars, the feeling being, that, of course, we want every population group in this country to be better than the best. And if we don't make it, this noble goal will guide the way. And so there are different ways of thinking about that.

Also, the process of accommodating changing priorities over the decade. I have already mentioned September 11th, 2001 and how that changed everything. In Healthy People 2010, we did not address all hazards preparedness in any significant way. Certainly this document, 2020, must do that. And things changed throughout the decade. So, how do we look at changing priorities as the decade evolves?

We will hope that lead agencies will

continue to step up and guide and direct different topic areas. We hope that the consortium will stay robust throughout the decade and help us. We always rely on the public. And this is a document, as I said, that is not from the federal government. It's for the nation as a whole. These are priorities that are, as I said, looked at by public health experts from around the country as well as our own smart people in the government to say, these are things that need to happen. Please help us move this agenda forward.

The format of Healthy People 2020 is something that we are considering. Because Healthy People 2010 is about six inches thick, it's in two volumes. It's very unwieldy. And if we're talking about not limiting the number of objectives, you can imagine what the printed document might look like. Having a web based format would be a lot more flexible. For instance, if some of you, any of you, are interested in all of the objectives in Healthy People that have to do with blood safety and availability, there will be a search function, we anticipate, where

you could search through all the chapters and find a blood safety and availability objectives. Anyone can do that. Vision and hearing, cancer, heart, et cetera, et cetera. Public health infrastructure. But, we are thinking about a web based format.

More general issues that we are considering: How are we going to implement this? What kind of targets do we want to set? And most, or very, very importantly, what about data sources and data? As we begin 2020, we have objectives that do not have data sources. With the understanding that these objectives were so important that they needed to be in Healthy People, Healthy People itself drives data development because as we set these -- put these objectives and targets in without data sources in the beginning of the decade, we said, if there is not a data source available by mid decade, these objectives will be dropped. And only six percent of the objectives that we started with in the beginning of the decade without data sources had to be dropped in mid course. So, people were right. Healthy People drives the

development of data sources.

I know and you know that in this tight budget place we are, there are -- there's some problems with supporting data sources. As you all know, data is expensive to gather. So, we've got all of these issues to develop -- to work on.

Again, which objectives need to be retained? Which need to be dropped and what other objectives do we need to add to reflect the cross cutting determinants of health? We are moving forward.

We are moving now from focus areas to more topic areas. This is just the way we seem to be going. As we move to topic areas, for instance, blood safety and availability, for instance, as a topic area, it may not have its own focus area, but be throughout the document in different areas apropos to where they would fit best. And so we are -- do we need to create new topic areas? Would the 2010 targets still be appropriate for this cross cutting approach? And are the 2010 data sources still good for the direction we're moving in 2020? We've got a lot of questions yet

to answer.

I assume and hope that this afternoon's federal advisory committee meeting will be productive and give us some guidance. I would hope that you all would join the Healthy People list serve and check the website that is there, visit our public comment website that -- it's the same website, that's healthypeople.gov, just click there to make comment, attend advisory committee meetings and join the Healthy People consortium. And I want to invite those of you in the audience who represent different organizations to also consider joining the Healthy People consortium. We want broad input. We have to have broad input in order to get everyone on the wagon with us.

The office of disease prevention and health promotion is the coordinating point for Healthy People and this is our telephone number and the HP2020@hhs.gov and our office telephone number, if you have questions and want to talk to one of the leads on Healthy People 2020, that's the way to get in touch with them. I'm really pleased that you are interested in Healthy

People and I hope that this is just the beginning of some work we can do together to improve the health of the American people. Thank you so much for having me.

DR. BRACEY: Thank you very much. We'll now open up for questions and comments from the committee.

DR. EPSTEIN: Thank you very much. I appreciate this overview. You know, being inside the government, we do hear about this perhaps more than others and we have our own agency objectives which are also tracked. But, speaking more broadly in general, you get what you pay for, and whereas I appreciate that this is not primarily a government funded initiative, I just wonder if you could comment at all about how these things do get funded?

REAR ADMIRAL SAWYER: How the process itself is funded or --

DR. EPSTEIN: The actual deliverables or the actions that will improve, you know, people's health? Is there any linkage between the program as a set of goals and objectives and funding mechanisms?

REAR ADMIRAL SAWYER: Every grant that goes out from the Department of Health and Human Services, every request for applications or requests for proposals has in there a statement saying, how does this proposal advance the goals of Healthy People 2010? Every one of them. And so at the top of every bit of money that is given out by the federal agencies at HHS, there must be a connection with the objectives and targets of Healthy People 2010. We hope that will continue into Healthy People 2020.

But, as far as driving this from the department, other than that, there is not a budget to drive the achievement of these targets. It's a very interesting difference in our government, which is not centralized, and a centralized government, say, like Korea. I visited Korea this summer because Korea is the government that picked up Healthy People 2010 and just absolutely put it in place in Korea as their national health plan. And so they wanted to understand from us where we were going for 2020. So, at the invitation of the Korean government, I and a couple of

my colleagues went over to bring them up to date on what we were doing.

Very interestingly, being a centralized government, they can drive Healthy People right through. In other words, they had the money that say you must do so and so. Anybody in Korea who wants to do anything related to any of these objectives is required to take these objectives and go with them.

Very different here. We have sort of a buffet line, a smorgasbord. We put it out there in states and localities and take these objectives and targets as they wish. It's not centralized and there are certainly advantages and disadvantages in that. Thank you for the question.

DR. BRACEY: Have a question or comment for Ms. Birkofer.

MS. BIRKOFER: Thank you, Dr. Bracey. I'd like to ask the Rear Admiral, when you spoke about the data collection and the fact that it's specific and scientific, et cetera, is there any feedback mechanism on how often will you assemble the data and then push

it out? And how will you use the data to determine if your program is working? So, would there be a feedback mechanism to providers or to others in the system that could have an impact on healthier lifestyles?

REAR ADMIRAL SAWYER: Thank you for the question. Our partner, our essential partner in Healthy People, is the National Center for Health Statistics, and NCHS manages the data for Healthy People 2010 and will again for 2020. And there is a website called data2010 that is updated as NCHS gets the data and crunches the numbers, puts it out. That's sort of an ongoing data collection place for the data sources of Healthy People 2020.

NCHS data2010. It is on the CDC website because NCHS lives there, but it is very specific to Healthy People. Data2010.gov.

DR. BRACEY: Dr. Kouides, comment or question?

DR. KOUIDES: To what degree are the objectives focussed on any specific ethnic group? For example, obesity epidemic in the Hispanic population?

REAR ADMIRAL SAWYER: All of the objectives that are population based have data that is available on every population group. And so there are many objectives to Healthy People 2010 that this is broken down -- that population groups are in.

DR. BRACEY: Question or comment, Dr. Holmberg?

DR. HOLMBERG: Just to follow-up on the funding issue, is there an opportunity for foundations or local government to fund different projects?

REAR ADMIRAL SAWYER: Absolutely. And what we hoped is within communities, as communities choose their issues, saying that this issue that we have in our community is an issue that the federal government says is critical to improving the health of our nation, often helps get the grants and funding from private organizations. Of course, private organizations cannot fund my office, unfortunately. But -- or any of us in the federal government. But, certainly there are ways for the private sector to help advance the cause of Healthy People 2010.

DR. BRACEY: Dr. Duffell? Did you have a question?

DR. DUFFELL: I think I noted on one of your slides, you had a pictorial of the engagement of different parts of different organizations that were contributing to the program, one of which was called corporate, and looked like --

REAR ADMIRAL SAWYER: Was called what? I'm sorry.

DR. DUFFELL: Corporate. I think the scale on that indicated to me it was less than five corporate entities. I guess that's industry; is that right? Industry members?

REAR ADMIRAL SAWYER: Yes. That was the consortium. We just opened the consortium up in October or people -- things are coming in every day.

DR. DUFFELL: Does that mean there's five industry consortiums like advo med, medical devices, factory associations?

REAR ADMIRAL SAWYER: That's a very good question and I don't know the specifics on that. I

will certainly get that answer to Dr. Holmberg who can get it to you.

DR. DUFFELL: The feedback I would offer you is that those are the types of organizations that have a broad based membership with clearly hundreds and thousands of memberships and all of the industry, including Gambro, I'm here representing today, now has part of their part is to improve public health.

REAR ADMIRAL SAWYER: I hope you will join us if you have not already.

DR. DUFFELL: The most efficient way, the comment I'm giving you, is to try to attract those industry consortium groups, Medical Device Manufacturing Association, National Electronics Manufacturers Association. When you get their interest, you get a broad based representation across our industry, and certainly with their memberships or contributions open to the avenue for a J & J, an electronic, a Gambro to step in and actually have a more active engagement as a representative of that larger consortium.

REAR ADMIRAL SAWYER: Thank you for that comment.

DR. BRACEY: Dr. Klein?

DR. KLEIN: Thank you. Are there outcome measures by which we can measure the impact of the Healthy People 2010 on improving the health of the US people?

REAR ADMIRAL SAWYER: Are there measures other than the 467 objectives and targets?

DR. KLEIN: I'm wondering in terms of outcome, how we demonstrate that, in fact, the program is improving the health of the country?

REAR ADMIRAL SAWYER: Well, I think because of the nature of the objectives and targets, moving toward the target, reaching the target, et cetera, is by its implication, an improvement of health. For instance, if we have an objective that says every child should be screened for vision and hearing deficits by the time they are four, and we reach that target, you can assume, and I believe that if we have reached the target population, that we have caught early some

vision and hearing deficit before a child went to school that may have implications for their learning ability, et cetera, et cetera.

Moving on, we know that education is one of the most important determinants of health. And so in that way, we look at the overall picture. I don't know that I'm answering your question, but I think that there is no -- currently there is no DOW Jones of health. I know that CDC has been working on trying to get a measure of health that might get at what you're asking. But, Healthy People does not have that average type of measure that I think you're getting at.

DR. BRACEY: Dr. Triulzi, what's your question?

DR. TRIULZI: Thank you very much for the presentation. My question gets at how the objectives translate into reimbursement for the primary care physicians or caregivers that may have to implement vision screening, as you mentioned, or maybe the recommendations are to do colonoscopy at age 40 instead of 50, or mammography. And does that translate into

CMS reimbursement for those? Does that require Medicare to reimburse for those? And if so, unless that connection is there, then how are those objectives met?

REAR ADMIRAL SAWYER: There is no direct tie in with CMS reimbursement. As you probably know, CMS is limited by Congress on what type of reimbursements CMS can offer. There has been some flexibility given to the Secretary of Health and Human Services beginning in January 2009 to give Medicare the authority or the Secretary to give Medicare, CMS, the authority to cover preventive screenings that are recommended by the US preventative services task force, which is represented in Healthy People's objectives and targets. But, because something is in Healthy People does not necessarily translate into funding for it. I'm very pleased that this exception has been made by congress to give the secretary the authority to move towards the USPTF recommended preventative services.

DR. BRACEY: Dr. Ison, question?

DR. ISON: So if one of the objectives

today is to understand whether or not the medical management of blood and plasma donors aligns with the 2020 and 2010 goals, what specific issues are addressed in the 2010 and 2020 goals related to blood donors and --

REAR ADMIRAL SAWYER: There is one objective in 2010, the focus area 17, medical product safety, to increase the proportion of persons who donate blood, and in doing so, you assure an adequate blood supply. That is the objective in Healthy People 2010 relating to blood centers. The target for that objective is 8 percent and the baseline in 2000 was 6 percent.

DR. BRACEY: Dr. Haley?

DR. HALEY: Is there an objective on iron deficiency, identifying iron deficiency?

REAR ADMIRAL SAWYER: I can't answer that. I do not think so, but I can, again, this is something I can follow-up with Dr. Holmberg.

DR. HALEY: I thought there was a section on diet and nutrition and surely there would be an

objective, a nutritional objective on iron deficiency.

But, for no other reason, in the prenatal population.

But, for which, if there is such an objective, which I think there would be, that it would be easy to add a sub objective for the donor population?

DR. BRACEY: One question in terms of, I guess, the process of how this works, I would imagine that control of hypertension would be an element of Healthy People 2000. So, if that is an objective, there are numerous guidelines. How does Healthy People 2010 and 2020 interface with the various agencies that are promulgating guidelines, the various agencies and organizations that are putting forth educational materials? Is the thought that you would evaluate all that's going on and then comment and try to meld this into sort of a more uniform approach?

REAR ADMIRAL SAWYER: One of the most important aspects of Healthy People is that there are focus area leads, as I mentioned, and for instance, the National Heart Line and Blood Institute has input into Healthy People, and through NHLBI and other areas in

the NIH and the CDC, there are, I call them our smart people, who know of these organizations that put out guidelines on hypertension. And they bring that to the table in their own focused area groups as they look at in Healthy People 2010, what should be the objective for our nation regarding hypertension, regarding iron levels, regarding hyperlipidemia, et cetera, et cetera.

And so we have direct contacts with outside organizations through the federal interagency work group.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: I guess one concern that I have is the risk of fragmentation of effort. It's perfectly clear that the spectrum or menu of things that we have discussed yesterday could go on in the donor room more effectively than managed donor health and thereby public health can be woven into 2010 or 2020 Healthy People objectives. But, the question in my mind is whether there ought to be a topic about management of donors as part of public health? So, should we bundle rather than fragment and actually seek

a topical initiative in the 2020 plan? Because I think that could have a greater impact in the long run. That's not to any way negate the comments specific to blood pressure or iron or glucose, but there is a bundle here that might itself become topical.

REAR ADMIRAL SAWYER: I cannot say that that will happen. As I told you, we are just beginning to look now since we have gotten the framework and mission and goal statements ready to be cleared through the department. We are just beginning this afternoon to discuss with the federal advisory committee the development of objectives and how we're going to do it. And whether there will be -- what type of topic areas we will have in Healthy People 2020.

I certainly encourage all of you to make your opinions known through the Healthy People list -- through the public comment site, and as we move forward, there will be opportunity for presentations to the federal advisory committee, much like you all have, as we move on. We have a meeting today. Our next meeting is in January. I think it's the 17th and

18th of January, but then we have a meeting in February, I think around the same time. So, this is a very active federal advisory committee and your opinions certainly are welcome and necessary so that Healthy People can be all that we hope it will be.

DR. BRACEY: We have time for one more question or comment. Dr. Holmberg?

DR. HOLMBERG: Actually, I have two questions, and I'll sort of say them both at the same time. First of all, I think what Dr. Epstein was talking about is, would it be advisable for one advisory committee to make a recommendation to the secretary directed to another advisory committee? So, that's one question. And secondly, I just want to add a comment, and sort of a comment/question, on objectives for focus areas that could be potentially in the 2020. As you mentioned, right now, we only have blood donations and it's basically looking at increasing the percentage of blood donors.

REAR ADMIRAL SAWYER: That's right.

DR. HOLMBERG: Of course, that was designed

at a time when the nation was looking at a decrease of about six percent of the population due to mad cow disease, and so over the evolution of 2010, there are several emerging issues that have come out and are listed in mid cycle review, such as reducing medical errors, improving communication to better inform consumers and enhancing capacity of postmarked surveillance to expeditiously detect previously unknown problems with medical products.

And so my question is, how do we -- do we have to make a conscious effort to raise those emerging issues so that they get picked up in 2020? So, two questions: One advisory committee advising another advisory committee, and secondly, how do we roll issues up?

REAR ADMIRAL SAWYER: First of all, I don't know the intricacy of the Federal Advisory Committee Act. And so I cannot answer legally whether or not this committee can advise another committee. But, I know you've got vary smart people on this committee that can go as individuals and represent certain

organizations in addition to exploring the opportunity for you all as a group to make a presentation to the federal advisory group of the nation's health objectives. So that part of the question is, number one, absolutely essential for you to make your views known, and number two, whether you do that as individuals or a group or body, I know you can do it as individuals.

The second part of the question regarding the advisability of making your concerns known to the committee and to the federal interagency work group, by the way, I'll tell you, everyone else is. There are organizations that show up at every one of the six national meetings we have to make sure that their issue, for instance, deciding whether blood safety availability should be a topic area, there is -- the advocacy groups are out there at every meeting. We have breast feeding advocates there saying that you know, advocating for their cause, that of all the things that we can do to improve the health of the nation, we know that it starts at birth and breast

feeding should have its own topic area. And we should have objectives for improving the number of mothers that breast feed, length of time they breast feed, et cetera, et cetera. So, yes, everyone who wants to be in Healthy People is advocating to them to be there. So, I would encourage all of you there to make your concerns known.

DR. BRACEY: Thank you very much and then we'll move on. Our next speaker, covering topic one which is current status professional standards of donor health and public health will be Joshua Penrod. Joshua Penrod is vice president of Source and a representative of PPTA. He will present the Plasma Protein Therapeutic Association's programs and standards to protect donor health and public health.

MR. PENROD: Good morning. Thank you. I have some good news for committee right off the bat, that typically what happens before I give a presentation in front of a large audience is that I drink Red Bull. Didn't do that this morning. So, hopefully what I have to say will be moderately

intelligible. And if there is a degree of content there that I can't quite make a connection because of my lack of Red Bull, I have a couple technical experts in the audience that I can call on to help me out.

So, what I am going to be talking about today, I'm going to be talking in very broad brush strokes painting a general overview of the system that's currently in place within the plasma industry. I'm going to talk somewhat about donor regulatory requirements. I apologize I wasn't able to be here yesterday morning and I apologize in advance if some of this is duplicative. In context, in the broader sense of the industry and some of the important uniqueness or unique items that make the industry different, I wanted to start here with a quote that has stood the test of time. This was in a preambulatory statement to the regulatory structure first issued over 30 years ago. And this is basically the foundational aspect of the regulatory structure upon which the industry is based and I think it's worth noting in here. I would dig into my colleagues' vast regulatory library prior to

find it, but I wanted to note it for the record here for purposes of this today, that "the commissioner conclude that standards, regulatory structure, must contain provisions to protect the health of plasma donors to ensure continued healthy donor population to serve as a source of plasma."

I think that's important to note because here the plasma donor is recognized as the cornerstone of the industry and around which all of the standards are placed for the production of plasma and everything flowing from that. So, I want to talk a little bit about the plasma donor and some of the elements insuring a quality donor. You have four major areas for discussion here. One is selection. A lot are done through regulatory requirements, regulatory guidances, operating procedures done within plasma centers, industry standards and so on. This also flows through screening processes, testing, making sure the donor understands, and I'll be getting into informed consent a little bit later, again, in broad brush strokes, and most importantly, the qualifications of the donor, to

make sure they're a healthy donor, they're able to donate and that they are also donating healthy plasma.

So, two major considerations in terms of donor recruitment, donor selection and donor qualifications is the health of the donor. And in two major senses, one is donor safety. That is, making sure that the donor him or herself cannot be harmed by the donation process. And secondly, patients, making sure that the plasma itself is safe to be used from the manufacturer.

So some of the steps that are taken toward donor qualification includes significant screening process, which a questionnaire is part of that, getting information about the current health of the donor, information about any chronic, serious medical conditions, medication history and questions about risk of transmissible agents. On the date of the donation the donor, the first question in the questionnaire is, are you feeling well and healthy today? And a lot of the discussions that occur and some of the information that could be disclosed at that point include if the

donor discloses a history of heart or lung, kidney disease or anything related to that. Has the donor had any bleeding disorders, any transmissible diseases or behaviors that act as surrogates for transmissible disease.

In terms of medications, make sure the donor is healthy to donate. In terms of risk to the recipient, making sure there are no agents within the plasma and anything that medication would be used for in terms of treating underlying disease the donor may have. Some of the screening elements that are involved, donor. There's a lower limit for donors, and also, importantly, donor weight is related to the volume of plasma that could be collected from the donor. In addition to that, blood centers take blood pressure, pulse, hemoglobin, hematocrit, total protein measurements.

Physical examinations are performed on first time donors and annually thereafter. We do like to have a cadre of all of our donors that donate often. And so the physical examination is repeated at least

annually. This examination included vital signs, surface examination, skin, nose, head and neck and so on.

So, talking about donor education, having donor understand basically the process, how the plasma is used, the importance of remaining healthy and so on. Plasma centers do, I can certify plasma centers do, provide educational information on risks. Donors are then quizzed on their understanding of the risk behavior and we also have further educational management that we're going to be putting out to public comment in the very near future supporting the ideas of the educational efforts to make sure that donors understand the importance of a healthy lifestyle. This is going to include information on smoking cessation, proper nutrition, so on.

So, how do we define donor care within the plasma industry? As I mentioned at the outset, that cornerstone, quote, the donors have to be fit to donate plasma. This means that there's an extremely complex web of regulatory requirements and other requirements,

including our industry standards, that add up to good manufacturing practices. This is an industrial process. Plasma centers are not medical facilities and they have extraordinarily high standards for product quality, product safety. In terms of the examination of the donor, if a donor is found unsuitable for whatever reason to donate, the plasma center will issue referrals advising the donor to consult with a physician. The plasma center itself is not in a position to render medical advice or render medical treatment.

We do perform infectious disease testing.

There are, of course, many deferrable conditions that would be addressed. If for whatever reason a donor is deferred, the donor will be counselled, discussed in terms of what his or her next steps should be, and that includes, most importantly, consultation with the physician.

In line with that too, the records that are kept within the plasma industry's process is that they're manufacturing records. And as such, sometimes

these records have to be investigated or researched if there's something that goes on downstream in manufacturing process where you have to look at a donor history. Post donation information is a good example of that. So, the records are in place there as a guide throughout the entire manufacturing chain from the donation through manufacturer.

That's an important distinction to make as I understand the difference between manufacturing records and medical records. Manufacturing records are actually the property of the company whereas medical records are actually the property of the patient.

So, in terms of informed consent, they do vary from company to company. I know there was some discussion of this yesterday. It's also important to recognize that, and I think this was touched on briefly yesterday, that donor consent or informed consent procedures may vary from state to state. I'm not an expert in this. I do know that there can be separate state requirements depending on the statutory provisions. But, as such, many of the donor consent

forms that I have seen are very similar. They inform the donor of the side effects, nausea, dizziness, so on and so on. It's important too that oftentimes the informed consent works in conjunction with many other forms that the donor has to read and be quizzed on, such as the donation history questionnaire?

In addition, some plasma centers engage in special collections for which there is a specialized or customized consent form as part of that process. As I mentioned a little bit earlier, part in parcel with this is donor deferral notification. They are instructed by regulatory structures and good manufacturing practices. So, I tend to think this was probably touched on in detail yesterday, so I don't want to go into it again. The regulatory citations that I use, the regulatory requirements and reporting adverse events, I'm just going to say here, I'm not sure how much this was discussed yesterday, but there has been discussion of other regulatory initiatives that extend reporting requirements. They have not been finalized yet. I know that PPTA has commented on them

from time to time as that situation evolves.

So, what we were asked to do by Dr. Holmberg is to talk a little bit about donor fatalities. This question has been brought in front of BPAC, it has been in discussion in the industry in 2003, 2006 and again now in 2008. But, that's information that we have with the associations, the analysis provided to the public by the Food and Drug Administration for the three consecutive years, fiscal years 2005, 2006 and 2007, that while there was a temporal link, there's is no causal relationship between the donation and the fatality. I think it's important to know because what tends to happen, this is my personal opinion on this, is that you have a number out there, I'm not sure what the number that was used in some of these years, I think 13 was the most recent year, there were reports received by the agency, but you tend to draw a bulls eye around that number 13 and say, 13 out of how many? But, the important thing here is that 13 were decided -- were determined not to be related to the donation. So, the actual number that

should be under consideration is that there is zero fatalities associated with donation.

The donation environment, I'm sorry I don't have any pictures here, I couldn't secure any in time before this meeting, but I wanted to sort of give you an idea of what's it's like inside the center. PPTA does have a facility requirement or facility standard that has certain requirements requiring lighting, cleanliness, auditable company policy related to cleanliness and a basic professional appearance of the centers. In addition to that, the company has separate policies. It takes a while to donate plasma. So, I know some centers have wifie desks, specifically centers that are around colleges and universities where students are doing research or writing papers while they're donating. They're able to do that. They also have radio outlets, sometimes they have DVD players and televisions, so on.

The donation environment, of course, also incorporates some other standards and regulatory requirements that include a well trained staff and

efficient operations.

So, this close to the holiday season, I'd like to include the Department of, my colleagues and the whole blood sector, but I wanted to note here so close to today's holidays, it's extremely important to recognize the important of both blood and plasma collection. The bottom line is, plasma donation and blood collection are safe. The numbers here through the past three years have, you can see that the donations have gone upward. And, in fact, there have been zero fatalities linked out of 15.3 million collections done last year, I think, speaks well of the safety of the process.

And I would also point out too that plasma donation is life saving. These are products that are made into plasma -- made into products which save thousands of lives all over the world. Very, very chronic clotting serious diseases, and the therapies that are made from the commitment of the plasma donor is a high impact and high value.

We were also asked to touch on some of the

elements of public health -- and I -- and plasma collection. I wanted to take this opportunity to inform the committee, that we do have -- we are undergoing a strategic review process at our association, some very high level long-term goals over the next several years. In the division that I was involved in, which specifically did discuss ways of creating a new infrastructure for interchange of information regarding the emerging infectious diseases, that including a structure for communications between and among us as an industry, we as an industry and regulatory authorities, and -- but purveying information to our state groups. And basically a structure that can facilitate rapid exchange of relevant and accurate information.

So, in conclusion, plasma products save thousands of lives all over the world every day. Plasma donations save. Plasma donors are heroes. The industry is working very hard to encourage donation. I'll also invite you to take a look at our new website. We have a new website dedicated specifically to

donation of plasma, donateplasma.org and the old steady standby, pptaglobal.org. That's recently undergone a major revision and face lift. So, thank you.

DR. BRACEY: Thank you very much.

Questions or comments from the committee? Dr. Epstein?

