

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ADVISORY COMMITTEE  
ON  
BLOOD SAFETY AND AVAILABILITY

THIRTY-SECOND MEETING

AUGUST 23, 2007

Georgetown University Conference Hotel  
3800 Reservoir Road, Northwest  
Washington, D.C. 20057

Thursday, August 23, 2007

LIST OF PARTICIPANTS:

ARTHUR W. BRACEY, M.D.

JERRY A. HOLMBERG, Ph.D.

ANN MARIE BENZINGER

WILLIAM DUFFELL JR., Ph.D.

ANNE MARIE FINLEY

PETER KOUIDES, M.D.

DAVID E. MATYAS, J.D.

GLENN RAMSEY, M.D.

SUSAN ROSEFF, M.D.

LINDA THOMAS-WADE

MATTHEW J. KUEHNERT, M.D.

DR. JAY S. EPSTEIN

DR. HARVEY KLEIN

CDR. MICHAEL LIBBY

JAMES S. BOWMAN, M.D.

MARISA SAINT-MARTIN, M.D.

ROBYN ASHTON, R.N., M.S.

JOHN ARMITAGE, M.D.

MATTHEW PAYNE

KATHY BRINSFIELD, M.D.

ALLAN E. WILLIAMS, Ph.D.

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## 1 P R O C E E D I N G S

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3 THE CHAIR: Would you go ahead with the roll  
4 call, Dr. Holmberg?

5 DR. HOLMBERG: Dr. Bracey?

6 THE CHAIR: Here.

7 DR. HOLMBERG: Ms. Benzinger?

8 MS. BENZINGER: Here.

9 DR. HOLMBERG: Ms. Birkofer?

10 (No response)

11 DR. HOLMBERG: Dr. Bloche?

12 (No response)

13 DR. HOLMBERG: Dr. Duffell?

14 MR. DUFFELL: Present.

15 DR. HOLMBERG: Ms. Finley?

16 MS. FINLEY: Here.

17 DR. HOLMBERG: Dr. Kouides?

18 MR. KOUIDES: Here.

19 DR. HOLMBERG: Dr. Lopez is absent. Mr. Matyas?

20 MR. MATYAS: Present.

21 DR. HOLMBERG: Dr. Pierce is absent. Dr.

22 Ramsey?

1 MR. RAMSEY: Here.

2 DR. HOLMBERG: Dr. Roseff?

3 MS. ROSEFF: Here.

4 DR. HOLMBERG: Dr. Sandler is absent. Ms.

5 Thomas Wade.

6 MS. WADE: Here.

7 DR. HOLMBERG: Dr. Triulzi is absent. Dr.

8 Kuehnert?

9 DR. KUEHNERT: Here. Sorry I was late  
10 yesterday.

11 DR. HOLMBERG: We'll forgive you for now.

12 DR. KUEHNERT: Okay.

13 DR. HOLMBERG: Dr. Epstein?

14 DR. EPSTEIN: Present.

15 DR. HOLMBERG: Dr. Klein?

16 DR. KLEIN: Uh-huh.

17 DR. HOLMBERG: Commander Libby?

18 CDR. LIBBY: Present.

19 DR. HOLMBERG: Dr. Bowman? I'm sure Dr. Bowman  
20 will be here later; he's probably fighting that traffic  
21 from Baltimore. Dr. Saint-Martin?

22 Ms. SAINT-Martin: Here.

1 (Laughter)

2 THE CHAIR: The nick of time.

3 DR. HOLMBERG: And Ms. Ashton?

4 MS. ASHTON: Here.

5 SPEAKER: That's just-in-time delivery.

6 DR. HOLMBERG: There you go. Okay. Just some  
7 quick comments -- we did pass out to you today two  
8 documents; the first document is the comment from the  
9 Committee of 10,000 that Mr. Cavanaugh gave the  
10 presentation yesterday, and several of you had asked for  
11 this to be -- to have a copy of it, so that is available  
12 to you. And then also the questions from today we'll --  
13 is also in front of you.

14 Also just want to remind everyone of the same  
15 conflict of interests that I read yesterday, and the -- I  
16 won't go through all of the details on that, but I was  
17 also in hopes that this morning we would have Ms. Nelson  
18 with us; she may be showing up a little bit later, but for  
19 those that had potential conflict of interests we have  
20 determined the waivers, and so there is a waiver statement  
21 that she will be providing to each one of you.

22 Again in the conflict of interest statement that

1 I read yesterday, it was stated that if we felt that there  
2 was a potential conflict of interest we would put in a  
3 waiver and that if that subject should come up in the  
4 future, then we would definitely have some documentation  
5 and also give you guidance as far as your role in that  
6 discussion.

7 I also would like to remind the people that  
8 would like to speak from the microphone that if there's  
9 any potential conflict of interest that you express that  
10 and also that you mention your affiliation. And once  
11 again, please do not, if you're going to be speaking from  
12 the floor, do not start speaking without introducing  
13 yourself. We do not have a transcriptionist present; it's  
14 all being recorded, and it will be then transcribed later,  
15 so it's very important for the transcriptionist to know  
16 who is speaking.

17 Again, I'd also remind people to turn their cell  
18 phones off, or into the mute position, and I think we were  
19 very good yesterday, and we didn't have any problems with  
20 that. I think we had more problems with the people next  
21 door, and the 20- or 30-year celebration that they were  
22 having.

1 THE CHAIR: Thirty-five.

2 (Laughter)

3 DR. HOLMBERG: Thirty-five? Okay. Well, with  
4 that I'll turn it over to Dr. Bracey. Thank you.

5 THE CHAIR: Good morning and welcome. I was  
6 struck by the importance of the data that was presented  
7 yesterday regarding the blood supply from the perspective  
8 of the donor centers, and also the importance of our need  
9 to evaluate policy with respect to reporting and  
10 monitoring of these data.

11 I think that it's going to be very important for  
12 us to hear all of the presenters today and also to have a  
13 very robust discussion, and thinking about the issue that  
14 will be presented to us which will be to develop  
15 recommendations for the Secretary.

16 I think that we may need to, later on in our  
17 discussions, do a gap analysis to assess what we've heard  
18 and to think about what else we need to hear prior to  
19 making those recommendations. I think that we will  
20 probably need to form a subcommittee that will meet in  
21 between meetings and come back with a solid set of  
22 recommendations for the Assistant Secretary. But let's go

1 ahead and proceed with the presenters for today.

2           There is one insert that we have, and this is a  
3 follow-on to the previous meeting's discussions with  
4 regard to the safety and monitoring or surveillance of  
5 transplantation, adverse events, and Dr. Kuehnert handed  
6 out a document yesterday, from UNOS and it's entitled,  
7 well its title is, "OPT and UNOS Policy Proposals for  
8 Public Comment," and it's dated June 15, 2007. Dr.  
9 Kuehnert, would you like to discuss that?

10           DR. KUEHNERT: Sure, just briefly, the handout  
11 is informational only but concerns a topic included in the  
12 May meeting, bio-vigilance, specifically following up on  
13 something of increasing concern which is organ transplant  
14 safety. The -- and it's important to consider given the  
15 expanded charter that the Committee has that includes  
16 organ and tissue transplantation. So yesterday we heard  
17 about tissue safety and this is the other side of  
18 transplantation.

19           The document is a -- something that was released  
20 for public comment. That public comment period has closed  
21 in the interim between the last Advisory Committee meeting  
22 and this meeting. Nevertheless I thought it would be

1 useful as it looks at organ transplant, disease  
2 transmission recognition and reporting. The policy tries  
3 to balance the urgent need between the need, urgent need  
4 for organs against the risk of transmission, which unlike  
5 blood and tissues is left up to the discretion of the  
6 transplant center exactly, you know, what that risk  
7 profile is, what that acceptable risk is of transmission.

8           So I think what's described here is a starting  
9 point for assessing risk in this setting and the status of  
10 interventions for addressing that risk including an  
11 advisory group to collect reports and analyze data and  
12 eventually a network, which you heard a little bit  
13 yesterday on the TTSN, which UNOS has been awarded the  
14 cooperative agreement for, to provide an intervention for  
15 organs and which will also extend to intervention in  
16 tissues as well.

17           So hopefully the Advisory Committee can review  
18 this document and then periodically hear progress on  
19 what's going on in this field.

20           THE CHAIR: Thank you, and overall on my reading  
21 of the document I would sense that this is really a  
22 bolstering of the surveillance activities within the realm

1 of transplantation.

2 DR. KUEHNERT: Right. I think there's a lot of  
3 questions still to be answered and that's why I wanted the  
4 Committee to start to get familiar with it, because not  
5 too many people are, and I think, you know, this is the  
6 one committee that I think can address these issues. A  
7 lot of the other committees that exist for organ  
8 transplantation are really focused appropriately on  
9 equitable distribution, and the safety issues really are  
10 not addressed. And so I think this committee is the one  
11 that can look at those gaps and perhaps encourage  
12 addressing them, in asking the real difficult questions  
13 about how the safety issues are going to be addressed.

14 THE CHAIR: Okay. Well, we look forward to --  
15 Dr. Holmberg?

16 DR. HOLMBERG: Yeah. Matt, do you think that  
17 this is a topic that should be presented at the next  
18 meeting? Should we have an update? I think one of the  
19 disadvantages that we have had with this is that we missed  
20 the comment period and that -- it sort of got by us  
21 without our notice. So I'm just asking would it be the  
22 Committee's desire to have this as a discussion point, as

1 an update?

2 THE CHAIR: Well, I think from my perspective I  
3 think it would be very important as a discussion point,  
4 but particularly as the data begins to come forth, that we  
5 would see this data on a periodic basis.

6 DR. HOLMBERG: Well, I think my opinion would be  
7 that it is important, and it would be appropriate, I don't  
8 know what else is planned for the agenda, but I also think  
9 it's very essential that HRSA be the focal point for the  
10 topic since they're the regulatory agency for solid  
11 organs.

12 THE CHAIR: Okay. Well, we'll look forward to  
13 hearing more about that activity. Moving on to our agenda  
14 for this morning then, we have an update on donor  
15 resources, who represents the voluntary blood donor; Dr.  
16 John Armitage from the -- who was the CEO of the Oklahoma  
17 Blood Institute, will present that topic for us.

18 Dr. Armitage has a vast experience with blood  
19 collection activities and has noted in his information,  
20 his biographical information that he is a donor of more  
21 than hundreds of units, more one could count, and so Dr.  
22 Armitage, we really look forward to you because this has

1     been part of our missing link connecting to the donors.

2             DR. ARMITAGE: Well, thank you very much for  
3     that introduction and working at a blood center, one of  
4     the real pleasures is getting to donate a lot, being asked  
5     often to help out.

6             Thank you, Dr. Bracey and Dr. Holmberg and the  
7     whole committee for letting me speak today on behalf of  
8     the Association of Donor Recruitment Professionals. My  
9     talk "Short Circuits: Blood Appeals and Donor  
10    Recruitment" does relate to the donor resource and the  
11    interface of our industry with the donors, so I think it  
12    is not directly titled as in the program, but certainly  
13    speaks to those issues and perhaps in the question and  
14    answer we can also talk about that representation.

15            My talk, as the title suggests, is about some of  
16    the expedient nature of the appeals we undergo during  
17    shortage as well as perhaps some of the negative  
18    consequences of being in that pattern of appeal and  
19    response, and my talk is going to be divided into  
20    essentially four parts.

21            I'd like to take the opportunity to explain a  
22    little bit about the association of donor recruitment

1 professionals first, since this is the first time we've  
2 had the honor of presenting before this committee. After  
3 that I would like to do a survey of current appeal  
4 practices and how they're rolled out by the various  
5 collectors in this country, and then move on to some of  
6 the correctives or enhancements that may assist in  
7 appeals; if it is a device that we are going to rely on  
8 during critical periods, we can certainly look at ways to  
9 improve the outcomes.

10           And then lastly talk about maybe the underlying  
11 disease that causes the symptoms of appeal, which is the  
12 interventions we may start to think about to improve  
13 overall collections. So with that introduction, I'll move  
14 on to talk briefly about the ADRP. You can read on the  
15 screen there, although I guess for the transcriptionist,  
16 maybe I should read this.

17           Its mission is to provide education, development  
18 and resources for the donor recruitment professional and  
19 its vision is that we're a worldwide industry leader in  
20 the field of donor recruitment with an ongoing commitment  
21 to shape international policies and standards and to  
22 develop marketing strategies and specialized resources for

1 the donor recruitment profession.

2 This is an organization that's been around for  
3 30 years and longevity is sometimes a sign of success; it  
4 was an offshoot of the state blood banking meetings in New  
5 York; it is a non-profit organization; its offices are in  
6 Austin, Texas; its membership is growing and it's now  
7 approximately 600-plus, mostly representatives of blood  
8 centers and blood collection agencies, but also we have  
9 representation from the National Marrow Donor Program and  
10 various trade associations.

11 The membership tends to be mostly recruitment  
12 department representatives from the director and manager  
13 level in particular, also supervisors and many frontline  
14 recruiters who get involved with us oftentimes through our  
15 annual conference.

16 We had a scope of involvement including PR and  
17 communications professionals, telerecruitment experts;  
18 many field reps, the folks who go out to the sponsors and  
19 make the contacts, and get the commitments and get the  
20 donors; also physicians. We're increasingly finding  
21 administrators, blood center officials, also association  
22 officials interested in the work we're doing, perhaps as a

1 function of increasing pressure on the blood supply that  
2 the recruitment folks are a little bit more on the focus  
3 for people to interact with.

4           We have many vendors, and in fact we get the  
5 benefit of their excellent entrepreneurial ideas and can  
6 see some of the ferment going on in the area of  
7 recruitment as a result, and we would love to have more  
8 regulators, people involved with policymaking. I think  
9 that's an area that we're just now getting involved with  
10 as a focus for some of the key adjustments that could help  
11 recruiters in general.

12           We are a new national organization as you can  
13 see from this list; again, perhaps I should read it for  
14 the transcription -- Canada, Finland, Germany, Kenya, New  
15 Zealand, South Africa, the United Kingdom, the United  
16 States, and Vietnam are all current members; we have a  
17 larger list of members who come in and out of the  
18 organization on an annual basis. Our president is from  
19 the United Kingdom right now with the National Health  
20 Service in England, Gavin Evans; our executive director is  
21 Deborah Swift; this is a new fulltime position for us and  
22 it reflects, again, the growth and success of the

1 organization that we're able to get the administrative  
2 resources to be more of a consistent presence.

3 Our annual conference upcoming in the spring is  
4 in Halifax, Nova Scotia, I invite you all to attend and if  
5 you can't attend please visit the website for the  
6 organization, which is [www.adrp.org](http://www.adrp.org) and I think you will  
7 find some interesting resources there.

8 Certainly when I'm talking about the need for  
9 appeal, we've all been in blood centers where all of a  
10 sudden the bottom fell out of our inventory or our  
11 collection numbers went down the tubes or down the drain  
12 so to speak; this is a reality that even the best of blood  
13 centers faces at times, and one of the reflexes is to make  
14 a big noise and to try and get attention during this  
15 critical moment for the inventory and for the safety of  
16 patients.

17 But much as depicted in this picture, there can  
18 be some negative consequences if not done with extreme  
19 care and forethought. And moving on to a description of  
20 the current status of appeals across the country, I've  
21 been in six blood centers now, I'm kind of an itinerant  
22 blood banker of sorts, but it's also given me the

1 opportunity to get up close and personal to many different  
2 types of appeal. And they are heterogeneous in their  
3 deployment; some centers like to use them, some centers  
4 are adverse to using them; their execution varies  
5 dramatically; some centers are very good at doing appeals  
6 and some go on appeal in form, but not so much function,  
7 which can be problematic because if it is a valuable  
8 resource for the community to call on help, one wants to  
9 have an intense effort to make the most of that appeal  
10 while it is ongoing.

11           Also the utility, there are various centers that  
12 seem to think there is a good benefit from going on  
13 appeal, and others who tend to think that there is not  
14 much value on appeal, although oftentimes those centers  
15 still continue to go on appeal which is an interesting  
16 phenomenon.

17           Certainly in certain locations appeals can be  
18 chronic, we all recognize that they're cyclic, the  
19 underlying problem being the low booking periods during  
20 the holidays and during the summer are set up in  
21 particular for bringing the margin of safety, the margin  
22 of supply into a position where interventions are

1     drastically and urgently needed.

2             You can have a general appeal where you go after  
3     all blood types; you can have targeted appeals, targeted  
4     by blood group or by product type. Again, different skill  
5     sets are needed; different messages are needed in both  
6     those circumstances. It can be triggered -- oftentimes  
7     when you've got poor underlying bookings, you only need a  
8     weather event or an upcoming holiday weekend to really  
9     push the decision to go with an appeal.

10            Interestingly enough, some of the recruiters I  
11     respect most even think at times of this as a marketing  
12     tool; an appeal is something that is planned for, it gives  
13     you media access at oftentimes free or reduced rates, it's  
14     a good motivator for recruiters as well as for sponsors,  
15     volunteers and donors, sometimes it can even be linked to  
16     a promotional item or a promotional campaign that just  
17     fits in perfectly because now you're getting news of this  
18     great promotion in addition to the message about the need.

19            So I've seen people use this perhaps not  
20     necessarily in the emergency mode, but more in a marketing  
21     mode, which is, I'm not sure of the ethics of that and  
22     there are some dangers with that in terms of credibility

1 that should be recognized.

2           Isolated -- you can have when you host or when  
3 you call your appeal, you can do it in either as an  
4 isolated center; you can be part of a group of centers  
5 locally that are also in some trouble in relying on this  
6 at the same time. There's the phenomenon of the piggyback  
7 or "me-too" appeal, when your neighbor goes on appeal,  
8 there is a decision often whether or not your center  
9 should take advantage of that energy and that moment to  
10 also go on appeal lest you lose the donor's interest,  
11 should you come and ask for your own appeal 2 weeks later  
12 for example, after the donors have maybe been motivated by  
13 an alternative site for giving their blood.

14           There's also rolling or staggered appeals; this  
15 often happens in large organizations, multi-center  
16 organizations where different sub-units go on appeal in a  
17 staggered basis which is actually a good protection for  
18 the overall blood supply, because you're asking different  
19 communities to step up at different times; you're not  
20 asking for a one-stop answer at one moment and then left  
21 with nothing else to rely in a kind of a system-wide  
22 approach.

1           And very rarely you have collaborative appeals  
2     and I think we're trying to see more of this, thanks to  
3     the work of many of the associations, and certainly at  
4     state level even -- I know New Jersey recently had a  
5     statewide appeal and I think that's an avenue that should  
6     be investigated more, and earlier in the appeal decision-  
7     making process, how to bring on a group kind of sentiment  
8     to this or a group dynamic to this.