DR. EPSTEIN: Well, I think that the donor safety strategies that have been put in place over the last three decades are quite laudable. But, I do want to inject a note of caution about the fatalities that occur post donation in donors, whole blood donors and plasma donors. What you said is absolutely correct. FDA in its review of the cases have not been able to establish causality. That doesn't mean it isn't still possible. And in the cases where there have been autopsies, there's been a preponderance of coronary artery disease found. And it raises the question whether there should be some greater effort to screen for coronary risk factors before people donate. So, for example, we found, again where the data have been available, a preponderance of fatalities in persons with high body mass index. And one of the issues

that's been under discussion with the industry has been obtaining height as well as weight so that an estimate of the BMI could be obtained.

And as you know, we had a cooperative effort specifically with PPTA to see if we can't improve the data gathering that could help us analyze cases when they occur. Now, this is all in the context of rare events. I do want to emphasize that. You stated it, Dr. Triulzi stated it yesterday, donating is highly safe. Certainly reasonably safe. But, I think, and again, we have also learned by looking at the rates, that the fatality rates in donors are well below the actuary expected rates in persons of comparable age and gender. So, we select a healthy population and the fatality rates are very low and lower than the general population. But, that doesn't mean that we couldn't do better if we could establish cause. I don't think that we're done with the effort in figuring out whether there are attributable causes and how to identify them and translate them into the measures. Again, most of the focus has been on doing a better job with cardiac

risk factors because of the autopsy findings.

MR. PENROD: Right. That's actually a good segway, so thank you. We do have a medical directors task for in PPTA whenever this issue comes up, that's the go to group that we consult with for this. We are in the process of, as you mentioned, having a uniform norm for reporting process. We are working on that and hopefully we'll have that.

DR. BRACEY: In the interest of time, one more question.

MS. FINLEY: I just want to -- thank you very much, Dr. Bracey. I wanted to ask Dr. Epstein and Joshua whether this is something that should be included. We're addressing the safety of the whole blood donor, maybe we should also include this concern in our recommendation. If you're asking for information, and the industry organization is already moving in that direction, maybe we should reinforce the interest of the committee in that manner in our recommendation.

DR. EPSTEIN: Not sure it's a question for

me, I think for the committee as a whole. But, what I can tell you is that the FDA still has an eye the ball here and we are both here and we are interested in continuing to study adverse events, as we mentioned yesterday, and has been mentioned several times, that was a proposed rule which would create mandatory reporting for serious adverse events related to donation as well as transfusion. And we are interested in advancing the tools that would enable us to better analyze fatalities when they occur.

Recognizing that the vast majority may be unrelated causally. But, still there may be some that are related and we remain interested. I think it's a question for the committee as a whole, whether there's a need for recommendation in this area. This is something we are already pursuing.

MS. FINLEY: I think it's something we should acknowledge in the recommendation. I mean, it wouldn't be complete if we didn't acknowledge that there was a movement afoot to making these events mandatory.

DR. ISON: Can I ask a question here?

DR. BRACEY: There are a couple of other questions and I think we can get to them. Dr. Klein, a question?

DR. KLEIN: We heard yesterday a guess of about 8 million volunteer blood donors, about 35 to 40,000 visits a day, I wonder how that compares with what the number of -- and number of visits in the plasma industry, and as a second part, you obviously do much more extensive physical exam, and I'm wondering, where is the referrals that you have to physicians because of either physical findings or abnormal laboratory tests? Is there any data on what kind of follow-up there is that these people actually go to see physicians?

MR. PENROD: Basically, beginning in the time frame for preparation for this discussion, I haven't been able to cull that type of data out. It's something we'll certainly consider in the future.

DR. BRACEY: There was comments or questions. Last question.

DR. ISON: One of the things that we're being asked to comment on is the donor safety. And so we heard yesterday with whole blood donors, a lot of statistics about adverse effects that weren't just death. Do we have any data on loss of consciousness, those kind of things, that in my mind would be of equal concern.

MR. PENROD: It would be interesting to know, but again, in preparing for this presentation, I didn't have time to do the data gathering. We don't have any studies on that.

DR. BRACEY: Thank you. We'll go on to our next presentation, and this is under topic five current experiences in donor health and public health and that will be presented by Dr. Anne Eder. Dr. Eder is the executive medical officer of biomedical services at the national headquarters of the American Red Cross and has done much to provide information to the field on outcomes after the donation process. Dr. Eder, thank you.

DR. EDER: Thank you for the opportunity to

address the committee.

I know we talked about the responsibility of the blood center to donor and public health. This is our view. Blood center's responsibility is to provide a safe and adequate blood supply and ensure the safety of blood donation for donors. So, I will be presenting data upon donor reactions. I probably won't have to go into much detail. I understand some of it was presented yesterday. But, I will also be talking about our responsibility to notify and counsel donors of significant findings in test results. And I will be presenting data of our infectious disease test results. And finally, to advise the donors, I'll be talking again hemoglobin and donor screening criteria and identifying the links, I hope, to public health recommendations and other public health efforts that stem from our activities in blood donation.

This is a view of the American Red Cross. We have 35 regional blood centers that collect blood across the country organized into these shaded divisions. And we have five national testing labs that

perform the testing that I'll be presenting. Across the county, we serve about 3,000 hospitals and distribute more than 6 million red cells, 1.7 million plasma products and more than 700,000 apheresis platelets.

So, I agree with Yogi Berra that it helps to know where you are going so you end up where you want to get. So, this is a talk in three parts: I will be presenting our data on adverse reactions to blood donations that focus on donors. Then presenting the infectious disease test results and talking about hemoglobin and donor health deferrals.

So, first adverse reactions to donation. So, it is absolutely true that most donors have uneventful donations and feel good about donating blood. Two to 10 percent of donors, however, will experience a reaction after donation. And the tip of the iceberg are those donor groups who experience more medically serious provocations associated with blood donation. In the Red Cross, this is the system that we use to systematically capture data on donor adverse

reactions. And adverse reactions can be thought in two big buckets: Those systemic reactions and phlebotomy or venial related reactions. The systemic reactions are symptoms like we call prefaint or presyncopal, that are, you know, the same symptoms of public speaking: Rapid heartbeat, sweating, diaphoresis that might lead to loss of consciousness. We make a relatively -- a pretty arbitrary distinction between a short loss of consciousness and a long loss of consciousness. One associates with other symptoms, loss of bladder and bowel control. And we make a separate category for loss of consciousness injury relating from falls and we capture prolonged recovery. In all of these categories, we also look at -- capture separately cases where the donor seeks additional medical care for medically serious or for some reactions.

So, again, bear in mind that most donors do not experience reactions, but that the risk -- this is a graph of the rate of reactions per 10,000 donations as a function of the donor's age which ranges from 16 in some states to over 70. There is no upper age limit

in the Red Cross.

What you see, however, is that the risk of reaction is increasing with decreasing donor age. So that in the youngest age groups, as many as more than ten percent of donors may experience some reaction. The most common reactions are mild and consist of these faint symptoms, this short loss of consciousness and small hematoma. And these differences between successive age groups are clinically significant.

I'm going to now focus on the tip of the iceberg which have the more serious complications in talking about donors. So, the demand for blood and the restrictions on donor eligibility in recent years have led to increased recruitment of high school donors. Most states allow donation by 17 year olds without parental consent, although a few still maintain that requirement. Several states have legislation or allow variances for a lower minimum age, which is now 22 or more states allow donations by 16 year olds with parental permission, two states allowing without parental permission. The Red Cross requires parental

permission from all 16 years old and follow applicable stay laws for 17 year olds.

Looking at the syncope and the syncope related complications, this graph shows 16 and 17 year olds compared to 18 and 19 year olds compared to donors older than 20. Again, this is the rate of reactions per 1,000 donations in the different categories: Short loss of consciousness, long lost of consciousness, prolonged recovery and syncope or loss of consciousness with injury. And what you see, again, is the significant difference -- the increased reaction rate in 16 and 17 year olds compared to older donors. In the loss of consciousness category, more of concern, in the loss of consciousness with injury category. To put a number on this for you, this is about 80 injured 16 and 17 year olds. Most of these injuries are head injuries resulting from falls and about 30 percent of them required additional medical care. So, facial lacerations required stitching, a broken jaw, head injuries, that's bumps and bruises.

If you're thinking the rates are higher in

16 and 17 year olds, there's a greater proportion in first time donors which we know is another -- a stronger predictor of reactions. You'd be right, but this shows that apples to apples comparison of the different stratifications for female donors compared to male donors and first time donors compared to repeat donors in the different age categories.

What you see is that for first time donors, who are the youngest first time donors, still have a higher rate of reactions than older sub groups. And this pattern holds true in each of the stratifications.

We want donors to have the best experience that they can for their own health, but also because we know that a bad experience will, as you would know without data, will decrease the likelihood that they will return to donate. So, this graph shows the return donation pattern of 16 year olds who have a minor reaction compared to a control group, and those who have a more serious, what we call major reaction, compared to a control group. So, in the control group, what's interesting about this is that these young donors have

a high rate of return. This is an extremely high rate of return for any donor group. But, even a minor reaction will decrease the probability that the donor will return, and a more serious or major complication will reduce it further.

Then why recruit young donors? I've already mentioned, if you compare 16 year olds to 17 year olds, if you look at their behavior over the course of a year, what we see are that the youngest donors come back and donate the most often. So, they come back and donate even though those who have had a reaction, might come back to donate. And this drops off in the college years and then picks up again.

So, donors are less likely to return if they experience any complication. Even a temporary deferral will reduce the probability that a donor will come back and donate. So, it's important to understand that while we may try to -- that broadened global deferral requirements have detriment in reducing the probability that a donor will come back and donate. So, even a temporary deferral has an adverse effect on

the supply.

And reentry efforts, donors are deferred for false positive tests. In many cases, we can get them reentered. But, these efforts typically are only associated with a 10 percent yield, which perhaps is not surprising.

So, in conclusion, blood centers have dual responsibility for providing an adequate supply of blood to the communities we serve, and protect the safety of their volunteer donors. Any negative experience will diminish the likelihood of blood donation and our increasing dependence on recruiting and retaining young donors requires a committed approach to donor safety, especially on high school drives.

What should we do for our young donors?

Last summer, I had the pleasure to be on the working group task force that was led by Dr. Roberts who you will hear after me, and the group came up with recommendations in every area of the process. And it's important to appreciate that there is no magic bullet.

There isn't an intervention or any one thing you can do that will prevent more than 50 percent, significant portion, of reactions. Attention to the entire process is important. This process includes predonation education, which are set under supervision and intervention such as water. Water has been shown to reduce -- water consumption almost immediately before or within ten minutes of donation has been shown to reduce reactions. And that's an important improvement, but it's also important to keep in mind that in 17 year olds, reaction rates went from about 12 percent to about 9 percent. So, you're still at 9 percent in young donors compared to 5 percent in older donors. An important improvement, but not the solution. If you lower the other aspect, you're not likely to realize the benefit of giving water to donors.

Post reaction instructions. We have additional data, which I won't present today, which suggests that the safety profile is favorable and supports increasing automated collections on high school drives with monitoring.

So, part two. The screening that we do for infectious diseases, this is not a comprehensive list, but I'm going to just touch on HIV, hepatitis, bacteria screening that we do for platelet donations and talk just very briefly about Chagas. So, this is a snapshot of what we see in a quarter in the top panel. And it shows the fourth quarter of 2007 to the fourth quarter of 2006, just to show that the marker rates that we see in whole blood donors for Hepatitis C, Hepatitis B, HIV are relatively constant. These are the rates, these are the numbers, to give you a sense of the numbers that we deal with during a calendar year, so that for Hepatitis C, we see almost 6,000. For repeat reactive, but only about 2000 confirmed.

The difference here are those donors who are told this is likely a false positive, you're not likely infected, but don't come back to donate, which is a difficult counselling message to deliver, but that's what it is. But, these are the truly infected cases that are identified during the year. And this is out of the denominator of 5.7 million.

For *T. cruzi* or the Chagas disease, this was as of the end of 2007 where we had 103 confirmed antibody positive donors in our screening. Just to reiterate that the education, selecting and testing that we do are important and reduce the risk and select for a healthier population, this shows the marker rate in first time donors compared to the prevalence of Hepatitis B in the general population and the marker rate and repeat donors compared to the general population. What you see is significant reduction -- significantly lower marker rates among repeat blood donors compared to the general population and -- I'm sorry, first time blood donors compared to the general population, which is even lower, as you would predict in repeat blood donors compared to the general population -- or compared to instant cases in the general population.

Another example of participation in the public health effort is the AABB Chagas Bio vigilance Network where we contribute our data. And it's mapped on the website. And this shows you the confirmed with

the positive cases of Chagas disease across the country. So, what we've learned from this is that we have more antibody positive donors than was previously appreciated at a rate of about one in 25,000.

More recently we introduced -- we have also -- I'm going to switch gears now and talk about the bacterial screening that we do for platelets and talk about actually some pretty interesting public health and individual health issues that we have identified since implementing bacterial screening platelets. We implemented bacterial culture as a quality control test, not as a donor screening test, in March of 2004. Donors of bacterially contaminated components are evaluated by regional medical directors to determine the possible significance to their health and the acceptability for ongoing donation.

Bacterial culture is different from bio testing in that the contamination may be a result or maybe occurred during the collection or processing and may not be -- may not indicate really anything for the donor, or could indicate possible asymptomatic chronic

infection. Most typically, the contamination that we see, accounting for about 72 percent of the cases are staph and strep species that live on the skin and contaminate the collection during the collection procedure.

Exceptions to this, however, an important exception, we'll talk about is strep bovis, which has associated with colon neoplasms and indicates the presence of significant disease in some cases, and the viridans strep which has been associated with dental endocarditis in donors.

In contrast, when we identify other isolates, they're more likely to have significance to the health of the donor, although still, it's more likely that they don't. This is a pretty low yield activity. But, when we detect a gram negative such as E. coli, klebsiella, it is possible that the donor is harboring a chronic infection that hasn't caused them any problems, but they don't know about it. And, of course, there's always exceptions in this category, because basically, this is a little nasty to think

about, basically bacteria -- any fecal contamination can also be on your skin.

So, what you have seen in counselling donors with positive bacterially contaminated donations, in 58 of those cases, we have identified issues either that the donor knew about or identified shortly after donation. As I mentioned, viridans strep is also associated with dental conditions. And none of this is a recommendation to change our screening process. This is just an indication of -- actually, the relatively low yield of identifying issues. Only 58 of the donations that we have screened so far had an identifiable donor related possible source in the process. E. coli, they thought they had recovered from mild food poisoning and so forth.

I want to call your attention again to strep bovis, because this isolate in blood has been associated with colon cancer and with other colon neoplasms. And so this is an opportunity to link to the Healthy People 2020 and take this opportunity to inform these donors, who are probably at greater risk

than the general population, and need to understand the public health recommendations for colon cancer screening.

So, we have been linked to Healthy People 2020 among our medical directors and identifying the importance of colon cancer screening in those donors who have -- who are found to have strep bovis. The other exceptional case is one of isolating a strep species in a 50 year old man who met all other criteria for apheresis, his platelet donation, but had a positive culture for abiotrophia, nutritionally variant strep. On follow-up interview, the donor reported, now that you mentioned it, I have had fevers and night sweats. But, he attributed this to the stress of losing his son earlier in the year. Repeat cultures were positive and he was diagnosed with previously unknown condition having blood bacterial endocarditis.

On the flip side, we have identified bacteria in platelets which they thought would have public health significance which turned out not to. So, we have had five donors between 2004 and 2007 with

confirmed positive listeria monocytogenes. This is a bacteria that's usually linked to contaminated food and outbreaks. So, this finding is reportable to state health departments, CDC was involved and CDC published a case report of our asymptomatic donor in southern California.

The isolate from our donor who was perfectly healthy, hadn't been sick, didn't get sick, his isolate was identical to three other isolates from patients. But, no epidemiologic connection was identified. The common source was not identified. And the conclusion was really the appreciation of listeria monocytogenes might cause asymptomatic bacteremia which wasn't appreciated.

We have also had a temporal clustering of three cases in Virginia, New York and Ohio in healthy donors in September of 2005, but again, no common source was identified. So, this is a case where something we thought would have public health significance, that instead, what we have learned about listeria is that you can have asymptomatic bacteremia

most likely and you might not identify a common source.

So, in all of these examples, the public health connection is that we report to state health departments, report all illnesses HIV, hepatitis, listeria. These efforts have advanced present standards to protect the donor and recipient and led to the standard to improve the way we limit bacterial contamination during the collections of apheresis and other platelet products, and has contributed again to our understanding of the epidemiology of infectious diseases in the United States.

Okay. Final topic. Hemoglobin and other donor selection criteria. I know this was covered yesterday, I won't go into much detail, but just to remind you again that the cut off -- the minimum hemoglobin standard for whole blood donors is the same for men and women, 12.5, and that women, the normal curve for women is shifted lower than the normal curve for men, and that a woman at 12.5 may be perfectly healthy and may have even adequate iron stores, but may be deferred from blood donation.

In contrast, in men who fall into the category that may be accepted for whole blood donation and yet fall below the criteria for anemia which is 13.6 for men and 12.0 for women. So, to reiterate, female donors can have normal hemoglobin, but fall below the cut off, additional iron supplies will not improve. So, if you have the hemoglobin screen, and then you're found to be iron deficient hemoglobin is a poor surrogate for iron status. And the counselling message is complicated and depends on the gender, donation frequency and other factors.

Two Red Cross centers are participating in the NIH sponsored study called RISE, which is the REDS Donor Iron Status Evaluation, and the goals of RISE are to evaluate the effects of blood donation intensity on iron and hemoglobin status. Identify the optimal laboratory measures that predict the development of iron depletion and hemoglobin deferral in blood donors, and to formulate optimal blood donation guidelines by establishing a model that predicts the development of iron depletion and hemoglobin deferral in individual

whole blood donors.

Just to give you an idea, I think this came up also yesterday, that with the hemoglobin requirement, hemoglobin results in the deferral of 8.5 percent of presenting donors, and of course, almost all of them are women. My math is off here obviously. But, about 20 percent of presenting women will be deferred for low hemoglobin, some of whom are at their normal baseline with replaced iron status. Similarly, blood pressure, same story. Hypertension is considered 140 over 90, zero and we accept donors up to 180 over 100. So, the counselling message for a donor who is accepted could consider, or in some ways should consider, what that value means to the individual. Whereas by the time you're deferred, it's a different message. And we do encourage our blood donors to carry their blood donor card and offer them the opportunity to record blood pressure, hemoglobin and anything else they want and keep a record for themselves because what it means for the individual, who is different, depending on whether they're a 40 something year old

woman or a 60 something year old man who started at 16 and still being accepted, but now is in the same neighborhood of lower hemoglobin. So, the challenge is to provide appropriate counselling. With the current criteria, healthy donors may be deferred, and conversely, donors may be accepted with values that have potential significance for them individually. So, our effort is to identify optimal blood donation guidelines and counselling messages to promote public and individual health. So, thank you for your attention. I'll just reiterate our responsibility is a safe and adequate blood supply and take any questions that you have. Thank you.

DR. BRACEY: Thank very much. Questions or comments for Dr. Eder? Mr. Matyas?

MR. MATYAS: Dr. Eder, on the first topic, which is donors basically 16 to 20, recommending that the number of donors over the years continues to decrease generally and we need to increase the supply of people willing to donate, does the American Red Cross have an opinion, or do you have an opinion as to

whether or not the net effect of these negative reactions to -- with that pool of donors is otherwise yielding any positive effect or actually creating a negative effect by having them donate?

DR. EDER: Right. I presented the twelve month follow-up data, so it appears that in this younger age group, their commitment to donate has been positive. What we need to do is longer term follow-up to see if they donate at a younger age, will they -- will that college later -- can we move that up? Can we give them a good experience in high school so they remain committed in college and are able to really commit to life long blood donation? It requires more further study, but at least the twelve month follow-up that we have really suggests that these donors come back and donate.

DR. BRACEY: Other questions? I have a question regarding when, for example, you follow-up on a donor -- bacterial, a bacteria is detected, that donor is referred to their attending physician? Is that the -- how does that work?

DR. EDER: With every positive culture that we identify, our physician has to evaluate the donor's record, determine if follow-up is needed and determine what the donor should be told. In most cases, a known skin contaminate doesn't require a follow-up. Early in our experience, we were referring more donors to their primary care physicians for follow-up blood cultures which were almost empirically negative. The case that I presented really is the exception where we diagnosed a significant condition in an asymptomatic blood donor. But, it depends. That's when we really do these is why we focus -- we have seen the importance of counselling donors with strep bovis because those donors have gone -- in the ones we have follow-up, have gone back. We have reiterated they be screened for colon cancer. And so it requires interpretation by one of our physicians on an individualized counseling message.

DR. BRACEY: What would happen if a donor perhaps didn't have insurance? And if they, in fact, do have insurance, do they pay the -- what is the impact on the donor?

DR. EDER: We had one case with strep bovis. Actually, a donor -- the answer is, our physicians are incredible and have been able to get donors who did not have medical insurance to the appropriate health care facilities where they could be evaluated. So, we had one -- one case sticks out in my mind only because it was a donor who had two donations, and we don't have -- you know, we only can count them on one hand, donors that come back and have another bacterial contaminant, and that donor probably has something going on with their health and really needs to be evaluated. In that case, our physicians had been available to identify follow-up care from services available in the community. It's a really commendable approach.

DR. BRACEY: Thank you. Dr. Triulzi?

DR. TRIULZI: Very well done.

DR. EDER: Thank you.

DR. TRIULZI: Are there any Red Cross sites that offer the extra health screening measures? Or if not is that a national policy not to?

DR. EDER: It's not a national policy not to. But, none of our centers currently screen cholesterol, screen PSA. None of our regions currently are offering cholesterol, PSA or anything not related to the donation experience. In my opinion, we need to focus on what we're doing and figure out how to get more targeted counselling messages based on the enormous amount of data that we collect on donors. If a region wants to partner with a chapter, offer cholesterol screening in the community, they can. I'm not aware that any of our regions do that.

DR. BRACEY: Question from Dr. Ison?

DR. ISON: Getting back to the bacterial contamination question, are there standards as to turn around time for attempting to contact the patient? And what happens if the result comes back on Sunday?

DR. EDER: Well, our routine cultures? You mean our routine results that we get on donors who are not patients? They're healthy.

DR. ISON: Right.

DR. EDER: I mean, this isn't a critical

value that something needs to be done immediately. So, no, we don't have criteria for turn around times. I can see Dr. Benjamin wants to jump in here.

DR. BENJAMIN: Since you asked the question about a patient -- wise --

DR. ISON: Well, maybe again, so let's say that the platelet bacteria comes back positive on a Sunday.

DR. EDER: Right. The donor is contacted on Monday or Tuesday or early in the week. As soon as feasible.

DR. BENJAMIN: If you're talking about if a product has been transfused from that collection, the patients are notified.

DR. EDER: Donors?

DR. BENJAMIN: Patients the product has been transfused, sent out from the blood center to the hospital, identified probably within half an hour and products are retrieved and the patient is immediately, on a Sunday, 3:00 o'clock in the morning, we have constant monitoring for that. So, be clear, the

patient isn't addressing --

DR. EDER: Sorry. I misunderstood your question.

DR. ISON: I'm interested in both.

DR. EDER: The immediate action is taken on the product to intercept that product. The cases of sepsis associated with transfusion though have been not detected by the current testing that we do. In other words, we culture a platelet product and our culture remains negative for five days. And it's a limitation of the sampling and the testing that we do. We have been able to intercept components when they have been released. What often happens is we get the result, we get the result and we find the platelets hasn't already been transfused, but there was no reaction. The action of the product is immediate. The action to counsel the donor happens within a reasonable amount of time. But, not overnight.

DR. BRACEY: Question from Ms. Wade?

MS. WADE: Yes, thank you for your presentation. I just have a question in terms of

reaching out to minorities at the younger potential donors. And my question is it in the area of hemoglobin. I would just like to know what is your view in terms of individuals with sickle cell trait? I pose the question because one in twelve African-Americans carry, as you know, sickle cell trait. But, in our area, there is some agencies that would defer a potential donor because of the trait, and then there is another one a few miles down that will accept a new donor that carries the trait and I'd just like to know your view is on that.

DR. EDER: Sure. Within the Red Cross, donors with sickle cell trait who meet the hemoglobin criteria are accepted for donation. I think that was a pretty universal practice in blood centers. We don't routinely screen donors with sickle trait. We don't routinely screen for hemoglobin S, but there are instances where our blood centers perform testing on donated blood for hemoglobin S, and we recommend that the donors be appropriately counselled regarding that.

So, it doesn't prevent -- it doesn't affect

-- they're still eligible blood donors, but now for the small -- and I should say, units are screened if they're intended for transfusion to a patient with sickle cell disease, it's usually because they're trying to assess their treatment. But, blood from individuals with trait functions normally and can be transfused to others. It's not often -- it's often -- there's often a transfusion practice to select hemoglobin S negative blood, for example, for transfusion to infants. So, what I am just trying to say is a small proportion of donated units are screened for hemoglobin S, and we recommend that donors be informed of that finding even though they can continue to donate blood. They may not know they have that trait although many of them already do.

DR. BRACEY: Just for clarification, the trait is not associated with anemia. So, again, the content of hemoglobin is normal in that sense.

Dr. Kuehnert and then I think we have to move on.

DR. KUEHNERT: I think more of a comment than to ask you a question. Great presentation. I

just wanted to point out that you have really highlighted some of the public health benefits of some of the donor aggregated data. We're talking about donor safety and donor health to the individual, but not really -- there are not any questions really directed toward the public health benefit of aggregated data. And I applaud the Red Cross to collect this information and also would encourage thought about the need for aggregated national data, not only at the Red Cross, but from other blood centers.

DR. BRACEY: Thank you. Our next speaker is Dr. Merlyn Sayers. Dr. Sayers is sitting in for Dr. Celso Bianco who could not be here today. Dr. Sayers is the CEO and president of Carter Blood Care and past president of America's Blood Centers and has been involved in many blood banking activities including being a member of this committee.

Dr. Sayers?

DR. SAYERS: Many thanks, Dr. Bracey. So, I'm in the sense of a surrogate here, I'd like to assure those of you that understand me, I share your

disappointment. So, what Dr. Bianco had been asked to do, he was asked to speak about the duties of America's Blood Centers and to say something about how those center are very involved in some public health measures, testing unrelated to conventional testing for infectious disease and various immunohematology tests. So, since I have this agenda, a few words about America's Blood Centers, what members do regarding blood donors, how members have differing approaches to wellness, what the basis is for offering those additional tests or not offering them, how varied the nature of those tests might be and also to address some of the questions about blood center's roles in public health, and then make a few hints as to what ABC centers would really appreciate from your group.

So, I'm not going to risk lulling you into coma by going through this because many of you have seen this boiler plate on many occasions before. Sufficient to remind you that ABC covers something like 66 blood programs, and the numbers are huge. If you combine America's Blood Centers' experience with

American Red Cross' experience, something like 40,000 individuals a day do donate. One point I need to be emphatic about has to do with the fact that in Canada, obviously the issues are very, very different. And where there are opportunities here for blood centers to provide additional testing, in Canada, donors, the population at large can get that sort of additional testing free of charge because of the way health care is provided in that country. So, when I talk about America's Blood Centers' experience when it comes to the additional testing we refer to, that does not apply to the Canadian America's Blood Centers' members.

This is an illustration of where ABC centers are influential. Here is an aside. We used to do this illustration before we did it in blue and white, we used to do it in red and blue, but then this is regarded as demagoging on the part of ABC member centers. So, we decided to change. ABC member centers are influential.

So, the question is what ABC medical centers do regarding blood donors and a lot of this has

been covered in previous presentations. So, what ABC member centers do is collect, require informed consent, and then they perform that required testing. As Anne said earlier, we put one bullet there on sickle cell hemoglobin screening, and certainly many centers do that, particularly on those donors whose products are going to be used for transfusion purposes to the newborn.

ABC member centers notify donors about their test results. And you can read through what that notification is. As I said, we have covered much of this before. A lot of the notification about test results is by mail, by telephone, but if there are HIV confirmed positive donors, that counselling is usually conducted in person.

That final bullet there deserves some comment. If individuals are deferred from future donation, those donors are notified, but many centers do not notify donors about results that do not lead to deferral unless additional testing for red cell antigen, for red cell antibodies, HLA antibodies,

antibodies to cytomegalovirus. Those individuals are not necessarily notified about their results. We have included sickle hemoglobin screening there. I think it might be worthwhile pointing out that at our own center in Texas, if individuals are identified as sickle trait positive, they are indeed notified.

So what about this additional donor testing by ABC member centers? Some of the centers that do not provide additional tests believe that these additional tests could be inappropriate incentives to donate. Some of the centers believe that if these additional tests are indeed provided, then they should be done for all donors, including those donors that might have been deferred. And in Anne's presentation, you saw a number of reasons why donors are deferred, specifically for low hemoglobin and hematocrit. So, some member centers believe everybody that presents for donation, whether they are accepted or not, should have access to these additional tests.

And some center members believe that these additional tests are not, in all cases, accepted as

beneficial. And I think prostate specific antigen screening is a case in point. Certainly a number of years back, PSA testing was heralded as an important contributor to understanding the risk of prostate cancer in men and I think that assumption is being revisited, and the importance of that assay as a stand alone risk is being revisited particularly.

Some of the member centers that do provide the additional tests, what do they think? They think that additional testing is a recognition for the charitable donation made by the donor that they are an acceptable incentive to donate, that they contribute to public health, keep the donor base potentially healthy, and they are also a public health service which is provided to the community.

Some have asked Mary Townsend, the medical officer for the blood center in Amarillo to carry out a survey amongst ABC member centers, and what Mary asked were a number of questions about additional testing, and she discovered something like 50, 52 percent out of 65 member centers responding within ABC do actually

offer infectious -- offer testing beyond the required infectious disease and hemoglobin testing. So, what sort of tests do these member centers offer? You can see on the vertical axis there, the nature of the tests, and with an N of 53, you can see the total cholesterol which may include HDL, and is all non fasting, is the most frequently offered additional test. Some other programs to a lesser extent offer lipid panels. Some even offer PSA, non fasting glucose and hemoglobin A1c.

Mary Townsend also asked ABC members what tests their programs did not offer but were considering? In this and you can see the same list of potential wellness tests that were being offered or considered to be offered by our member centers.

How is the donor notified of the test results? More often than not, the donor is invited to a website from the blood center. Some blood programs have call ins where the individuals can identify themselves or herself with a private identifier, get the result that way. Some donors are notified by e-mail.

Some donors get a phone call from the blood center.

When Mary was doing her review of the experience of the ABC centers, we were reminded that the Oklahoma Blood Institute may provide -- really has a long history of looking at doing a health screening beyond infectious disease, hemoglobin. What I must say though is that the donor health screening that is offered at OBI, while some of it is offered as part in parcel as part of the donation, much of the testing is offered separately from the donation and is charged. So, here is the chronology of events the Oklahoma Blood Institute started out with blood pressure with donation, ALT testing back in the days when that was a surrogate for hepatitis. In 1986, OBI began cholesterol testing, in 1990, offered anti-HBS offered to selected donors. But, those assays that are referred to in 1995 and 2001, prostate specific antigen and heart check programs are offered to donors at a markedly reduced cost. They're not done free and they're not performed at the time of the donor's donation.

What about heart check? I think Dr. Davey mentioned in his presentation yesterday, Oklahomans are justifiably proud of their risk ranking in obesity, diabetes, hypertension and lipid abnormalities. In fact, both of us in Texas are in a state of constant competition, who can claim the greatest risk for.

So, heart check against the background of those sorts of Oklahoma challenges was created to screen for common risk factors to vascular disease and we included what those risk factor screens are at OBI. And as I said before, those are not conducted at the time of donation and the donor is charged a modest fee for that check.

Apparently at OBI, you do not have to be a donor to pay money and have a heart check. And the reason for that is OBI shares with a number of other blood programs the hope that the community will alter its opinion as to the community blood program and see it not so much merely a collection and distribution center, but see the community blood center more as a location for health screening.

So what commentary has there been about additional testing of blood donors? We have heard mentioned today on iron issues, there was a workshop that was reported in summary in *Transfusion* in 2002. We heard Dr. Whitaker yesterday speak to blood centers, community health resources, that's a reference to an article that he had published in *Vox Sanguinis*. And then I wanted to include a section, 9215 at the recent Montreal AABB which was entitled Routine Health Screening of Blood Donors, Analysis of Issues. And that really was an absolutely outstanding section, certainly not because of any contributions from Dr. Sayers or Thomas, but because Nick Calonge, who is the chief medical officer of the Colorado Department of Public Health and Environment, made a very, very analytical and informed presentation. And he is chair of the US Preventative Services Task Force. And I will refer you to that address for the USPSTF's recommendation statements. His really was a significant contribution of all of us who are interested in the possibility that the community blood

program and donation can be an opportunity for further inquiry into prevent diseases and I sincerely hope AABB repeats that session at the next meeting. No presentation is complete without any flavor into the illegible slide. Here is mine contribution.

Sufficient to say that the Foundation For America's Blood Centers does make grants available to member centers to pursue topics that the Foundation believes will be beneficial to the donor community. And there are a number of initiatives currently open for application under the title, For The Sake Of The Patient. And building community wellness is one of those initiatives. So the Foundation -- America's Blood Center Foundation is to prepared to fund some whose objective is to encourage community centers to be stronger health care advocates empowering individuals in their service area to better manage their own wellness once there have been insights into what sort of risks they might be found. They mention the Mississippi Valley Regional Blood Center because they have adopted a slightly different strategy when it

comes to providing additional health opportunities.

And here is how it's outlined. Many of you know about Dr. Katz who is the medical director for Mississippi Valley, who not only in the blood bank, but occasionally admits to being an infectious expert. So, this is what the MVRBC has initiated. And they have a program for donors who donated at critical times during the summer of 2008 received vouchers for a flu vaccine later. And what leads them to believe was that this approach increases the number of healthy donors who are able to donate during the winter.

So, this also then poses these questions:

Are blood centers health facilities? Is provision of health information unrelated to donation one of their duties? Do blood centers have an ethical, legal or moral obligation to provide such care? And if some of the ABC members provide such services and we know that half of them do, would this place other centers in the position that is not generally regarded as a standard of care? And then obviously any of these strategies cost money in how that's managed.

Against that background, what ABC member centers would appreciate from this advisory committee, they appreciate that this committee recognizes that the members are a very diverse group, that wellness programs for donors are not funded by the federal government or by the states and cities. They'd appreciate this committee understanding that decisions of available size and type of voluntary testing and public health programs or wellness initiatives are made by the member center in conjunction with the local community. Like politics, all blood donation is local. Many boards are particularly interested in these type of wellness initiatives. Other boards of different centers do not feel that this is a part of their blood center's mission.

ABC members would also appreciate the recognition that blood centers are reimbursed by the hospitals they serve. Ours is a fee for service exercise. And we would be disappointed and if the advisory completed recommended some mandate as far as additional testing was concerned in there is no

availability of financial support for implementation of such mandates.

ABC will recommend for, we hope, that the advisory committee will recommend support for research, particularly research on additional donor testing would be most appropriate. And that's a very relevant recommendation for support particularly given how much additional resources would be to evaluate if PSA was found. We recommend support for research on the impact of wellness programs on the health of individual donors and also the potential role the blood centers may have in public health. I will be happy to refer to any questions you have to Celso. Thank you.

DR. BRACEY: Thank you, Dr. Sayers, for that great presentation. I'll open the floor for questions and comments. Dr. Klein?

DR. KLEIN: We asked this question today, so I'll ask you again today. Do you or ABC have any data as opposed to opinion about whether the wellness programs have any impact on the donation frequency or the selection of new donors?

DR. SAYERS: Dr. Klein, if you're not tempted to scamper off for tea, I have got some information that I'm going to show in a subsequent presentation which relates to our experience. And there is a diversity issue within ABC members. So, some ABC members see these types of initiatives as untenable because they're unacceptable incentives. Others regard them as an acceptable incentive. Our own center does not address the incentive issue at all. We do not say, come so that you can get, because we really want to separate these wellness initiatives from any sense of that they be conducted as an incentive.

DR. BRACEY: Have you any foundations or any of the centers that provide some of this additional testing, valid sources of funding, as you mentioned it's a hundred percent funded by the entities that provide the test.

DR. SAYERS: Dr. Bracey, if you're not tempted to scamper off after tea, in my presentation, I have the foundation support.

DR. BRACEY: Okay. We will await that.

Dr. Kuehnert?

DR. KUEHNERT: I just wondered if any of -- if you're aware of any blood centers that have offered either hepatitis A or hepatitis B vaccine. You mentioned flu vaccine which was important for donor health. But, it seems that hepatitis vaccines would also be of added benefit of possibly preventing entry of pathogens.

DR. SAYERS: There are hepatitis B vaccination, but we don't offer hepatitis B vaccinations to donors. But, Anne, is there anything different at Red Cross? She says no.

DR. BRACEY: If there are no more questions or comments, we're at the point of a break. Let's take a 15 minute break and reconvene at 11:00.

(A brief recess was taken.)

DR. HOLMBERG: Committee members, can you please come back to the table? We're about ready to start. Can you please come back?

DR. BRACEY: We're ready to resume if the committee members will return to your seats. The next

speaker, continuing on the theme of current experiences in donor health and public health is Dr. Robert Jones. Dr. Jones is known to many of us in the field of blood banking. He is the president and CEO of the New York blood center and he's been an ongoing advocate for the medical -- advancing the medical aspects of the blood banking industry. Dr. Jones will speak to us on the New York blood bank and community health centers.

DR. JONES: Thank you, Art. Thank you to the committee for the opportunity to come talk to you all today about some subject that we have been thinking about for a long, long time. I was thinking about, coming down this morning, about talking with this committee, being with this committee before, and all my recollections really have to do with sort of the glass half full -- or half empty subject of blood availability in the past. So, always asking for temper reasons on these things. So I'm glad, very glad, to see that the committee is now addressing a really positive and a really great opportunity for industry in the blood world, what we do day to day to offer

something to the public other than the charitable contribution to contribute. What can we do for them? So, we have been thinking for a long, long time about this at the blood center. And here is a little bit of a background. Every day over 400 -- not every day. I wish every day. Every year we pray for 2000 every day, we never get to that, but every year, we interact with over 400,000 healthy people, and I put that healthy in quotation marks because I think any of us who are physicians understand that healthy is a relative term. In our area, and we go through the entire metropolitan area, interact with our organization to donate blood every year. Now, I'm just going to add something to this slide, as I was talking with someone earlier, that we spend about \$160 million in direct costs on that. Just keep that in mind as a denominator because it will come up in another slide.

Now, also in the past, our organization has demonstrated the ability to conduct large scale screenings for a variety of reasons. And we have also routinely conducted market research after these

screenings, before and after, to test the desirability from the donor's point of view and to demonstrate the acceptability and value of these programs to blood donors.

Here's some examples of things we have done in the past, and we have heard things like this from our previous presenters, and I assume, as I understand some yesterday, Rick Davey presented some of this work in his talk yesterday. We, of course, many, many years ago, this is before I was getting involved in the blood system, we were looking at anemia with professional shall counselling and referrals too. That was found to be fairly effective if terms of screening people who did have anemia.

About five, six, seven years ago, when we were looking at our activities and sort of the routine of how our donor specialists interact with the blood donors, it occurred to us that we actually take the blood pressure. And -- but it also occurred to us that the reason for taking the blood pressure was to answer one question: And that is, yes or no, you are eligible

to donate blood. And as an Ann pointed out, as you take a blood pressure, it's a reading, an actual metric, it's not just an off and on answer. It's an answer that leads to a relative health indicator.

So, we started working with our donor specialists to understand that when you take the blood pressure, one thing you can do is just share the number with the donor. That's relatively straight forward. We also created a lot of literature around this and we would give the blood donors the literature to understand what that reading means. We started making referrals to local hospitals. Most of this was done in Brooklyn where there is a higher rate of hypertension because of the higher African-American population. And that was moderately effective. We actually got people to go to the hospital.

Then we got into other donor screening programs. We heard some of those earlier from Merlyn taking place at ABC centers. We offer cholesterol screening, not at every donation or every drive, but for those donor groups that have requested it. The

program has been well accepted. We don't find people say no, I don't want this. They'll take it. It's only been modestly effective in stimulating health care follow-up or generating repeat donations. This is a repetitive theme, I think, and it parallels what people in drug companies know as compliance. Medical compliance. Even though you can put -- lead a horse to water, but you can't make them drink. That sort of thing. We see this in these kind of screening programs. And the next one is a very good example of that.

So, my background was in iron metabolists and iron biochemistry and iron medicine when I first came, many, many years ago. So, it occurred to me that we should go out there and look at our blood donors for the mutations that lead to primary hemochromatosis. And those of you who know about primary hemochromatosis, it's a very subtle onset and now, this goes on, you've accumulated iron over your entire life, and then suddenly you find out that you have liver disease, heart disease, diabetes or all of the above,

that you have iron overload. Now, about seven years ago, eight years, maybe a decade, we learned about two mutations that can lead to primary hemochromatosis C282Y, H63D, specific mutations. So, we started screening the Long Island blood services donors with their consent, and the acceptance was 95 plus percent, to screen for these two mutations with the idea to identify those who have the mutations, in either homozygous or heterozygous state, counsel them about this, at least report this to them, and say, you are homozygous and particularly you should come in and have your iron -- serum iron tested so you can see whether you're really affected.

And then the eventual idea was that we would develop a relationship, a special relationship, with hemochromatosis carriers and/or effective because the treatment for hemochromatosis is what we do every day. Draw blood.

Well, this really didn't get off the ground very well because of this compliance issue I brought up. We had a lot of trouble getting people who were

homozygous to come in and get iron tests. Most of them said, well, I'll go to my doctor. Of course, you can go to your primary care physician. You can mention hemochromatosis, they, that's not a serious disease. It only affects very small numbers of people. Besides, I'm really not sure what it is. So, that didn't get off the ground very well.

What we did learn, very, very importantly from this project, was that the acceptance or even genetic screening, I remember having discussions with the staff about doing genetic screening, and this goes back, you know, like eight years or so, and there was tremendous anxiety amongst our staff about doing genetic screening would chase away of donors because of the sensitivity around privacy and so forth. Well, we didn't see that. So, that's good news.

We also learned something about ourselves which is that if you do complex testing like this, you can actually organize it in a way that gets the data through our system and back to the donor. And that's an important thing to learn about yourself when you're

looking at other kinds of screening projects. Now, this, this, of course, led to -- this is kind of a side issue here, but it's important for us, around the same time, we saw it various from FDA to be able to incorporate hemochromatosis blood donations into the blood supply. We currently carried a caseload, I guess if you will, of 130 patients who are referred to us by private physicians, mostly, who we are actually phlebotomizing, and that does -- that's not a huge amount to the blood supply, but every drop counts back to the days of blood availability when I came here. That's been a successful program. I think -- I personally think we can make that much bigger in the metropolitan area.

Here's where we're going with this. I have been talking about this, those of you, Harvey and so forth, when I was on the AABB board, I used to talk about this to people. What are you talking about? Well, I think there is a potential huge role for blood programs to be involved in public health not only for the donors' point of view, from the individual's point

of view, for the aggregate. Someone mentioned that earlier. So, we have -- we have noodled this around for a long time and I started looking at contacts with various local foundations in New York City. We found one that was interested in this, turns out their board of trustees was just start of thinking about prevention in their medical care projects, cancer all this, and the chairman of the board says, maybe this is costing a lot of money. Maybe we can do something in prevention and we can save some. So, we put in a proposal to this foundation, and sure enough, we were funded.

This proposal calls for two phases: The first phase is kind of a pilot phase. We call it Community Based Cardiovascular Risk Case Finding. It is really on-site kind of point of care, face to face, working directly with the donors to counsel them on the spot. Smaller, much smaller, much more resource contingent, and since of we are doing it in Brooklyn, as I said before, where there's, number one, there is a higher rate of uninsured, there's a higher rate of hypertension and cardiovascular disease, and it's one

of our most under penetrated areas for blood donation.

So, I think, well, okay, maybe something will happen.

Then there is the second phase which is what we call Center Wide Donor Cardiovascular Disease and we also have one with diabetes in there because diabetes is one of the specific things we're looking at. So, cardiovascular and diabetes risk assessment. This aim, our 400,000, it's also aimed to be much -- human resources less intensive, not face to face. In fact, as this would get to where it's a stable system and status quo, it would be transparent, except for the donor who would make a choice on the touch screen, yes or no, whether they want to participate in this. And they may on the next touch screen answer a few more questions they might not have answered on their routine blood donors.

Now, the other thing I will talk about briefly, it's been -- Anne did a beautiful job about this, the Donor Reaction Reduction issue and I'll talk about that. That's something that became very, very important to all of us, and certainly myself this last

summer. So, here we are with our pilot phase, we're charting minority population, under served community, donor drives, mostly community groups, that's Brooklyn.

Prior to the blood drive, we provide educational materials to the donor group describing the program, trying to make sure they understand what will happen.

We want to do some risk assessment based on modified framing and protocol following point of care random total cholesterol HDL determination, and considering the following risk factors: Obesity. We're actually looking -- we doing a study right now on self reporting to see how accurate that is, what is the window variability? We know there will be a window of variability, we just want to understand what that is so we can incorporate that into our risk calculations.

Hypercholesterolemia, diabetes, point of care, A1c determination, hypertension obviously something we already do, incorporate personal family history of cardiovascular disease, history of smoking. All these will have been done on-site with the donor. So, it's going to be resource intensive. This is a learning

phase for us. What is valuable to the donor? What is valuable in the community and impact on behavior change?

So, then there will be counseling if referral is indicated determined by the stratified risk, individual risk factors identified, and referral to a private MDs or community based health resources. In Brooklyn, there are many community based health resources that we have access to.

Here's how we'll evaluate the outcome.

This is all starting, I think, next month; right Debbie? Person who's running the program over here. So, we're going to contact the donor participants after a two month period to determine if the donor has had medical follow-up and engaged in a risk reduction program. We have done this before, so we know we can do this. As I said, it's moderately effective. We're going to see how this works. It's a bit broader. I think the public -- the public's mind is changing about this. They're more aware of prevention. So, we're all here at a golden moment. I think having this

discussion is really a moment in time when we'll look back a say, yeah, things were starting to change.

We're going to assess the acceptability and value of the program to community based donor groups. In other words, the people we work with to get blood donations are not so much the individuals, but these donor groups and people who are running them. Also, determine the potential contribution to augmenting community participation in blood program donation activities.

That means the donors come back. Do we have more donors show up? That's the long-term impact on blood supply.

Phase two: This is really the bigger program. It's different from the community case finding phase. Donor, date of collection and blood sampling will be done at the donation site with testing evaluation and counseling for lifestyle recommendations that will all be automated through IT. That's a follow-up to donation. I think of this point, I think none of this could even be thought about five years ago for a couple reasons. One is the testing technology

was just too expensive. You couldn't do A1c testing five years ago without running a column. And it was very expensive. Now A1c is much more or available. And then the -- more importantly, I think, is the information technology. You know, we're all in the blood business, we're kind of locked into IT, but there's an evolving technology, web based and so forth that you can really do a lot more with data than you ever could before, organizing, creating reports, creating value, data information, and getting it somewhere like to the blood bank.

Screening health information by PASI which stands for peer assistance self interface. What that means is that we are soon, hopefully within the next year, moving to a new platform where our blood donors, rather than filling out forms which they have been doing forever, they'll be entering their health history through a touch screen methodology. Actually, it will make the process longer, but it will be more meaningful to them. And we can add very easily a few more questions that are related to cardiovascular risk and

diabetes risk. We'll have centralized laboratory testing. Well, we do that now. The numbers of tests that we would add always comes up about fasting versus nonfasting. I'll be happy to talk to anybody about that. Centralized laboratory testing we already do. And then provision of laboratory test results and interpretation of screening electronically. We're setting up a medical advisory group that will advise us -- there are all kinds of articles out there that tell us how to do this now. We want our own medical advisory group to tell us, what are the best things we can do as a blood center to offer these people? And then automated feedback of personalized risk profiles and laboratory values with recommendations for the need for medical follow-up and possible lifestyle changes. All of this is already available. You can go out and buy a package like this, not even buy it, you can get it off any website, American Heart Association, so forth. So, this is not something we're going to necessarily dream up. We will have this committee to help us, to advise us on how best to make choices.

Participants will access their profile and lifestyle recommendations via a dedicated website e-mail or post. We're not sure. We'll probably do all of them. How are we going to evaluate this? Efficacy will be measured by whether participants found at risk actually follow-up with their providers and whether they have or will change lifestyles to reduce risk. We do focus groups all the time. We learn a lot. We do pre and post. We'll probably do that. We'll have surveys. We'll have follow-up studies of donor acceptance and efficacy providing questionnaires and focus groups. And then the data will be gathered via on line web based surveys. This will be an automated process, accessing their individual profiles, because this is a real -- this is a real important point. When you talk to public health people about this, they just like die. You've got to be kidding? Most of our blood donors, 70 percent are repeat blood donors. So, you can actually do longitudinal studies here. And that's what matters. When we're trying to determine whether something is happening because of intervention. So, I

don't think we're not -- thought too much about this as blood people except for the fact that we know that return donors are safer donors. But, there is real value here.

The impact on blood donation can be assessed at the end of each year, physical analysis relating to screening on impact participating donor groups versus not participating donor groups. We're not doing this to get more blood donors. We hope it does bring more blood donors and more blood donations. But, every time we try something like cholesterol testing and so forth, and in the past it's always been more of a marketing tool. We're trying to move beyond that to say, look, this is something important we can do as a medical organization for the public. And especially for the public that comes to us. If more people come and we have more blood donations, that's great. That's a great side effect. I'll tell you about the cost of this in a minute. I've made a rough calculation that if we see 5 percent increase in blood drives as a result of blood donations, that it will pay

for itself.

Okay. So, what are the benefits? Donors with cardiovascular risk factors will be identified and counselled, follow-up health care, and they will become self aware. And I think all of us in the health care world are starting to understand that self awareness is the first step, you know, like first step in twelve steps. Donors living in areas without previous access to screening will be given medical and public health resources. I think that's really important, especially in New York City. And to the community. The State of New York, Department of Health and the City Department of Health of New York City Department of Health are very interested in this. We have been talking with them about this for about a year. And particularly the city. Dr. Tom Friedman, who is the commissioner of health, has gone on record, he wants to improve health of New Yorkers. He's the one who's having all the restaurants you know, put the calories on the menus and taken the bad fats out of their cooking. And so this guy is really working. And he loves this.

So, we are going to have the aggregate, cumulative and longitudinal data collected on the profile of the donor population. Where -- not made available, they want it. They want it yesterday. So, we'll be working very closely with them. Composite data that comes in, we believe can be of some value to our corporate partners, our companies that run blood drives with us, and to the blood center, benefits of free cardiovascular screening may attract new blood donors as well as increase the frequency of blood donations.

Here's something about costs. I want you to remember the figure that I gave you. For the more resource intensive program, it's more expensive. We know that. But, the good news is we got the funding to cover that. We have a little point of care testing, we're going to target about 7,000 donors, and then the system wide testing, costs drop way down because the more test you do, automation. So, this turns out to be overall, as we estimated so far, a program that if we didn't have any funding at all, would cost the blood

center maybe two million dollars. Remember the denominator, 170. So, for a pretty small increment, one to two percent of total cost, we are adding a lot more value to the community. At least as we see it right now. And, of course, the good news is we have got some nice funding from this foundation.