9           Again a few of the things and a few of the  
10    consequences I'm about to talk about are not related to  
11    centers that go on appeal intermittently. I think even  
12    experts need help as this slide attempts to demonstrate,  
13    but people who -- or centers rather that rely on this  
14    consistently and repeatedly may be at risk of the negative  
15    consequences that can accrue through over-utilization of  
16    appeals.

17           First of all, I think centers should recognize,  
18    and don't often do this that an appeal is really a failure  
19    indication, it means that your fundamental recruiting  
20    processes and collecting processes have gone to such a  
21    point that your inventory is in jeopardy.

22           Not everybody in every blood centers thinks of

1 this this way, but I think the general public and donors  
2 would see repeated attempts to make an urgent message as  
3 not indicative of smooth operations.

4           Reactive patch, again this is something that  
5 does often get you out of the short term, but as a patch  
6 or a mask to fundamental weakness, but does not correct  
7 those underlying causes often. It's a diversion from the  
8 medium- to long-range planning that may perhaps improve  
9 the fundamentals of recruitment, but the energy that's put  
10 into a good appeal often detracts from the longer term  
11 planning and really leads to this appeal-to-appeal  
12 phenomenon, where the longer range in -- blood recruitment  
13 longer range is a minimum of 2 months, but ideally 4 to 6  
14 months in terms of minimum planning.

15           This is oftentimes a distraction from that kind  
16 of preparation. It's a confidence-sapper oftentimes when  
17 done repeatedly with the hospital customer and the  
18 healthcare providers and it is a stressor and dissatisfier  
19 for staff who are often asked to work harder on the  
20 appeals setting with an onrush of donors if successful, or  
21 certainly asked to do extended hours, that sort of thing  
22 for the collection staff, and it can create or exacerbate

1 tensions between the recruitment staff and the collection  
2 staff within a blood center which is a key relationship to  
3 keep on the best possible terms. So again there can be  
4 negatives within the organization itself.

5 As an industry I think it's an interesting  
6 phenomenon, and this is a very tolerated practice. I say  
7 tolerated because again, I think, it is a sign of weakness  
8 that we allow to come up every summer, essentially you'll  
9 see appeals -- every holiday season you'll see appeals.  
10 But we haven't really addressed this in terms of our need  
11 for urgent correction and I appreciate this committee  
12 probing into this area and starting to think about some of  
13 the things we might do to correct this ongoing phenomenon.

14 There's little done in the way of studies; for  
15 example it's a well-known anecdote but not supported by  
16 data that you shift donors during appeals, you ask your  
17 regular donors you may be getting in September to push  
18 their donations say, up to August. So you shift them to  
19 times when you need them more, but you don't necessarily  
20 create a lot of new first-time donors and if you do get  
21 first-time donors, their retention in the system is not  
22 well-documented.

1           I think these are things that we owe it to  
2 ourselves to study in more detail, what are the outcomes  
3 we are pursuing and are we achieving those? There are few  
4 correctors or enhances that the industry is brought to  
5 bear, there has been some good work through the  
6 associations. We do occasionally have national level  
7 appeals. I don't think they've reached the effectiveness  
8 level yet, that the frontline recruiters use the national  
9 appeal to their best advantage. That's perhaps something  
10 that we could work on, the tools to run up underneath the  
11 concept of a national appeal for example.

12           We don't have enhancements that are widely used  
13 or available for recruiters to get the message and the  
14 urgency of an appeal. These are all left to the  
15 individual blood centers essentially to adapt and create  
16 themselves. That is something that we could perhaps do a  
17 better job of as a community or as an industry rather than  
18 leaving it to the individual centers.

19           And these are weakly managed and coordinated as  
20 an industry. We don't know who is under appeal at any  
21 given time particularly. We don't know when somebody is  
22 planning, a neighbor might be planning to go on appeal and

1 we do not communicate or coordinate that. We again leave  
2 this to a patchwork of individual centers response.

3           The negatives for the public in again getting to  
4 the concept of the effect on the donors and on the public,  
5 it can be anxiety generating. You hear there is a  
6 shortage, and you've got an upcoming surgery, certainly  
7 that's not a good message to hear. It can be confusing,  
8 particularly in competitive areas, often times one center  
9 is on appeal and another center is not. So that can  
10 create quite some confusion amongst donors who don't  
11 understand we're not one collecting agency.

12           It can create behaviors that are maladaptive  
13 amongst the donors. You can unlink a donor from their  
14 regular sponsor group and pattern of giving by pushing  
15 them forward a few months. Now not -- they are not  
16 available to give during the regularly scheduled corporate  
17 drive for example, they're deferred, and they may fall out  
18 of that pattern as a result of not being part of that  
19 group. Or the group itself can have a less successful  
20 drive at that corporation which can have negative  
21 consequences down the road in terms of the morale of the  
22 folks involved with that drive, the sense of success that

1 every good sponsor want to have. You're essentially  
2 draining away some of their donors for this need and not  
3 allowing them to cultivate that success.

4           You train some donors for a crisis trigger.  
5 Some people get in the habit if they hear the crisis often  
6 enough of using the appeal as the reason they give. They  
7 no longer motivate themselves on a schedule. They figure  
8 that they will hear when there is a need and they will  
9 come out when there is a need. Others, you immunize or  
10 you numbed the effect of the appeal simply by presenting  
11 the message so often that they stop taking it seriously or  
12 considering it as a recruitment pitch today to themselves.

13           There is also a credibility risk as I mentioned.  
14 Just this past weekend in a state, I won't mention unless  
15 I'm pressed, this is an article, the title of an article  
16 that was in their local newspaper, which can be very  
17 troubling. It says, "Blood supply is on the wane, but not  
18 affecting area hospitals." I don't know if I read that  
19 and didn't know much about our industry, what I would make  
20 of that article.

21           Knowing what I do about the industry, I see that  
22 as a very dangerous warning sign that some of the ways we

1 handle our appeals are being investigated and could come  
2 back and really have negative consequences for us. So  
3 being that we probably won't get out of appeals in the  
4 short term, although it's certainly a goal that we should  
5 all entertain, being so successful that we don't have to  
6 ask for emergency help.

7           What could we do in the here and now if we are  
8 going to use this method of recruitment, what can we do to  
9 make it more effective? I think we are so much stewards  
10 of this tool. It's much like we are the -- may be the,  
11 the crew of the ship, the cruise liner, and if we see  
12 people using our life boats for pleasure cruises or  
13 perhaps they're out whale watching, we have to be aware  
14 that our life boats are being deployed in that fashion.  
15 We may think that's agreeable and it may be the right  
16 decision, but we have to steward this tool, I think, as an  
17 industry, with some caution.

18           What can we look for in the short term that  
19 could help us? We need vehicle and leadership for  
20 improved coordination, whether that be on the local,  
21 state, or regional level. There is not an owner right now  
22 in the industry of appeals. There are people who assist

1 during appeals, there are people taking interest in  
2 appeals, but there is no side or owner that you can go to,  
3 to find out what is happening in this area.

4           There needs to be some consideration of standard  
5 terminology and standard thresholds for appeals. I've  
6 been in blood centers that think they're nuancing the  
7 message by using the term "urgent" versus "emergent." I  
8 don't think that the public knows that we are making a  
9 distinction, but maybe there is some value to coming up  
10 with terminology distinctions as well as thresholds for  
11 when to use them. Again, "critical" and "serious" might  
12 be another example used differentially by the blood  
13 center, but not effectively communicating anything to the  
14 public that is scaled or triaged.

15           Tracking: When centers are going on appeal, the  
16 duration of these appeals and the outcome of these  
17 appeals. I think this is something that could be acted  
18 upon fairly quickly, particularly if the center has some  
19 benefit by co-opting in and I'll talk about that in the  
20 next slide. But certainly a collaborative or cooperative  
21 undertaking where a part of the responsibility of the  
22 blood center would be to reporting these sorts of

1 trackable outcomes, I think could be attractive.

2           And info sharing: Part of looking at an appeal  
3 is trying to understand the national scope and regional  
4 scope of one's appeal. Again, sharing -- neighbors  
5 sharing information on this is something that should be  
6 encouraged and not as it is now often done in secret, done  
7 as part of an internal activity as opposed to a more  
8 public activity. Since essentially we are -- the center  
9 is using a public resource, it is using the ability to  
10 declare an emergency in that community, it should be  
11 viewed, maybe, as more of a community activity than an  
12 individual center's activity.

13           And I think there should be more effective  
14 sharing of best practices or effective practices. As I  
15 mentioned, some centers will have an appeal which consists  
16 possibly of a press release. And they won't throw much up  
17 underneath it, beyond that. A good appeal is actually a  
18 highly coordinated complex activity when done right, and I  
19 think that centers should be given the tools to think of  
20 their appeals in those terms and perhaps more education of  
21 recruiters, of administrators on this subject would be  
22 beneficial. For example, there is some skill in the

1 announcement timing. The communication plan, whether it's  
2 wire or e-mail, whether it's press releases, what have  
3 you, there is -- they're all best practices in this area.

4           Multiphasing: Some centers look at an appeal as  
5 almost a three-phase. I've seen as many as three-phases  
6 do an appeal in terms of trying to give it legs, so to  
7 speak, with the public. Other centers, it's a one-off  
8 kind of event and they move on. I think if you are going  
9 to call the public to action, you should try and get the  
10 most value, the most -- the longest leg, so to speak, from  
11 that activity. Where you target in the calendar your  
12 appeal is important to know that you should be looking at  
13 open drives, places where the public can go in large  
14 numbers and knowing that your schedule will support those  
15 kind of drives as opposed to picking a time when there are  
16 a lot of closed corporate drives or closed drives that are  
17 not accessible, you may be asking for help but not  
18 offering the right venues.

19           A lot of times, if you go into a center, you  
20 cannot, even though the media is making an appeal message,  
21 you would not be able to necessarily know they are on  
22 appeal when you walk into that blood center. The hours

1 might not be extended for operation, there may be no  
2 messages up related to appeal whatsoever, and the staff  
3 may not be updated and aware of the status of the appeal.  
4 So that when the donor comes in to say, I am here to help  
5 with the O emergency, the staff physically looks back and  
6 says, "O emergency, are still under an O emergency?"

7           So again, some centers do not do a good job of  
8 getting that frontline messaging to their tele-recruiters,  
9 to their collection staff, and trying to keep a  
10 coordinated effort under way. A hospital coordination, I  
11 think the article I just mentioned, there has to be  
12 coordination with the hospital. If you've got a reporter  
13 who hears about the urgency of this play, then walks down  
14 the road, and asks a few of the hospitals how they're  
15 doing and they all say hunky-dory, never been better,  
16 you're going to be in a world (inaudible) with your donors  
17 over time in terms of credibility, I think we've touched  
18 on that.

19           Very interestingly, I have never seen an appeal  
20 start with an end point. These are open ended, we'll run  
21 it as long as we can and while it's effective. Again,  
22 that's kind of an interesting concept, if you're trying to

1 reach an inventory level of safety. Usually, this is a  
2 consequence of the fact that the inventory level of safety  
3 is not reached, so the appeal becomes indefinite, but even  
4 beginning with the end in mind, as CABI (phonetic) might  
5 instruct us, would be a discipline that would be good for  
6 blood centers, I believe.

7           And also rebound planning. As you shift donors,  
8 as I mentioned maybe from their September donation to  
9 their August donation, now you create potential problems  
10 in September by moving that person, and planning for that  
11 rebound phenomenon is important in this and perhaps gets  
12 you out of some of this crisis management by anticipating  
13 that consequence.

14           What could we do in terms of finding a champion?  
15 It's interesting, I think we search for people who care  
16 about this problem. A lot of times we start looking after  
17 the situation as risen to a national level or severity  
18 level, that's unfortunate. Because usually the horse is  
19 out of the barn by that point. You're already in trouble  
20 in many areas by the time there is this nationalized  
21 sentiment to do something. Engaging help earlier in any  
22 disaster or urgency is a good thing. So I think we need a

1 champion who may be can own some of this marshaling of  
2 resources earlier rather than waiting to a severity level  
3 that is again problematic.

4 We need standardized access to celebrity  
5 spokesperson for example. You know, different agencies  
6 have these, different blood centers have their  
7 celebrities, but having one national person who could  
8 speak on this subject might be beneficial. These are all  
9 just suggestions, there is no magic here, it's  
10 brainstorming. A professionally designed product to use  
11 in marketing will be very good.

12 Right now, and I'll show an example in a second,  
13 most centers are left to their own devices, that's because  
14 of the nature of our industry being divided as it is.  
15 Having unified tools would probably enhance the quality of  
16 those tools and potentially get us better results.

17 Cultivated communication channels; the champion  
18 might help us cultivate government agencies for blast e-  
19 mails, certainly outreach to patient advocacy groups, even  
20 on a targeted basis where for example the American Cancer  
21 Society might contact a local chapter and say this is a  
22 significant issue, the sergeant general has asked your

1 state to become involved. We could build those channels  
2 if we have the leadership and the desire.

3 Also corporations. There are some tremendous  
4 corporations, I believe -- well, there are some that are  
5 already interested in our work, Saturn comes to mind,  
6 they've done a lot to try and promote the Saturn Blood  
7 Donor Day. We need outreach at a corporate executive  
8 level that would help us get more corporations, that at  
9 least in times of urgency might send those e-mails, might  
10 do something on their paychecks to remind people of the  
11 need for blood, might open up channels that right now are  
12 generally closed, and particularly at an industry level  
13 are closed.

14 And then community preparedness messaging, you  
15 know, we live in a time when homeland security is very  
16 important. Yet, we run a blood supply some days at three  
17 -- three days supply of certain blood types, even counting  
18 what's in the hospital and what's in the blood center, and  
19 doing that math. It's interesting if we had a three day  
20 supply of surgical sutures, I think we would be seeing a  
21 rush to get that surgery done quickly. Somebody would try  
22 and get in, make sure they got their surgery before all

1 the sutures were used up, same with gauze.

2           These are not nearly as critical in many cases  
3 as blood transfusion is, yet, we have at a day's supply,  
4 three days supply of blood that is almost standard at some  
5 time -- some months of the year. Again, I think,  
6 community preparedness messaging could speak to that. I  
7 often when speaking to donor groups say, if we had a three  
8 days supply of tomatoes in Oklahoma City, you wouldn't be  
9 able to find a can of tomato paste from Oklahoma City to  
10 Sacramento. People would hoard it, people would get  
11 concerned, yet, blood does not at this time register that  
12 level of concern.

13           This is an example of kind of the home grown  
14 messaging. This is from several years ago when I was with  
15 the American Red Cross in Charlotte. This is a nice  
16 message, but it lacked some of that professionalism that I  
17 think we might desire. This was used in hospitals to try  
18 and get the patient population, but more importantly the  
19 family and friends of the patients interested in donating,  
20 we could do a better job at this and this is not to  
21 denigrate this effort, I think it was a great effort given  
22 the resources allowed for it.

1           Another thing that very interesting that we as  
2           an industry could work on is getting feedback mechanism.  
3           A lot of times in the blood center, we do not know the  
4           consequences of our shortage. Certainly, in general  
5           terms, we can know there are quality of care impacts. But  
6           having a way that we could take those general concerns and  
7           get specific related to our current issue of shortage  
8           would be helpful. It could give us texture to our  
9           messaging, to our donors, and also to the media, if we  
10          knew some of the current consequences of a shortage.

11           And listed here are some of the kind of  
12          integrated scale, some of the consequence which we know  
13          may be happening out in the hospitals but certainly being  
14          able to say that somewhere in the state of Oklahoma,  
15          again, blinding some of the details for the protection of  
16          the hospital and for the protection of even patient  
17          information would be desirable. But saying that you were  
18          having a disrupted delivery of blood to your hospital that  
19          you were having to adjust your orders to try and get the  
20          units that you need, that's a first level.

21           Also multiply cross matching units, three  
22          patients, one unit, whoever needs it first gets it, and

1 then you repeat that for the next unit on the shelf. That  
2 kind of -- that's a waste of resources for one thing.  
3 Possibly it's a hazard for error at another level, but  
4 certainly it's an indication that there is stress and  
5 strain on the system. We should know that if we want to  
6 talk intelligently to our donors and to the media.

7           Delayed transfusion, reducing doses,  
8 particularly of things like platelets. Those are things  
9 that happen earlier rather than later in the -- I'm sorry,  
10 happen a little bit later in the triage, and again, we  
11 could use that effectively to motivate people, I believe.  
12 Again, what happens here is a hospital and they are  
13 starting to do these, does not communicate these issue  
14 very widely at all.

15           There are obvious reasons for that. You don't  
16 want to create a sense of panic; you don't want to appear  
17 as an unreliable healthcare provider. There has to be  
18 some recognition of that sentiment when creating this  
19 system of communication. We don't want to disincentivize  
20 this sharing of information, but right now this sharing is  
21 not going on particularly well at all.

22           Clinic waits: Somebody who isn't discharged

1 because they don't have appropriate hemoglobin for example  
2 or platelet count. These are consequences that I believe  
3 are meaningful to the public. No one wants to think that  
4 if they have a loved one in the hospital that they're  
5 going to be there extra days because of our inability to  
6 supply this product.

7           And then very serious consequences listed there  
8 at the end. Diverting patients from one hospital to  
9 another because of the supply issues. Mistransplants; I  
10 know of one case or at least have heard rumor of one case,  
11 where a certain individual was unable to get a transplant  
12 because the local institution didn't have the blood to  
13 feel confident under -- to do that procedure. That's a  
14 remarkably bad outcome, I would assert.

15           And then postponing elective surgeries, again a  
16 very difficult proposition, not only for the hospital but  
17 when you think of the impact on a patient who's prepared  
18 themselves psychologically. A family that's there perhaps  
19 to support that patient, and then perhaps an employer who  
20 has made allowance for that person to be off, to be told,  
21 well, not this time, two weeks from now maybe, or a month  
22 from now maybe. That's a -- it has significant economic

1 and psychological impacts.

2           At any rate, those are some of the things that  
3 we might look at as information worthy of sharing from  
4 hospital to blood center. And looking at this in -- as I  
5 race to close here. Looking at this in a broader picture,  
6 obviously we're interested in getting a better supply and  
7 a bigger supply for the long term. When you look at  
8 appeals, and may be even getting better at doing the  
9 appeals, you're looking at treating a symptom and perhaps  
10 doing a better job with that symptom. The underlying  
11 cause is that we're not doing an effective job overall in  
12 recruitment that allows us to go through these.

13           Weak spots in the calendar; we certainly want to  
14 work smarter, that's a goal. And listed here very  
15 quickly, and I won't go into all of the details, we need  
16 marketing grants. So lot of times our research is  
17 wonderful epidemiology on donor recruitment, it's great  
18 trend lines. It's really a technical look at the data.

19           This is a marketing activity. When you have to  
20 get 15 million people to show up every year, the industry  
21 has to recognize that we're going to have to get  
22 comfortable with the thought that this is a sales issue,

1 and sales require a different type of research than does  
2 an epidemiologic exercise.

3           So putting money -- seed money into centers of  
4 excellence that might figure out how to use text  
5 messaging, as an industry, not as an individual center,  
6 and certainly there are places like Puget Sound that are  
7 doing a magnificent job at looking at technology. Of  
8 course, they are assisted by their location and their  
9 association with Microsoft in doing that, not all centers  
10 have that opportunity and hats off to Puget Sound for  
11 taking advantage of that, but as an industry, we need to  
12 think about seed money to do grants that look at some of  
13 the things listed here, public domain campaigns, good  
14 marketing materials that are available to everyone, better  
15 diversity recruitment tools, an area which is a critical  
16 failing for us right now, and is a real harbinger of bad  
17 things to come, say in the year 2025, when the  
18 demographics have continued to shift in this country.

19           And these centers of excellence should be  
20 required to make their products, their end-deliverables  
21 accessible to the whole community. It's great to give a  
22 grant to an organization that then runs off and creates a

1 great tool, but if that tool remains only with that  
2 organization, we've missed a great chance, I believe, to  
3 spread the good news.

4 Recognition, I think, you know, when I was going  
5 up, they had the President's Award for Physical Fitness,  
6 and that was considered a great honor. Why couldn't we  
7 have an equivalent recognition, maybe a graduation with a  
8 donor recognition at that event. That has worked well  
9 locally in Oklahoma. People who donate four times before  
10 they graduate, high schools that do this, it's really  
11 considered attractive recognition by those high schoolers.  
12 Perhaps on a national level that would work, also.

13 Also a symbol, an affiliation for donors  
14 nationally. There is no symbol for a blood donor right  
15 now. You can't put it on your license plate, you can't  
16 put it in the window of your car. Perhaps there should be  
17 some symbol that says I'm a blood donor. An increased  
18 affiliation out there, which can only help us.

19 And lastly, we need a lot of help getting into  
20 the curriculum right now. It's pretty well recognized  
21 that early education about the need for blood is important  
22 for our long term success. And right now, curriculum

1 access has become a huge issue. If its not part of the  
2 testing requirements in many constituencies, many school  
3 systems, it's very hard to get anything about blood and  
4 health related to blood onto the agenda. We need some  
5 help getting this as a module, perhaps in some of the age  
6 group curricula.

7           And lastly, I think we should remember that  
8 there are demand issues that we need to look at who is  
9 ordering what and try and level out some of the behaviors  
10 in transfusion and utilization that just exacerbate our  
11 problems with appeals. I'd love to say that we're doing a  
12 great job around the country on O-negative usage and that  
13 when we go on a deal, we've used every last unit to its  
14 best advantage. I know that is not the case.

15           And this is a responsibility that we have,  
16 particularly in blood centers, but throughout the  
17 transfusion industry to try and fix this, these  
18 disparities and these outliers who are potentially not  
19 using this resource in the best fashion.

20           I couldn't resist throwing something up about  
21 deferrals, since I was in Washington and there are some  
22 opportunities here to rationalize our deferrals, to add

1 dimensions beyond the donor, I think TRALI is an  
2 interesting example, recently of focusing on a risk, that  
3 is really probably a patient physiology problems as much  
4 as it's anything else. It's -- perhaps in the continuum  
5 of a febrile transfusion reaction that we would have never  
6 considered differing the donor for somebody who had a  
7 febrile reaction.

8           But yet in this regard, because of the severity  
9 of the consequences, we have been aggressive in the donor  
10 aspects and the -- of this problem, but have not even  
11 addressed the 10 percent that might be approachable  
12 through universal leuko reduction, which is probably  
13 easier for the blood supply certainly to enact, than going  
14 to the measure of testing a lot of female donors for  
15 example.

16           Require or pursuit of re-entry mechanisms, I  
17 think that should be required with new tests for example.  
18 A lot of the manufacturers are not engaged in the ultimate  
19 development of re-entry mechanisms for these donors, it  
20 would be wonderful if they were.

21           Sundowning some of the rules to forced review on  
22 an automatic fashion, I think would be beneficial, you

1 know, let us see if the conditions are still the same as  
2 when we thought it was a good idea 15 years ago to  
3 implement a rule, and then lastly, we should think of  
4 developing communication templates. And in this case I  
5 think we've started to do a good job of creating documents  
6 that inform the donor, for example, you have this positive  
7 test and this is what it means. I think we need to take  
8 that a step further and proactively have materials that  
9 explain the new test.

10 To the sponsor who is about to hold a blood  
11 drive, or to the donor who is walking in the door, who may  
12 need to know a little bit about the new rule, particularly  
13 coming up with the possibility of having tests for variant  
14 CJD. I think the communication of that test would be much  
15 improved on a national level and should be improved, so  
16 that people aren't scared away for example, from getting  
17 tested.

18 Those sorts of dimensions to our deferrals, I  
19 think, are needed. We have to think of the front end, and  
20 the front end is not just the deferred donor after the  
21 fact, it's in advance of them ever showing up. So  
22 hopefully, with a little bit of attention, we'll have the

1 supply of life saving fluid we need, and if you have any  
2 questions, I'd be happy to answer. I'm sorry for going on  
3 so long.

4 THE CHAIR: Thank you Dr. Armitage. In the  
5 interest of time, could we perhaps limit the questions and  
6 comments to burning questions, comments, committee?

7 Well, one comment and one question is in terms  
8 of preventing the point of appeal, one thing that seems to  
9 me is that the public really has minimal awareness and  
10 that's one of our questions. What's your perspective on  
11 public awareness of blood? And for example, when I drive  
12 to the airport, there are a series of colors related to  
13 the alertness for, you know, terrorist activity. Is there  
14 any such thing for the public that exists for public?

15 DR. ARMITAGE: I think it's variable, I think  
16 some centers have indicators in their newspaper that they  
17 try and keep the indicator level for example, out in front  
18 of the public. I was hearing from Dr. Roseff (phonetic)  
19 that the -- in Richmond, they screen across the bottom of  
20 the TV, so there are mechanisms that different centers  
21 have used to try and alert people on a regular basis.

22 The trouble is it's a patch work and we're

1 relying on each center, each collector to come up with its  
2 own strategy and its own resources. I think we could do  
3 better by increasing the overall effort and awareness, and  
4 building, maybe, if not national, regional tools to get  
5 the message out. I think, we as an industry struggle, you  
6 know, may be it's because it's admitting failure to a  
7 degree.

8 THE CHAIR: To the mike, yeah.

9 DR. ARMITAGE: May be it's because we're  
10 admitting failure, but we don't like to talk about appeals  
11 and coordination of this. It's something sometimes,  
12 almost secretive for a blood center because they don't  
13 want to advertise that they're having trouble to their  
14 competitors and such. So we have to break through some  
15 bad psychology here, I think.

16 THE CHAIR: Thank you. We'll then move on to  
17 the next presentation by Matthew Payne, who is the deputy  
18 director of ASPR, the office of the -- from the Office of  
19 Assistant Secretary for Preparedness Response. And the  
20 topic of the presentation is --

21 MR. PAYNE: It's an overview of ASPR.

22 THE CHAIR: An overview, okay, an overview of

1 preparedness.

2 MR. PAYNE: Yes, just a quick overview of ASPR  
3 and thank you so much for inviting us to come talk to you  
4 today. It's our pleasure to talk a little bit about our  
5 organization, an organization that's grown quite a bit  
6 over the past year or two, and today, I'd like to  
7 highlight some of those changes, some of the work that  
8 we're doing. I -- and how some of that may relate to some  
9 of your interests.

10 So today, I'll talk a little bit about the ASPR  
11 organization, specifically, the different components of  
12 our organization. I'll talk a little bit about the  
13 Pandemic and All Hazards Preparedness Act. This is a new  
14 law that -- it's had a dramatic impact to our  
15 organization. It actually led to the renaming of our  
16 organization to the Assistant Secretary for Preparedness  
17 and Response. And then I'll focus on two components of  
18 our organization. Our Planning and Emergency Operations  
19 Group and then the Biomedical Advanced Research and  
20 Development Office. Those are really the two largest  
21 components of our organization, and then if we have some  
22 time at the end, I'd be happy to answer any of your

1 questions.

2           The mission of our office is to lead the nation  
3 in preventing, preparing for, and responding to the  
4 adverse health effects of public health emergencies and  
5 disasters. And the short version of our vision is "A  
6 nation prepared." It's a very big vision, for us to have  
7 a nation prepared. But we're really putting an emphasis  
8 to focus on the local responders, the state responders,  
9 get the emphasis back to the folks who truly are the first  
10 responders in any disaster emergency.

11           This is our organization. We represent about  
12 400 to 450 people. A year ago, year and a half ago, we  
13 were half that number, so we've had a very, very, dramatic  
14 increase in part because of the new legislation that we'll  
15 talk about. The four main components of the organization,  
16 the one that I am a part of is the Office of Policy,  
17 Strategic Planning, and Communications. Then we have the  
18 Biomedical Advanced Research And Development Office, which  
19 -- their predominant function is working in the  
20 development of medical counter measures.

21           The Office of Science, Medicine and Public  
22 Health. The major function for that group is

1 international preparedness. Working with the office of  
2 Global Health Affairs at HHS, but also providing our  
3 office with medical and scientific expertise. And then  
4 the Office of Preparedness and Emergency Operations,  
5 that's a response group. And as I'll talk in a couple of  
6 slides here, with the transfer of the Hospital  
7 Preparedness Program from HRSA, they also have a very  
8 large role in the preparedness activities.

9           So the -- our roles in major programs, first and  
10 foremost, enhancement of state and local preparedness.  
11 This is accomplished through activities such as the  
12 Hospital Preparedness Grant program. It's also working  
13 through our regional coordinators. Earlier, this Spring,  
14 working with Dr. Holmberg, we sent notices to all the  
15 state emergency management officials, encouraging them to  
16 engage with community blood centers on preparedness  
17 activities.

18           And we've learned through a variety of responses  
19 and exercises, there are gaps in the preparedness of the  
20 community blood centers in the areas of getting generator  
21 power during a hurricane, if there is a loss of power,  
22 making sure that that happens in a timely fashion.

1 Transportation of blood and blood products in the time of  
2 emergency and communications. So this letter (phonetic)  
3 encouraged those emergency management directors to engage  
4 with the community blood centers directly in the planning  
5 and preparedness activities in the case of a hurricane or  
6 an earthquake or some other event that could disrupt the  
7 blood supply or result in the need for additional blood or  
8 blood products.

9           Development and implementation of national and  
10 departmental plans and policies. This spends a full  
11 spectrum of preparedness activities. Working on the  
12 development of pandemic influenza preparedness plans,  
13 development of playbooks for a variety of disaster  
14 response scenarios, whether it's responding to an anthrax  
15 attack, a hurricane, an earthquake or a radiological  
16 event. We do take an all hazards approach for both the  
17 naturally occurring events and the deliberate events.

18           Departmental and inter-agency planning and  
19 response; our focus is very collaborative, and we'll talk  
20 about in a couple of the slides, that collaborative  
21 nature. Working not only within our department, with the  
22 various operating and staff divisions within department,

1 but also within the federal inter-agency committee. I'll  
2 talk a little bit about our relationships with the  
3 department of homeland security, and some of our other  
4 ESF#8 partners, Department of Defense, Department of  
5 Veterans Affairs and others.

6 And then I won't go into the rest of the items  
7 that I've listed there, but you can see, providing  
8 leadership and international and we'll talk more about the  
9 medical counter measurements management aspects.

10 So PAHPA, the Pandemic and All Hazards  
11 Preparedness Act. Not my favorite acronym, but it works.  
12 The significance of PAHPA is for the first time it  
13 codified HHS as the lead federal public health in medical  
14 agencies to respond to emergencies, which is very  
15 significant within the national response plan. Part of  
16 that directed us to engage DHS, the VA, and the Department  
17 of Transportation developing inter-agency agreements to  
18 assume operation control of federal public health and  
19 medical personnel and assets during incidents, that's a  
20 very significant activity for us.

21 That does not include engaging with the  
22 Department of Defense; the Department of Defense always

1 retains the operational control of their own assets. It  
2 also created for the first time, the Assistant Secretary  
3 for Preparedness and Response. This is a Senate confirmed  
4 position, currently held by Rear Adml. Craig Vanderwagen,  
5 who has been with the department for quite a long time,  
6 recently with the Indian Health Service, but also has a  
7 significant disaster response portfolio, serving as our  
8 senior health official during the Katrina response in  
9 Louisiana; working in Iraq, following the initial invasion  
10 and helping to establish health centers in Iraq, and also  
11 deploying in South-East Asia following the tsunami. So he  
12 comes with a vast background, and is really helping us to  
13 advance the preparedness and response issues of the  
14 office.

15 Adm. Vanderwagen serves as principal advisor to  
16 the secretary on public health and medical preparedness  
17 and response issues, and has the deployment authority for  
18 federal personnel. As you note, it includes the National  
19 Disaster Medical System. This is for us another major  
20 significant portion of that legislation.

21 For those of you who are familiar with NDMS,  
22 NDMS originally was established within HHS, as a

1 partnership among four agencies, DOD, VA, FEMA, DHS, and  
2 HHS. When DHS was created and DMS was transferred to DHS,  
3 this law transfers it back to HHS, which we are very happy  
4 to have, and to welcome them back to us, and we think that  
5 it helps us to respond more effectively and efficiently to  
6 disasters and emergencies. It is still absolutely a  
7 partnership between the same agencies, but it provides us  
8 with immediate medical response assets, the DMATs, which  
9 are very important to us.

10 Additional things, we just talked about the  
11 transfer of NDMS, and I also alluded to the transfer of  
12 the Hospital Preparedness Cooperative Agreement program.  
13 This is about a \$400-500 million preparedness grant  
14 program which has been managed by HRSA for several years.  
15 So, again, that is a significant activity for us.

16 Recently, the request for proposals was  
17 submitted to the states and the territories and the few  
18 select cities. So there will be awards made for this  
19 year's cooperative agreement programs, I assume. It  
20 created the BARDA, and also called on the ASPR to  
21 coordinate, but not lead the Medical Reserve Corps  
22 program, the emergency system for the advanced

1 registration of volunteer health professionals; the  
2 strategic national stockpile; and the city's readiness  
3 initiative.

4           The first item, the MRC is managed by the  
5 sergeant general, the ESAR-VHP program, again by Office of  
6 Public Health and Science, and then HRSA. SNS and the CRI  
7 programs are both managed by CDC, but as a result of the  
8 law, we have a much closer role in the execution of those  
9 programs, leading international preparedness and response  
10 initiatives.

11           And another significant event for us is starting  
12 in 2009; we have to deliver a national health security  
13 strategy. The National Health Security Strategy, for  
14 those of you who are familiar with the quadrennial defense  
15 review, that's what we're equating this to, is that every  
16 four years, we are going to have to provide a report to  
17 the Congress and to the public on the status of public  
18 health and medical preparedness activities.

19           And that's going to cover the spectrum of  
20 preparedness and response, the medical countermeasures  
21 management, the preparedness grant programs, response  
22 assets, so this is a major undertaking for us. And

1 something that we have never provided in this type of  
2 package. So it's going to be quite challenging and  
3 hopefully very -- very helpful for a lot of our  
4 constituents.

5 I focused just a little bit on the components  
6 for emergency operations. The primary response assets  
7 within the department, and I've just listed just a few.  
8 The Secretary's Operations Center, that's really our  
9 coordination center within the department. There are  
10 other operations centers within the department at the FDA,  
11 at the CDC and at other elements. And this is the  
12 overarching departmental coordination center.

13 We have talked about, the transfer of NDMS.  
14 NDMS is composed of thousands of physicians and nurses and  
15 other medical providers who are organized in the teams  
16 that can deploy to a disaster site, be self-sustaining for  
17 at least 72-hours and provide field medical care. Also  
18 the NDMS system includes Patient Evacuation System, which  
19 is led by DoD, and (inaudible) of hospital care component,  
20 which is led by both DoD and VA. So it's a very  
21 significant program for us.

22 And then the uniformed officers of the public

1 health service: As uniformed officers, they can all be  
2 called up, deployed to disaster situations as was the case  
3 in Katrina, which was. I believe the most significant  
4 response for the public health service in the department  
5 surpassing the response to 9/11.

6           The Emergency Support Function 8 partners:  
7 Emergency Support Function 8, for those of you who are not  
8 familiar with the National Response Plan; the National  
9 Response Plan is functionally divided, and ESFA is the  
10 part of the pie that deals with public health and medical  
11 response. HHS is the lead agency for that function and  
12 supported by a variety of other federal departments and  
13 agencies including DoD and VA. DHS is the overall  
14 coordinator of the federal response, but HHS has the  
15 responsibility for leading the public health and medical  
16 component.

17           And obviously, we worked very closely with the  
18 Medical Reserve Corps teams. That the MRCs are not  
19 federal assets, those are local volunteers, established  
20 locally, controlled locally. We provide them with some  
21 limited funding and support and in an emergency we try to  
22 coordinate very closely with them to maximize the response

1 effort.

2           The Hospital Preparedness Program: The focus  
3 here, there are two major cooperate agreement programs in  
4 the department. This program and then the CDC program,  
5 the CDC program is focused more on the public health  
6 community.

7           This program is focused more in the hospital  
8 setting. There is an emphasis on tiered and regional  
9 response. In many of the activities that we do, we  
10 support the engagement across the community, across  
11 disciplines, and then across states, because as we saw in  
12 Katrina, many of the scenarios that we're preparing for --  
13 are going to surpass the capabilities and capacities of  
14 any local community of a state or possibly of a region.

15           So, we need to encourage our planners to  
16 coordinate with their adjacent communities, their adjacent  
17 States, and are working through the emergency management  
18 assisting compact, which is a mechanism to provide State-  
19 to-State support, not a federal initiative, but something  
20 that we support entirely. And that's really the focus of  
21 those, those activities.

22           The last bunch of slides said that I'll talk to

1 you -- focuses on the BARDA. And BARDA was established  
2 through the Pandemic and All Hazards Preparedness Act.  
3 And the primary function of BARDA is to facilitate  
4 collaboration among the U.S. Government industry and  
5 academia, to support advanced research and development of  
6 medical countermeasures, and promote innovation and reduce  
7 time and cost of the medical countermeasures.