Now, I'm going you -- you all talked about this earlier, but I got involved with this, I guess, last spring when we started seeing the impact of the reaction rate in our 16 year old donors which we had been doing for about a year. And it forced us to step back and look at this young donor situation. I became very alarmed about some cases that we were having. And I think Anne described a raise, and when you're the president of an organization, you are suddenly faced with having to deal with some lawsuits of young people who collapsed, hit their face, break their jaws. I mean, it's not a pretty picture. It only has to take one or two to really upset the organization. So, I volunteered, actually, to -- we've got to wrestle this to the ground because it's also after a conversation I

had with someone out in Scottsdale about the Red Cross experience. I said, we got to get on this as an industry, pan industry, not just -- let's all get together on this. So, we had this great task force. I think we set a record of getting something done in a short period of time. Terrific people and we came up with not only a study, or sort of putting the data together, but we really did step back and look at the big picture, everybody has the same experience, and the teenage donors, as we have become more reliant upon these young people, it's there.

So, I'm not going to go into all our data.

It's pretty much like everybody else. We have some information on serious injuries because we looked at our claims. And at that time, we estimate about one in 200,000 donations, maybe a little bit higher results in serious injury. So, our actions are aimed at the reduction of reaction rates in teenagers and we adopted the actions that I'll show you in a minute.

We know that we can't -- no matter what we do, we're not going to eliminate all reactions. But, I

believe that if you can create a safer donation environment that you can certainly come close to eliminating the serious injuries. You're not going to be able to do too much about the injuries that take place and the reactions that take place after they leave the site. That's an issue. That's an issue that I hope we start to work on. And I don't really have any ideas about that. That's a problem. I think we need to work on.

Here's what we did. We modified the donation site layout. We did predonation hydration, muscle tension exercises. This is pretty much the list of what came out of the task force. We increased post donation recovery procedures. We actually enforced the ones we had first, escort, so forth. We were doing root cause analysis following on all post donation falls and serious injuries and we're tracking rates of injuries, routine quality assurance indicators.

And finally, I just want to wrap it up by saying that donor safety is clearly the responsibility of our blood centers. But, also I think we're evolving

in a real positive way how we as an industry can reposition ourselves or actually position ourselves forward, not reposition ourselves, in addition to someone said from just a collection distribution center, to really provide health value, not only for individuals who every day step up and do a wonderful thing for another human being, but also for the aggregate. What can we learn about the population, the healthy population of the United States. Thank you.

DR. BRACEY: Thank you, Dr. Jones, for the great overview of your activities. Questions and comments from the committee. Dr. Triulzi?

DR. TRIULZI: Thanks, Bob. Question for you. I see a potential paradox that the more value that's provided by offering cardiovascular risk assessment and any future expansion of those programs, the more likely that you may attract a donor who is coming in for the program as opposed to donation. And so one question is, is the program related to presentation and registration and not to actually have to successfully donate?

DR. JONES: No. It's related to presentation. So -- now, someone who is deferred, they won't be offered it again when they come back. Because we wouldn't even register them at that point.

DR. TRIULZI: So, are you in agreement or is it your opinion that if you do offer any of these extra health screening programs, that it would be linked to presentation and not to donation?

DR. JONES: Yes.

DR. KOUIDES: I have several questions. The first one, regarding the feasibility of a hemochromatosis monitoring program, usually outside of a blood center, the standard of care would be typically for a physician to write the orders every, you know, to renew the orders every three months and decide on a ferritin range, a target ferritin range and see the person at least once a year in reviewing a medical history. Is that what you're doing currently at the New York Blood Center?

DR. JONES: Yes. I think it actually goes above that standard. Our medical staff is in contact

with the referring physicians. It's not always the best communication, but we do -- if it breaks down at all and we see it, we do everything we can to contact them. Most of the physicians now are really happy for us to do this. They won't have to do it in their office. I mean, there are a few, I guess, hematologists still left that want to do this, but deal with the bags and all that.

DR. KOUIDES: You're staff is fine with supervising that over time?

DR. JONES: Yes, and working with the referring physician though.

DR. KOUIDES: The second question is, would you anticipate, after your present roll out, that if you decide to offer this screening program, would it be at a discounted rate in terms --

DR. JONES: If we're going to continue to this do, this is the ultimate discount. We won't be charging. We don't charge for it now.

DR. KOUIDES: If that's the case, perhaps maybe it will be appropriate for discussion. Does that

raise issues of an incentive that from perhaps an issue from the FDA's point of view in that sense?

DR. BRACEY: We can discuss that.

DR. JONES: Let me just comment on that.

In the past, had you offered something like this, the actual monetary value would have been so high that I think it might have been an incentive. It will be an incentive for people because it's easy. It's easier than going to their doctor's office and getting this information. So, obviously, there are philosophical sides to this. I believe personally that as you balance the value, not only to the donor, but also public health value, that it overrides whatever incentive concerns you might have. And that's just my personal opinion and obviously the aggregate of everybody's personal opinion.

DR. ISON: Getting back to the issue that you raised with these young donors that keep passing out, do you have any information yet on what you have done? And if you do, do you know if these people are passing out and they're recognizing it and not telling

people or that they're just not recognizing that they're going to pass out?

DR. JONES: Well, we have implemented all this and we have now -- just finishing up the first high school season. We're looking at the data. We don't really see a big difference, quite frankly. And I just think we need to -- the key is here, because I think we're really looking at this very hard right now, as an industry, not just everybody, you know, you see these injuries and you just say, we have got to do something. So, I don't have any really good information as yet about whether these -- this list, which was a composite of lists of best practices from all over the county. Now everybody is doing everything for the most part whether this can have a big impact on the reaction rate. It should. But, so far, we don't see that. I'm trying to remember what your actual question was.

DR. ISON: The second is, do we know if these teenagers are passing out because they just don't want to tell anyone they're feeling lightheaded?

DR. JONES: I don't think that's so much --

I think they really don't know when they're going to go down. I mean, you ask them, they don't -- passing out, and it's a dangerous situation. So, I believe that the post donation environment has to really become much more vigorously enforced. There are some centers for high school drives, they're recovering all the kids on mats down on the ground. Of course, you can't do that everywhere. But, in a big high school drive, which those of you have ever been on one of these things, is like working on bordering on chaos. Getting them up, seriously, it's just an amazing site. But, if you get them down on the ground, if they fall, they're not going to injure themselves.

DR. BRACEY: Dr. St. Martin?

DR. ST. MARTIN: I was just wondering about the referral, the community based referrals, and how that process is handled and whether you are actually working in partnership or collaboration with the safety net providers and community health centers? One of the concerns is now people are coming in and getting all of

these health screenings done. Maybe they're saying, you know, you don't need to go see a provider or even if they do find something wrong, and they tied into the community for them to know what's going to be done so they can pull the information on the website, get all the labs done, or are they coming in blind and they said, I was told I have hemochromatosis and, no, I didn't bring anything with me.

DR. JONES: You have just recapitulated the whole conversation we had with the State Health Department about this. What I tell them is, you know -- they say, how are you going to do this? I say, we're going to work with you. We're going to work with you, the State Health Department, because they're the ones that have this network out there of community based health centers. Actually, partially through the foundation that we're getting money. They're connected to these groups too. So, really, I think it's very exciting that a blood program like ours and everybody else's, it's been pretty isolated and capsulated in the medical care world is now starting to interdigitate

because we have this valuable information and we will provide a real benefit to the community that we never did before. But, that -- all those questions were exactly the questions we had for the State Health Department. And I said we're going to work with you and they said, that's great. Let's work together. Those questions aren't answered.

DR. BRACEY: We have a question or comment from the floor?

UNIDENTIFIED PARTICIPANT: Actually, I just wanted to add to that that we are working with community based outreach groups in our underserved communities, especially with the initial phase of the face to face, and we will have a list of organizations who we have already arranged with that we may be referring people. And every donor will get a printout of all the laboratory findings and their overall health, cardiovascular risk assessment. And in addition, even if somebody is not determined to be at real risk, we do have the disclaimer that this does not represent, that you don't need to go to your doctor.

This isn't an instead of going to a doctor and be evaluated.

DR. BRACEY: Thank you. We'll move on then to the next presentation and that will be by Dr. Sayers as Dr. Sayers. He is still the CEO and president, I understand, of Carter BloodCare, and we have given him less than a minute, but we actually will be gracious and give him his full time.

DR. SAYERS: Thank you, Dr. Bracey. I'm pleased you mentioned that because I'm indebted to Dr. Bianco to be present. But, as you can see from the agenda, my presentation is scheduled for 11:30, at the same time that you have the public comment scheduled. So, I suspect this is Dr. Holmberg's hint that I need to be brief. So, we will be brief.

Public health opportunities and particularly cardiovascular and diabetes risk assessments, as we have looked at them at Carter BloodCare, the work at Carter BloodCare, this program serves the now Fort Worth Metroplex and some 54 surrounding counties. We draw close to 400,000 donors

a year, and we are the largest blood program in Texas, and Dr. Bracey would confirm that in Texas, size really does matter. Steve Eason is the director of the Carter BloodCare Foundation, and Shankar Goudar is Carter BloodCare's chief information officer and I think it will emerge from the glimpse of information that we have derived from our risk assessment study. But, I think it will emerge. I think it will emerge. I could say, can you hear me, but those of you who can't wouldn't hear the question. So, I think it's going to be emerging, the study, just a glimpse that I'm going to show you that the presence of powerful and wizard chief information officer is a compelling benefit to any of these large scale risk assessment strategies. Doug Bolgiano from the Puget Sound Blood Center has been central to some of these statistical analogies which I'm not going to go into, and all of his testing is done in blood system laboratories which are on the premises of Carter BloodCare in the Dallas, Fort Worth Texas.

What is the background to this? It goes

without saying that we recognize the epidemic of heart disease and stroke, something like a million deaths a year in the USA. We have heard reference to those misfortunes in the Rear Admiral's presentation earlier this morning. The CDC has developed a public health action plan, and there is the address of that action plan, and it emphasizes public education of communication.

And then even though we have been doing cholesterol screening on blood donors since 1996, and literally have hundreds of thousands of information points in those studies, something that Dr. Eder said in 2003 really struck home. And in quoting her, in carrying messages to the public about how disease and stroke prevention control, seek out new and nontraditional venues and partners into a state wide community program that we thought was a very good representative of a new and nontraditional venue and partner when it comes to identifying ways to broadcast risk information to individuals who might be unaware that they are in that category.

So, what was our strategy as far as cholesterol investigations were concerned? Nonfasting total serum cholesterol levels are measured on all donors. Doesn't matter whether you are a first time donor or a repeat donor, you both will have a total nonfasting serum cholesterol measured at every presentation. We're particularly interested in values above 200 because values below 200 milligrams per deciliter are regarded as desirable. And the reference to that is the Third Report of the National Cholesterol Educational Program Expert Panel on High Blood Cholesterol in Adults. That's an NIH publication you can refer to. So, we are particularly interested in donors who have a value of greater than 200 milligrams per deciliter because essentially, if you go to the expert panel's opinion, individuals who do have a random value greater than 200 are individuals who are indeed candidates for a more formal fasting blood. And donors are advised to review their results by logging in to Carter BloodCare's website. An individual who has donated can get a unique number, he or she can use

that number to go to the website and see what the random cholesterol value was at the time of their donation.

So, as I said earlier in the preface to this sermon, I'm just going to give you a glimpse of some of the events that we have been able to uncover. Here's one of them. What we have in this illustration are percentages of male in blue and female in red donors at various age ranges, and those age ranges are shown on a horizontal axis. And they reveal the percentages of those donors who have cholesterol values greater than that cut off level that the expert panel regarded as an indicator for a more important fasting blood test. So, when I first saw this, I mean, it was a reminder to me how naive I was in terms of understanding cardiovascular risk epidemiology as measured by random cholesterols. There's a lot of distribution for males, and we saw that that actually declined with age. We have been looking at potentially older men who had values greater than 200. And subsequently discovered that, in fact, cholesterol

values do decrease in males with age. When I first looked at that, I thought, goodness. Is that drum roll in the age range of 45 and older attributable to the fact that those individuals just die of heart disease or alternatively, is that evidence of the efficacy of statins? But, this reflects more of what is, I believe, a common understanding that cholesterols do decrease in men with age.

Obviously cholesterols increase with women with age, particularly post menopausal women. But, over here is an indication of the significance of risk as measured by cholesterol greater than 200 of the population that we regard as -- and they regard as healthy levels. These individuals who believe that they're healthy enough to come and donate. Revealing to them their cholesterols suggest that they may be healthy enough to donate, but a significant percentage of them are individuals who have some cardiovascular risk.

I told you earlier that a donor is given a unique number at the time of donation. When he or she

goes to the website, this is the sort of information that's available. That donor will be told his or her blood type, number of lifetime donations, number of donations they made in the year, how many gallons they donated. They'll be able to make an appointment. They're told whether they're eligible for whole blood donations or apheresis donation. Then the histogram below, is something that is particularly popular with donors that do go into find out their test values.

What the histogram shows is the individual's cholesterol history at each donation. And that yellow bar there is the NIH level above which additional testing might be suggested. And then right at the bottom of that would be web page, you can see the individual who is reviewing his or her results is invited to visit the NIH by logging onto that site that's shown there for more information. That's proven to be particularly valuable for individuals to identify what their related cholesterol levels are.

That aside, you saw that something like eight or ten percent of youngsters, teenagers, actually

had cholesterols greater than 200. This has proven to be a group that we are particularly interested in largely because of the number of the school districts in the areas where we draw donors. A number of school districts are particularly interested in the fact that youngsters are nonetheless at risk of cardiovascular disease as evidenced by the cholesterol values greater than 200.

So, this is the distribution, males and females, female distribution shifts slightly to the right, nonfasting total cholesterol in teenage blood donors between 17 and 19. The vertical bar divides those individuals above and below that expert panel's cut off and the individuals to the right are something like eight percent of the Texas teenage blood donor population evidencing risk for cardiovascular disease, or at least evidencing the need perhaps for fasting testing.

Dr. Jones spoke about longitudinal studies. I wish I could show you some of the other elements that we have in this regard, but bear in mind number

that a number of donors are regular donors. And this does give you an opportunity to look longitudinally at the what might happen to their cholesterol values. So, here I have illustrated the cholesterol screening experience of 258 women who donated blood at the age of 17 in 2002 and then came in again in 2006. So, we really regard these sorts of studies as the pace of change studies. So the horizontal is the cholesterol value in 2002, on the vertical axis, the cholesterol value is four or five years later in the same individuals in 2006. So, you can break these quadrants down. The Lower left quadrant represents those individuals of the 258 whose cholesterols less than 200 at both visits in 2002 and then again in 2006. The individuals to the right, the lower right quadrant, are those individuals who had an elevated cholesterol in 2002, but then in 2006 on their return visit had a cholesterol which was below that cut off level. And there's only a handful up there, probably five or six out of 258. And the upper left hand quadrant shows those individuals who were less than 200 in 2002, but

migrated into the degree that would justify a fasting lipogram. They migrated during that four year period. And then the top right hand quadrant are those individuals who were above 200 in 2002 and are still above, and perhaps even higher, in 2006.

And segmenting our donor population in this way really raises so many opportunities. What are the characteristics of those individuals in the various groups? What happens to their weight? What happens to their blood pressure? What happens to their lifestyle? What changes account for their shifting between these various quadrants. And there are any number of studies that this type of analysis would invite.

Questions have been asked about ethnic differences. What we have here are percentages of teenagers and the random cholesterols of 200 milligrams broken down by male and female gender and also by ethnicity. Donors are invited to declare their ethnicity at the time of donation. So, we can then review or experience with those youngsters and point to the fact that African-American women are at the

greatest risk of elevated cholesterol among people of that gender whereas Hispanic men have a risk for a cholesterol value of greater 200 milligrams per deciliter, which is almost twice of their population counter parts.

One point I could make about some of the cholesterol studies relates to what I haven't shown you. Remember, I said our chief information officer was something of a wizard. He certainly is. We can actually go in and look by age, by ethnicity, by gender and discover which individuals are the individuals who are seeking out their results. Is it just the worried well or is it the individuals who are seeking out their results, those that really should because they have elevated cholesterols? And we have done a number of evals to answer that question. So, about A1c, we have heard mention of that in a number of presentations today, yesterday. This does reflect the overall glucose during a two to three month period. It's not influenced by recent meals, doesn't rely on fasting samples, and recent literature suggests that elevated

values are a predictor of diabetes and increased mortality. So, it's been a concern, A1c determinations, all we have is an unlinked study we performed something like close to 10,000 A1c analyses, and as I said, it's only a study of the frequency distribution on the left, the A1c level is shown low. Those percentages are important. If the A1c is being used as monitor of the success of diabetes control, then you want to hear something like 67 is probably acceptable, but greater is certainly unacceptable. So how big is that tail?

In this unlinked study, something like five percent of blood donors have A1c values greater than six percent. And that was an alarming and startling discovery. And if we confirm that that is indeed what the prevalence is of elevated A1c, it would suggest that a significant percentage of the population are candidates for a serious study as to whether they are indeed prediabetic or not.

Just a few final comments. It goes without saying, blood centers have access to an enormous amount

of information on donors, and we can capture that data in a format that we think is useful to the donor and useful for analysis. We can do targeted studies of segments of the donor population and we could add Texas to the group of panels that are being done today. What we really need are collaborators who have a much better understanding than we as blood bankers have of the importance of epidemiological drives, and we need collaborators who can provide to us techniques to intervene when it comes to high school kids. Experts in behavior modification would be ideal partners in ongoing studies that we would like to pursue.

And then finally a comment about financial support. Because donors do not pay for this, these insights into their risks, in fact, all of us at Carter are indebted to those foundations that I have named there who have supported these donor health screening activities. One thing that I would say is in encouragement to others who are thinking of foundation support, and as you can see from Dr. Jones' experience, foundation support is forthcoming. When we take our

messages to foundations, at least in Texas, the message being that we have an opportunity for healthy individuals to gain insights into what sort of risks they might be unwittingly harboring, foundations have been excited by that possibility, enthusiastic and generous in their contributions. And that's my story and I'm sticking to it.

DR. BRACEY: Thank you, Dr. Sayers.

Questions and comments from the committee? Dr. Ison?

DR. ISON: I have two questions: Do you have any information first with the hemoglobin A1c, about how many of those people with elevated hemoglobin A1c actually knew they had diabetes? And the second question is, do you have any information on patients that had fat lipids above 200 that have repeat fasting lipids that were --

DR. SAYERS: In answer to that first question, I said during the presentation that it's early days for us for A1c, so I don't have an answer for that. When I showed you that -- as far as your second question is concerned, when I showed that

longitudinal study, I mean that would point us to a group of individuals who would be particular candidates specifically for the sort of question that you are asking. So, what did you do when you got the result? No, first of all, did you go in and find out? If you did, what did you do about it? And do they have the results of fasting? We don't have sorts of studies anywhere beyond that.

DR. BRACEY: Dr. Kouides?

DR. KOUIDES: Dr. Sayers, you mentioned that you have looked at the data of who is accessing their information in terms of worried well. What do they show?

DR. SAYERS: We're doing that in a piecemeal fashion. We don't have those results yet because the first question we asked was, are there any ethnic differences when it comes to which individuals go in to seek out their results? And what was intriguing to us is that there are ethnic differences. African-Americans are less interested in finding their results than Asians. And Asian men seem to be, by

comparison to other ethnic groups, the most curious for their test results. So, it's early days there. But, we can get the answer to that question.

DR. ISON: You said access to internet or lack of interest?

DR. SAYERS: I don't think it's access to internet because individuals can also phone in and get their results.

DR. BRACEY: Other questions or comments for Dr. Sayers? If not, thank you very much. We are at the point of the public comment. And we do have a public comment from John Paulson of Targeted Personal Wellness. Mr. Paulson?

MR. PAULSON: My name John Paulson. Targeted Personal Wellness it started as a personal research project in 2002 with a publication in May of 2002 in American Scientific. I think the American cover story on the Fire Within. I certainly enjoyed Dr. Jones' and Dr. Sayers' presentations, but both are based on a pre 1990 understanding of cardiology. As showing in this last month, American Heart Association

key note speaker, who is the key researcher in C-reactive protein, that, in fact, there was a question, a quandary that came to them from looking at Framingham. That is that 50 percent of the people who had high cholesterol did not die of a heart attack. Conversely, of the people who died of heart attack in Framingham, 60 percent of them had a normal or a low cholesterol. Now, in retrospect, that sounds like an 800-pound gorilla sitting in the room that nobody noticed for a long time. The public -- publication by the chairman of the cardiology department in 2002 was to, in fact, to restate a better understanding of the risks of estimating cardiovascular risk over a ten year period. That's interesting to me because having given only -- I guess what I'll do is just do a brief bullet point. Targeted Personal Wellness is an effort to add another sector of donors, a whole distinct population group, to help the wellness sector through providing incentives distinct to proactive people seeking personal wellness information. And we do that by trading super donors in exchange for information

derived from the testing of donor blood by blood banks.

The second page is how HRCRP improves relative risk accuracy. You'll notice this is -- groups of three. The single derived point is this: That in studies as large as 15,000 to 27,000 individuals, individuals variance will invalidate a single test marker -- a single marker test unless the subject's past marker level is known and a repeat test has to be done in two to four weeks. The second slide, unless you think we're looking at stale statistics, are accumulated repeat heart attacks or deaths. And as you can see, they fit very neatly. That if you have either or high LDL or high CRP, that's about equal. But, if you have both, it's measurably less.

I'll refer about the American -- related to HP 2010 goals. American Heart Association called for a national surveillance system for heart disease and stroke. They've not done it. But, there's two goals that are boldfaced for you, is the detection and treatment of risk factors, reduction in smoking, high blood pressure by 25 percent. And secondly, earlier

identification and treatment of heart attacks and strokes. In fact, it's interesting because HSCRIP was named in the Rockefeller Institute findings of Oswald Avery in 1931. In fact, he was also the guy who discovered DNA and documented it. But, he didn't get the Nobel because he didn't do anything about with it. He just saw it, regarded it as a curiosity and left it. That to me is --

The second question is about how much would it cost a blood bank to do a program like this? I'm an econ major, so I did a marginal economic analysis of increased blood bank sales because that would be the standard which would be the donor -- the dollar production of such testing. That to me is where the rubber meets the road. As I pointed out yesterday, people pay as much as \$139 for a four part CT scan, or in Life Line, that does that. They did a prototype study, which is the next page, convenient heart disease and diabetes blood tests now offered by Wisconsin Life Line Screening where they started their screening, to cover the costs, at \$89 a screen. They reduced that

because the surplus of turn out they had to get that screen to \$79. That's important because that's real world numbers. That isn't market surveys. And in the production of these kinds of numbers, we have to look at a different way of looking at C-reactive protein. What was left out -- my omission was, C-reactive protein has two sources of understanding of its nature. The medical we've heard a lot about, that it's nonspecific and it's too costly. The wellness perspective takes another view point because it's coming from a different direction. What does a donor need in terms of personal wellness information if they are proactive? They need a single test that is the gateway to the possibilities for serious decline in their health in a period of time sufficient that they can make lifestyle changes.

Now, because we have a surplus of doctors here, we all know about the discouraging results of encouraging obese or morbidly obese people to, in fact, take action in a manner which is in their control. We think TPW can be a better tool for encouraging people

to, in fact, make choices they would make after the heart attack if they survive. Before the attack comes, to forestall or delay it. And that will get people's attention. If you -- if they are told that this is, in fact, a monitoring process, of course, that's why it's presented as the chief point, which was for this reason, within any single person's life which TPW is aimed at, finding that apex of high sensitive CRP is like finding a submarine under water. From before World War II forward, the navy had very interesting technique called sonar. If you can't see it, how do you find it? Well, you go ping, ping, ping, ping, ping and you may find nothing. Conversely, in a dangerous situation, you may go ping, ping, ping, ping, RING, RING, RING. And that's what monitoring is about in medicine. CRP in Texas targets personal wellness.

DR. BRACEY: Mr. Paulson, we're running short on time. How much longer do you think this will take?

MR. PAULSON: I'm just going to say we have contact information here and that I can be contacted

through those sources. Because there is a difference of Framingham risk is short on important cardiological risk factors of inflammation and genetic history. TPW is -- I might say to like Dr. Carter in Texas hold 'em. We'll raise you and we'll call you. We'll raise you qualitatively and we'll call you simply because by inserting those two factors, you have a truer risk of cardiovascular events within the next ten years. And that's the point of the material I've provided. Thank you. Any questions?

DR. BRACEY: Thank you.

MS. BIRKOFER: I have a question. Is TWB a for profit entity?

MR. PAULSON: Yes.

MS. BIRKOFER: Thank you.

DR. BRACEY: If there are no other questions or comments, we are scheduled for a break for lunch for one hour. So, then let's reconvene at two minutes after the hour.

UNIDENTIFIED PARTICIPANT: Just a reflection back on yesterday's committee, because when

we talked about mandatory reporting, people talked about HIPPA and confidentiality. I'll remind people that our organizations represent people with AIDS for many years who are very interested in secrecy. But, when name reporting came up, the AIDS community responded a hundred percent negative. We had to ask ourselves a question. National interest is at stake. We talk about blood and national interest, national interest. We had to evolve our own thinking inside the committee to say where's the middle ground in state and local governments and federal government where we could accept this kind of reporting in the national interest and not destroy our people's desire to be confidential?

And I make that comment connected to, we're wasting too many resources with too many systems at a time when we don't have those resources and that greatly concerns us. Thank you.

DR. BRACEY: Thank you. We will break for lunch and reconvene in an hour. Thank you.

(A luncheon recess was taken.)

DR. HOLMBERG: Can we have the committee

members come back to the table please? I think some people may still be at lunch, but hopefully we'll have a quorum.