8 It also has developed the Biodefense Medical  
9 Countermeasure which is management developed and fund, the  
10 de-advanced development fund. Why this is a significant  
11 is it funds the development of products across the so  
12 called, "Valley of Death," that gap between the initial  
13 basic research that NIH is funded and the procurement  
14 through the BioShield legislation.

15 When we procure a countermeasure to provide to  
16 the Strategic National Stockpile, that gap between the  
17 two, we found was a significant deterrence to industry to  
18 make the necessary investments in these types of  
19 countermeasures, whether it is for anthrax vaccine or  
20 smallpox vaccine, botulinum antitoxin -- a variety of  
21 different countermeasures. It will also last for  
22 milestones payment which is, which is a significant change

1 for us.

2 Roles and responsibilities of BARDA: I spoke to  
3 the -- the coordination aspect -- I have a slide when we  
4 talk about the partnership with a variety of our  
5 departmental colleagues in the execution of our  
6 responsibilities under BARDA.

7 It supports, the assistant secretary in leading  
8 the Public Health Emergency Medical Countermeasures  
9 Enterprise, and allows for the analysis and prioritization  
10 of the procurements and the developmental process.

11 So, the Public Health Emergency Medical  
12 Countermeasure Enterprise: The enterprise consists of  
13 four components of the department, ASPR, CDC, FDA and NIH.  
14 The developmental process as you would expect, there is no  
15 single organization within HHS that is responsible for the  
16 entire lifecycle of these countermeasures.

17 S, we have to do this in a collaborative manner,  
18 so that we can go from the basic research all the way to  
19 the acquisition delivering into the Stockpile, and  
20 delivering into the arms and mouths of the people who need  
21 it. So the enterprise governance board is the group that  
22 manages this process, provides recommendations to the

1 secretary to prioritize the requirements to align our  
2 research and development activities and to set the  
3 deployment in U.S. strategies.

4           The enterprise service is a mechanism for  
5 implementing our medical countermeasures mission, and it  
6 addresses both the natural and the deliberate activities.  
7 Again the all has its approach here, and it allows us to  
8 integrate more effectively, affectionately with the  
9 Strategic National Stockpile, our BioShield activities and  
10 our pandemic influence activities.

11           Some of the major milestones over the past year  
12 or so is there are many reports in strategic plans which  
13 are available publicly on our website which I will put up  
14 in the next slide, with detail how we are approaching the  
15 medical countermeasures management activity, how we are  
16 trying to ensure that we are have a balanced portfolio,  
17 that we are -- in making the investments in the right  
18 activities at the right time so that -- where we can get  
19 the most bang for the buck, where we can take advantage of  
20 a research that's further or long in the development  
21 process.

22           It might allow us to cross off a threat that is

1 posed to us. Some of those include the PHEMCE strategy  
2 for chemical, biological, radiological, and nuclear  
3 events. The implementation plan for PHEMCE and the Draft  
4 BARDA Strategic Plan, and the reason that the Draft BARDA  
5 Strategic Plan is drafted is because we are still in the  
6 process of hiring the board of director, the statute  
7 called for the secretary to appoint a director of the  
8 Biomedical Advanced Research and Development Authority,  
9 that process is concluding very soon.

10 And it was very important that person once hired  
11 had the ability to have their hand in what that strategy  
12 is going to be. So once that person is hired that  
13 document will become final, and it might look just  
14 slightly different.

15 All the things that I have talked about are  
16 available on our website, it is very easy to access our  
17 website, we have integrated with the Department Of  
18 Disaster and Emergency Site. So if you go to HHS.gov, on  
19 the left-hand side to see disasters and emergencies  
20 throughout the HHS website, click on that that brings you  
21 to us.

22 It has -- it's formatted a lot like the

1 PHEMCE.gov site but it will also bring it to the office  
2 specific site of ASPR where you can learn more about  
3 BARDA, the Office of the Planning Emergency Operations and  
4 the other activities that we do.

5 With that I -- it was a quick presentation, we  
6 just scratched the surface of some of our areas, but I'll  
7 be happy to answer any questions that you might have or  
8 talk to you on a break.

9 THE CHAIR: Thank you Mr. Payne. Lots of  
10 activity, there are questions, comments from the Committee  
11 Dr. Epstein?

12 MR. EPSTEIN: I know time is brief and the  
13 subject is large, but could you just comment where you see  
14 securing the blood system and you know, blood system needs  
15 and disaster within this larger framework?

16 MR. PAYNE: Uh-huh.

17 DR. EPSTEIN: Because I think that there's been  
18 a general sense that we're a little bit marginalized that  
19 you know, we haven't been served in the first round of  
20 considerations and we're sort of trying to find our  
21 linkages. It's of course very heartening to hear that all  
22 this is happening. But where do we fit?

1           MR. PAYNE: Uh-huh. Thank you for that  
2 question. The letter that I mentioned earlier that went  
3 to the emergency management directors, that letter also  
4 emphasis to how HHS has identified the blood and blood  
5 products as a component of the critical infrastructure.

6           And as a result of that, the issues that you are  
7 discussing today are included in our efforts working with  
8 the Department of Homeland Security in critical  
9 infrastructure protection. The goal there been of -- if  
10 an event happens where there is a disruption to the power  
11 grid or the transportation nodes that blood and blood  
12 products are high on the list of activities that need  
13 attention.

14           Whether, you know, as I mentioned before whether  
15 that's making sure that there is a sufficient power  
16 provided that there is communications, capabilities so  
17 that we can know where to distribute the products that are  
18 needed, or getting the right transportation assets.

19           So, it is a priority for us, it is part of the  
20 critical infrastructure protection activities. Obviously  
21 that is a joint effort with us, and the Department of  
22 Homeland Security.

1 Does that help answer your question?

2 DR. EPSTEIN: Yeah, thank you.

3 MR. PAYNE: Okay.

4 THE CHAIR: Question from Dr. Kuehnert?

5 DR. KUEHNERT: A very, very nice presentation.

6 I just wanted to follow-up with that, because I think, and  
7 there is a fair amount being done at the federal level on  
8 this specific issue of blood safety, and actually in a  
9 disaster situation, perhaps more importantly, availability  
10 at the federal level, but, really where the rubber meets  
11 the road is at the local level.

12 MR. PAYNE: Uh-huh.

13 DR. KUEHNERT: And you know, the various  
14 scenarios that we have played out in exercises have shown  
15 that it comes down to does -- the blood center knows the  
16 health department, as the health department know the blood  
17 center, and are they talking to each other. And I just  
18 wondered what's being done to help encourage that. I  
19 know, there has been some inclusion in various  
20 presentations, but I wanted, what specifically is being  
21 done to make sure that connection happens?

22 MR. PAYNE: Sure, sure, thank you.

1           The -- what's been done from our office is,  
2 across the 10 federal regions, we have regional emergency  
3 coordinators in each of those regions. With the transfer  
4 of NDMS to HHS, that included all of their regional  
5 emergency coordinators.

6           So, we very rapidly went from having a regional  
7 staff of ten, one in each of the regions to having three  
8 to four in each region, which gives us a lot more depth  
9 out there. What that provides us is an ability to engage  
10 more directly in the preparedness and planning activities  
11 at the state and local level, because we couldn't agree  
12 with you more -- that is where the emphasis needs to be,  
13 they are the ones that will be the first to feel the impact,  
14 and have to deal with the long-term consequences of any of  
15 these events.

16           So, the letter that we send to those emergency  
17 management directorates was also sent to our Regional  
18 Emergency Coordinators and also sent to the Regional  
19 Health Administrators, to emphasize to them the importance  
20 of engaging in the blood community, in our planning and  
21 preparedness activities, whether that's developing the  
22 concept of operation plans for a local community or state,

1 whether it's engaging in a local, state or federal  
2 exercise, but that message has been delivered to them, and  
3 hopefully will be able to show the work that's been done.

4 DR. KUEHNERT: Great, thanks.

5 THE CHAIR: In terms of one of the charges that  
6 we'll have to or issues that we'll have to consider,  
7 strategic stockpiles, this Committee would then make a  
8 recommendation, which would go to HHS, and I'm just trying  
9 to understand the review and approval process if this  
10 Committee makes a recommendation on a particular item  
11 that's considered to be of importance, and it goes the  
12 assistant secretary, then if the assistant secretary would  
13 then approve of the recommendation, what then is a process  
14 for having that actually added to the stockpile? Where do  
15 the dollars come from to cover the need?

16 MR. PAYNE: Sure. Without getting into  
17 specifics because that's not exactly my area of expertise  
18 here, but as I mentioned the Enterprise Governance Board.  
19 The Enterprise Governance Board is the managing body that  
20 includes FDA, NIH, CDC, and the assistant secretary in  
21 making  
22 those decisions which include the strategic national

1 stockpile. I presume that any recommendation that was  
2 provided to him will be discussed within that group, and  
3 then either -- further recommendation be made to the  
4 secretary or decision to be made.

5           The resources that are available, I am not sure  
6 which of the funds that we have, if they can be used for  
7 the types of recommendations that you might make, you  
8 know, those could included the same that provide for any  
9 of the medical countermeasures, you know, that we're  
10 discussing through the BioShield Legislation or through  
11 others. But I just don't know the specifics on that.

12           THE CHAIR: Okay. Dr. Ramsey?

13           DR. RAMSEY: Yeah, thanks -- very nice  
14 presentation. Could you or Dr. Holmberg, comment on the -  
15 - how the inter-organizational -- does this change how the  
16 inter-organizational taskforce fits into this structure?  
17 I am referring -- and as a disclaimer I'm as you know I'm  
18 on, I'm a CAP representative to that Committee, but does  
19 this -- I'm just curios whether this changes the reporting  
20 system for the task force?

21           MR. PAYNE: No it doesn't. It does not -- once  
22 the ESF8 has been activated, then it is our responsibility

1 to reach out and communicate, and interact with the task  
2 force. So, the responsibility for the task force is still  
3 in place.

4 THE CHAIR: Dr. Epstein?

5 MR. EPSTEIN: Well, this is really a related  
6 point. Historically the ACBSA that's this Committee is  
7 advisory to the secretary, but the recommendations have  
8 largely addressed by the Assistant Secretary for Health,  
9 and to the extent that this Committee has been dealing  
10 with disaster preparedness and response in terms of making  
11 recommendations, it raises the question of whether our  
12 recommendations are getting or should get equal audience  
13 with ASPR.

14 THE CHAIR: Thank you.

15 DR. HOLMBERG: If I can answer that question?

16 THE CHAIR: All right.

17 DR. HOLMBERG: Yes they are and in fact on  
18 several occasions I have both briefed Dr. Agwunobi, the  
19 Assistant Secretary for Health and also the Dr.  
20 Vanderwagen on various issues and recommendations and even  
21 based on my last meeting with them the decision was to  
22 move forward with a recommendation to the Enterprise

1 Governance Board.

2           So there -- you know, there is a lot of  
3 interaction. Yes, we are under -- my office is under the  
4 Office of Public Health and Science. We report, I report  
5 directly to the Assistant Secretary for Health, but when  
6 it comes to preparedness, and response there is a mutual  
7 agreement and a mutual coordination. So, really any  
8 recommendation that would come out of this Committee would  
9 first go the ASH, and then go over to ASPR.

10           And that may even go over, officially through  
11 the memo, a memo, which would then probably then be  
12 followed-up with discussion on how do we move forward on  
13 the particular recommendation.

14           THE CHAIR: Ms. Finley?

15           MS. FINLEY: I have a question Dr. Holmberg. Is  
16 FDA represented on the BARDA Blood Working Group?

17           DR. HOLMBERG: Yes it is, and I'll explain that  
18 a little bit later.

19           MS. FINLEY: Okay, thanks.

20           THE CHAIR: Any additional questions for Mr.  
21 Payne? If not thank you very much for a wonderful topic.

22           MR. PAYNE: Okay, thank you very much.

1 THE CHAIR: Okay.

2 At this point we are scheduled for a break so  
3 why don't we reconvene in 15 minutes, that would be 20-  
4 off?

5 (Recess)

6 SPEAKER: -- to double its capacity in a given  
7 day, what is the limit of the industry's capacity, you  
8 know, how much -- you know, what -- yeah, what -- how much  
9 can we collect in any given day, maximum, is that known?

10 DR. HOLMBERG: I do not know that answer, I  
11 don't know if Dr. Bianco knows the answer, I think that  
12 maybe one of the contributing factors might be the  
13 availability of equipment, supplies --

14 SPEAKER: Right.

15 DR. HOLMBERG: Testing.

16 SPEAKER: Right.

17 DR. HOLMBERG: And I think what we heard  
18 yesterday was that there were a lot of vendors that said,  
19 "Yes, we can supply things, but it's not our business  
20 model, but if somebody could come with the money, they  
21 would stock things up, I think we're seeing that the  
22 business philosophy throughout the country is just in time

1 delivery, but Dr. Bianco would you want to mention?

2 DR. BIANCO: Oh, I have to agree with all that  
3 you said, the only thing that I would add is that our best  
4 experience or our worst experience is September 11 and  
5 there the capacity was increased by at least threefold.  
6 There were local shortages of reagents or bags that were  
7 compensated by other people by -- you see that during a  
8 period of maybe a month, we collected at least 500,000  
9 units more than would be the number of units required to  
10 maintain the system so that's at least 20,000 and 15,000  
11 units a day.

12 DR. HOLMBERG: Yeah. Now, when you start  
13 looking at that and what I wanted to make sure that we had  
14 a good handle on even though that back of the envelope  
15 calculation looked really high, that's not what's going to  
16 be required on the first day, okay. Definitely, there's  
17 going to be a lot of casualties, there's going to be a lot  
18 of fatalities, but what we're -- you know, there will be  
19 supportive, because of course -- and the hematological is  
20 going to go out first and then the GI syndrome is next, so  
21 definitely, it's -- you know, there's going to be some  
22 supportive care for those people that may receive lower

1 dose radiation.

2 THE CHAIR: Dr. Epstein.

3 DR. EPSTEIN: Jerry, I got a little confused.

4 Under the BARDA organization chart, maybe you could put it  
5 up again, you had a separate working group for the blood  
6 and tissue requirements and for rad-nuke (phonetic), is  
7 that not correct, and if that's so I have two questions,  
8 which is when you then showed us the organization chart,  
9 were you showing us the -- okay, so here you have -- third  
10 one down on the left is rad-nuke and it's separate from  
11 blood and tissue requirements working group. Okay, you  
12 then went to showing us an organization structure a few  
13 slides down, was that then rad-nuke or was that blood and  
14 tissue and then the third question is so when you're  
15 bringing the National Blood Reserve concept to the  
16 enterprise board, are you bringing that as part of rad-  
17 nuke or are you bringing that as blood and tissue and are  
18 they the same?

19 DR. HOLMBERG: Well, hopefully, they're all the  
20 same to answer your third question first. What we tried  
21 to do is if you'll look at the right-hand box under ASPR,  
22 George, Alexander, Joann Atapraser (phonetic) Norm Coleman

1 (phonetic), Judie Bader (phonetic). Actually, Norm and  
2 Judie are the rad-nuke people. And we have cross  
3 pollination with the various working groups so that it's  
4 not just a silo that we are trying to merge our  
5 requirements together, and of course as you -- I think  
6 what you're referring to is that blood really does cut  
7 across to each one of those other areas and so we have to  
8 make sure that there's cross pollination and that we are  
9 cross talking and making sure that the requirements are  
10 consistent with the other working groups, so there's a lot  
11 of collaboration that is going on here.

12 Peter Heinman (phonetic) is our modeler that  
13 does all the modeling for all of the groups, working  
14 groups, so we do have that -- in fact what we've done is  
15 even with the treatment files and the evidence based  
16 guidelines, we are working with all the working groups  
17 together.

18 DR. EPSTEIN: Well, where I'm heading with all  
19 this is if you're going to the enterprise governance board  
20 with the proposal for a blood reserve, we heard yesterday  
21 that the blood organizations no longer support that  
22 concept and I guess, the question is whether the blood

1 organizations are of that opinion both with regard to  
2 radiological disaster and then other forms of disaster and  
3 shortage, because it seems from the kinds of numbers that  
4 you've shown that there may be a greater need for a  
5 reserve to address radiological disasters, and so that's  
6 perhaps more a question for our industry colleagues than  
7 for you Jerry, but in my mind, it raises the question of  
8 whether they were prepared to go to the enterprise board.

9 DR. HOLMBERG: I don't know if anybody from the  
10 industry wants to comment -- my marching orders were  
11 actually the recommendations that came from this  
12 committee, and we did work through the National Blood  
13 Reserve with a lower number that was more economically  
14 feasible and a mechanism of keeping the blood in local  
15 blood centers so that it was not just a virtual type of  
16 blood reserve. Actually, the first time that I really  
17 heard the task force talk negatively about blood reserve  
18 was at the last June meeting, so the -- I'm a little  
19 confused too, and I really would like to have confirmation  
20 on what the blood group -- I mean, even though the blood  
21 community may say that they don't think it's needed, I  
22 think that what we're asking and may come out as a

1 recommendation from the committee here is that should we  
2 continue on down that path.

3 SPEAKER: Well, yeah, I think one of the things  
4 that I was thinking of when we heard the information  
5 yesterday is that a major component in the consideration  
6 was cost and historical model where the blood demand was  
7 not very high, I think that the committee in its  
8 deliberations on this particular subject will have to look  
9 at all of the available models and really focus -- the  
10 cost is important, but that shouldn't be the primary  
11 issue, but -- Ms. Weekman (phonetic), you wanted to make a  
12 comment?

13 MS. WIEGMANN: Sorry. Thank you. A couple of  
14 points in response to Dr. Epstein's questions, the  
15 taskforce has reconsidered its position on the blood  
16 reserve primarily looking at the scenarios that we've  
17 faced in the past and the available numbers that are out  
18 there, we have not seen detailed modeling on the rad-nuke  
19 scenario so I think that before we could make an ultimate  
20 decision on that we should be able to see those numbers --  
21 the gut instinct that I have in looking at them first is  
22 similar to what Dr. Bianco said in terms of if you need

1 the 40,000 units weeks out that the blood community could  
2 probably get the -- the public would be so energized that  
3 they would want to give that we may be able to meet those  
4 needs, but I think it needs some further analysis clearly.  
5 And then one point I wanted to ask, Dr. Holmberg, when you  
6 say you've made a suggestion for reserve to this  
7 committee, is it -- what type of reserve is it, is it the  
8 actual physical reserve that this committee discussed a  
9 few years ago in terms of when we suggested that there be  
10 10,000 units of red blood cells or what are the parameters  
11 of the reserve you're talking about -- virtual versus real  
12 and which products and what have you?

13 THE CHAIR: Dr. Holmberg?

14 DR. HOLMBERG: Do you mind me getting into the  
15 details?

16 THE CHAIR: That's fine, yes, fine.

17 DR. HOLMBERG: I don't want to spend a whole lot  
18 of time on this, but the concept that we have put forward  
19 is a model of 2000 units and that model would be divvied  
20 up around the country in strategic locations, especially  
21 utilizing the blood centers that would then -- would --  
22 could compete in a grant or a contract if you will, and

1 their requirement would be to have a minimum -- if there  
2 were only -- and I'm -- this is all hypothetical --

3 THE CHAIR: Yes.

4 DR. HOLMBERG: I'm not trying to give any  
5 information out here that may not be appropriate, but  
6 let's just use the hypothetical that each blood center  
7 would be required to maintain 500 units of group O, they  
8 would be required under a vendor managed inventory to  
9 collect those 500 units, maintain those 500 units for a  
10 two-week period of time, and then rotate the 500 units.  
11 So there would be a continuous staggering of their  
12 inventory and moving their inventory.

13 The reason why we have looked at a vendor  
14 managed inventory is that it still gives the capability  
15 back to the blood center, it gets the government out of  
16 purchasing blood, we cannot purchase blood. And so one of  
17 the things -- we don't want to interfere with free trade  
18 and what is happening, you know, the industry, and so what  
19 we would do is the call for release of that blood would be  
20 at the discretion of the assistant secretary for  
21 preparation and readiness, and if blood were needed then  
22 that blood would be released to go. And so it's not a

1 virtual -- it's an actual, but with a two-week cycle, it  
2 would then permit blood to be reintroduced into the  
3 inventory and help raise the tide to increase the amount  
4 of blood that would be available for -- to try to help in  
5 a situation of moving it from a three-day supply upwards  
6 to a five-day to seven-day supply. So that's simply what  
7 it is in a nutshell.

8 THE CHAIR: Okay, I think Dr. Bianco, did you  
9 have a comment that you wanted to make and then we'll go  
10 to the committee members.

11 DR. BIANCO: I don't want to throw sand on the  
12 gears, but I honestly believe that the impact of such a  
13 reserve would be small and I have concerns on how it would  
14 make sure that these 500 units at a center would be in  
15 addition to what they already maintain. I remember my  
16 times at New York Blood Center, we had on the shelves  
17 about 13,000 to 15,000 units. In times of shortage, we  
18 had 10,000 and so the 500 units are relatively small  
19 amount, and I don't see a problem, I -- I'm concerned a  
20 little bit about the utility. Currently, the way the  
21 system is managed in terms of disaster is what we call  
22 "hub and spoke system," and that's part of our agreement

1 even with the military in which when -- they have  
2 requirements to request products from us that we have some  
3 hub centers that are close to military facilities to  
4 handle the blood, and then we have the spokes, we have the  
5 rest of our centers that then will refuel the hub that  
6 will send that immediate shipment, and I think that's the  
7 model that we thought for.

8 I'm sure that the Red Cross has a very similar  
9 system that -- then we involve everybody, but we have one  
10 place that can immediately respond to a need and then fuel  
11 back from other centers. So I think it's meritorious to  
12 think that you could have a safe supply that is there  
13 guaranteed. If the ASH asks a blood center to provide  
14 some blood in a emergency situation to somewhere, I'm sure  
15 that all the organizations would be more than willing to  
16 come and help. So maybe those couple of million dollars  
17 that this will cost could be employed on something that  
18 would be more helpful.

19 THE CHAIR: Thank you. From the committee, Ms.  
20 Finley and then Dr. Cutis -- Kouides and then --

21 MS. FINLEY: I very much appreciate the  
22 comments that both Teresa (phonetic) and Celso made. I do

1     however want to point out in fairly strong terms that you  
2     are basing your response, which, granted is somewhat  
3     informal, you know, during this meeting, on your past  
4     experience, which is fine, except that there are scenarios  
5     out there that you may not have considered.

6             Specifically, if there were acute radiation  
7     incidents in multiple locations around the country and we  
8     saw multiple location involvement in -- at 9/11, you have  
9     a lot of people fleeing; you may be overwhelmed and unable  
10    to respond. At that point you may be unable to ship from  
11    another section of the country. I've no doubt the people  
12    in other unaffected parts of the country will want to  
13    respond, and I've checked that with a couple of people  
14    prior to coming to the meeting. However, I -- the  
15    responsibility for accurate modeling of this is clearly  
16    with an ASPR.

17            And I'm concerned that we are being sounded out  
18    about our position relative to a blood reserve, I don't  
19    think we have adequate information here, I think there  
20    needs to be -- in this country, as opposed to other  
21    countries, where the blood collection organizations are  
22    part of the government, we need to make sure that we have

1 a very firm number from ABC and ARC and all -- you know,  
2 and AABB, about how much elasticity they have, and then  
3 work that into the model with the understanding that there  
4 may be multiple scenarios. I'm personally unwilling to  
5 give up the concept of a reserve at this point, and if,  
6 you know, I understand correctly from Dr. Holmberg's  
7 presentation, that they are moving this to the enterprise  
8 board, I think I would not be comfortable as a committee  
9 that we have consulted this. These are very important  
10 plans for the country; we cannot do them on the back of an  
11 envelope. You know, this BARDA has expanded considerably  
12 in the last year, their plans are, you know, being  
13 presented, but there's still a lot of work to be done and  
14 I am concerned that there are scenarios that the blood  
15 banking organizations are not aware of or haven't  
16 considered or haven't been information from to which they  
17 can respond.

18 THE CHAIR: Thank you, can we have Dr. Kouides,  
19 and then we'll go back to Dr. Bianco.

20 DR. KOUIDES: I have, Jerry, two questions.  
21 First is along the lines of -- you'd mentioned the 500  
22 units as the amount needed in storage, is there a

1 consensus as how much is needed. We heard yesterday that  
2 in prior, you know, disasters here, it's at most what 200,  
3 you know, units of red cells, there is a discordance from  
4 what we heard yesterday from Ms. Sylvester and what you're  
5 telling us; you used the different scenario of the Madrid  
6 bombings and also the battlefield. So is there a  
7 consensus -- how did you arrive at that number, "500"?

8 DR. HOLMBERG: Well, to be honest with you, the  
9 "500," is only a -- again, hypothetical, okay, I'm not  
10 saying that that's what it would be, it may even be less  
11 than that depending on the availability of blood centers  
12 that would participate or compete for grants to  
13 participate in this, but what I'm saying is that our model  
14 -- current model is 2,000 units versus the initial model  
15 that was for 10,000 units that would've cost millions and  
16 millions of dollars. Is that enough, it would be 500 -- I  
17 mean, hypothetically what I was saying was 500 per  
18 location, if we had four different locations. And the  
19 concept that was expressed there was the 500 per location  
20 would be strategically put just like the SNS in various  
21 locations around the country.

22 Now, one of the things that, you know, we're

1 talking about some scenarios, but there are really 15  
2 different scenarios that the DHS has told everyone to  
3 start looking at, and you know, I think that we have to  
4 take -- I appreciate the comment about the modeling, yes,  
5 the back of the envelope is -- it was a starting place to  
6 realize to say, "Hey, we need to do a reality check here,"  
7 but the modeling -- and Dr. Heinman is responsible for  
8 that; we actually have three different modeling teams that  
9 are working on this at the present time to really search  
10 out the numbers and to help us.

11 SPEAKER: Okay.

12 DR. KOUIDES: And may I -- a quick comment -- my  
13 second question is.

14 THE CHAIR: Sure.

15 DR. KOUIDES: You had decided about radiation, I  
16 think Teresa addresses too for the initial phase, that  
17 includes what timeframe, because as you know when you do  
18 total body radiation for a bone marrow transplant, you do  
19 not become transfusion dependent for five to, you know, 10  
20 days?

21 DR. HOLMBERG: But you also have to understand  
22 with the rad-nuke, that there will be blast injuries.

1 DR. KOUIDES: Okay.

2 DR. HOLMBERG: Okay, so you'll have blast  
3 injuries, you will have combined blast and radiation  
4 injuries and then you'll have radiation injuries from the  
5 fallout, and so, yes, and then based on the amount of  
6 exposure, you're going to have either the hematological  
7 and the gastro and then of course, even with the psi the  
8 noise level, you know, as we saw with the Madrid, the  
9 tympanic membrane rupture and I will show you -- I think I  
10 have it in one of my presentations, I may have taken it  
11 out of this one, but actually, the destruction of a house  
12 had a five psi, and it's very dramatic. And so when  
13 you're -- depending on where the ground zero is, but  
14 definitely, it's the blast injuries that we're concerned  
15 about.

16 THE CHAIR: Another important element would be  
17 the burns as well what their high blood --

18 DR. HOLMBERG: Exactly and that has us very  
19 concerned, because I'm sure that you've read in the papers  
20 about the number of burn beds that are available in this  
21 country; we have a critical shortage of burn beds and --  
22 even in the city, so --

1           THE CHAIR: Right. Commander Libby and then  
2 we'll go to Dr. Bianco and then Dr. Kuner (phonetic) --

3           CDR. LIBBY: Okay, thank you, the -- now, the  
4 Unity Blood Program (phonetic) was set up in 1952 and the  
5 reason was to guarantee an available supply to our troops  
6 operating around the world and we do plan for, you know,  
7 disasters, potential disasters or conflicts from around  
8 the world and I want to say it's -- the issue is to  
9 guarantee an available supply. I know yesterday, we  
10 questioned what a -- define what a shortage is, you know,  
11 but I think also you need to define what an available  
12 blood supply is. And I think that's what Dr. Holmberg is  
13 trying to establish is, a guaranteed available supply.

14           We do have contracts with the Red Cross, we have  
15 contracts with American blood centers that we utilize and  
16 we do see shortages, but again -- you know, when you look  
17 at the civilian -- you know, civilian blood supply, you  
18 deal with contracts -- hospitals have contracts with  
19 suppliers, some hospitals don't, and then sometimes a  
20 hospital that has a contract, may get a different -- may  
21 get different priority, I guess, when blood is delivered.

22           But I think -- and that's -- you know, if

1 (inaudible) disasters. In our experience of disasters,  
2 even within the military, trying to get facilities during  
3 conflicts overseas, or in Iraq wherever else we operate,  
4 trying to get them to share blood products is very  
5 difficult, you know, somebody has something and they can't  
6 say they didn't get a re-supply, you know, so they're  
7 going to hold on to all our -- you know, what they have  
8 and won't share, other places will. So again, what --  
9 what's available, and then that's nothing that we look at,  
10 you know, in our theaters, how do we measure what is  
11 available for us in a theater to move around, and is --  
12 and nothing is the same thing if you look at it in the  
13 States, what is available, thank you.

14 THE CHAIR: Thank you. Dr. Bianco.

15 DR. BIANCO: Yeah, I just need to make a  
16 clarification. The fact that we are not supporting  
17 directly a blood reserve doesn't mean that we're going to  
18 oppose it, if any of our members of ABC want to be a part  
19 and respond to your request, obviously, they're free to do  
20 so. I just don't want us to put blood reserve as the  
21 solution and be happy and go home; our issues are  
22 transportation, fuel, communications, and we do not know

1     how to address those, it has -- that has been talked, that  
2     has been the ladder, that has been the communication with  
3     the States, but this is still an unresolved problem, so  
4     that's my only plea.

5             THE CHAIR: Thank you.

6             DR. HOLMBERG: And I guess, my comment back to  
7     the blood community was -- would be that we also need your  
8     help and even though we are actively going out to the  
9     States, we also need the blood community to be reaching  
10    out to the States and it needs to be bidirectional.

11            THE CHAIR: Well, I can tell you that at least  
12    in the State of Texas there is nascent activity involving  
13    hospitals. Within the last month or so, a emergency  
14    preparedness trial that engaged hospitals as well as blood  
15    centers was launched and actually it was unknown to me at  
16    the time, but my hospital is one of the hospitals  
17    reporting, and so at least it's beginning, and hopefully,  
18    we can see that statewide activity grow. Dr. Kuner, you  
19    had a comment or a question?

20            DR. KUEHNERT: Yeah, I just wanted to just bring  
21    out some realities here and that said, I think overall,  
22    we're pretty poorly educated on rad-nuke events and

1 consequences, and when I started on this working group, I  
2 knew absolutely nothing and I know a little bit, but I  
3 know enough to know that I don't know that much, and I  
4 just wonder what the plan is to, you know, take some of  
5 this very useful knowledge in the working group and convey  
6 it to the community, because, you know, we -- this has  
7 been said, you know, we've heard very, very different  
8 estimates, you know, hundreds of units versus 40,000 red  
9 cells alone, I mean, that is a huge difference, I mean,  
10 we're talking completely different kind of response, and I  
11 think part of it is just not knowing the different aspects  
12 of the event and you know, for us to all get on the same  
13 page, really have to have the same knowledge base and that  
14 -- I don't think that exists right now.

15 DR. HOLMBERG: Yeah, and I think that that's a  
16 very valid point and I think that as we have information  
17 available, that can be released in a public forum, then we  
18 need to come back to the committee, and to vet it with the  
19 committee, right at the present time, as I said and Matt  
20 just summed it up well, is that I think all of us are  
21 learning a lot about rad-nuke, and I think that there's  
22 other than Dr. Bader and Dr. Coleman, you know, us blood

1 people are not the experts as far as all the damage that -  
2 - and the clinical problems. However, saying that I think  
3 that the next -- and we -- that's one of the reasons why  
4 we've been learning over the last six months, but as we  
5 develop the models and we develop the requirements, and as  
6 we are permitted to be able to bring that back to the  
7 committee, then we will do that and vet it.

8 DR. KUEHNERT: yeah, I just was concerned,  
9 because it looked like the -- since the working group had  
10 taken on a broader function and we're going to move on to  
11 other scenarios before we moved on that we, you know,  
12 remember that that just keeping the rest of the community  
13 educated as far as we -- as much as we can about what  
14 we've learned, so that -- again, we're on the same page,  
15 so just -- right now, we're on totally different pages, it  
16 just seems like.

17 THE CHAIR: Ms. Wagman (phonetic), you had a  
18 comment?

19 MS. WIEGMANN: Yeah, I would echo those points  
20 in that I think we all have the common goal, obviously, of  
21 trying to serve patients needing blood, but AABB would  
22 welcome the opportunity to work with the task force and

1 with HHS to learn more so that we -- can be able to make  
2 informed decisions when we're making judgments about  
3 whether we need reserves or other policies, and then as a  
4 second point just in response to what you had said, Jerry,  
5 about our needing to reach out to the states and getting  
6 the blood centers to do so, we have tried to do that and  
7 we will continue to do that, because we've welcomed your  
8 work on that, and we think that that's an ongoing issue of  
9 we try to put out materials from AABB and the taskforce  
10 just as ABC and Red Cross do to blood centers that they  
11 need to be in meeting with their state and local health  
12 departments and emergency planners on a frequent basis so  
13 that their -- those offices are aware of the priority  
14 status of blood.

15 THE CHAIR: Thank you.

16 DR. HOLMBERG: And let me just comment on the  
17 working group, as you noticed all the members of that  
18 working group are government employees, and so because of  
19 some of the natures of the information that we discuss and  
20 also preparatory information on mitigations for  
21 shortfalls, it really has to be government, but as -- and  
22 that's why I keep saying, as I'm permitted to give

1 information, we will be transparent with that information.

2 THE CHAIR: Thank you. Dr. Roseff.

3 DR. ROSEFF: I think disaster planning is sort  
4 of -- you know, you're caught between planning for the  
5 worst disaster and not over planning for the worst  
6 disaster, but we always err on the side of, I think, we  
7 have to -- making it a little bit worse than we see, which  
8 may end up in us losing blood and allocating more  
9 resources, but when we talk about our disaster planning in  
10 terms of what we've seen, I don't think we've seen the  
11 worst, I mean, I wish we did, but I think there are people  
12 with far greater imaginations than I have, and so I was  
13 glad to hear the nuclear radiation scenario, because  
14 that's not just red cells now, we're talking about  
15 platelets that outdate very quickly.

16 And even having this, you know, five-day supply  
17 of red cells or seven-day or an eight-day, that doesn't  
18 sound like a lot, when you start thinking of what might  
19 happen in terms of our worst disaster. The other issue  
20 is, I don't think that we can necessarily predict long  
21 term, our disasters that we've had -- something like 9/11  
22 was, you know, a very, I think, isolated incident in a

1 sense. What happens if we have something that goes on for  
2 weeks, where there are needs that are beyond that initial,  
3 you know, one-week period, I think we need to model that.  
4 The other issue is our donors, we talked about -- and we  
5 talked about pandemic flu in the past. We don't know what  
6 our donors are going to do, we say, our donors are going  
7 to come out, we're going to mobilize them, but let's say  
8 they don't want to comet out, because they're afraid of  
9 getting the flu, maybe our staff can't come out.

10 SPEAKER: Right, exactly.

11 DR. ROSEFF: So again, I think we depend on our  
12 donors as a resource, but we haven't talked about what's  
13 going to happen if our donors can't mobilize or if it's in  
14 multiple parts of the country where we don't have that  
15 same backdrop that we have now. So I think that needs to  
16 be thought about too in terms of looking at very, very  
17 different kinds of disasters versus what we have now. So  
18 I think the idea of a strategic blood reserve, though it  
19 may not be in one place or you know, a physical strategic  
20 blood reserve, I think we still need to think about that  
21 as a concept, again, if it's over collecting, and realize  
22 that we're going to have an outdate problem, but still I

1 think that needs to still be a part of the discussion as  
2 opposed to, you know, saying, "We have what we need, we've  
3 proven we have what we need, we can mobilize based on what  
4 we've done, you know, again, my imagination isn't that  
5 great, but there are people who do have better  
6 imagination, so keep that in mind.

7 THE CHAIR: And Dr. Roseff, I appreciate your  
8 comments and just to echo and strengthening -- strengthen  
9 your comment about the rad-nuke using more than just red  
10 cells, you also have to remember and I'm sure you're very  
11 much aware of this, but I had mentioned about the skin --  
12 bone marrow, stem cells, plasma, I mean, there's a lot of  
13 blood and tissue products that would be used in a scenario  
14 like that.

15 SPEAKER: And it's huge.

16 THE CHAIR: Dr. Ramsey, question or comment?

17 DR. RAMSEY: Yeah, thanks. A lot of scary  
18 thoughts I guess, the -- in trying to think about the  
19 magnitude of what this could be, we're really talking  
20 about a nuclear detonation, it's almost unimaginable and  
21 probably no one could -- really could, you know, cope with  
22 this. You -- I wouldn't be too sanguine about our past

1 experience in the -- if we really expand the scope of this  
2 to the concept of, you know, rather than just a few  
3 buildings being hit on a certain day, you know, dozens of  
4 buildings being hit on a certain day.