DR. BRACEY: We're now in the phase to have committee discussion of all that we've heard and again, the important point would be to respond to the questions that we received from the assistant secretary. We, in part, did that yesterday evening regarding the informed consent statement, and we do have a draft of that which was provided by Dr. Pomper. Did you want to walk us through your draft?

DR. POMPER: Well, it's there for everyone to read. I began by stating that I think that the status of informed consent for blood and plasma donation is generally adequate, and with the descriptor that informed consent is performed nationally, and they are defined specific elements of the process, but yet there is a recognition of individual regional interpretation and state law as well. It's not stated in there, but implied. But, however, based on this discussion of the committee, there is emphasis placed

on the consideration of an element of uncertainty regarding blood donation risk, particularly with repeat donor effects, so that the second paragraph highlights that a little. And it concludes with the committee recommends that DHSS encourage the participation of those in the blood and plasma sector organizations to evaluate the scope of the informed consent, but include both known risks for a single donation and the current cumulative -- I'm not sure if that's a little too heavy of a statement, but I thought it was a place sort of jumping off of.

DR. BRACEY: So, you want to ask your question, Dr. Holmberg?

DR. HOLMBERG: My first impression is that we have heard also from Dr. St. Martin about the informed consent on the tissues, and some of the struggles that they're dealing with with making sure that people have the information. And I don't know whether it's the same issue with the living organ donors, but do we want to make this -- does the committee want to make this a little bit more general

instead of just the blood donor and plasma donor?

DR. BRACEY: I guess my initial thinking was that we would focus primarily on the blood piece recognizing that there are some significant differences. Dr. Ison?

DR. ISON: I would support that. I think that there are significant issues with regard to consenting for tissue, and particularly living donors, but there are very different issues related to risks and whatnot, are very different in blood. So in this case, I think it does make sense to attach them as linked issues. Maybe something this group can think about at some future point.

DR. BRACEY: One of the questions yesterday regarding the recommendation that would be made to the secretary is whether this would be the appropriate group to address the issue. And so if we could go back to the draft, so here it says, committee recommends that the department encourage participation of many blood and plasma sector organizations to evaluate the scope of informed consent. So, it's largely directed

toward the term industry.

How does the committee feel about the current wording? Mr. Matyas?

MR. MATYAS: I was going to encourage participation. How is it that the secretary would, in fact, encourage participation as opposed to either convening a group? Is there an existing -- are there committees or structure? Intentionally, and rightfully so, I know it's kind of vague, but at the same time, I don't know if it gives enough teeth to it by putting it in the industry's perspective.

DR. BRACEY: I like your comments. I would think that a different approach rather than simply to say encourage. Dr. Epstein?

DR. EPSTEIN: I'm a little bit troubled. We have a very broad charge here. We have six specific questions, and it concerns me that we have not first framed the big picture. I think the big picture here is the recognition that something like ten and a half million people donated blood, either for transfusion or source plasma annually at multiple times per year, that

that results in encounters with collection centers that contribute to events and findings related to the donor health. At the same time, those encounters provide potential opportunities to advance individual and public health. These considerations, if we go into specific considerations, such as the rate of adverse events in younger and older donors, the fact that we accept donors with abnormal hemoglobins and blood pressures, et cetera, et cetera, warrants further consideration on communication, health information to donors, validation of tools to encourage adequate medical follow up to address medical conditions, and that this is an important issue because it has a bearing on maintaining a healthy donor base, potentially expanding the donor base, and that there is a broader issue additionally have fostering public health consistent with the HHS goals of Healthy People.

That within that framework, issues that need to be addressed include informed consent, collecting and managing donor health information, potentially expanding wellness testing, et cetera, et

cetera, et cetera. Because I just think we're going to be here until midnight working each of six separate questions, and I think that in doing so, we kind of lose the big picture.

Let me also just jump to my own personal conclusion, which is I'm not sure that each of these issues is right for recommendation for HHS. I think what we have done here is we have opened a window on a rather large subject which is of a very significant impact to public health, and that maybe what's really needed is for a task group to develop some kind of a light paper. Because what troubles me is the lack of the evidence for effective outcomes. I don't have any hesitation thinking that why don't we do something about heart? Why don't we do something about blood pressure? Are we doing something about hemoglobin? We probably should be doing something about sickle cell screening, ta-da, ta-da, ta-da, ta-da. But, the actual experience suggests that some of it works and some of it doesn't.

So, are we really in a position to

recommend actions or interventions in the donor room without first advocating further studies? And I'm very impressed by the studies that are ongoing. I think what we've heard from the AABB about data gathering related to adverse events, and 72,000 adverse events related to donation in one year in which 11,000 were significant? Twelve percent adverse events in donors 16, 17 years old? These are startling things.

But, on the other hand, what are the remedies? And so I'm just a little bit nervous about the specificity of the recommendation. I think there is a big picture to communicate here, that the importance of dealing with it as part of individual and public health should be noted and that we really ought to hint at the need to support studies of appropriate interventions.

DR. BRACEY: I guess in my thinking, initially I was parsing out of informed consent issue from the bigger picture because there is clearly a bigger issue, picture, that needs to be dealt with in terms of the broad public health implications which

informed consent might fit under that banner.

But, I guess I was thinking that initially that the informed consent question might be separate from the broader public health concern. But, we could incorporate that as a sub. And I think that the data that we've heard or the information that we've heard thus far really does suggest that we need more studies, that we're not, at least in my opinion, ready to make a strong recommendation vis-a-vis health care screening. But, again, I'd like to get the consensus of the committee on that. Dr. Ramsey?

DR. RAMSEY: I think at least from the time the speakers had allotted, I guess we didn't hear a whole lot about whether there was information on whether this action increases donors' participation. These efforts obviously have a financial aspect and we'd like to think that, I'm sure the blood centers, collection agents, would like to think that this adds to their mission for collecting blood and supplying blood to the communities. But, it doesn't sound as though there's -- though there's some information, it

doesn't sound like there's a big consensus on whether or not it actually improves the donor base. It certainly adds to community awareness and information about donors' health, but it's difficult so far for me to hear how it adds to donors. I think that's part of the ongoing studies that we're part of for the information we need.

DR. BRACEY: Let me ask this again: Just one concept that really struck me, and I think that came after Dr. Domen's talk, is the concept of a donor's bill of rights, which I thought was a very good idea to sort of frame precisely what those donor's rights are. I was trying to separate that from the public health issue. But, does the committee feel that we should put those two -- combine them?

MS. FINLEY: I would stay away from a donor's bill of rights at this time. We haven't heard evidence that donors need for it. But, I'm sure it happens, but it's not in a blood collection organization's interest to do that. So, that's kind of poor management. Secondly, I don't want from a public

policy perspective, I would strongly advise against getting into a situation where you've got a donor's bill of rights and recipient's bill of rights. There's too much, forgive me, blood spilled over those issues in the past. It's too inflammatory. I think we'd be here not only all night, but all day tomorrow trying to work that out.

Thirdly, I just wanted to share a concern that I have, and I know that I'm not the only person who feels this way on the committee, that in addition to the sensitivities that the blood collection organizations have about being considered community or being asked to perform community medical screenings, there is an ethical issue that I think we haven't really fully explored going down that path. They are in the business, so to speak, of blood collection. I don't think you can say that they can be both, both community health point of contacts as well as this other thing. If part of their marketing, you know, they perform services for people that are making donations for them, you know, that helps recruit and

bring in and retain their donors, I think that's fine.

But, I'm not looking to achieve health care reform on their backs. And I think there's some ethical issues that need to be worked out regarding that. Thank you.

DR. BRACEY: Dr. Triulzi?

DR. TRIULZI: Thank you. I want to make a statement that's not dissimilar from Ms. Finley's and then propose a potential specific recommendation that our committee can make. And in my opinion, the extra health screening measures, I don't think we were really here to debate which ones are better than others. It's really the venue or process, not whether cholesterol or C-reactive protein or one or the other, since they don't add safety to either the donation process or future recipient, I think it's incumbent that we ensure that they don't increase risk. And we have had no data presented that says that a robust public health screening won't result in testing behavior, potentially attract donors who could decrease the safety of the process. And that's why I had a few questions to Dr. Jones about, this should be linked to registration

or presentation and not to donation. And my understanding is that that's not true of some of the centers that do do this. And so my specific proposal would be along the lines that if the center does engage in any public health screening measures outside of those that are required by the regulatory agency, that those must not be linked to donation only and must be part -- either separate from donation or linked to a registration presentation process. Because I'm not convinced that there's a risk associated with bringing in donors who maybe shouldn't be donating or have incentive other than altruism to donate.

DR. BRACEY: Other discussion? So, would it be fair then to deal with the questions in lump sum recognizing, as suggested by Dr. Epstein, the potential of these interventions to advance the public health with sub bullets and with provisions as noted by Dr. Triulzi that these would not be restricted simply to donations, but more broadly applied? Would this committee feel comfortable with proceeding in that direction?

MS. FINLEY: I mean, if I understand you correctly, you want to list the interventions, these tests that --

DR. BRACEY: Oh, no. Not specific tests. We simply would list the blood center as a place that has much -- frequent interface with the public, and where information might be gained regarding the use of certain measures to enhance the public's safety, the public health.

MS. FINLEY: I don't think we've heard enough evidence to support it. I don't think there's any way that we have enough evidence in that regard to meet the Healthy People's 2020 standards. And I'm very uncomfortable moving -- I personally am very uncomfortable with that. I think we haven't heard the evidence for it. There is -- there could be testing behavior. That's always been a concern. If blood banks or blood collection organizations want to do this and it helps them retain their donor base, I don't really have a problem with it. But, I don't think that we're in a position to add -- to say that that's an

important public health issue.

DR. BRACEY: No, this would not be mandated, but it would be presented as something that offers potentials for future studies so that we can gain information about what happens to individuals that actually receive these screenings and also what happens in terms of the adverse events at the time of donation having a reporting mechanism whereby we can analyze both positive interactions as well as negative interactions at the time.

MS. FINLEY: I'm much more comfortable with positive interactions than negative interactions than I am to do anything that imply the blood collection organizations would have to, as best practice, take --

DR. BRACEY: No, I don't think this --

MS. FINLEY: Or say that it is best practice.

DR. BRACEY: No, that would not be said. There's not enough information. Dr. Kouides?

DR. KOUIDES: We have to add to that that there's not data presently showing that it does

increase retention. That would be the primary reason to support this type of program. You're also suggesting mentioning it in terms of being consistent with Healthy People's 2010 and 2020, but I think that's outside of our scope.

MS. FINLEY: I agree.

DR. BRACEY: The one that thing is actually in our scope, as Executive Secretary Holmberg points out, is that under one of the subtopics on Health People 2020 is this notion of adequacy of the blood supply, reporting -- the biovigilance piece that we actually currently have fits nicely into one of the 247 elements of 2010.

MS. FINLEY: The biovigilance is different than, you know, donor -- we're here to talk about donors today and donor protection. And I just -- I don't -- I'm supportive of the concept of mandatory reporting if we think there may be an issue here with donor injuries or adverse events. But, I just don't see the levels of support here and the evidence to warrant a recommendation.

DR. BRACEY: Mr. Matyas?

MR. MATYAS: Kind of going back to what I am hearing, consensus and what Jay has said, and then going to the November 24th Federal Register Notice and reading it over again, it seems as though the statements which could be defined as one of the things that occurred is, we don't have any recommendations. We have looked at these things and we think that further study of them needs to occur and that we support that fact that there be further study. And the notion of informed consent, which is where we started, is we don't have a recommendation nor do we necessarily believe that it's for HHS to come up with a recommendation to involve others whereas some of the other screenings we think, and issues discussed, should be further studied and encouraged.

DR. BRACEY: Okay.

MS. FINLEY: I'm sorry. Encouraged is not a word that I think I can support. I want to be clear.

MR. MATYAS: Encourage the studies.

DR. BRACEY: Encourage the study. No,

we're not encouraging the screening. Dr. Lopez-Plaza?

DR. LOPEZ-PLAZA: Is one of the things we have been discussing about doing this testing, that testing to increase wellness awareness, one of the things I think we have forgotten is to stay focused on is that the resources of the blood centers, as is very well known in the community service. How they can actually maybe perhaps serve more as promoting programs of healthy behavior with other community committees. They're just focusing on just the donors to do some additional testing, because I think the data has shown all the screens they're doing now work in certain population, and the findings that all the screenings are done, you know, I think that we need to not only look at testing we do for donors is going to move the donor, as example, of wellness. I think we need to look at other resources that the blood centers might have and that might not be as costly.

DR. BRACEY: Again, we're thinking actually in terms of this as not something that would be broadly applied, but further their study subgroups. But, Dr.

Pomper?

DR. POMPER: I just wanted to at least clarify. I think there might be a misunderstanding. My take on what Dr. Triulzi was implying was that essentially there's an ethical dilemma that we might address which basically, I think, actually both folks were thinking the same thing, which is if a donor center -- we're not encouraging sort of extra curricular health work up, but if a center would perform that type of activity, then it should be -- not dependent on the person actually having to donate. In other words, I think it's reasonable because that might then incentivize the person to want to go donate and go through that process rather than, say, perhaps be screened out at the history section prior to, say, a blood draw where a lot of the screening may require blood tests. So, my -- I think that was the implication. And so it's really just -- I really don't have a problem with the recommendation to keep the ethics on the -- keep the onus on the donor. If they're going to offer this type of service, it should

not be contingent on the actual donation process, but merely showing up and registering. To me, it seems similar to the hemochromatosis evolution where that began it shouldn't be driven by the donor process. If that's the same.

DR. BRACEY: There was a comment --

Dr. Benjamin?

DR. BENJAMIN: I just want to make clear, I agree very strongly about all that. I'm not sure a recommendation has to go something like Jay said because from the FDA.

DR. BRACEY: Ms. Birkofer?

MS. BIRKOFER: Thank you, Dr. Bracey. I have a question and a comment. My question to you as chairman, do we have to do a recommendation?

DR. BRACEY: No, we do not have -- there's no obligation to make a recommendation. And what I sense is that in terms of a specific recommendation that would encourage, support, discourage additional wellness testing, we're not at that point. We are at the point of saying that we need to have more

information so that we can understand the impact of these interventions in terms of improving health.

MS. BIRKOFER: My comment would be that to make a recommendation that we don't have enough data to make a recommendation, to me, is not an appropriate recommendation to make to the secretary -- we're not to make. So, I would suggest that this discussion, Mr. Matyas' point of the need for additional data information, similar to Ms. Finley, should be reflected in the minutes. I think when you make a recommendation as an advisory committee, it should be a weighty, well thought out important recommendation. And I think we dilute the value of this committee by making recommendations that we don't have enough data to make a recommendation.

DR. BRACEY: Well, true. One of the -- there are recommendations and responses to questions. So, we have a series of questions that have been put forth to the committee. And so it's a matter of semantics in a sense. We could either choose to have a recommendation that covers the broad topic or we can

respond to the questions. And as you point out, the discussion, in part, addresses the questions. But, more specifically, we could simply respond to the questions, and therefore, there wouldn't be a recommendation, but simply a response to the questions.

Dr. Epstein?

DR. EPSTEIN: Yeah. I think what I envision here is, first of all, a general overarching statement. I have been drafting one I can read similar to the comments I made earlier. But, then I think what we need to do is highlight issues. So, for example, we would then say that, evidence suggests that donors may not be fully aware or comprehend fully the risks of donation including the donation. Therefore, the committee recommends that evaluation to be done to improve donor awareness of the actual risks of donation. We could also as a finding highlight the startling finding whereas expansion of donor base has led to recruitment of younger donors 16 and 17. Evidence suggests that they have unusually high adverse rates, and therefore, additional studies should be

supported to identify the underlying causes and potential remedy. Something like that.

Then you just move to the second one, which is, that whereas the potential exists to expand public health through additional wellness testing of donors, the risks, benefits and cost effectiveness of these measures remain undetermined. Therefore, we recommend support of pilot programs to investigate the potential utility and net impact of programs such as cardiovascular testing, diabetes screening, ta-da, ta-da, ta-da, ta-da.

DR. BRACEY: So, in my impression, to speak to the issue -- if we don't speak to the issue, that leaves a void as I see it. And I think there are important studies that need -- there's more information that needs to be gained, and I think it would be important for us to speak to the issue. And I don't see that as diluting the issue. Dr. Kouides?

DR. KOUIDES: Two points: First one, I think we don't have the data about the role of the blood center as wellness. I think we have heard enough

data, going back to informed consent, that there are definitely gaps in terms of -- Dr. Pomper highlighted those groups, and I don't think it's inappropriate for us to specifically state that informed consent should address the iron deficiency issue, the syncope issue in the younger patient, and I guess we just have to decide how we move that along. That's one point.

Second point, going back to Dr. Epstein's point, in terms of the committee suggesting pilot programs, should we even suggest that? Because there is, I think, evolving consensus here that there's ethical concerns moving away from the altruistic effort of a -- the altruistic nature of a blood donation. And I think that first, at least, highlight that or mention that and decide if it's even worth us supporting.

DR. BRACEY: So, let's do this, so that we can begin to pen something: I would suggest that we take some of the introductory language from Dr. Epstein and then work that into what then might end up as a final recommendation response, call it what you will.

So is that fair?

MS. FINLEY: Yes.

DR. BRACEY: Are we ready? Dr. Epstein?

DR. EPSTEIN: Again, I'm happy to read the draft overarching --

MS. FINLEY: Do you need a couple minutes?

DR. EPSTEIN: I think we then have to deal with the issue -- we have to deal with the consent issue, we have to deal with consequence of repeat donation issue, particularly iron. I think we have to deal uncertainties related to other wellness testing, et cetera. But, Dr. Ramsey, did you want to --

DR. RAMSEY: We'll, parenthetically, I was going to interject just a point, not necessarily for our statement, but as I was thinking the last couple days, I also wanted to add another aspect of blood donation that we didn't discuss is Tolley's donation, how Tolley's donors make up a small four, five, six percent of whole blood donations. That's another piece of the donation field that where they are getting -- they are getting some health screening, they are getting some testing, depending where they're donating,

and they're adding to the blood supply. They are reporting Tolley's donation, so perhaps that would be another area. And they have donor reactions more so than the other populations. So, that's for future reference that might be another point to think about, area we need to think about.

DR. BRACEY: So, are we ready to?

DR. HOLMBERG: I just want to follow up on that, the Tolley's. I think that two mortality -- deaths in 2007, I'm not sure, but also, I don't know if you picked up when Dr. Whitaker was presenting a national blood collection utilization study, but the sense at the tail end of the nineties is extremely -- and the -- actually, only one third of the Tolley's blood was actually used in 2006. And so when you start talking about economics, I think a calculated average price, there is like a \$72 million expenditure just to support the Tolley's programs.

DR. RAMSEY: We may not get to return back, not necessarily.

DR. KLEIN: Mr. Chairman, I'd like to

recommend, since there's always so much confusion about donors and patients, we certainly heard that at this meeting as well, we really focus on the donor and leave the patient donor whose issues are really quite different to another session.

DR. BRACEY: Good point. Dr. Epstein?

DR. EPSTEIN: I support that and also would note that the patient donor has a doctor, which is a fundamental distinction here. That accountable person is managing the suitability for donation and the reason for the medical follow-up and so forth. So, kind of leaves out of this whole domain of the health role of the collection center in general.

DR. BRACEY: Good points. Dr. Kouides?

DR. KOUIDES: I'd like to acknowledge that many donors may not have a doctor. They may not have access to health care. And they don't --

DR. BRACEY: Tolley's donors, that's directed. And the issues are that they are quite different in terms of the risk. So, it would be -- it's an important consideration. Dr. Pomper?

DR. POMPER: Very, very briefly, I did want to highlight also that we may consider blood and plasma donation as elements of altruism versus incentive for those groups. So, just to keep that.

DR. BRACEY: Good point. Good point.

DR. KOUIDES: I just want to add in terms of plasma donation, I think there should be plain language accounting the fact that in difficult economic times, there's going to be more, you know, people, you know, perhaps more people donate than perhaps people who don't speak English. There's issues we should address, informed consent form, should be in other languages and it goes back to what Mr. Durbin had discussed, there has to be some -- that reality, what's happening in the Texas Mexico border.

DR. BRACEY: Good points.

UNIDENTIFIED PARTICIPANT: I guess I would ask whether this statement would include both blood donations and plasma or in terms of the corporate setting. There's a long standing, well developed informed consent process for plasma donors. And I

don't think the risks that are stated there have anything to do with the source plasma donation.

Also, in the facilities that have non English speaking donors that they take, the whole process of including the informed consent has to be given in their native language. And it's generally established.

DR. BRACEY: One of the questions actually that was posed by the assistant secretary, I thought that, for example, under what ethical responsibilities to follow up on donor health if medical conditions are detected, really that's covered by the AABB standard 5.2.3, that they are to be communicated. And so, to me, that's basically a done deal. What I am not sure about is under item B here, if adverse events occur as a result of donation process, then what are the responsibilities to follow-up? And that sort of gets into that issue. I'm not saying that you would specify what the donor bill of rights is, but really, it implies that it would be some sort of donor bill of rights because perhaps there's a different approach to

management of these events from organization to organization.

DR. BENJAMIN: Just to make a point, this is legal ground now. Adverse events include a legal basis for things and they are covered in the courts essentially. We have to now respond to donors appropriately and show good care.

DR. BRACEY: Otherwise -- Ms. Finley?

MS. FINLEY: With regard to B, I think that deals more directly with whether or not we need a mandatory effort for the reporting process. I don't think it's really addressed by a donor bill of rights. And I think if we were going to consider a donor bill of rights, I'd want to see a different set of presentations to support that.

DR. BRACEY: Again, I am not saying that we would -- we're not going to draft a donor bill of rights now. Whether or not we consider that, a donor bill of rights is a good concept.

MS. FINLEY: I'm still looking for the problem here. Candidly, I haven't heard anything to --

you know, that's more complex than a bunch of high school kids who are probably not having breakfast before they donate. That may be a problem with that group, but apparently not, and if that's the case, give them some cookies and lay them down.

DR. BRACEY: I think it goes beyond that. There are donors that actually -- because it's in blood centers that do have pretty serious injuries.

MS. FINLEY: I'm not putting that down. Is there a growing problem? I'm still looking for the definition here of how big a problem exists. The department is concerned about it. I don't have any problem saying, you know, we might want to look at informed consent. We might want to look very specifically at the donor entry, in this particular donor population, because they are different and they're approach to this may be affected by things like weight and attention to details like eating breakfast or whatever. But, I'm not convinced based on what we have seen here, that there is a huge problem that warrants a wholesale addressing these concerns.

UNIDENTIFIED PARTICIPANT: I'm just going to add the comments you made about standards and donor and consent, there is coverages, I can't quote the exact location, about adverse events, AABB standards do talk about care of donors after the donation and keeping the records and those sort of things. Those were comments that Dr. Benjamin said that they are a risk management issues at facilities.

DR. BRACEY: Dr. Pomper?

DR. POMPER: I just wanted to comment to characterize the, I guess, the degree of the problem. There are numbers that Dr. Eder presented said that there were injury in five per 10,000 donations in the 16 to 17 year olds. That actually on par. One in 2000 is very similar to the rate of bacterial contamination of platelets that come up positive in culture. And that's a number of people who are reacting to developed specific guidelines. So, that's a big number. To a degree it certainly needs to be considered, I think, fairly strongly, especially they're younger people that we're considering, and also the issue of informed

consent and are they prepared to face some of the realities of being altruistic that they may encounter unexpectedly?

DR. BRACEY: Okay. I think that -- Dr. Ison?

DR. ISON: The other point that I wanted to make is the thing that concerned me the most from our discussion is we got a great sense of what's the incidence of adverse events in the blood donor population. But, we haven't gotten any information, my understanding it's not even required to be reported for adverse events in the plasma population, and I think in my mind, the biggest concern that I had from the entire discussion is we have got this -- I agree, it's probably is a significant issue, although small percentage of patients being affected in the blood population who have no clue what that risk is in the plasma population. And so we can't even say, are we giving appropriate consent? Are we addressing the appropriate issues if we don't even know what the risk is?

DR. BRACEY: Good point. I think we need to start drafting the statement and response. But, we do have a comment from the floor.

MR. PENROD: This is Joshua Penrod, PPTA. One thing about the adverse events related to plasma donors is that I'm sure the industry is working on issues. It's just that I didn't have it today to present today. So, I think I want that to be clear. The second point is, if the committee is going to be making recommendations, a fundamental question seems to be making recommendations based on evidence or based on lack of evidence. That seems to be fairly critical at this point in time especially depending on what tense you use in your verbiage. And third, I want to clear up about the Texas Mexico border issue is that the standards and regulations apply equally all over the country irrespective of where a particular center is placed. Whether it's Del Rio, Texas or Minnesota or Northern California or North Carolina. They're uniform equal standards, equal regulatory, equal quality and level of compliance.

DR. BRACEY: We have a question?

UNIDENTIFIED PARTICIPANT: I just wanted to remind you that the risk of injury and reactions in the young people was something that the industry has already taken action on. Dr. Jones, as you mentioned, led a task force, and over the past few months, I would say most blood centers have made changes to the process. So that your recommendation to pay attention to that is fine, but it's already getting attention.

DR. BRACEY: Thank you for that clarification. I think we need to start working on a draft. Ready for introduction?

DR. EPSTEIN: Sure. This is the introductory section. Annually, approximately ten and a half million people donate blood for transfusion or source plasma for further manufacturing, many on multiple occasions. These encounters with blood and plasma collection centers can result in outcomes that are of health significance to the donors. These include a spectrum of adverse events related to donation per se and medical findings related to vital

signs, hemoglobin level and infectious disease state. Current practices vary regarding collection of safety data and notification and medical follow-up related to adverse health information. At the same time, donor encounters in blood and plasma collection centers provide a potential opportunity for expansion to include -- of donor health within the larger context of maintaining a healthy and robust donor base and of promoting public health considering -- I'm sorry, consistent with HHS goals for Healthy People. However, the actual risks, benefits and cost effectiveness of specific practices that go beyond assuring safe donation and safe effective blood products are not established.