5           On the other hand, maybe another way to -- you  
6 know, another aspect of this would be what can the health  
7 system really absorb, I mean, there'd be thousands and  
8 thousands of casualties, but what realistically, how many  
9 ORs are there, how many -- you know, like we talk -- like  
10 these (inaudible) in a mass casualty situations, how many  
11 ORs do you have, how many radiology beds do you have, what  
12 is the real, you know, the boundaries of this in terms of  
13 what could really be used, I guess, maybe -- and maybe  
14 that's one way to sort of get a handle around this --

15           THE CHAIR: Right, you know, one of the things  
16 that I was thinking about last night and it -- and to some  
17 degree wouldn't -- would morph into your question is what  
18 happens when you switch from the civilian mass casualty  
19 scenario to the military like mass casualty scenario,  
20 where, you know, the field of injury is not as well  
21 contained where it's, you know, broad, where -- as Dr.  
22 Holmberg mentioned, you may have to consider using walking

1 donors, abbreviated testing. I mean, there are lots of  
2 scenarios that I think require consideration, and to me,  
3 yes, the sort of resounding messages that we need to  
4 assess the models and get the experts that can, you know,  
5 give us the best.

6 MR. HOLMBERG: A couple more things if I could  
7 just -- and these are kind of footnotes to all of this,  
8 one is that in a radiological event, the public would be  
9 told to stay inside --

10 THE CHAIR: Right.

11 DR. HOLMBERG: -- for a certain period of time.

12 THE CHAIR: Right, right, right.

13 DR. HOLMBERG: -- and second and third, I guess,  
14 if we really didn't -- if we really needed -- and this is  
15 a regulatory question, I know we're going to hear about  
16 this a little more, but you know, just as a footnote, also  
17 if you're going to try to start radiating all the blood  
18 products, you know, the 28-day outdate for red cells comes  
19 in there and is that something -- it could be looked at I  
20 guess. And then the other -- in terms of burns, I don't  
21 know what the -- you haven't mentioned derivatives and I  
22 don't know if -- how much of an impact it would be, I'm

1 not being a burn expert in terms of, you know, albumin  
2 immune globulin, I don't know, but --

3 THE CHAIR: Well, one of the things that we'll  
4 need to do is move into our general discussion phase, and  
5 I think a lot of these issues actually roll over into that  
6 general discussion. If there's -- Ms. Finley has specific  
7 question related to Dr. Holmberg's presentation --

8 MS. FINLEY: I just wanted to just try and  
9 synthesize this both for myself and for my colleagues. My  
10 understanding of the charge for later this afternoon is  
11 that we're going to -- the issue is the interplay between  
12 current availability and what we might need, recognizing  
13 that we don't have those scenarios, and frankly I don't  
14 think this committee is ever going to see them, those -- a  
15 lot of those threat assessments are not things that are  
16 publicly -- Jerry might see them, but, you know, the rest  
17 of us are not.

18 So for purposes of today, we can speculate or we  
19 can look at the very specific contributions that we can  
20 make with the limited information that we have. We know  
21 that there are issues about availability to some extent on  
22 an -- a regular basis, we know that there are some

1 variables in terms of scenarios that we can at least  
2 recognize from reading the newspaper that might overwhelm  
3 the system. And thirdly, we know that there are  
4 occasionally shortages or we're running pretty close to  
5 the line on things like platelets, which we know we will  
6 need for -- in an ARS situation.

7           The issue about the reserve and people's  
8 feelings about it came up yesterday and I understand from  
9 Dr. Epstein's comment that that was, you know, somewhat of  
10 a surprise to him. Maybe we can word a question today  
11 that kind of synthesizes that and says based on the  
12 information that we have knowing that HHS is working  
13 forward through this BARDA committee to look at scenarios,  
14 we just want to express some concern about the fact that  
15 there is -- we -- you know, we don't have a ton of  
16 elasticity in the existing blood supply, we know the  
17 donors are willing to step up, but we have concerns about  
18 some scenarios.

19           Therefore, we may direct, you know, we may want  
20 to consider the issue of the reserve in more detail with  
21 more specific information at our next meeting, which gives  
22 you five or six months to, you know, to kick it around in

1 the committee that you currently have, and then possibly  
2 to get some information. If it turns out that there are  
3 players that need to be involved in some scenario  
4 planning, that would give them some time to maybe get some  
5 of the security clearance and make them a resource. There  
6 are situations where consultants can be brought and maybe  
7 this is one of them. So I'm -- I just -- I want to make a  
8 positive contribution at the end of the day, but I know  
9 that we're not going to have that information.

10 On the other hand the relationship between  
11 availability and what we might need in some of these  
12 scenarios is pretty clear and if there's a question about  
13 reserve, I'd like at least to put the question on the  
14 table, even if we don't decide, yes, we should have one  
15 or, "no," we shouldn't have one, but at least that we  
16 recognize that there's an issue there and take some steps  
17 towards trying to, you know, get a position.

18 THE CHAIR: Okay. What I --

19 DR. HOLMBERG: Can I just make a comment --

20 THE CHAIR: Dr. Holmberg, yes.

21 DR. HOLMBERG: -- because Ms. Ashton -- slipped  
22 me a note here, and I forgot to mention it. It really

1 follows up with what Matt was talking about the education  
2 aspect of things and Dr. Bader did a fantastic job, you  
3 can go to the -- a web site through the National Library  
4 Of Medicine and it's called "REMM," and it is designed for  
5 clinicians to really help the clinician walk through a  
6 rad-nuke event and what kind of therapy -- it's a -- it's  
7 all evidence based reference documented material and she  
8 did a fantastic job as far as the blood aspect of it. Dr.  
9 Kline was the primary reviewer on that, I looked at it  
10 also, but the -- he's the primary expert on looking at the  
11 transfusion medicine aspect. So it does -- there is  
12 transfusion into that, and I would encourage the committee  
13 and I'll send that out and --

14 SPEAKER: Yeah, I'd appreciate that, that'll be  
15 very helpful.

16 THE CHAIR: Okay, what I'd like to do is, prior  
17 to lunch, have some discussion regarding the issues that  
18 have been presented, one issue presented and you have the  
19 questions before you, relates to whether the current  
20 system -- whether there is a current system for management  
21 in the U.S. of blood inventories and then whether or not  
22 that the -- actually drills down to the blood centers and

1 the hospitals. I'll just use that as a launch, it appears  
2 to me that from the discussions that we've had, number  
3 one, we really have a window into hospitals, but it's a  
4 narrow window.

5 SPEAKER: A frosted pane.

6 THE CHAIR: Yeah, a frosted pane. And the blood  
7 centers have very good data, but I think basically we're  
8 lacking -- we need more data from the hospitals before  
9 we'll be able to really fully assess the U.S. inventories,  
10 now, a question that I have -- and I continually harp on  
11 this, is forget the current restrictions, is it a good  
12 idea -- or should we know what the total inventories are,  
13 because the inventories are not transparent. And so for  
14 the purpose of planning, would we direct the assistant  
15 secretary to seek mechanisms to make blood inventories  
16 system wide transparent, so we'll -- any comments or  
17 questions from the committee, Ms. Finley?

18 MS. FINLEY: Without that information, I don't  
19 see any way that the enterprise government -- the  
20 governing board can successfully develop scenarios that  
21 they're trying to do. So I think that would be a very  
22 positive contribution from the committee towards the issue

1 in general; both for domestic, current domestic  
2 consumption and for threat assessment.

3 THE CHAIR: Dr. Ramsey.

4 DR. RAMSEY: I -- maybe I could ask of Dr.  
5 Bianco or other members how widespread is -- would be the  
6 practice among blood centers of obtaining information from  
7 their hospitals about inventory?

8 DR. BIANCO: It is very variable, some blood  
9 centers will have direct connection, because they run the  
10 transfusion services, and so they manage the inventories,  
11 others have reports, but in general, I would say that the  
12 blood centers have no access for hospital inventories.

13 THE CHAIR: Okay. Comment from --

14 SPEAKER: I can just speak for the Red Cross --

15 SPEAKER: (Off mic) yeah.

16 THE CHAIR: Go ahead.

17 DR. BENJAMIN: -- in the same way. Limited  
18 access to data, we do on a limited basis in some regions,  
19 collect routine data, and I can tell you that that data is  
20 not necessarily reliable, because the hospitals have an  
21 incentive not to necessarily tell you exactly what's on  
22 their shelves. And the second issue; I participated when

1 I was in one -- running -- the blood bank in one of the  
2 Harvard hospitals in Boston some time ago --

3 (Tape interruption)

4 DR. BENJAMIN: -- pre-versional (phonetic)  
5 BASIS. If you ask a hospital what their inventory is, you  
6 better tell them what time of day that you want that  
7 inventory, because the inventory at midnight is very  
8 different to the inventory at 7:00 a.m. when two-thirds of  
9 their blood is sitting in coolers in the OR, out of their  
10 inventory, but half of that blood's coming back, and so it  
11 depends on what time they get their delivery from their  
12 blood center where they ship their blood to within their  
13 hospital. The simple question of what is an inventory  
14 within an hospital is another open book. So to get back  
15 to the original question, we have limited data and it's  
16 very patchy around what's happening in the hospitals.

17 SPEAKER: Thank you.

18 THE CHAIR: Thank you Dr. Benjamin. Now, the --  
19 what the -- one of the things that -- again, I keep  
20 harping on the example of the petroleum industry and I  
21 don't know how factual their data is, but you can go to  
22 the web site of the U.S. Department of Energy and find out

1     how many barrels, thousands of barrels of a given oil --  
2     type of oil, well, is produced in a given time. And I  
3     would think that with our computer systems being as they  
4     are that if the codes could be made more uniform, let's  
5     put it this way, there are easy ways to get at the  
6     information.

7             And so I think that moving forward, it would be  
8     advantageous for us to recommend that in order for us to  
9     make, you know, decisions based on information, we need to  
10    have the hospital data and some mechanism needs to be  
11    explored for making that easy to retrieve, Commander  
12    Libby.

13            CDR. LIBBY: Out in the DOD, we do have a  
14    system, we have a Defense Blood Standard System that all  
15    our facilities are required to use and with that, we do  
16    have a Joint Medical Asset Repository Program that pulls  
17    data out of that system and we have the scheduler set a  
18    certain time as midnight, but we can schedule several  
19    times a day, where it can see how much blood at any  
20    facility is cross matched, when it's going to expire, and  
21    if it's in transit, and what's sitting on the shelf. And  
22    I know the BASIS is -- we're working on some programs in

1 coordination with Health And Human Services, but there's  
2 the BASIS system is it -- does it define an available  
3 inventory and cross match it or is it just a total  
4 inventory or -- we're going with that if --

5 SPEAKER (Off mic): Do you want to --

6 THE CHAIR: Commander Henry?

7 LCDR. HENRY: With BASIS, we ask them to report  
8 the same time each day, and therefore the fluctuations  
9 don't matter to us, we look at the trends at the same time  
10 each day, and we define available units based on their  
11 definition. So what -- if they have a good number of  
12 units sitting in coolers and they want to include all of  
13 them, we ask them to always include all of them, so we're  
14 looking for more standard reporting, not necessarily the  
15 same reporting for me to an institution, because we're  
16 looking at fluctuations, not necessarily the management of  
17 their supply.

18 SPEAKER: So your reports are standardized for  
19 maybe facility, is that what you're saying, is --

20 LCDR. HENRY: We want the facility to be  
21 consistent. If facility A is different from B, that's  
22 fine, we just want them to be consistent within their own

1 facility.

2 THE CHAIR: Dr. Bianco.

3 DR. BIANCO: I'd like you -- a request for you  
4 to extend a discussion not just to what the inventory is  
5 and at what time it was done, but what is going to be done  
6 with those numbers, I think that the major resistance that  
7 has been found with BASIS, and Henry may confirm that is  
8 that people are concerned -- what are they going to do  
9 with those numbers? Are they going to take my inventory  
10 and move it somewhere else, are they going to tell the  
11 blood center that they shouldn't ship any more for me,  
12 because I have much more than the hospital next door? I  
13 think that there is a need for understanding of how those  
14 -- the analysis will be made and how the numbers are going  
15 to be used.

16 THE CHAIR: Right, that's a good point.

17 LCDR. HENRY: If I can respond.

18 THE CHAIR: Oh, yeah, Commander Henry.

19 LCDR. HENRY: So the reason why we're not  
20 looking at so much detail is because BASIS is not a  
21 management system, we're -- we didn't intend, and we don't  
22 intend to manage anybody's inventory or supply, there's

1 better questions such as where is your blood in the  
2 hospital, what do you intend to do with it; we're not  
3 concerned, because we're not managing the inventory; they  
4 need to know that, but we don't. All we need to know is a  
5 consistent daily reporting of how much blood do you have.  
6 If you consider the blood you have only on the shelves or  
7 in total in the hospital, that's fine, just be consistent  
8 with that.

9           And then we have the luxury of not needing to  
10 know the data, because we have the luxury of not having to  
11 manage their supply, it's just strategic and it's  
12 strategic at the public health level, not the --

13           (Tape starts abruptly)

14           DR. BIANCO: I -- I -- I would like you -- a  
15 request for you to extent the discussion, not just to what  
16 the inventory is and at what time it was done, but what is  
17 going to be done with those numbers.

18           I--I think that the major resistance that has  
19 been found with BASIS and -- and Henry may confirm that --  
20 is that people are concerned, what are they going to do  
21 with those numbers? Are they going to take my inventory  
22 and move it somewhere else? Are they going to tell the

1 blood center that they shouldn't ship anymore for me,  
2 because I had mach more than the hospital next door?

3 I think that there is a need for understanding  
4 of how those -- the analysis will be made and how the  
5 numbers are going to be used.

6 THE CHAIR: All right, that's a good point.

7 LCDR HENRY: I can respond.

8 THE CHAIR: Oh yeah.

9 LCDR HENRY: Sorry.

10 THE CHAIR: Commander Henry?

11 LCDR HENRY: The reason why we're not looking at  
12 so much detail is because BASIS is not a management  
13 system. We didn't intend and we don't intend to manage  
14 anybodies inventory or supply. There is -- there is  
15 better questions such as, the ratio of blood in the  
16 hospital, what you intend to do with it? We're not  
17 concerned because we are not managing the inventory. They  
18 need to know that, but we don't. All we need to know is a  
19 consistent, daily reporting of how much blood you have.

20 If you consider the blood you have only on the  
21 shelves, or in total in the hospital, that's fine. Just  
22 be consistent with that. Then, we have the luxury of not

1     needing to know the data because we have the luxury of not  
2     having to manage their supply. It's just strategic, and  
3     it's strategic at the public health level not the, "I'm in  
4     the business of the blood level."

5             The folks, who are in the business of blood,  
6     need to know greater detail than we do in the public  
7     health service.

8             THE CHAIR: Dr. Roseff?

9             DR. ROSEFF: Yeah, this has been alluded to but  
10    one of the impediments of sharing data of course, you  
11    know, with competitive issues, you know, the blood center  
12    that's competing with another blood center, doesn't want  
13    them to know how much they have.

14            By the same token, when you brought up sharing  
15    with the - I guess the blood center -- we know, does the  
16    hospital share with the blood center? I think that might  
17    create some tensions too, you know, does the blood center  
18    have jurisdiction of, or where they sent the blood based  
19    on the hospital inventory or where they think the blood  
20    is.

21            So I think that if we are talking about having  
22    national data it has to be somewhere that is anonymized

1 in some form, if it's for the process of data collection -  
2 - and again that it can't be used in these situations  
3 where you're concerned about competitive issues.

4 THE CHAIR: All right, Dr. Holmberg?

5 DR. HOLMBERG: I will answer those questions  
6 later on today. I don't think we really want to get down  
7 into the weeds on BASIS right now.

8 But to answer your questions little quickly, we  
9 are in the process of accreditation and certification  
10 under the protection of the Critical Infrastructure  
11 Information Act, which came into effect last September  
12 2006. And under that there is protection of sharing the  
13 data, civil litigation all -- all the protection and it is  
14 only for the need to know.

15 THE CHAIR: Dr. Benjamin?

16 DR. BENJAMIN: Just -- just a brief comment that  
17 if it is true that there is no consistency in how  
18 hospitals report data to BASIS that it's not really  
19 feasible then to make comparisons between hospitals,  
20 between areas, between regions, and in-- in our question  
21 whether its actually -- whether you can actually define  
22 what is adequate of inventory comparatively, if you are

1 not measuring the same thing in the same place.

2 THE CHAIR: Okay we'll get to that later on in  
3 the afternoon. There are additional challenging  
4 questions, and these are whether the data is linked to  
5 collected efforts.

6 And as we saw yesterday with the report from  
7 ABC, it as appears that within the blood centers the  
8 information is available is in fact used for things such  
9 as issuing the pills. Other questions would be, is the  
10 public generally aware of the blood inventory status? And  
11 I think we address that earlier today in the talk by Dr.  
12 Armitage and that is that the public is aware of extreme  
13 conditions, but not generally aware of -- of the blood  
14 inventory status.

15 And we - we did hear yesterday that there is  
16 linkage to the ASH in terms of, when we reach a certain  
17 level of the PO through the system that has been set forth  
18 in the blood centers, and we have not addressed whether or  
19 not there is a system that prevent disparities, and I  
20 think earlier Commander Libby referred to the fact that  
21 some hospitals that may have contracts -- there may be  
22 preferential treatment in certain local scenarios -- and I

1 think that's actually a very important area for a  
2 discussion, and I'd be interested to know the Committee's  
3 prospective on disparities in terms of available  
4 inventories in times of shortage.

5           Should there be a system? Or should it be  
6 managed? How should one manage disparate blood  
7 inventories regionally?

8           SPEAKER: I think it's a good question I don't  
9 know if we have -- have the information to answer it.

10          THE CHAIR: Right, well, one of the things that  
11 -- that I said at the - at the beginning of the day is  
12 that there --we have good information that we are getting  
13 in this meeting. We are getting a lot of information from  
14 the blood centers. We are getting a lot of good  
15 information from the government. The missing piece that I  
16 see still, is the piece from the hospital -- the trenches.

17          SPEAKER: Uh-huh.

18          THE CHAIR: What is done in terms of triage?  
19 What is done in terms of assessing shortages? For  
20 example, you know is the blood inventory in 80 percent of  
21 the hospitals controlled by the donor center? Or is it  
22 controlled by the hospitals in 100 percent of the --

1 hospital inventories? I think, that would be an important  
2 information to know.

3           There are some places where the blood center is  
4 very involved in looking at what the various inventories  
5 and there are other models the lean models where the blood  
6 centers basically move the blood out to the hospitals, and  
7 then often the hospitals will be in a position of sharing  
8 information with one another to try to resolve short-  
9 fullness.

10           But that's a piece of information and I think we  
11 -- we need and so the way I see this, is that we have a  
12 general picture and a lot of information about specific  
13 entities, so, I think that we will need to form a  
14 Subcommittee, to look at what the gaps are in the  
15 information that we -- that we need in order to make the  
16 best decisions, and to the plan to have that information  
17 brought to us so that we can have the best recommendations  
18 moving forward.

19           But Dr. Bianca, you've got a comment?

20           DR. BIANCO: I -- I just want to mention that  
21 you are touching in an very, very difficult problem. And  
22 I don't know if just even a Subcommittee will be able to

1 resolve it, because of the multiple ways by which people  
2 manage it. Is it -- you almost need a national survey  
3 done by experts that go and interview different hospitals  
4 and all that, and understand how these systems work.

5 THE CHAIR: uh-huh.

6 DR. BIANCO: But even in your hometown, you have  
7 hospitals that have strong collection services, and a  
8 blood center. And the hospital that has the collection  
9 service, who only -- the reason why they're -- there is  
10 preference is because some hospitals who establish a  
11 contract with the -- as Commander Libby said, with the  
12 blood center -- and the blood center is committed to that  
13 hospital.

14 They know that they are going to need so many  
15 units as such date and that's the effort they are going to  
16 make. But the other center that collects units will only  
17 call the blood center when they need O-negs or when they  
18 run out of platelets -- so what we call the "Cherry  
19 Picking," in -- in -- in--in our field -- and so it  
20 becomes very difficult to understand, and there -- there  
21 are market forces and a lot of things that control that  
22 and even if we wish that we had a prefect world and -- and

1 could allocate in more or less in the way that there isn't  
2 a very serious attempt by HRSA to allocate the organs, so  
3 that it's fair to everybody.

4 Here it is much more difficult to do with blood  
5 -- then we don't know enough about the whole system. So,  
6 I feel that a very detailed survey of behaviors on how  
7 people manage their inventories at the hospital level may  
8 help, but it's a very, very difficult issue.

9 THE CHAIR: No, I agree wholeheartedly with the  
10 difficulty, in fact, one of the things I think is that  
11 it's important to have the folks involved in the blood  
12 industry assess what happens -- but equally important  
13 would be to assess the response of the treaters -- the  
14 surgeons, the anesthesiologist, to make sure that all of  
15 the groups that are impacted will have a you know, a say  
16 in this and so that perhaps we could reach an  
17 understanding because ultimately, at the end of the day  
18 what we're trying to avoid is a scenario where there is  
19 within a given region -- one area that -- one facility  
20 that may be rich, and all patients are treated and another  
21 facility where treatments are not available and potential  
22 harm may occur.

1 THE CHAIR: Dr. St. Vincent, I'm sorry.

2 DR. ST. MARTIN: Martin.

3 THE CHAIR: St. Martin, sorry.

4 (Laughter)

5 DR. ST. MARTIN: I just wanted to -- maybe go  
6 back to some of -- I just wanted to go back to some of the  
7 things that Dr. Armitage had presented on, in the issue of  
8 public awareness, and just at the frame of reference --  
9 several years ago the Health Resources and Services  
10 Administration instituted a social and behavior grant  
11 program to increase organ donation, and they looked at  
12 basically some of the best practices to try to increase  
13 organ donation. Looked at what you know what motivates  
14 people to sign donor cards, or to donate organs.

15 And you know, the question is been, what is the  
16 status of that type of intensive research for the blood  
17 donor population, to try to figure out what are the blood  
18 best practices? What really motivates donors? Is knowing  
19 the status of the inventory going to motivate people to  
20 donate you know what -- what messages do we need to put  
21 out there?

22 THE CHAIR: Now, that's a very important area

1 and -- well Dr. Holmberg do you want to?

2 DR. HOLMBERG: Thank you for making that intro  
3 into the HRSA Report. I was tempted to send that report  
4 out -- it's very lengthy. But if the Committee would like  
5 I can sent it out on the --- on the C.D. Drive and I'll  
6 give you that report on Organ Procurement. It was a very  
7 interesting survey on how that happens. The other thing  
8 too that HRSA has, is there work place partnership  
9 programs, and it also emphasis not only organ donation but  
10 also blood donations.

11 THE CHAIR: Let me -- and I'll get -- who wants  
12 to comment? Dr. Roseff? Let me just summarize and then  
13 we'll get to your comment.

14 What we have to do today is to hear more  
15 information in terms of availability of bloods supplies.  
16 We've heard lots of information throughout the course of  
17 the days and at one point that I think that-- I hear  
18 consensus on, is that we need more transparency, we need  
19 more information.

20 I think that and we'll be able to crack the  
21 message along those lines, but all of the things that we  
22 are talking about are so important that I really feel that

1 A, that we need more data and that B that we need to do  
2 some work in-between meetings.

3 And so I'd like to make sure that this notion of  
4 having a Subcommittee address -- this between meetings is  
5 -- is what the Committee feels about that -- that  
6 recommendation at this point - Ms. Finley?

7 MS. FINLEY: I - I'm perfectly fine with that  
8 personally but I just wanted to make sure that that's -  
9 there are provisions fro Subcommittees under FACA -- I  
10 don't know the answer for that question.

11 DR. HOLMBERG: Yes, yes there are.

12 MS. FINLEY: Okay

13 DR. HOLMBERG: The only stipulation what in this  
14 Committee has -- had Subcommittees in the past. What we  
15 are obligated to do in a census is a Federal Advisory  
16 Committee. We are requiring to have that Subcommittee  
17 report completely back to the full Committee, no decision  
18 is made by the Subcommittee. But it has to be agreed upon  
19 by the full Committee.

20 MS. FINLEY: Okay thank you.

21 THE CHAIR: Right Dr. Epstein?

22 DR. EPSTEIN: Well I need some clarification of

1 what we want a Subcommittee to do. The principle  
2 question we seem to be wrestling with is elasticity of the  
3 blood system, and I recognize that there are set of  
4 related issues about equity, or its fairness in  
5 distribution.

6 Is it realistic that the subcommittee would be  
7 tasked with bringing that some kind of expert report, or  
8 not? And is that really the goal? Is -- is the goal for  
9 the Committee to come up -- Subcommittee I'm sorry -- to  
10 come up with an answer or a candidate answer to the  
11 question of elasticity?

12 Because, I think part of the problem here is  
13 that many people have been asking that question for many,  
14 many years with no clear result. And exactly what do we  
15 think a Subcommittee will do over period of a few months?

16 THE CHAIR: Right. My vision on -- is that the  
17 Subcommittee would look at the body of data that full  
18 Committee's reviewed; assess where the gaps are, make a  
19 determination in terms of what are the pieces of key  
20 information we need to hear before we can set forth with  
21 the final set of recommendations to the ASH on blood  
22 availability and preparedness and systems for managing the

1 blood shortages.

2           So primarily to -- to go back and assess what  
3 we've heard and then to look at the landscape and asses  
4 what's missing, and to ensure that we get that input so  
5 that when we make our final -- final recommendation to the  
6 ASH that we've -- we've heard everything tat we need to  
7 hear.

8           Well, that's my thought on the Subcommittee's  
9 effort.

10           MS. FINLEY: So if I can follow-up a question?

11           THE CHAIR: Yes, Ms. Finley.

12           MS. FINLEY: The goal then is to come up with a  
13 recommendation for you know -- I mean, just to flush-out  
14 the recommendation that the Committee has to the  
15 department relative to the questions that need to be  
16 answered regarding elasticity of the blood supply?

17           THE CHAIR: Well again with regard to elasticity  
18 of the blood supply that is an answer that I think that we  
19 have heard some information on. We don't have the full  
20 amount of information because we don't have good data as  
21 of yet, we have some data but not full data from the  
22 hospitals.

1           So the concept would be to not only look at that  
2 but also to assess other -- other potential factors that  
3 can impact on blood utilization?

4           And those would be factors such as -- when -- is  
5 a given hospital environment how does -- how is the blood  
6 shortage actually managed? Are there are --is there  
7 information on best practices for managing the blood  
8 shortage? Things like delaying electric procedures, what  
9 does one do in the context or setting of a transplant when  
10 you will have a blood shortage? Is there a difference when  
11 there is the shortage of platelets? What about reducing  
12 the doubts?

13           You know they are a lot detail --

14           MS. FINLEY: Uh-huh.

15           THE CHAIR: -- that otherwise we haven't  
16 addressed.

17           MS. FINLEY: How would we get the information?

18           THE CHAIR: Well, there are --there will be  
19 discussions --

20           MS. FINLEY: Uh-huh.

21           THE CHAIR: -- of blood shortage is upcoming at  
22 for example, at the American Association of Blood Banks

1 meeting, there is going to be some discussion in the  
2 pandemic session on the management of this. There will be  
3 information this coming forth from the State-wide  
4 preparedness activities that are happening in certain  
5 States not all states.

6           And so again the idea would be to see if we can  
7 gain more information in terms of practices, within the  
8 hospital environment. And also to address another issue,  
9 which we haven't talked about, and that is the use of  
10 blood in situations of medical futility.

11           There are State laws, and we don't know what all  
12 those State laws are. So we don't you know, we can't  
13 really talk about the practice of the management of  
14 outliers because what you will find in most hospital  
15 settings is that there are about 5 percent to 10 percent  
16 patients that use 85 percent of the blood. And that's the  
17 reality. And there is -- there is varying approaches to  
18 that in different hospitals scenarios.

19           And I mean, that's an area that's totally  
20 unexploited -- we -- we haven't explored that.

21           MS. FINLEY: I - I think those are laudable  
22 questions we should -- somebody should be asking them.

1           I guess my question is, how do we compel the  
2 information? You know in an Advisory Commission setting  
3 HHS gives us information and then take an  
4 interdisciplinary review of it and then make  
5 recommendations to the secretary.

6           How do we compel participation for example by  
7 hospitals, or States, or whatever to give us the  
8 information that we need to look at to I guess make  
9 recommendation to the secretary about this very important  
10 issue?

11           THE CHAIR: Well, again in terms of this Gap  
12 Analysis --

13           MS. FINLEY: Yeah.

14           THE CHAIR: -- we try to determine what are the  
15 pieces that we need? And then we make the effort to get  
16 that -- and we may not be successful.

17           MS. FINLEY: Okay.

18           THE CHAIR: But I mean it -- but it will be in a  
19 - the idea is having an attempt --

20           MS. FINLEY: Okay.

21           THE CHAIR: -- to get that information.

22           MS. FINLEY: I'm just -- I'm just wondering, do

1 we have authority under FACA to do this? I mean, I've  
2 never had a situation myself I don't know. Or do we get  
3 it through Jerry? I mean, how do we --?

4 DR. HOLMBERG: Yeah, I would be your conduit.

5 MS. FINLEY: Okay.

6 DR. HOLMBERG: If the Subcommittee met and there  
7 was a requirement for information --

8 MS. FINLEY: Yeah.

9 DR. HOLMBERG: Then I would be the one to go out  
10 and try to get the information for the Subcommittee.

11 MS. FINLEY: Thank you.

12 THE CHAIR: Dr. Epstein?

13 DR. EPSTEIN: I'm - I'm struck that we maybe  
14 attempting to reproduce an exercise that happened in the  
15 early 2000s. After 9/11 the general accountability office  
16 was asked to assess whether there was an adequate blood  
17 supply, and it was also looking at that question in the  
18 wake of the of -- VCJD risk-based deferrals.

19 THE CHAIR: Uh-huh.

20 DR. EPSTEIN: And I'm just wondering whether the  
21 task that we are putting before our Subcommittee isn't  
22 really the task that was historically put before the GAO?

1 Or is it -- what we're asking again is whether the blood  
2 system is adequate and how -- how it addresses -- how it  
3 defines and addresses to the shortage situations and how  
4 it response to such situations including potential  
5 disasters?

6 Because I'm just thinking that this task is  
7 perhaps just too large for -- for the Subcommittee.

8 THE CHAIR: Uh-huh.

9 DR. EPSTEIN: I hear clearly what you are saying  
10 are -- which is that we can help this effort by  
11 identifying gaps in the knowledge.

12 But -- but I just think that in the end what you  
13 are looking for is a comprehensive assessment of the  
14 nature of what GAO does as its core business.

15 And so maybe the essence of the recommendation  
16 from this Committee is to identify the fact that there are  
17 current gaps in knowledge and how our system works. And  
18 therefore unable to comment how resilient it is, or how  
19 prepared to address disaster, and that therefore a broad-  
20 based assessment is needed such as could be obtained  
21 through a request for a report from the GAO.

22 THE CHAIR: Now that's a good -- yeah that's a

1 good comment. Because again I think the real concern is  
2 that we are unable, I think, to really render an informed  
3 opinion. And we need more data, and the idea that I had  
4 is that perhaps we could figure out the way to mine that  
5 data through the efforts of the Subcommittee.

6 But if on the other hand we issue a statement or  
7 a recommendation stating the fact that we need more data,  
8 and there's another arm that's more appropriate that can  
9 help us get that information that would -- that would  
10 suite the purpose of the -- the struggle that I'm having  
11 is that we -- we don't have enough data to have the fine -  
12 -- a -- a strong final recommendation on a lot of these  
13 issues. We know -- we need more data but -- but that's -  
14 that's where I think we're stuck.

15 THE CHAIR: Ms. Finley?

16 MS. FINLEY: The --- that's an excellent  
17 suggestion, thank you Dr. Epstein.

18 The HHS Inspector General can also do that study  
19 and they're under the direct supervision of the secretary.  
20 So they can compel that out -- they've mechanisms we don't  
21 have as an Advisory Committee.

22 So, if it's considered an important priority for

1 the department you know, that's something the secretary  
2 could -- could address.

3 THE CHAIR: Right -- again and I think that as  
4 we've bolstered blood as a critical component of the  
5 infrastructure yet we don't really have a --

6 MS. FINLEY: Yeah.

7 THE CHAIR: -- good concept of how much actually  
8 it is, there is and how it's used at -- we -- we have to  
9 get that information through the best available mechanism.

10 And so Dr. Holmberg, would that be something  
11 that the -- you know, the OIG and HHS you would foresee  
12 as, working to help us gaining that information?

13 MR. HOLMBERG: Well, of course the Committee can  
14 make any kind of recommendation. I -- I think that what  
15 you need to be careful of is not to be very -- be  
16 prescriptive. But you know it's -- you make the  
17 recommendations.

18 THE CHAIR: Okay, thank you.

19 With that unless if there are other comments we  
20 are a little after the lunch-hour. We have additional  
21 presentation here. Why don't we regroup at 1:15p.m.?

22 All right?

1 (Whereupon, a luncheon recess was taken)

2



1 you can't leave.

2 (Laughter)

3 DR. HOLMBERG: What time?

4 LCDR. HENRY: 4:30.

5 DR. HOLMBERG: Okay. Hopefully we will be done  
6 by then.

7 (Laughter)

8 MR. HOLMBERG: Okay, Mr. Chairman?

9 THE CHAIR: Okay. Welcome back we have a slight  
10 change in the order.

11 Our next speaker will be Kathryn Brinsfield, who  
12 is the Medical Director of Emergency Preparedness  
13 Boston EMS System and for Boston MMRS and the DelValle  
14 Emergency Preparedness Training Institute. She will  
15 discuss Reserved Donor Strategies.

16 Dr. Brinsfield?

17 DR. BRINSFIELD: Hi.

18 THE CHAIR: Welcome.

19 DR. BRINSFIELD: Thank you, and thank you for  
20 inviting us to come and speak to you. Just to give you a  
21 little background about myself.

22 I'm an emergency physician. Most of what I know

1 about blood is trying to get 0 negative at 2:00 in the  
2 morning, so don't hold that against me, okay?

3 (Laughter)

4 DR. BRINSFIELD: But I do have some  
5 qualifications as a, somewhat of an expert in disaster  
6 response working both with National Disaster Medical  
7 System responder was the -- the Deputy Director of the  
8 first team in at Ground Zero, and have worked within that  
9 system and also within the City of Boston planning for  
10 many different events.

11 So, I think I've -- if you'll forgive me, that's  
12 really what I am going to try and bring to the table as a  
13 different sort of approach to what you've been looking at.  
14 So we want to talk a little bit about disaster  
15 preparedness, really where we stand with the one-day blood  
16 supply, the fact that we're very concerned about potential  
17 weapons out there, what we think the transfusion needs are  
18 going to be for casualties based on numbers that have been  
19 produced in other papers, and some of the different  
20 possibilities.

21 We've been sitting, working with this on a  
22 Committee for about the last 16 months, and I think the

1 beauty of our Committee is that it really pooled together  
2 people from all sorts of different types of background,  
3 walks of life, from the military, from local -- we've  
4 talked to the FDA, we've had some people participate from  
5 the CDC, CDC, the Injury Control Division, American Red  
6 Cross, the U.S. Military, some hospital blood bankers, and  
7 also pooled in some of our trauma surgeons and ICU  
8 physicians to try and really get -- also some of the state  
9 GPH emergency preparedness types, to really try and get a  
10 cross-section look at what is the issues, and how could we  
11 solve some of the issues.

12           So we know, you know, not to go through it --  
13 what you know more about than what I know, but we know  
14 that we exist in area where we are regularly moving around  
15 maybe scheduled surgeries, that we don't have a blood  
16 shortage necessarily, but we're always going through  
17 periods of being a little bit low, maybe not, you know,  
18 perfectly as well-stocked just we'd like to be.

19           We know that there are, certain amount of  
20 inventory that we have in the area. We think we probably  
21 have based on a kind of back-of-the-envelope calculation  
22 at any given time about 5000 packed cells, if we knew

1     there was going to be a disaster, before they started  
2     elective surgeries in the morning.

3             So that's a back-of-the-envelope calculation,  
4     we're working right now, actually Dr. Harrington is  
5     working right now with the ASPR Officer trying to do, a  
6     statewide blood account which is now turned into, a  
7     probably a four-region blood count using the basal system  
8     to try and get a much better sense of what really exists  
9     out there and what's really there, what do we really need.

10            But this is our reality.  Anybody who is  
11     familiar with New England recognizes the person on the  
12     left, right?

13            (laughter)

14            That would be Tom Brady, and that would be after  
15     the Patriot's second rally, the rally after the second  
16     Super Bowl, and you just, you need to remember the slide  
17     for me a minute, and particularly I want you to remember  
18     what that looks like in terms of population density;  
19     because when we have planned events we get very many,  
20     where they have this kind of population concentration that  
21     are very difficult for us to completely secure.