The following issues warrant specific consideration by the secretary. And then there's a list. Informed consent, iron status in the donor, do other health screening, et cetera.

What I envision, for example, with informed consent, do we talk about the gaps? That there are adverse health consequences of both immediate and

repeated donation? That data suggests that they're not well understood or recognized by donors suggesting that current informed consent could benefit from sort of objective behavioral validation? Iron status, because it leads to undue rejection of many healthy donors, particularly women, and that health consequences of becoming iron deficient may exist and that the risks of managing iron have been, you know, evaluated with -- or maybe it can be further evaluated. Wider health screening, the whole issue of undue incentives versus the effect -- positive effect on the donor base versus just the effectiveness of delivering health information or who follows up. So, that's what I envision.

DR. BRACEY: The only thing that I guess we have heard that was and -- that's not covered is the issue of event reporting. That would be something to add in there as well because we have heard that, you know, we need a better system.

DR. EPSTEIN: Yes. I debated that only because we have previous recommendations from the two advisory committees on biovigilance and it's been made

clear that donor event reporting should be part of the report. It's a little bit redundant. But, I agree there's still a gap.

DR. BRACEY: Dr. Holmberg?

DR. HOLMBERG: I just want to make a comment that actually, the adverse event reporting was a carry on to 2010 Healthy People. So, I think it may be worthwhile to reiterate that so it gets moved to 2020.

DR. BRACEY: All right.

DR. EPSTEIN: Can I make a practical suggestion? I think we have a number of issue areas to address. If we can agree what the areas are, then have a 30, 40 minute break, we might get us to the finish line.

DR. BRACEY: So, specifically, the issue area -- the issue areas would be application of screening assays to assess public health, issue area of adverse events associated with blood donation, the issue area of consent? I think I see three broad areas. Are there any other areas that any committee

members could think of?

DR. EPSTEIN: Yeah. It's reporting adverse events, if you wish to reiterate the importance. It's the informed consent related to lack of full donor awareness of potential adverse consequence of donation. And if you want to highlight what they are, the person that would highlight the issue of iron, because it relates not only to donor health, but to maintain the donor base. We lose so many donors. And then there's the issue of additional, whatever you want to call it, wellness testing or additional markers of health status.

DR. BRACEY: I guess one thing I was thinking is that for the recommendation, rather than have us drill down into a lot of specifics for those areas, I thought that simply sublisting the bullets, I don't know how the committee feels, but the level of detail that we would have for the recommendation, I wasn't thinking that we would have a lot of detail on those subtopics.

MS. FINLEY: I'm comfortable with the way

that Jay outlined the questions and the tone in drafting. I think that from a policy perspective, that supports what we have heard and it doesn't over stretch what the evidence was that we have been presented with. It also, if you want to link it to Healthy People 2010, we've got -- we can do that through the adverse incident.

DR. BRACEY: Dr. Kuehnert?

DR. KUEHNERT: I just felt -- I don't know if this has already been covered, but if what was mentioned was three main topics, adverse events, informed consent and then this additional wellness -- sort of wellness screening. It seems like it's something that some blood centers are doing, but do we necessarily have to support or not support it? It seems like it's just something that is -- might be of benefit, but it's not something that necessarily I feel like we have to comment on that.

DR. BRACEY: Again, I was thinking that we might comment on the potential opportunity of such interventions. Again, unknown, whether there would be

gains, but actually in terms of one other subtopic, if we parsed out the wellness from that, that we must do, that is, we must measure the blood pressure, we must measure -- you know, et cetera. So, the wellness, it would be a set aside. Then there are the biometrics that we always collect.

DR. KUEHNERT: So, there are two issues here that I think is confusing. At least to me. One is trying to achieve some both individual and public health benefit from the things that all blood centers are already doing.

DR. BRACEY: Right.

DR. KUEHNERT: And then the other very separate category, are those things that blood centers are doing in addition that might be of benefit, might not even be, we don't know, and, you know, whether the committee should comment on that. I don't know. But, I think the first category is something, I think that's sort of only what we should comment on. But, the second one is little --

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: I tried to separate those.

That's why I was listing it as notification and management of adverse health information versus the things learned in the normal process. The big issue there is how do we react to it? What do we do with it?

I agree with Matt. That's separate from additional wellness measures that could be brought into play.

But, I think we haven't probed the sense of the committee. I don't know where the balance is here, whether people think that supporting pilots, for example, is an appropriate recommendation or not.

MS. FINLEY: I feel very strongly that we have not heard evidence about the ethical issues of supporting pilots. Certainly there's inherent conflict of interest in collecting units and needing to maintain and benefit donors and providing services to those same donors. I think there are issues that we need to pursue if you want to pursue a recommendation in that regard. I'm also extremely uncomfortable about the fact that incentives are clearly within the FDA's regulatory jurisdiction. It's been a long discussion

for many decades about incentives. And I'm not comfortable that this committee look at that issue.

DR. BRACEY: Dr. Epstein, follow on that?

DR. EPSTEIN: I'm sorry. I have to clarify something here. The issue of incentives focuses in the FDA regs on paid versus non paid donation. There's a broad area which I call the problem of undue incentives which is really not in the regs. It's something that concerns everybody, but that is actually not regulated. What we regulate is whether there is payment to a donor or whether there are compensations that are readily convertible to cash and for which there is a market. And then the consequence of that is the label of paid donation.

With source plasma, we don't require the label paid, but it's accepted to be paid. So, what you're really getting at, Ms. Finley, is that there is a concern whether we're trading off safety of the recipient for bringing in more donors through incentives. But, to say that it's purely a regulatory issue, I think it may be, but it's an ill-defined

regulatory issue because at the present time, going back to the seventies, we have only staked out a regulatory terrain over payment and convertible to cash, not over incentives in general. When we look at incentives, and when questions are raised about incentives, particularly in the whole blood area, accept payment like plasma, the only question that FDA asks is whether it's paid donation, meaning an exchange of cash or something readily convertible to cash. We don't otherwise ask if it's an undue incentive. Maybe we should and maybe that's another issue for another day.

MS. FINLEY: I agree.

DR. EPSTEIN: But, that's not where we are with this current regulatory frame work.

DR. BRACEY: Dr. Klein? And again, one of the points of the -- we really don't have information that there is the sort of gain of unsafe donors. What we're saying is that would be something that is in need of study. Because currently there are incentives that are applied as we speak. And we don't know what the

impact of those incentives are.

MS. FINLEY: I think that there are issues about -- as I recall, we were looking at this when I was on The Hill ten years ago, something about was one of the issues, one of the wording phrases thrown around in policy circles, well, it was thrown around by us actually, and there are things of value that are offered to donors. And there is a level of discomfort from that. I think that this is such an important issue that we should ask Executive Director Holmberg to convene this topic in our next meeting. I don't think we've heard the evidence to support a policy recommendation related to this including whether we need more study.

If we need -- the part that's missing in our briefing is the ethical part. We didn't address whether we're bringing people into the system with something of value versus a payment. And so I'm extraordinarily uncomfortable making solid policy recommendations to the secretary on that particular topic for that reason.

DR. BRACEY: Again, I wouldn't envision that we would make it a policy -- the recommendation would be to gain more information. As you're saying, we need more information. We're not sure the information is in existence.

MS. FINLEY: We can always ask for more studies. But, again, I would have felt much more comfortable with a presentation on the ethical issues of something of value, which we didn't have. I think it's an important issue. I'd like to write a better recommendation to the secretary on that particular issue which is, in reality, was a subtext of what we've talked about the last two days. I think we can go forward and I would just -- if it's just up to me, I would leave that out.

DR. BRACEY: Dr. Klein.

DR. KLEIN: I agree with Ms. Finley on this issue. But, I think there's no need to actually recommend pilot studies. As we have heard this morning and in part yesterday, there already are pilot studies going on. We certainly haven't seen the data, and as

we were told twice this morning, that the data are not yet substantial enough even to evaluate. So, I think we can and should point out that this is a potential opportunity or a potential downside that the studies are going on at this point in time, that perhaps should be evaluated by this committee in the future. We need not pretend that there be other studies initiated before we find out what's happening with the studies that are already ongoing.

DR. BRACEY: Dr. Triulzi?

DR. TRIULZI: We know approximately half of ABC centers are already offering the health screening. That's about a quarter of the nation's blood roughly. And if we're aware as a committee that this is being done, and we believe that there's a potential for test seeking behavior, we don't know, yes, we don't know whether it does or not. I think we're incumbent upon ensuring that these programs are done unlinked to donation. Because unless you can prove that it's safe, then the assumption is, until it is, you can't link that to donation. And so while this is going on,

whatever data we want to collect, I, frankly, am comfortable with being neutral about the whole health screening offering, but I do feel since we're already aware it's going on, I think that we should specifically, my opinion, specifically say that it can't be linked to donation until the industry has provided data that it doesn't result in test seeking behavior.

DR. BRACEY: Dr. Sayers?

DR. SAYERS: I agree with Dr. Triulzi that test seeking behavior is something we discourage. Bear in mind, test seeking behavior is not the exclusive concern of blood programs that are offering wellness programs, wellness opportunities. The reason I say that is this: More than 40 million people in this country do not have health insurance. We do not know that they are seeking out information about infectious disease, HIV in the blood program. Presenting themselves as a blood donor, but in the background, behaving as a test seeking individual. So, there are other indications other than cholesterol screens where

we could be concerned about test seeking behavior.

That's the one side of the coin.

The other side of the coin is, what evidence do we have that test seeking behavior currently actually is associated with a risk for transfusion recipients? I think the evidence of risk to transfusion recipients is so negatively small that it would be difficult, almost impossible to attribute specific risks to test seeking behavior given the low likelihood that there are, indeed, transfusion transmitted complications occurring at the rate that they do.

DR. TRIULZI: Can I respond to that?

DR. BRACEY: Yes. Go ahead, Doctor.

DR. TRIULZI: I think the difference is that the wellness screening doesn't add any safety to the recipient or the donor's donation process. So, any increased risk, without any benefit to the recipient, I think has to be questioned. And so I think that it's not incumbent about proving that test seeking behavior is not occurring -- I mean, you have to prove that it's

not occurring, not that we have to prove that -- assume that it's not an impact because there's no benefit to the recipient. There is no benefit to the donation safety either.

DR. SAYERS: We were probably talking about the same thing here. But, I would suspect that the best way to measure a downside to test seeking behavior would be at the level of likelihood of complication in transfusion recipient and I doubt we're going to be able to do that.

DR. TRIULZI: I don't think it's measurable. That's why we can just be done with the issue but just not linking it to donation and linking it to registration or presentation.

DR. SAYERS: Then all we have done really is given ourselves certain epidemiological impact. I think we will be losing the opportunity to really put the spotlight on what the opportunities offered to the individual to uncover whether he or she is at risk. And if we can do that without running the risk of criticism with this promotes test seeking behavior, I'd

like to think that we can find a way to do that.

DR. BRACEY: Let's hear from Dr. St. Martin.

DR. ST. MARTIN: I'd like to say I think this needs to be studied as a public health model for screening, for mass population screening, but not necessarily in context of blood donation. I think the issue is, does this really help the health of the population, not the health of the blood donor population or even to bring in more donors. I don't know that the outcome measures that were presented at this point really answer the question, does this help the overall population or not? Does it bring in more donors for us? Is this going to increase our donor base by five percent? We need to know, does this help the community's health?

DR. BRACEY: We do have a draft up. Let's hear from Dr. Kessler and then let's start going into the draft. I think that from the discussion that I hear thus far, we're pretty fixed on three of four broad topics. I may have missed one. One is clearly

the issue of the usual measures that we measure during the course of examination, the biometrics, hemoglobin, et cetera, how do we respond to those? The other is the issue of informed consent. And a third piece is the adverse separate, and sounds like there's less enthusiasm now to make any recommendation vis-a-vis health promotion. But, we'll discuss that further as we go through the draft. Dr. Kessler?

DR. KESSLER: I just wanted to say that if we do health screening, and we don't have funding from grants or something, if it's something that blood centers have to fund themselves, and eventually the grant money is going to run out, it's not something that we'll be able to fund to do unless the person donates. Don't forget, the unit is tested after the fact, and blood centers are not going to be in a position to just draw tubes of anybody who presents and to do testing from an economic point of view. And so that might be something that in the end, it will just die because we can't afford it.

DR. BRACEY: Let's look at the draft and

keep all these thoughts in mind as we work through it.

It's on the screen. There's the introductory piece describing the number of individuals that pass through the system. Actually, no, if you could start right there, yeah. Annually, approximately 10.5 million people donate blood or source plasma through manufacturers on multiple occasions.

You need to do a comma after donors -- after -- no, per se. So, if you could change longer to larger.

DR. EPSTEIN: Just a moment. I'm just adding in this text.

DR. BRACEY: So, here in essence we're talking about -- we're making a statement that there is -- we're sort of saying that there is the potential to advance the health of the donor population by virtue of the interface with our system. There was some discussion about whether we would want to actually make that statement. But, I think that's a reasonable statement to include. Is that okay with the committee?

MS. BIRKOFER: I guess my concern is, I'd

have to defer to my colleagues again in the appropriateness of including source plasma in the recommendation at all. Because as Josh Penrod pointed out, source plasma collection centers are for the sole purpose of collecting plasma for manufacture. They are not public health entities nor should they be under the regs. So, I don't know if Josh or Mary want to clarify that comment as to the appropriateness of including source plasma. I don't think it is, but I'm not the expert.

MR. PENROD: I think that the concern here basically is that, as I mentioned upon my presentation this morning, is that the system is set up for collection of plasma and is a component of a larger system that is set up to provide highly safe, high quality finished products. And certainly there are elements in common with some of the discussion here, but I think it's proper to recognize there's a fundamental difference in the system for the production of finished therapies.

DR. BRACEY: That's understood. I guess

what we're saying is that there is a potential assumed if there were some wide web of, you know, public health resource available, which there currently isn't. So, if you had an individual that had an abnormal biometric finding, we would not expect that you, the plasma entity, would manage that person. But, that person then might be referred. So, the potential exists for advancing the health even in that setting.

MR. PENROD: I understand. I think that relates back to, again, my apology for missing the discussion yesterday, some of the discussion that this committee had and some other parties have had regarding biovigilance issues, and as far as I understand it, and my colleague Mary is more the person, of course the folks from AABB, but that product is well developed at this point. So, I just don't know that I can give you an educated view, close to an educated guess, on where we are.

DR. BRACEY: What's the committee's feeling regarding plasma versus blood?

MS. FINLEY: I think the point is well

taken that's it's not part of the evidence that has been heard, and so it shouldn't be included. Second issue is, we cannot link this thing to broader issues on health care reform. We don't have the ethical presentations related to that. I'm very opposed to this. If you can find some way to get around that, we're good. I'm okay. I'm not comfortable with that language.

DR. BRACEY: Dr. Ison, then Dr. Epstein.

DR. ISON: I would take it a step further.

We have not seen any evidence to say these interventions are improving the health of these individuals.

DR. BRACEY: Can we go back up to the wording? Dr. Epstein, I'm sorry.

DR. EPSTEIN: Well, one point that's been overlooked in terms of impact incentive is that if it's real, it should affect market rates so that one can actually follow this. The question is whether the concern about the undue incentive is strong enough to want to prevent the pilot even recognizing that the

impact of the incentive can be monitored through effects on market rates. And again, I would reiterate that this is a very murky area because there are lots of incentives that blood centers dream up. And some of those kind of give us gastric acidity and some of them don't. And we don't actually intervene except to decide if they're equivalent. I agree with Anne Marie that we may want to look more critically at that whole paradigm. But, what we're really talking about is kind of a belt line question: How significant is the concern about an undue incentive? And I think that where some folks are coming from is, of course offering wellness testing is going to bring people in who are test seekers whereas others are saying, maybe, maybe not. And I don't think we really have a clear sense. Now, I think what we need to consider is Dr. Triulzi's point which is that it can't possibly contribute to recipient safety because it's testing above and beyond making units safe. I think that's what is leading Anne Marie to say it's an ethical concern. If you provide any incentive that won't improve safety, but might

decrease safety, why are you doing it?

But, the problem with that framework is that it also precludes trying out new things. And we find ourselves in this circle many, many times whereas we can't try it out because we don't know what the benefit might be and because it might cause harm. But, remember, it might also cause benefit.

MS. FINLEY: Okay. I could live with a combination of what you just said and what he just said, but not the broad statements that are here. I don't think the record supports it, but I can live with that. If you come up with some simple one or two sentences on that topic --

DR. BRACEY: I guess what I'm -- maybe -- we haven't specifically stated that there will be a gain. I mean, here it simply talks about a potential opportunity. I mean, we're not specifically stating that. To me, it doesn't seem so -- it doesn't stretch the issue. But, how do the other committee members feel? Ms. Birkofer?

MS. BIRKOFER: I'd like to refer to Dr. St.

Martin because my comment was off point to your question, Dr. Bracey.

DR. BRACEY: Dr. St. Martin?

DR. ST. MARTIN: I was just going to state it seems overly positive and overly optimistic. I think a better thing to say might be to -- just to state that current status is that several blood centers have embarked on programs to offer broader screening without -- it seems like it's giving a value there that may not be supported yet.

DR. BRACEY: Okay.

DR. EPSTEIN: I think you really need to look at the next sentence in context because I added a caveat in the sentence which is that -- could you just scroll down a little bit? However, the actual risk, benefits and cost effectiveness of specific interventions that go beyond the insuring the safe donation and safe effective products are not established. To me, it's the two sentences together because it's self evident that there's a potential opportunity there. I mean, of course, it's of

potential public health significance to offer cholesterol tests and to report back abnormal blood pressures and so forth. To me, that's self evident. It's just that the actual outcome, the actual effects just are not known. To me, I don't think you can read the two sentences in isolation. You put them together in the paragraph.

MS. FINLEY: Can you pull that into the second paragraph? Just make -- might be easier for policy makers to read.

DR. BRACEY: You'd like to break the lead statement --

MS. FINLEY: Would it be possible to obtain a copy of this just to read?

DR. BRACEY: We can get you a copy.

DR. EPSTEIN: Put a paragraph where the words start, at the same time, that's sort of the next section.

DR. BRACEY: Ms. Birkofer?

MS. BIRKOFER: Can we go to the top please of the recommendation or the answer to the questions?

DR. BRACEY: You want to --

MS. BIRKOFER: I want to see the first line.

DR. BRACEY: Actually, this is unrelated.

MS. BIRKOFER: Unrelated, so we'll stop abusing ourselves. So, again, if you have approximately 10.5 million people, and you're saying donate blood for transfusion or source plasma, first of all, if you're going to include source plasma, the number is obviously low because Mr. Penrod noted in his presentation 15 million source plasma donations. So, the number is wrong.

DR. EPSTEIN: That's not donate --

MS. BIRKOFER: Again, go back to the point on removing source plasma. It's not appropriate. Even if you look at the potential, Mr. Penrod already said that the physicians or the people on-site at the plasma collection center refer. Period. They already refer into the health system to the appropriate treater. That's it.

DR. BRACEY: But, that referral represents

a potential gain in health.

MS. FINLEY: With a potential conflict of interest. I'm sorry. I'm not finding ways to get around this.

DR. BRACEY|: How does the rest of the committee feel vis-a-vis the question of plasma inclusion versus exclusion?

DR. POMPER: I'm noticing that we have -- I agree, we have seen no data presented on plasma donation. In fact, it's all -- correct me, please, all the information presented was from the nonprofit sector. And yet I don't see, I have not heard the inclination to study this process on the industry side. So, I agree there's no data to make any statements about that. And I also don't see any -- I can't anticipate that we would see any in the future suddenly the effects of donation on that side of things. So, we're actually left with a paucity of information that --

DR. BRACEY: Dr. Klein?

DR. KLEIN: It just seems to me that to

point away from blood donation, as a public health official, forgetting for the moment that I also collect blood, that the opportunity to study and help potentially ten and a half million people, more than 40,000 relatively healthy individuals a day passing through facilities that are capable of doing something is an opportunity. And that's all I see. It may turn out that one could do something that would be remarkably good for the US public health. Maybe totally neutral, or may turn out to be very expensive and not worth the time.

But, I think we would be remiss if we didn't recognize that this is almost -- it's certainly singular, if not unique, in the United States that you would have this many healthy Americans who are interested in being stuck by a needle and seeing a medical personnel. And there are opportunities there, whether we wish to recognize them or not, I think we ought to comment on it.

DR. BRACEY: Okay.

MR. PENROD: I did want to make sure that

it's clearly understood that there was not an underlying study, it's the fact that we didn't have time to cull any data out. It's not in my presentation. There's not a paucity of information.

DR. BRACEY: So, the consensus first of all, the question is, is the language -- I think reading it in its context, the caveats are there. The opportunity, I think, is recognized. We have the question of the specificity of the point of interaction, whether it be donor, blood donors or plasma donors, and in honesty, I think that the information that we need -- would need to gain, would be sufficient if it were only on the blood side. And I have no particular compulsion to include the plasma side. But, I'll open that up for discussion from the committee. How does the committee feel about that?

DR. POMPER: Fine either way. Just the question included plasma.

DR. BRACEY: Good point.

DR. ISON: I think the other thing that we need to hit on is this introductory statement that

includes both is then followed by some of the other issues which actually do apply to the plasma community, risk with recurrent donation. So, I mean, that -- I think as written, I agree we need to make sure the numbers of donors is appropriate and accurate, but I think the sentence needs to include both.

And then, even though the plasma community isn't doing this or isn't looking at a health promotion, if it was something that was a significant benefit to the healthy population, then maybe it would be something down the road. So, I don't think we should exclude them specifically from this especially since we're not recommending that they have to do this.

DR. BRACEY: So, then there is consensus --
Dr. Epstein?

DR. EPSTEIN: I think we ought to, at this point, just make sure we've got the numbers right. First I'd like to suggest that we add the word allogeneic. What I did was take the 9.5 million allogeneic donors, and I added approximately one million source plasma donors. We have industry here,

you can clarify whether you think it's one million, 1.2, whatever, we'll use your number, but what I did is historically used one million donors donate between twelve to 15 million source plasma units per anum. So, I think we should correct the figure and I would definitely add the word allogeneic in there because that was the number I used. Any other comments?

DR. KUEHNERT: Can you just say about ten?

DR. BRACEY: Approximately.

DR. KUEHNERT: Round up.

DR. EPSTEIN: We have experts here who can tell us the right number.

DR. BRACEY: Ms. Birkofer? What is the right number? Oh, here. Mr. Penrod?

MR. PENROD: Thank you. Again we don't have the complete number. I suspect that Dr. Epstein's estimate is fairly close. We have track total donation numbers. Generally speaking, the amount of donors at given plasma center systems, plasma collection systems, is considered competitive information. So the trade association and other companies don't really express

that number to us because quite frequently plasma collection centers are in competition with each other in localities. So, I get questions from reporters all the time, very interested in knowing these numbers, but we don't know. I suspect that Dr. Epstein's estimate of a million is right. The number may range 800,000 to over a million, around there. And donation frequency can vary widely. So, I suspect that ten million plasma donors is not out of the realm of ordinary.

DR. BRACEY: So then perhaps we round -- is it okay if we round it to make it ten million? That's a depressing number. We would -- again, we would include plasma and blood collection because, again, this is not mandatory -- we're not making mandates.

DR. EPSTEIN: As far as to insert the word allogeneic --

DR. BRACEY: Allogeneic, good point, to separate out the -- let's pan down a bit. We have separated out the paragraph, and so then it goes on to state that the following issues warrant specific consideration. Event reporting in donors, informed

consent and we have broken out pieces of injury, iron loss positive test, donor notification of follow-up with adverse events and medical findings. Oh, yeah, so we have iron status as a separate piece because of the concerns that we have heard in the session. Can we modify that a bit? Do we need to be that specific? Can we just say iron status in donors?

DR. KOUIDES: What about syncope in the younger population?

DR. BRACEY: I think that's under donor notification and follow-up adverse events.

DR. EPSTEIN: What I envisioned was one or two sentences under each of these headings. If our approach here is telegraphic, then I think we ought to mention a few more particulars. And then, you know, being those are the general statements, we haven't figured that out whether we support further studies, some favor some don't study pilots, et cetera, et cetera, and we have added a statement that suggested that recognizing studies are ongoing. But, I think we should decide whether we're elaborating each of these

points or just making them telegraphic. I was only listing them.

DR. BRACEY: I guess my thought was more telegraphic, but I need the committee's sense.

MS. FINLEY: Telegraphic. We'll be here all night.

DR. BRACEY: Okay. Yeah. So, is the committee comfortable with telegraphic?

MS. BIRKOFER: Yes. Please.

DR. BRACEY: We do have the issue of wider health screening. So, part of the discussion has been that, you know, we haven't seen extensive data. These -- well, actually these are ongoing. So, really we do want to focus on undue incentives. So, we would leave that in because we would really need to know what the impact of these incentives are.

DR. POMPER: If it's just going sort of telegraphic, we should have something about women and men and hemoglobin. That's part of that data that was reported by two different sources. Seems fairly consistent. So, there was some interest in, at least,

highlighting that there are differences.

DR. BRACEY: So, perhaps not to much related to -- in a sense, that's in part related to iron status --

DR. POMPER: Little more detail. Just say iron deficiency.

DR. BRACEY: So, you would have anemia, donor anemia?

DR. POMPER: Donor anemia relative to gender.

DR. ISON: Or even consider reevaluation or at one point for exclusion based on hemoglobin.

DR. BRACEY: Reconsideration of donor acceptance based on gender specific hemoglobin? That would be gender specific.

DR. LOPEZ-PLAZA: Again, are we -- what's the intent of this? Is this intent of actually providing that therapies as service to the donor? So that would be -- number 2 is, by just stating that, are we going to conference in here? Because I mean, what do we really want to do with that? We think that the

donor centers can help with the healthy patient or healthy person kind of program? Should we just not focus on the screening, but all their activities that they can have?

DR. BRACEY: You're speaking in terms of education?

DR. LOPEZ-PLAZA: Yeah, education. I mean, I think that screening is one of many ways, but again, there's a lot of content in here regarding increase the blood safety. Just because of, you know, maybe some donors might be seeking the testing just because they don't have money to pay for that testing. And then again, I think the donor centers are -- have a very unique position where they really can reach out to the community. And we're just screening donors. We're only doing screening probably less than 10 percent of the total population. I think if they do those activities, I think that there's more than just screening that they can do. Maybe we present it that way and would not be that much of an ethical issue. Because I'm very concerned that when we start doing

this kind of screening, are we going to donor physician by primary care physician? That's a big issue.

DR. BRACEY: Right. Again, but what we're doing here, we're being telegraphic. So, under wider health screening, that actually could incorporate the community.

DR. TRIULZI: I had suggested under wider health screening. That we have heard we have a currently beneficial effect on donor base, which I believe means the number of donations. So, beneficial effect to donation, then we want beneficial effect on donor health, which is what Dr. St. Martin brought up and mentioned the number of donations. The outcome doesn't impact donations, does it impact donor health? And I think those are the three major issues that we discussed.

DR. ISON: One other thing we haven't talked about is, is there a downside? If you test one that doesn't have insurance, you show hypertension, is that going to limit their ability to receive treatment or increase the cost of their insurance if they are not

insured by themselves? We haven't heard that. My understanding is it could have an impact even if it's delayed. So, we actually may be worsening the ability for these individuals to access health care by doing this screening outside of a standard health care process. I think that there's a lot of issues here that we haven't even gotten into.

DR. BRACEY: That's a good point. So, we can perhaps put in unexpected adverse outcomes associated with findings -- positive findings.

DR. ISON: The one issue that I was just going to bring up before, although this is very efficient to do the bullets, will the secretary understand? He hasn't been able to listen to our entire discussions. Just hearing these bullets, is he going to understand what we mean by this or do we need to put a sentence or two in with each point?

DR. HOLMBERG: Good question. I was going to say that collectively within the public health service agencies, we will probably be responding to some of this, but it would be helpful if there were

some sort of descriptors behind it. I think it would give a lot more clarity and stand alone. Once, again, you have to remember that these recommendations go up on a website, others are going to view it. I think we need to be clear on it. We don't need to have a lot of verbiage on it, but we do need to be clear.

DR. BRACEY: Comments from the floor?

UNIDENTIFIED PARTICIPANT: A potential downside, and I don't think this has come up at all, but blood centers and plasma centers are highly regulated GMP manufacturing facilities. And I would worry about diluting the primary mission of these facilities, particularly when you talk about wider health screening of communities. And the fact that we are not -- they're not health clinics. We're not free health clinics. They're regulated manufacturing facilities. There's only so many things you can do as a GMB. And I worry about having these broad initiatives, reach out to the community. We can't forget our primary mission.

UNIDENTIFIED PARTICIPANT: I'd like to also say, and follow-up with some of what's been said, having heard the conversation, what would this mean to someone, and my focus is on compliance and regulatory rolled up in just a couple of lines. We're saying to the secretary that there is something that warrants attention to me means there are problems that warrant the secretary's attention. The very first thing we talk about -- just one or two lines under adverse event reporting, I don't think -- is donor event reporting? I don't think it's -- donor event reporting is regulated. There's standard regulations. It sounds like there are reporting events that are going unreported. I think the way it is phrased, will the secretary not having heard these discussions and know what we're talking about, it's a great concern to me. As I read the paragraphs that are there now, I also think, AABB doesn't have a policy -- obviously a number of members make its own decisions, these are local decisions about doing additional things geared toward safety of donation process with the donor and say to

recipient safety, there are things -- just the way it's worded here is what I have concern about.

DR. BRACEY: So, part of the issue is whether we would have greater specificity and sort of a broad -- broad sweep? Clearly, greater specificity will be fairly time consuming. It could be done, but I would not want to -- I think that creating greater specificity if it's in haste would not be a good idea. So, the question is, if we submitted a statement to this effect, without specificity, would it still be useful to the secretary? So Dr. Holmberg? What are your thoughts? We do have the option -- we do have the option of working this through in the sense of a subcommittee, if you wanted to have greater specificity. But, I think the key question is whether if we had a telegraphic response, whether it would be useful.

DR. HOLMBERG: Well, once again, I think that for the clarity of whoever reads this, including the secretary and all those people in between including the individuals that may read it from the web, I think

that it really needs to have either a sentence or two behind each statement to give the indication of the committee's thought.

DR. BRACEY: I hear a move to request for greater specificity? Dr. Klein?

DR. KLEIN: I think Dr. Epstein's original suggestion, if you put down three or four of the issues, and then explain what they are, what is the issue here, because I suggest that probably looking at the lines that we have telegraphed here, probably no more than three or four people on this committee would agree with what each one of these meant or what we meant by them, let alone someone who hasn't sat through the day and a half of discussion. So, I think we need to discuss in pithy fashion what the issue is in event reporting in donors, what the issues are when we identify informed consent and set it up.

DR. BRACEY: Okay. Other comments?

MS. FINLEY: I would include a line under wider health screening a question, mission dilution and conflict of interest. Question mark to address the

issues that we have discussed.

DR. LOPEZ-PLAZA: First event, adverse effects of that like --

DR. BRACEY: Dr. Lopez-Plaza is saying we can put unexpected adverse outcomes. In other words, there could be unexpected?

DR. KLEIN: Once again, I think you're going to have to explain that. Just putting those down there, no one is going to understand what that means.

DR. BRACEY: And then we also, as another bullet, mission dilution and what was the rest?

MS. FINLEY: Conflict of interest.

DR. POMPER: While we're adding bullet points, cumulative effects of repeat donation. Just anywhere on the list.

DR. BRACEY: Right. That would go up under adverse informed consent.

DR. POMPER: There could be adverse effects.

DR. BRACEY: Actually, it would --Would you make that a separate bullet? You want to restate it,

Dr. Pomper?

DR. POMPER: Just cumulative effects of repeat donation.

DR. BRACEY: Dr. Holmberg?

DR. HOLMBERG: Since we're just putting thoughts down for right now, and I do hope the committee expands upon these, but the thing is, I think what's impressed me when we've heard this morning about informing the patient -- or I'm sorry, informing the donor of positive tests, I would like to at least be specific on some of that to emphasize the sickle cell testing. I was really taken by the fact that not all blood centers give that to the donor, sickle cell.

MS. FINLEY: There is also, pointed out by Dr. Holmberg, one other additional recommendation at the top about lost --

DR. BRACEY: We're not going to lose that. I think what I am going to do right now.

MR. MATYAS: To that point, Dr. Holmberg, is putting that in as the bullet right now that says donor notification and follow-up with that person about

medical findings, putting in a little more specificity on sickle cell?

DR. HOLMBERG: I think it's up -- next sentence up or next bullet up, positive test, informed consent, that they will get their result if the donor is tested.

DR. BRACEY: We'll expand on that. That will be an expansion.

DR. HOLMBERG: I just don't want to lose that thought.

DR. BRACEY: So the question in terms of the process, do we want to flesh this out now or later? What are the committees' thoughts about fleshing it out now?

MS. FINLEY: I would strongly encourage the committee to flesh it out now because people are going off, it's the holidays, to give ourselves one hour to do it now or we can pull into sub groups and do it. But --

DR. BRACEY: Why don't we do this: Let's look at the major bullet points then. So, let's break

into -- let's break into -- is the committee okay with breaking into subgroups to address the specific areas?

So, even reporting, should we have -- let's have a quorum of four? Who wants to do event reporting?

MR. MATYAS: There's seven main bullet lines.

DR. KOUIDES: Standard groups? You want to call --

DR. BRACEY: Do you want to do it in lots?

DR. EPSTEIN: My suggestion here, it's a much slower process to work de novo as the committee as a whole. I think we'll move faster if we break for half an hour and get a candidate to etch each bullet. I don't think that's an undue sacrifice of our available time and think it will move us more likely to the end.

DR. BRACEY: Let's organize into groups then. Event reporting? No more than four.

DR. HOLMBERG: Ison, Haley.

DR. BRACEY: Informed consent? I'll volunteer for that. Cumulative effects of repeat

donation? Of donor hemoglobin based on gender specific hemoglobin? Actually that's very specific.

DR. ISON: It just probably needs to add a sentence that shows data was presented.

DR. BRACEY: Let's not do this. We'll just put a sentence on that.

DR. HOLMBERG: Who's doing cumulative effects?

DR. BRACEY: Dr. Pomper and Dr. Ramsey. Donor notification of adverse events? We need a volunteer. Mr. Matyas? Anyone else? Dr. Ison, are you committed? Ms. Benzinger and Mr. Matyas. Donor iron status? Iron status?

DR. ISON: Can't that just be combined with informed consent?

DR. BRACEY: Yeah, we'll lump that into informed consent. Wider health screen?

DR. KOUIDES: Cumulative effects would also be fine.

DR. BRACEY: Wider health screening?

DR. TRIULZI: All four sub bullets?

DR. BRACEY: So, you have those names?

DR. HOLMBERG: I think so. It appears that we grouped them into event reporting, informed consent and wider health screen?

DR. ISON: No.

DR. BRACEY: No.

DR. HOLMBERG: Because we have the separate groups for informed consent is Ison, Haley and Benjamin and we went to donor notification. Donor notification, we have Bracey --

MR. MATYAS: I had to step out for minute. Difference between event reporting donors and donor notification and follow-up of adverse events and medical findings? How are those different?

DR. EPSTEIN: Event reporting relates to aggregating national data.

MR. MATYAS: I understand. I just see them -- it's a sequential string of events. It's reporting on both individual basis and then a national basis?

DR. BRACEY: I guess the one implies a

larger aggregate data, the other is how you actually manage the individual themselves. So, do we have the groups? The groups are unclear?

DR. HOLMBERG: If everybody knows where they're going, that's fine.

DR. BRACEY: Let's go back over this again. We have event reporting.

DR. HOLMBERG: Even reporting, Ison, Haley and Benjamin. Then we have informed consent was Kouides, Bracey and Duffell. Then the accumulation effect was Pomper and Ramsey.

DR. BRACEY: What about donor notification?

DR. HOLMBERG: Donor notification was Matyas, Anne Marie. And do you want to go in on that one?

DR. BRACEY: Okay.

DR. HOLMBERG: I don't have the reorganization of donor acceptance.

DR. BRACEY: We were going to skip that.

DR. HOLMBERG: Okay. Iron status I don't have.

DR. BRACEY: We're putting that in informed consent.

DR. RAMSEY: There's the informed consent issue itself. Then there's various complications of donating which are maybe in need of separate attention aside from the issue of donor consenting.

DR. BRACEY: Right. But, we were going to just lump that together for the group.

DR. RAMSEY: Under the issue of informed consent, not under the issue of donors' iron testing? We should look at separately -- I just don't want to lose the intent of the committee.

DR. BRACEY: We would let that group make a recommendation.

DR. HOLMBERG: Who's doing wider health screening?

MS. FINLEY: I am.

DR. BRACEY: Epstein, Triulzi, Finley. Anyone else? All right. So, now we'll break into groups for about half an our.

DR. HOLMBERG: What about Dr. Klein?

DR. KLEIN: I was writing the hemoglobin one.

DR. HOLMBERG: Very good. Thank you.

(A pause in the proceedings.)

DR. HOLMBERG: Committee members, can you please come back to the table?

DR. BRACEY: All right. Committee members, please return to the table. We'll go over the detail of the recommendations.

DR. HOLMBERG: As the committee members are coming back to the table, I do want to make the comment concerning the Federal Advisory Committee Act. The Act rules do give us permission to breakdown into small groups, working groups or even subgroups. In fact, subgroups are permitted to even meet by way of phone and reconvene later. The stipulation that is provided in the Federal Advisory Act is that anything that is discussed in smaller groups has to be related back to the larger group and no decision is made by the smaller group by itself.

So, in other words, collectively,

everything has to be aired in open forum with the full committee hearing the comments. And so your decisions today, as far as your reports of these ideas will be presented to the total group, and any voting will be done as a total group and not as a subgroup.

DR. BRACEY: Okay. So, we are about a little less than five minutes from being able to post this. So, we are just waiting.

DR. HOLMBERG: What I would suggest is that we start discussion while this is being typed up, if we can start some thoughts.

DR. BRACEY: Well then, which was the first group in order?

DR. HOLMBERG: Event reporting was Ison, Haley and Benjamin.

DR. BRACEY: So, who would be the reporter? I'll tell you what. Let's go to informed consent which is my group. So, actually, under informed consent, what we did, as you will see, is we pulled out a large part of the recommendation that Dr. Pomper put together to emphasize the fact that there is no standardization

as far as the process or the content, and that raises some issues. And what we highlighted as specific issues what we felt warrant being addressed are elements that we heard about in this meeting. The risk of donation on repeated donation period. The risk of donation with respect to iron deficiency in women. The risk in the 16 and 17 year old donor group vis-a-vis the risk of the ten percent syncopal episodes, the one in 2000 risk for injury. And then, finally, the risk related to accepting men who, in fact, are anemic on presentation. Those are the specific four bullets that we highlighted.

DR. EPSTEIN: Sounds good to me.

DR. BRACEY: So then the next group would be the group that addressed donor notification.

DR. HOLMBERG: Can you sort of give us the summary of discussions?

MR. MATYAS: You're making me read my own handwriting.

MS. FINLEY: That is a problem; isn't it?

MR. MATYAS: It's phased kind of as a

question of whether further standardization is needed on the manner in which the extent of donor notification of medical findings after blood and blood products are tested. By way of example, should notification be done electronically, telephonically, or a method chosen by the donor. What categories of test results are required to be communicated to the donor, e.g., sickle cell and should follow-up questions be incorporated into the donor questionnaire when a donor returns after medical findings are identified? That's kind of where we were.

DR. BRACEY: Any comments from the committee? Okay. Then the we actually -- we have the draft up. With a warning. So, we have reviewed the general statements and so now we can look at the specific additions. So, under the consent piece, again, while parent status for informed consent for blood, you can read it, we recognize opportunities are -- there's no consistency with regional variation. So, then specifically as a minimum, the known risk of the donor -- at a minimum, the known risks of donation

are disclosed because currently there is informed consent and the known risks are disclosed. But, the scope of information -- the scope of informed consent might be expanded to consider --

DR. KOUIDES: Can we say should be expanded?

DR. BRACEY: Yeah, should. Should be expanded to consider the effects of repeat donation of general donor population. Effects of iron deficiency in women, the effects of collecting blood, which should say of collecting blood from anemic men using current donation thresholds, its effects on young donors, e.g. approximately 10 percent prevalence of syncopal episodes of 16 to 17 year olds, one in 2000 risk with need to mitigate that risk.

Then we also added a piece that I forgot which is the medical frequency of effective informed consent for repeat donations. Comments?

MS. FINLEY: It's says effects on iron deficiency. Iron deficiency on women donors? Is that what you're trying to say?

DR. BRACEY: Yes.

MS. FINLEY: Also put of instead of on.

DR. BRACEY: The second bullet, the effects of iron deficiency -- no.

MS. FINLEY: On women donors.

DR. BRACEY: We were particularly concerned about women related to the data. I mean, it was a real target group. You think they should have it more broad?

DR. TRIULZI: Restless leg syndrome, neurocognitive effects, it doesn't matter whether it's --

DR. EPSTEIN: I suggest gender specific effects of iron deficiency in women and men.

DR. BRACEY: That's good. So, the gender specific effects of women and men donors. By gender. So, that's what we had to offer under informed consent, in terms of questions.

DR. LOPEZ-PLAZA: If you're going to say gender specific effects of iron deficiency, should the next bullet be under that or not?

DR. BRACEY: Well, actually, this may or may not be related to iron deficiency. We were thinking that this could be studied here. We don't know. A lot of men are anemic.

DR. TRIULZI: So, you're considering 12.5 as anemic?

DR. BRACEY: Correct. Correct. So, then that's what we had to offer. The next group then would be -- actually, did I we hear from event reporting?

DR. ISON: No. That it's up -- we can --

DR. HALEY: Do you know where ours is?

DR. ISON: It's on a separate sheet.

DR. BRACEY: Do we have it?

DR. ISON: I don't know where he put it.

DR. BRACEY: So, do you want to walk us through this, Dr. Ison?

DR. ISON: Sure. So, basically what we discussed is that the published data suggested that there is disproportionate rate of adverse events in certain donor subgroups and that our recommendation is that national adverse event collection, correlation and

reporting using standard definitions as well as research on specific interventions to mitigate risks that should be considered. We weren't specific about, you know, whole blood versus group source plasma.

DR. HALEY: We were thinking that this is already going on in the U.S. biovigilance committee which includes the plasma centers. They are working on standardizing definitions, standardizing methods, and standardizing approaches. So we did not think that anything new needed to be invented. We just needed to support their efforts.

DR. TRIULZI: At least support it as opposed to consider it. Just the fact the office does support that effort?

DR. ISON: Yeah.

DR. TRIULZI: National biovigilance is supported.

DR. BRACEY: So, we'll make that change.

DR. HOLMBERG: Can you change consider to support? Last word?

DR. EPSTEIN: I think the thing that we're

supporting is efforts to develop a comprehensive national reporting system for donor related adverse events. Because here what we're focusing on is subsets. But, the bigger picture is that they don't yet have a national system for event reporting. You want to highlight the need for a national system for donor event reporting which is really not being involved. That's part of the AABB agenda at the home. But, it's really not part of the HHS agenda at the moment.

DR. ISON: Part of the reason I phrased it this way is we were told, although I did not get that impression at all during the discussion today.

DR. HOLMBERG: The initiative of AABB is really a joint initiative with HHS underwriting the development of that. And so it's a task force within AABB, but they hope to be ready to roll out a pilot by the end of March.

DR. TRIULZI: I think it would be useful for the committee to basically confirm for the secretary that, yes, we believe there are monies being

spent in a value way.

DR. ISON: Should we add an additional statement as well that basically reiterates the fact that it's important for both whole blood and plasma?

DR. BRACEY: Plasma?

DR. EPSTEIN: Again, my suggestion is the committee supports existing efforts to develop a comprehensive national reporting system for donor adverse events. You can say for blood and plasma donor adverse events.

DR. BRACEY: That would go following the first piece or after the first sentence?

DR. ISON: To replace the second sentence.

DR. BRACEY: The committee supports efforts to develop?

DR. EPSTEIN: Well, let me -- to develop a comprehensive national reporting system for blood and plasma donor related adverse events.

DR. BRACEY: That covers both events? The one that's ongoing?

DR. EPSTEIN: Strike the next sentence.

What it completely overlooks is that whole dilemma about what should be mandatory and maybe we don't want to step into that at the moment.

DR. ISON: We talked about that. We specifically side stepped the mandatory.

DR. EPSTEIN: That's where the real issue lies because this is already happening, but, remember, it's happening principally in the aggregated reporting. So, I don't think that's really a dilemma.

DR. BRACEY: I feel comfortable with what we have.

DR. EPSTEIN: All right.

DR. BRACEY: Let's go down to the next bullet point, sub bullet point, which would be donor notification. That's right?

DR. HOLMBERG: Do we donor notification?

MR. MATYAS: It's on the other screen where that one sentence was?

DR. ISON: On the other page that you got the last segment from.

DR. BRACEY: Mr. Matyas, you want to cover

that for us?

MR. MATYAS: Again, I think it needs to be reformatted the way the others are, but again, it reads whether further standardization is needed on the manner with which an -- and extent to which donor notification of medical findings after blood and blood products are tested, by way of example, should notification be required to be provided electronically, telephonically, or by any method chosen by the donor? What categories of test results are required to be communicated to the donor, e.g., sickle cell, when the donor returns to a center to follow-up questions related to test results to be incorporated into the donor questionnaire?

DR. BRACEY: Comments from the committee?

MS. FINLEY: I believe that what you mean up there is not blood, blood products, but blood donations, blood and plasma donations.

MR. MATYAS: Yes.

DR. EPSTEIN: Wait a minute. According to the regs, it's the donor you test. You may take a sample of a collection, but the donor suitability is

established by the test on the donor.

DR. BRACEY: So, after blood donor testing?

DR. EPSTEIN: Do we want to say blood and plasma donor testing? But, it's not just the testing because I thought we were also concerned about blood pressure and pulse, medical history.

DR. BRACEY: Good point. Evaluation and testing?

DR. RAMSEY: Notation after blood donation.

DR. EPSTEIN: After donor evaluation. I guess the product testing comes in because the platelets and bacteremia, so we could leave it in there. But, we shouldn't overlook that it's donor testing and product testing.

DR. HOLMBERG: After medical evaluation and blood donor testing?

DR. BRACEY: Right. So, it would be after medical evaluation, blood and blood donor testing.

DR. EPSTEIN: And donor and product testing.

DR. BRACEY: So -- and blood and donor

testing?

DR. EPSTEIN: It's blood testing -- that donor testing and product testing really is what it is.

DR. HOLMBERG: Put a comma after evaluation. Get rid of the and.

DR. EPSTEIN: The other way to get out is donor suitability determination and product testing because donor suitability includes all the things that you do. It even includes the medical findings.

DR. BRACEY: That's a better.

DR. EPSTEIN: So, blood donor suitability, testing and donor notification of medical findings after donor suitability determinations and product testing?

DR. BRACEY: Go back. Just wipe -- so donor suitability after donor suitability evaluation instead of medical evaluation. After donor suitability evaluation and product testing. And then you can strike the piece in red.

DR. RAMSEY: Doesn't seem like this clause is actually a sentence. There is something missing in

the format of the sense. Doesn't matter. See, there's no object of this clause.

DR. EPSTEIN: It was because it was introduced following issues requiring consideration by the secretary, bullet whether X, Y, Z.

DR. RAMSEY: You said manner in which donor notification after suitability evaluation. So, I've --

DR. EPSTEIN: Take the the word --

DR. RAMSEY: After donors notified, there's something wrong with the English somewhere. Medical findings performed after something needs to be in there.

DR. EPSTEIN: After the product testing, just add the words is performed.

DR. BRACEY: Further comments?

DR. RAMSEY: Donors are notified of medical findings? Which donors are notified of medical findings?

DR. BRACEY: Where is that?

DR. RAMSEY: Well, replacement of donors are notified?

DR. BRACEY: Okay.

DR. EPSTEIN: Take out is performed.

Further standardization is needed on the matter ...

Okay. Further comments?

MR. MATYAS: I'm sorry. Go to the heading.

We kind of really -- we thought that adverse events were being discussed by another group. So we really did follow-up of medical findings, not of adverse events.

DR. BRACEY: That's a good point. So, scratch adverse events. Findings. So, let's move on then to the next item which would be wider health screen. Dr. Triulzi?

DR. TRIULZI: So, wider health screening is an introductory sentence, so the secretary understands why this is a bullet, and so the committee heard statements from blood centers engaged in public health screening measures beyond those required for donor/recipient safety. The following issues/concerns arose from committee discussions on this topic. So, the first is mission dilution/conflict of interest.

Blood and plasma collection establishments have a primary role of manufacturing safe blood products. A risk exists that an expanded role to provide donor health screening unrelated to donor safety could result in a compromise to their primary function and could present an ethical conflict with their core relationship with the donor. In addition, absence of standard practices in this area could have negative effects on blood center competition. Meaning small members that don't have the resources to do this can't offer it, other donor centers could offer.

Second bullet, unexpected adverse outcomes.

Although the results of public health screening may alert the donor about a possible health risk, the results of such testing could potentially affect donor access to insurance or employment or unexpected cost for further medical evaluation.

DR. ISON: I think this is great.

DR. TRIULZI: Undue incentives. Public health screening programs by blood or plasma centers may create undue incentives for unsafe donors who are

test seekers given there is no benefit and safety to the recipient or donation process. Any such incentives should be avoided.

MR. MATYAS: To say avoided or to be further examined?

DR. ISON: I think that statement goes a little bit too far. And, you know, we haven't said that this should be avoided, we have said that it warrants further investigation.

DR. TRIULZI: It's almost unmeasurable. It's almost unmeasurable to say that the risk Hepatitis C is double.

MS. FINLEY: Though it should be very carefully evaluated.

DR. TRIULZI: So, the question is whether to -- it's a tough issue. Jay brings up, well, we've never proven the teacher could do that either or raffle tickets, or a whole number of other incentives. So, why treat this one different? I'm fine with carefully evaluated.

DR. DUFFELL: I wouldn't use the adjective

careful. You're insinuating by that word that it's somehow or another may not be.

DR. TRIULZI: You think just the word evaluate?

DR. DUFFELL: Just simply evaluate.

DR. BRACEY: Let's go back over that again. So, undue incentives? I guess the -- I guess my comment is that -- the negative attributes are well laid out. And should there be -- is a balance. So --

DR. TRIULZI: The magnitude of benefit being proposed for this, to my mind, is really different than a teacher or -- I mean, here people are paying 79 or \$89 for this. So, you can really kind of say, we know the value of this is and this is, you know, a magnitude difference than a mug a key chain, a t-shirt.

DR. RAMSEY: It gets back to community safety. Most discussions always do. It could be safety or availability or safety versus availability. But, safety and availability is two sides of this coin.

DR. BRACEY: Other comments on this

section?

DR. KLEIN: The benefits? Have we discussed that yet?

DR. TRIULZI: That's coming. So, beneficial effects on donations, beneficial effects on donor health, so those two are put together within a simple statement, that presume beneficial effects on the number of donations or donor health are desirable, but unprovable.

DR. BRACEY: Comments on that?

DR. ISON: Again, it's coming a little too negative in my opinion.

DR. BRACEY: Right.

DR. ISON: It's fine to do it the way it is or warrants further study, something along those lines, because this is really, in my way of thinking --

DR. BRACEY: I guess that was my concern.

DR. KOUIDES: There are potential benefits both to the donor and to public health.

MS. FINLEY: But, we can't quantify that.

DR. KLEIN: We can't quantify that.

MS. FINLEY: You want money to study the
NIH --

DR. KLEIN: I'd love that.

MS. FINLEY: Every recommendation can't be
we need to study stuff. I have no problems putting
that -- including that.

DR. TRIULZI: You want to say are desirable
or need to be studied?

MR. MATYAS: Why don't you just use the
same language, should be evaluated?

MS. FINLEY: Evaluated. Great.

DR. KOUIDES: There may be a role of a
blood center donor center if ongoing data demonstrates
increased the donations?

DR. BRACEY: Well, I think maybe we should
just focus more on the need for more data.

DR. POMPER: Are desirable. How about may
exist or improve? Just are desirable, I don't know
what that says.

DR. KOUIDES: Mean it's worthy of further
study?

DR. POMPER: I don't want to be imprudent, but I think there is some study out there and I think there is some possibility, more than just wishful thinking.

MS. BENZINGER: They offer the opportunity for preemptive --

DR. BRACEY: So, what if we -- so what if we strike -- I guess the presumed beneficial effects, I mean, it almost seems possible beneficial effects?

DR. TRIULZI: That's fine. If that word is ringing.

DR. BRACEY: That word is ringing. So, the possible beneficial effects on the number of donations or donor health are desirable.

MS. FINLEY: I don't have -- first of all, did we hear anything that says they may exist? I don't think we did. We didn't hear anything that said any evidence from the presentations that they truly exist.

DR. BRACEY: I think if you find individuals that are under the age of X, Y and Z and have cholesterols greater than 200, there are possible

beneficial effects.

DR. TRIULZI: I thought there was reference to donation and potential benefits of iron --

DR. BRACEY: Yeah, there is.

MS. FINLEY: So, we can state that.

DR. BRACEY: We're not talking about screening. We're talking about wellness screening, not necessarily donation.

DR. POMPER: Sorry. Okay.

DR. EPSTEIN: Our issue gets a little complicated here because if you see it as wellness testing, different from avoiding negative effects of donation is two different things. There are programs that in the U.S. and outside the U.S. that have shown unequivocally that you can maintain donors better if you monitor and give iron.

DR. TRIULZI: That might take us outside the scope of what this is talking about.

DR. BRACEY: We're trying to focus more on the wellness --

DR. TRIULZI: Unrelated to donor.

DR. BRACEY: Unrelated to donor.

DR. TRIULZI: Recipient as part of the donation process or transfusion, and clearly the iron is related to the donation process, cholesterol testing related to donor process. I think it's fine with me.

DR. BRACEY: Beneficial effects on donations and beneficial effects on donor health which is the bullet. The possible beneficial effects on the number of donations or donor health are both unproven again. I think the verbiage would be -- should be studied or --

DR. KLEIN: Again, it's is little negative. I don't think there's any question that screen populations for just -- despite what we hear from industry, for cholesterol levels can lead to intervention to healthy individuals. There's no question that screening for ferritin to pick up people with hemochromatosis, can be adequately treated. Go down the line based on which tests we select. So, I think it's unfair to say that screening individuals, not necessarily donors, is so negative.

DR. BRACEY: Perhaps if we just say -- strike are improved and say should be further evaluated?

DR. RAMSEY: They were providing donations and the donor health in one bullet here and that's probably part of the dilemma.

DR. BRACEY: Dr. Epstein?

DR. EPSTEIN: I think where the uncertainty -- first of all, I agree. It's kind of negative and it doesn't strike the right balance. We talked about that a little bit. The dilemma here is not whether managing elevated cholesterol is beneficial to individuals. Of course it is. But, what we have heard is that there is a lot of instances in which the follow up is ineffective. You do the study, you offer the tests, sometimes people don't want it, sometimes they accept it, but then they don't go to the doctor. So, it's the net benefit of the intervention that is unproven. We don't know that offering tests at a blood center ends up doing a thing for the donor.

DR. KLEIN: I agree with that. I think

otherwise we wouldn't have -- I think somehow you have to get into potential for including health.

DR. EPSTEIN: Exactly.

MR. MATYAS: By the way, the bullet in the next sentence are the same for the most part except it says, should be further evaluated. Beneficial effects on donations and beneficial effects on donor health, I mean, should be further evaluated. You can just strike the next sentence.

MS. FINLEY: How about should be further evaluated in this setting?

DR. BRACEY: We are at the point of needing to take action. So, Dr. Klein? What are the issues related to the quorum?

DR. KLEIN: If you want to see the hemoglobin section that I put together, that's another street and he's searching for it.

DR. EPSTEIN: Coming back to the earlier point, do we want to say that whereas the health benefits of medical -- of these candidate medical evaluations are well established, the evaluation in the

setting is unproven and should be further studied?

Because, again, nobody quarrels if there's a health value to elevated glucose or elevated cholesterol.

DR. BRACEY: That was in the first --

DR. EPSTEIN: The sentence we were just deliberating. So, it should be whereas.

DR. BRACEY: Beneficial effects?

DR. EPSTEIN: Whereas the beneficial effects of health screening. Whereas the beneficial effects of health screening and intervention are well established, the effectiveness of -- what do you want to call it? Wellness? Health wellness screening and the donor setting -- in the donor setting is -- needs to be -- should be further evaluated. Well, screening of donors --

DR. BRACEY: Just donor studies?

DR. EPSTEIN: I think donor studies.

DR. BRACEY: Just strike the rest.

DR. ISON: I think by taking that sentence out, you're losing the whole issue of what's the impact on donation is and what is its impact on health?

DR. KOUIDES: Should be further evaluation
in increase of donations?

DR. ISON: In its effect on donation
because it could also decrease donation.

MS. FINLEY: Impact on donations.

DR. BRACEY: On blood donations and donor
health, blood donor health.

DR. RAMSEY: For its effect.

DR. TRIULZI: Evaluate it for its effect?

DR. BRACEY: After evaluated.

MS. FINLEY: Up one line.

DR. BRACEY: So, evaluated --

DR. TRIULZI: After the word evaluated.

DR. BRACEY: Yeah, for its effect.

DR. EPSTEIN: Well, it's not just on blood
donations, it's on increasing or maintaining blood
donations.

DR. ISON: Decrease.

DR. BRACEY: Maximize. That sounds good or
optimize.

DR. KOUIDES: Optimize. Encouraging?

DR. BRACEY: No because it would carry over to blood donor health as well. So, optimizing blood donations and blood donor health. All right. So, now we move to Dr. Klein's insert.

DR. KLEIN: Whether or not you want to add this or where you want to add this would be up to the committee, but if you want to consider the issue of different acceptance standards of hemoglobin.

DR. BRACEY: So, reconsideration of the donor hemoglobin acceptance value, the normal distribution is higher for males than females. You know, we did cover that in part under the consent bullet. But, actually, it's good, I think, it's stated in two places. Because one issue is related simply to consent and the other issue is related to the physiology of it.

DR. ISON: Do we need to add a sentence about the differential definitions of anemia?

DR. KLEIN: It's there. Distribution of hemoglobin evaluation is higher for males than females.

DR. BRACEY: I think that covers it.

DR. KLEIN: Single consensus values for accepting donors which acceptance of a number of anemic males while excluding many normal females. Adopting different gender appropriate acceptance values would reduce the number of anemic donors bled without compromising the number of red cell units collected.

DR. ISON: Reducing the number of anemic donors bled?

DR. KLEIN: You may want to reword that, but the intent was to say you're bleeding men who are actually anemic, that distribution of normal hemoglobin values is 12.5 is a significant number of men are anemic. So, that's clear.

DR. BRACEY: Seems clear to me. Dr. Epstein?

DR. EPSTEIN: You probably have a reason to say consensus value, but to me it's not a consensus value because there is no consensus of males and females. Just a single value.

DR. KLEIN: We can say that. I said consensus because we've adopted it for the last 20

years or so. So, it appears to be someone's consensus.

But, I wouldn't have any problems with eliminating that word.

DR. BRACEY: Further comments?

DR. ISON: I guess the part that I'm still having -- the way I looked at this, this would actually expand the donor pool by allowing more female donors.

DR. KLEIN: And reduce some males.

DR. ISON: Right.

DR. KLEIN: So, it's probably -- actually I hear data of what statement was made, you wouldn't lose much. But, I don't think anyone really knows. Losing a few males and gaining a few females, what the balance would be. But, probably is not significant.

DR. KUEHNERT: Just a general comment. It might be useful in future meetings to summarize what's going on in another advisory committee meetings on the topic. Some of us here participated in BPAC on the iron as a topic. And so, that's some of the knowledge basis for some and not for others.

DR. BRACEY: Right. That's a good point.

So, we need to finalize. Can we take it to the top?

We'll vote on that. One more paragraph then. Starting here. So, annually, approximately 10 million people donate allogeneic blood for transfusion or source plasma for further manufacture. Many on multiple occasions. These encounters with blood and plasma collection centers can result in outcomes that are of health significance to the donors. These include a spectrum of adverse events related to donation, per se, and medical findings related vital signs, hemoglobin and infectious disease states. Current practice is varied regarding collection. Safety data notification and medical follow-up related to adverse health information. At the same time, donor accounts for blood and plasma collection centers provide a potential opportunity for expansion to include broader evaluations of donor health within the larger context of maintaining a healthy and robust donor base and of promoting public health consistent with HHS program of Healthy People 2001.

However, the actual risk benefits and cost

effectiveness of specific practices that go beyond assuring safe donation and safe and effective blood products are not established. The following issues warrant specific consideration by the secretary. And then we bullet --

Event reporting in donors, published data suggests disproportionate rates of adverse event in donor sub groups. Committee supports efforts to develop a comprehensive national reporting system for blood plasma donor adverse events.

Informed consent. While the current status of informed consent for blood and plasma donation is generally adequate, the committee recognizes that there are opportunities for improvement. Informed consent is performed nationally, but lacks consistency and a defined set of elements which has led to individual and regional variation. However, as informed consent is continuously refined and researched, emerging new risks for donation, especially repeat donation, are an opportunity -- or an area uncertainty. At a minimum, the known risks of donations are disclosed, but the

scope of the informed consent should be expanded to consider the effects of repeat donation on the general donor population, and gender specific effects of iron deficiency on donors, the effects of collecting blood from anemic men using current donation thresholds, the effect of young donors, e.g. approximately 10 percent effects on young donors, approximately ten percent prevalence of syncopal events in 16 to 17 year old donors, with one to 2000 injuries with the need to mitigate that risk. The method and frequency the effective informed consent for repeat donations.

Next bullet, reconsidering of donor --

DR. RAMSEY: This was struck.

DR. BRACEY: That's covered. Strike that.

Donor notification and follow-up with medical findings.

Further standardization is needed on the manner with which and the extent to which donors are notified of medical findings after donor suitability evaluation and suitability evaluation and product testing. By way of example, should notification be required to be performed electronically, telephonically or by any

method chosen by the donor? What categories of test results are required to be communicated to the donor, e.g., sickle cell. When donor returns to a center to follow-up questions related to test results be incorporated into the donor questionnaire?

Wider health screening. Committee heard statements from blood centers engaged in public health screening measures beyond those required for donor/recipient safety. Following issues/concerns arose in committee discussion on this topic. One, first bullet, mission dilution/conflict of interest. Blood plasma collection establishment's primary role is manufacturing safe blood product. A risk exists that expanded roles to provide donor health screening unrelated to donor/recipient safety could result in compromise to primary function and could present an ethical conflict for relationship to the donor. In addition, absence of standard practices in this area could have negative effects on blood center competition.

Next bullet, unexpected adverse outcomes.

Although the results of public health screening may alert the donor about a possible health risk, the results of such testing could potentially affect donor access to insurance or employment or unexpected cost for further medical evaluation.

Undue incentives. Public health screening by blood plasma centers may create undue incentives from unsafe donor who are test seekers. Given there's no benefit in safety to recipient or donation -- to the recipient or donation process, for any such incentives should -- no, process -- given that -- I think they need a comma there. Is that right?

MS. FINLEY: Yeah, after process.

DR. BRACEY: After process, given there's no benefit or safety to recipient or donation process. Any such incentives should be evaluated. Whereas the beneficial effects of health screening and intervention are well established, the effectiveness of health/wellness screening in the donor setting should be further evaluated for the effect on optimizing blood donations and blood donor health.

Next bullet is reconsideration of donor hemoglobin acceptance value. Normal distribution of hemoglobin values is higher for males than females, current single value for accepting blood donors, 12.5-grams per deciliter permit acceptance of anemic males while excluding many normal females. Adopting different gender appropriate acceptance values would reduce the number of anemic donors bled without compromising the number of red blood cells collected. I think that's the last bullet. That's it. Comments?

DR. TRIULZI: The 10 percent rate of syncope in young donors I think overstates it. It's not syncope at ten percent. That includes pre-faint. So, if you want to say syncope, it's far lower. It's one tenth of that. So, we don't want to overstate that.

DR. BRACEY: Right. Can we go back to that point?

DR. RAMSEY: We don't need the exact --

DR. BRACEY: Just the high prevalence of -- should we say presyncopal?

DR. KUEHNERT: Disproportionate high prevalence.

DR. TRIULZI: Yeah.

DR. BRACEY: Strike out the specific reference.

DR. TRIULZI: Just to give you a relative idea stated here, it's 32 events out of 10,000 in the 16, 17 year olds and 23 in the 18, 19 year olds. So, it's 32 versus 23. So, it's not a bowl you over kind thing for syncopal and more serious.

DR. BRACEY: Okay. So, then that would be?

DR. TRIULZI: But it is fair to say that it's disproportionately higher.

DR. BRACEY: Disproportionately high in prevalence.

DR. RAMSEY: Adverse events.

DR. BRACEY: Of adverse events.

DR. EPSTEIN: I would take out -- revise the whole sentence. It's the disproportionate prevalence of adverse -- prevalence of adverse events in young -- in the youngest donors.

DR. BRACEY: We can just leave that generic. We don't have to be specific.

DR. EPSTEIN: Just leave the -- strike all the rest of it.

DR. KUEHNERT: Just a minor thing in the first paragraph.

DR. BRACEY: First paragraph?

DR. KUEHNERT: Yeah. I think it should be infectious disease status, not infectious disease states.

DR. BRACEY: Okay.

DR. POMPER: But, one more word, submitting. Under the informed consent top paragraph, it says, however we think it was originally designed that made sense, but now with all the furthermores and additions or something like that --

DR. BRACEY: Just drop it and say as. Just start with as.

DR. EPSTEIN: There's sort of a logical problem there because we're saying that as -- first of all, it should be researched and refined instead of

refined and researched. Sort of cart and the horse reversed there. But, if it's researched and refined, are we saying that this area of uncertainty needs to be researched? Because if it's researched and refined, why is that an area of uncertainty?

DR. BRACEY: Yeah.

DR. EPSTEIN: The introductory phrase troubles me. Don't we just want to say that the risks for donation, especially repeat donation remain an area of uncertainty that should be researched and refined? Just the logic.

DR. BRACEY: I guess one thing that we wanted to state is, it's not a broken piece. We were sort of trying to say that we thought we had a reasonable process.

DR. EPSTEIN: Research and refined, uncertain effects of repeat donation warrant more investigation or more attention.

DR. ISON: Research because really it's the informed consent process that's getting refined.

DR. EPSTEIN: Fine with me.

DR. BRACEY: Research that's getting refined, the uncertain --

DR. ISON: Just give us refined.

DR. POMPER: Scratch continuously.

DR. EPSTEIN: Uncertain is related to the effects of donation and especially repeat donation.

DR. BRACEY: Where would that go?

DR. RAMSEY: Covered repeat donation in the bullets. We may not necessarily need it in production.

DR. ISON: I think it's there for emphasis.

DR. EPSTEIN: I think that's really it, that the risks of donation, and especially repeat donation warrant attention.

DR. BRACEY: Okay.

DR. EPSTEIN: Back up one line. Is it really emerging new risks? Are they really new?

DR. BRACEY: They're not new, they're just being discussed.

DR. EPSTEIN: I think -- yeah.

DR. KOUIDES: Increasing recognition?

DR. BRACEY: Just say no risk because we

don't know them. We discover them and they are the risks.

DR. EPSTEIN: The risks of donation, especially repeat donation, warrant further evaluation, further attention.

MS. FINLEY: There was a reference to Healthy People 2010. Did you mean Healthy People 2020?

DR. POMPER: I was going to say that.

DR. EPSTEIN: Yeah, 2020.

MS. FINLEY: The question said 2020.

DR. EPSTEIN: I know. But --

MS. FINLEY: The --

DR. KUEHNERT: Then it will be Healthy People 2020 plan or did you mean to say 2010?

DR. ST. MARTIN: There's existing objectives --

DR. BRACEY: Why don't we leave that 2010 since that's real.

DR. EPSTEIN: Can I raise a question? We had some discussion about whether objectives related to wellness of donors should become a topical area in

Healthy People 2020. I think that it would advance our cause if we were to recommend to the secretary that the evaluation for the potential of establishing donor wellness evaluation as part of blood plasma donation should become a topic for evaluation in Healthy People 2020, because part of Healthy People 2020 is developing databases. And the thing we want here is databases. And it's perfectly obviously that there is a public health implication if these things work. If you can get donors to improve their cardiovascular risk, diabetic risk, et cetera, et cetera, et cetera, hypertensive risk, through wellness testing or evaluation donor group, that comports with the objectives of Healthy People 2020 provided that it doesn't have a negative effect otherwise on donation. So, we kind of have lost whether that's a recommendation we're going to make to the secretary because it's a really valuable one.

DR. BRACEY: Yeah.

DR. RAMSEY: We didn't really hear enough about the details of Healthy People 2010 or 2020 as

they relate to blood, as they relate to the general area of donor safety. And blood evaluation might relate to some specific issues. We heard one specific area, but in the feature discussion, it might be helpful to examine that document and pull out the area that's of relevance to us.

DR. BRACEY: What if we take the thought and put it down on the piece on wellness and try to relate it to whether this wellness activity would warrant being a topic of consideration for Healthy People 2020?

DR. EPSTEIN: I see no reason not to suggest that the secretary consider whether the topic of wellness evaluation in the donor group should become a topic.

DR. KUEHNERT: This is the more -- Healthy People process is about more than just about wellness for donors. It's also about adverse events in donors too. So, as long as it incorporates that also and not just the wellness issue, then that would be okay. Just wouldn't want to limit it.

MS. FINLEY: I concur.

DR. BRACEY: A stand alone bullet or a bullet under wellness? You're saying a stand alone bullet?

MS. FINLEY: I think we were asked to address that in here. So, give it a bullet.

DR. BRACEY: Let's make it a stand alone bullet.

DR. ST. MARTIN: There was one more, I think, correction that we need to make in terms of grammar under the bullet that refers to -- down a little bit. Under the wellness and the negative adverse effects. That's bothering me about the wording of that one. Further down, unexpected adverse outcomes. That sentence, unexpected cost, I think there's something missing grammatically in there.

DR. BRACEY: So, under this unexpected cost?

DR. ST. MARTIN: Or could pose or could present.

DR. TRIULZI: Or result in?

DR. ST. MARTIN: Or result in unexpected cost. So employment, comma.

DR. BRACEY: Or result in? If we go down, we go down -- take it down to the end and we add another bullet, should this be a sub bullet?

DR. EPSTEIN: Yeah.

DR. BRACEY: It's a freestanding bullet. You want to leave it at the end? I was thinking of placement. Yeah. So, okay. Healthy People 2020 would be the header. So, the committee recommends that the secretary consider the potential for wellness testing as a topic area in Healthy People 2020.

DR. EPSTEIN: Well, it's for donor management including potential wellness testing. If the secretary considers issues of donor management to including potential wellness testing as a topical area or cross cutting topical area in the Healthy People 2020 initiative.

DR. BRACEY: Okay.

DR. KUEHNERT: That's management. I don't know if it's going to connect with the secretary

including donor safety and health.

DR. EPSTEIN: Okay.

DR. KUEHNERT: Something like that.

DR. BRACEY: So, donor safety and health management?

DR. KUEHNERT: Yes.

DR. BRACEY: As a topic area for Healthy People 2020?

DR. EPSTEIN: We have to strike on the first line the potential for comes out, the phrase, comes out.

DR. BRACEY: Okay. All right.

MS. FINLEY: What about the adverse events?

DR. EPSTEIN: That's safety.

DR. BRACEY: That's safety.

MS. FINLEY: Up above?

DR. BRACEY: No, it's in there.

DR. KUEHNERT: It comes as adverse events.

They have a current chapter for blood product safety, and safety encompasses adverse events monitoring. So, one could expand on it. But --

MS. FINLEY: But, you said you wanted a national reporting. And that doesn't -- donor safety doesn't say that.

DR. ISON: It's a separate -- I mean, we're recommending that they do that whether it's part of 2020 or not.

MS. FINLEY: Do we have that up there?

DR. BRACEY: That's included up above. This is just more broad. It's broad. I think we just want to recommend the topic right now. FDA and NIH will play hot potato. We better focus on getting this done. So, we have looked at the recommendation we have with flesh added to the bones, and in addition, a topic for 2020, is the committee ready to vote?

DR. HOLMBERG: We have twelve voting members? All in favor? Any opposed?

MS. BIRKOFER: Nay.

DR. EPSTEIN: Extensions? Proxies from anyone?

DR. BRACEY: No. What we then need to do -- so then it passes. What we then need to do is

close on the babesia recommendation which is at the very top. So, this reads the committee recognizes transmission of babesia by blood transfusion and organ transplantation as a current recipient safety concern. This concern is heightened by apparent increase in reports of transfusion transmitted cases in the last few years. Given the significant health risk of babesiosis and the current lack of accurate scientific information on the transfusion and transplantation risk, the committee recommends that the secretary support efforts to determine the general population and donor prevalence of babesiosis, its transmissibility by transfusion and organ transplantation, and the utility of potential safety interventions, e.g., donor screening and pathogen detection technology. Comments?

MS. FINLEY: I would add pathogen reduction technologies. At some point, we had a significant discussion about the fact that there is no test out there that we can use. One needs to be developed to achieve --

DR. KUEHNERT: That's through both of them.

DR. EPSTEIN: There's no screening test.

MS. FINLEY: Screening test development.

DR. EPSTEIN: Development of --

DR. KOUIDES: It's compounded. It --

DR. EPSTEIN: No, because it comes -- I put
it up on e.g. development of --

DR. BRACEY: Okay.

DR. EPSTEIN: Donor screening test and or
pathogen.

MS. BENZINGER: Do we need to include organ
and tissue transplantation?

DR. BRACEY: Red cells. The tissue is a
little soft, but I don't know how the committee --

DR. KUEHNERT: It's theoretically possible.

DR. BRACEY: Theoretically possible. All
right.

DR. KOUIDES: Significant health risk or
are we saying it was potential significant? I mean,
it's always dramatic and that we had discussion. But,
otherwise, it's probably not.

DR. BRACEY: Okay.

DR. EPSTEIN: Potentially.

DR. KOUIDES: Also, do we need to include general population or can we just say determine the donor prevalence?

DR. BRACEY: I think what we were concerned about is really knowing what the extent of the disease process is because that would be important for.

DR. KOUIDES: It seems a bit overarching.

DR. KUEHNERT: I agree with that. I was going to comment on that. The reality is I think you do need to know what the donor prevalence is because that will potentially inform you of risk factors.

DR. KOUIDES: You mean general population?

DR. KUEHNERT: I guess I would say something like determine donor prevalence of babesiosis in the context of the general population rather than have the committee recommend a study to do general population. It just seems a little overreaching. But, I understand what you're saying. You need to know what the context is. So I would just say that.

DR. BRACEY: Say that again.

DR. KUEHNERT: To determine the donor prevalence of babesiosis in the context of --

DR. EPSTEIN: Or in relation to?

DR. KUEHNERT: In relation to the general population.

DR. TRIULZI: Kind of the analysis in Chagas. You really don't have to study that in every state.

DR. KUEHNERT: Determine the donor prevalence of babesiosis in relation to the general population? There we go. Just get rid of the rest of the phrase then. Get rid of it.

DR. BRACEY: And the donor prevalence, get rid of that? Its transmissibility.

DR. KUEHNERT: That's good. We got a really long sentence.

DR. EPSTEIN: A, B and C. Can have A, B and C?

DR. BRACEY: Do you want to break them down? All right. Further comments on this recommendation? Is the committee ready to vote?

DR. HOLMBERG: All in favor? Any opposed?

Any abstain?

MS. WADE: Me.

DR. BRACEY: I think we're done. Is there any other business that the committee members would like to discuss?

MS. BIRKOFER: Did you say other issues? I would just like to have communicated to us, the e-mail would be fine, two things: One, more advanced notification of agenda items and topics for consideration prior to meetings so that we can be more prepared. And, two, I would like to have a sense of recommendations or for the work plan being submitted to the incoming secretary and his staff. I'm sure there's some type of transition in effect within the department side. I'd just like to know that the priorities are being communicated.

DR. BRACEY: Okay. Any other comments? If not, we stand a adjourned.

(Meeting concluded at 4:50 p.m.)

State of Maryland,

City of Baltimore, to wit:

I, Louisa B. McIntire-Brooks, a Notary
Public of the State of Maryland, Anne Arundel County,
do hereby certify that the within-named proceedings
took place before me at the time and place herein set
out.

I further certify that the proceedings were
recorded stenographically by me and this transcript
is a true record of the proceedings.

I further certify that I am not of counsel
to any of the parties, nor an employee of counsel,
nor related to any of the parties, nor in any way
interested in the outcome of this action.

As witnessed my hand and notarial seal this
2nd day of January, 2009.

Louisa B. McIntire-Brooks

Notary Public

My commission expires:

November 30, 2011