22            We have 4th of July , we have First Night, our

1 New year's Eve celebration, and sports events like this,  
2 and they all bring somewhat of same issues for us, which  
3 is a real significant density of populations. And this is  
4 from one of those events as well. This is what happens  
5 when you try and get to an emergency in those events. You  
6 know, you are really talking about what can be a 20-minute  
7 transport time to get from the middle of the crowd to the  
8 curb, just in terms of really responding to some of those  
9 things.

10 So, again, Dr. Harrington ran using the EMCAPS  
11 model which is the Johns Hopkins model -- she ran some  
12 numbers on what would happen if you exploded and IED, a  
13 5000-pound IED in an open area -- IED, Improvised  
14 Explosive Device.

15 Open area, meaning you are completely nullifying  
16 the effect that building repercussions would have on the  
17 event and we are looking at 25 persons per square foot  
18 because that's the best the model does. If you'll work  
19 with me I think that's more than 25 -- sorry, 25 -- right  
20 25-feet per person. Sorry I got that backward, didn't I?  
21 Yeah, anyway you got the idea.

22 So, here we have, you know, modeling that you

1 have a certain number of casualties. So we have traumatic  
2 injuries about 15 percent moderate to severe injuries,  
3 about 2,829 persons, which is a fairly significant amount.  
4 If we go and then, you know, to compare those to the  
5 Israeli experience, this is if you look at the next slide  
6 it's got the reference, I think that Dr. Shinar's paper --  
7 yes, this was accumulative data from over many years, but  
8 you can see that the number of moderate to severe  
9 traumatic injuries is about 20 percent. So, that's  
10 probably not completely off.

11 So if we use the EMCAPS model, we get about 15  
12 percent moderate to severe injuries. Those that would  
13 probably be needing blood and if we use then different  
14 numbers that have been published at how many packed, units  
15 of packed cells each person would need you can see that we  
16 start getting different number a units of blood that we  
17 think we might need in that event.

18 So, using the 3.85 units which was from a paper  
19 published in 1994, but was largely based on data for many  
20 years before that, as far back, I think some of the  
21 expertise for that paper came as far back as Vietnam --  
22 they had 3.85 units of pack cells per casualty, moderate

1 to severe casualty or casualty requiring blood, and if you  
2 look at some of these other numbers here you can see that  
3 some of them are actually going up to 4.5 units and 6.7  
4 units in the Israeli experience of packed red blood cells.

5 So, suddenly we start getting to numbers at  
6 12,000, 18,000 units that are well-above what we think we  
7 have on a daily basis. So for us, you know, we know that  
8 is not perfect, the modeling is not perfect, the count is  
9 imperfect but for at least this demonstrates that we very  
10 potentially have a real need.

11 And if you look at the national planning  
12 scenarios you'll know that most of those are talking about  
13 between 10,000, and 25,000 casualties. So, as in most  
14 other things you know, we are reaching a point now on our  
15 planning, we are planning for a 1000 casualties, is really  
16 something that we've already done and we're trying to work  
17 up to that to planning for the national planning scenario  
18 numbers, which got to be 10, 000 to 25,000 casualties.

19 Mostly we are concerned about the timeline. We  
20 know that the first 2 hours to 12 hours are going to be a  
21 critical period. We think we'll probably have enough  
22 blood to do initial transfusions for the first 2 hours.

1 But we are very, very concerned that we are not going to  
2 be able to move enough blood in within the 12-hour window  
3 to really be able to meet the backend need of those  
4 patients.

5 So, we think we'll be able to give them their  
6 first transfusion. We think in 12 hours we'll be able to  
7 mobilize blood from other parts of the country and other  
8 parts of the area, but we are very concerned with that  
9 window. And I say that fully understanding what it takes  
10 to actually move resources into an area that's been locked  
11 down and a disaster, and how difficult that actually is.

12 So, to bring those resources that would actually  
13 move the blood call, them up, get them ready to go, pack  
14 it up, and move it and unpack it and get it through the  
15 police barricades that will be setup can take an awful lot  
16 of time, and I actually think 12 hours is a little bit  
17 conservative for that. We have a lot of experience with  
18 trying to call up teams for disasters with the DMAT system  
19 and 12 hours would be very, very fast.

20 Because you know, you have to think through the  
21 other issues. The phone lines are not necessarily  
22 workable. Cell phones are down there, a lot of other

1 things going on in the time of the disaster that makes all  
2 of this so much harder than it would be on a day-to-day  
3 basis. Why this isn't really a military model of  
4 supplying blood? I think there is a lot of great  
5 experience, we can learn from that but this is a disaster  
6 that is instantaneous, we didn't plan it, there is no  
7 warning, and we are not moving at the rate of our supply  
8 chain. We don't necessarily have that setup before we go.

9           So, we took a lot of lesson when we tried to set  
10 this up from the U.S. military experience with Fresh Whole  
11 blood. We said, well, Whole Blood is something that we  
12 are talking about collecting from a donor and transfusing  
13 without the standard U.S. infectious testing to recipients  
14 within 24 hours. Our indication for this would only be  
15 severe life threatening injuries when blood components  
16 needed for resuscitation are not available.

17           So, if they didn't have life threatening  
18 exsanguinations, and we didn't have any blood that would  
19 be normally -- have gone through the normal testing  
20 procedures, this wouldn't be an issue. We are only  
21 talking about those particular situations. It would be a  
22 source of red cells, plasma, and platelets and the

1 military has transfused over 4000 units since 2001.

2           They recruit volunteer donors. They screen the  
3 donors, they give them questions, they do some infectious  
4 diseases testing. They type in cross-batch and they  
5 collect about 400 milliliters, 500 milliliters and then  
6 transfuse the whole blood immediately. So what we are  
7 talking about is really doing something fairly similar.

8           So, we are saying okay, we have a protocol in  
9 place. If a mass casualty event happens we are going to  
10 first start out, this is really hard to read on this  
11 background, I apologize; it didn't look so bad on my  
12 computer screen. We are going to first start out looking  
13 at, what are we seeing in the field and what patients are  
14 arriving at the trauma screen. All right, I am just going  
15 to have to read it to you.

16           So we get a pre-hospital casualty count and an  
17 observation. That can give us a rough number, we know  
18 it's not accurate, but it can give us a rough number if we  
19 think we are already over a 1000 casualties, that might be  
20 our cutoff point if our count of blood is about accurate.

21           We can also start talking to the hospitals; the  
22 hospitals can start talking to their blood banks,

1 directors, and seeing what their blood product needs are,  
2 if they are getting outside their needs, or if they need  
3 help moving blood around or if they are going to actually  
4 just go outside the ability to supply themselves.

5           So the blood bank director would evaluate the  
6 search capacity of the hospital products. Supply -- we  
7 would also get the public health authority involved, and  
8 say, at some level, and this is totally not decided at  
9 this point buy, you know, I am not sure exactly even where  
10 the legal authority for this rests -- who has the ability  
11 to release a Whole Blood waiver, it would probably be at a  
12 federal level to say that this is disaster, we've declared  
13 it a disaster for us at our local level, and our State  
14 level, and we are requesting a Whole Blood waiver.

15           And that would in-turn the contact the regional  
16 resources, the American Red Cross et cetera in our area to  
17 start moving some blood to the area. As you can see it,  
18 it also would contact the AABB taskforce and all of the  
19 work that Dr. Holmberg does, and into kind of coordinating  
20 that in to the federal government.

21           So all the while we're expecting that the  
22 transport of blood products is being done, that that's

1 happening at the same time we are saying we want to have  
2 the ability to activate a prescreened donor pool in the  
3 time period before that blood arrives. It maybe that we  
4 activate a prescreened donor pool, and that blood arrives  
5 and we never give a single unit and that would be just  
6 fine.

7           The prescreened donors all would be, have been  
8 prescreened within 3 months to 6 months depending on the  
9 final protocol,, and we have some basic idea that people  
10 who are screened within the last three to 6 months have a  
11 risk of conversion that's somewhere in the 0.001 to .003  
12 to.001 percent range, that their risk of conversion is not  
13 very high although of course there will be some.

14           Support staff would have to be called up,  
15 transportation collection staff people to do that whole  
16 end of the collection, and collect the Fresh Whole blood  
17 and transfuse the patient.

18           Now, there would of course be a follow-up  
19 testing arm on the patient and there would of course be  
20 the point at which the blood products arrive in the area  
21 and we can stop the whole collection piece and either put  
22 that blood into the regular pool and send it off to be

1 screened as normal or just get rid of it.

2 Is there risk? Yes, there is risk, there is  
3 always risk but, you know, we feel very strongly that .01  
4 percent or so versus the risk of exsanguination is a kind  
5 of a relative risk we'd be willing to live with.

6 So, we are talking about, we think red cells are  
7 going to be exhausted in our area at about a 1000 severely  
8 injured patients, moderate to severely injured patients,  
9 that Fresh Whole blood for emergency release is actually  
10 being effective in a military situation, and we are trying  
11 to develop a plan that would allow for a us to do this in  
12 a carefully prescreened manner, with a prescreen Walking  
13 Donor pool.

14 And that the benefits of survival of these  
15 patients with potentially fatal wounds outweigh the risk  
16 of the Fresh Whole blood. We know it's a 70 percent  
17 solution. It's not pretty, it's not perfect, but doing  
18 this at a local level, everything we do is not pretty and  
19 perfect. It's just trying to get what we can get done,  
20 and I do feel somewhat like we need something now, and  
21 until some of these other processes are in place reserved  
22 capacity exist, frozen capacity exist, we need an answer

1 for what we are going to do if this happens tomorrow.

2 So thank you for your time.

3 THE CHAIR: Thank you for a very interesting  
4 presentation; I'll open the floor to the Committee for  
5 questions and/or comments. Dr. Duffell?

6 DR. DUFFELL: You focused on whole blood, I  
7 mean, what about platelets or plasma?

8 DR. BRINSFIELD: We just felt like if we were in  
9 that much of a disaster situation we wouldn't have the  
10 ability to do components so that we would just be looking  
11 at transfusing whole blood if they were either a need for  
12 red cells or platelets, or plasma.

13 We didn't really try and quantify how much  
14 platelets or plasma we might need in the time of a  
15 disaster although of course that would be interesting to  
16 know.

17 THE CHAIR: One of the items that we've been  
18 struggling with, relates to different perspectives on the  
19 degree of blood-need in given emergencies or mass casualty  
20 situations. The historical data suggest that perhaps 200  
21 to 300 units would be needed to cover events, based on  
22 historical data. Your numbers are significantly greater

1     though we have also seen numbers related to nuclear events  
2     that are closer to your numbers.

3             Could you comment on those, you know, the  
4     reports of needing the lower amount? Obviously, your view  
5     is different but why do you think there is such a  
6     difference in the numbers?

7             DR. BRINSFIELD: I think one of the things we  
8     have to be careful is not to fight the last war. The  
9     terrorist are going to learn, they have obviously learned,  
10    now they are hitting 5 or 6 rail stations at once, they  
11    are going to learn to do something else next.

12            And I just want to, you know, in my job I look  
13    at as being one step ahead of that. You know, I realize  
14    that no previous disasters ever required this amounts of  
15    blood, that we've had always had enough blood but I don't  
16    want to find out that we don't have enough blood when the  
17    disaster happens.

18            THE CHAIR: Uh-huh, thank you. Additional --  
19    Commander Libby?

20            CDR. LIBBY: Yeah, I have a comment. I'm a --  
21    the head of the DoD Blood Program. Your slide there  
22    showed we did an infectious disease screening and result,

1 before you transfused the blood product that was collected  
2 from the walk-in blood bank.

3 I will tell you that there isn't time to do  
4 infectious disease testing even with rapid screening kits.  
5 And in Iraq it was very limited that we were able to get  
6 result prior to transfusion.

7 Secondly when you are always at kind of, this  
8 kind of situation and you're having to do emergency blood  
9 collection transfusion, which I've done, you always want  
10 to be aware of what is coming to the door next. So,  
11 you'll always do more, than what's needed in preparations,  
12 so you need to keep that in mind, and I -- how do you plan  
13 on doing the AB or H typing compatibility in this  
14 situation, how do you -- envision you can do this?

15 DR. BRINSFIELD: Sir, what we are trying to do  
16 actually is just run it through the hospital blood banks  
17 and have them do it by their normal process. Now I have  
18 spent some time talking to them and we know that they  
19 don't necessarily have the surge capacity within their own  
20 systems right now, and they would need to spend some time  
21 and some resources to build that up, but we figured that  
22 was the safest, safest way to do it.

1           CDR. LIBBY: Thank you.

2           DR. HOLMBERG: There is an interesting parallel  
3 in terms of benefit risk assessment as an example, we  
4 earlier today noted that for an organ transplants aside  
5 for a pre-testing with for HIV, there is in essence a lot  
6 of independence on the part of the treater to determine  
7 whether or not, you know, full testing is needed. And in  
8 this scenario there seems to be a parallel because, again  
9 in that event, it's a life saving intervention perhaps not  
10 as acute as the example that you presented, but it seems  
11 to me that in terms of that benefit risk assessment, there  
12 actually is a precedent though slightly different, it's an  
13 organ transplant but the infectious disease issues are  
14 similar.

15           Any other additional questions or comments --  
16 Dr. Roseff?

17           DR. ROSEFF: I think this is really interesting  
18 approach to use whole blood to truncate the process and  
19 get the blood there faster. I guess one thing that we  
20 have to think about too now is we need AB or identical  
21 donor, you know, as opposed to that stock of O red cells.  
22 So it changes the equation, but I think that's a really an

1 interesting thing that we really didn't talk about in  
2 using whole blood as our first line in certain kinds of  
3 disasters, interesting.

4 THE CHAIR: And then if in fact, if this were to  
5 take place, again we talk a lot about the errors  
6 associated with blood collection in the acute phase but we  
7 also need to be sensitive to -- then the hospitals have  
8 systems for, you know, monitoring blood administration,  
9 but this is different and so that sort of ephedrine  
10 (phonetic) will also have to be carefully looked at.

11 If no other questions, thank you very much --  
12 oh, Dr. Duffell?

13 DR. DUFFELL: Yeah, one quick one, this was  
14 actually for you Jay. In the advent of a natural disaster  
15 or a I mean, or a terrorist disaster, is there a sealed  
16 envelope somewhere inside the agency that someone pops  
17 open that says, okay we do this, we are waiving some of  
18 these testing requirements and release requirements that  
19 are normal standard because you know, D-day has happened?  
20 Is there something like that has already prepared  
21 prospectively?

22 DR. HOLMBERG: No. That's not to say that we

1 haven't done a lot of thinking about counter-terrorism and  
2 that we have -- or that we don't have candidate  
3 approaches, we do. But I think the issue here is how have  
4 we responded in disasters? I mean 9/11 was probably the  
5 closest thing to what we're talking about and the Agency  
6 did, urgently within a matter of hours develop a garden-  
7 stock, even make it available, and provided for regulatory  
8 flexibility to deal with an urgent situation perceived  
9 blood-need. It turned out that the blood need really was  
10 not there at the level that was forecast.

11 I think what -- well, first of all Dr. Williams  
12 is going to be talking about potential regulatory  
13 accommodations if we think that we need a national  
14 strategy for the use of an unscreened donor, or Walking  
15 Donor in this kind of urgent setting, and we think if we  
16 were to approach that it's not so much a question of  
17 having a sealed envelope, it's a question of having a  
18 well-vetted strategy that everybody already understands.

19 We would want to know in advance what the  
20 accommodations are, what the latitude is, who decides, how  
21 it gets tracked and so forth. So yeah, so that's the  
22 model that we would have in mind. And I think that the

1 overarching question is do we need this approach as part  
2 of preparedness, and as a national strategy? And if the  
3 answer is yes, then we can work toward having the frame  
4 work ready and available.

5 THE CHAIR: Okay, well, let's use that as a  
6 segue then into the -- thank you -- into the presentation  
7 by Dr. Williams.

8 Dr. Williams will present regulatory  
9 perspectives on disaster response. Dr. Williams is the  
10 Associate Director for Regulatory Affairs, the Office of  
11 Blood Research and Review, in the Center of Biologics  
12 Evaluation and Research.

13 DR. WILLIAMS: Thank you very much. You've  
14 heard a number of different perspectives on the topic over  
15 the past few days, and of course I'm going to cover the  
16 regulatory prospective but also within our office, the  
17 Office of Blood Research and Review, we have an active  
18 program of planning both for an pandemic event and other  
19 emergency events as does the Center for Biologics  
20 Evaluation and Research as does FDA as an Agency.

21 So, there will be a combination, both of the  
22 regulatory perspective and some of the areas that we've

1     been discussing and turning -- internally in terms of  
2     planning.  Also I have a couple of back ground slides and  
3     it shows to keep in because there are couple of nuances  
4     that didn't come out yesterday.  So a little bit of this  
5     you will have heard, but some of it maybe new in terms of  
6     some of the background.

7             Unlike other developed nations, the U.S. doesn't  
8     have a national blood system.  There are two major blood  
9     collection organizations, which collect about 90 percent  
10    of the blood in the country and the remaining 10 percent  
11    is collected in hospital-based collections centers and by  
12    the Department of Defense.  Most blood is -- appears to be  
13    stored a the hospital transfusion service level and  
14    reports of blood center inventorial levels should be taken  
15    with consideration of the fact that it's really the  
16    combination of Blood Center and transfusion service  
17    inventories that reflect the national blood supply.

18            And the major blood organizations assert  
19    strongly that there, they do have the ability to have both  
20    assess shortages and provide supply coverage in an  
21    emergency.  As you heard, the American Red Cross monitors  
22    customer inventories in some of its regions and ABC

1 monitors its members' inventories and post those on the  
2 ABC website in the form of a stoplight system.

3           It's been estimated that approximately one-half  
4 of the U.S. red cell supply is estimated to be life-  
5 sustaining and that the remaining 50 percent of red cell  
6 transfusions are elective and some uses, actually, are not  
7 well characterized and some of the thoughts that I'm  
8 bringing out came out of a meeting that we had with the  
9 AABB Pandemic Flu Task Force and it was really the blood  
10 collectors or you know, stressing the fact that some of  
11 the blood they just didn't know how it was being used at  
12 the hospital level.

13           Given that concept, the triage of available  
14 blood potentially could be a powerful blood shortage  
15 intervention, but efforts today to organize emergency  
16 triage beyond the local level haven't really been  
17 successful. Another factor is the growing importance of  
18 apheresis both for red cell collection and for platelets.  
19 Double red cell apheresis is a rapidly growing portion of  
20 the red cell supply.

21           In some centers it's approaching 30 percent of  
22 the total red cell collections and the industry goal

1 appears to be to optimize apheresis components collected  
2 from each donor and reduce the dependence on the component  
3 laboratories, combinations such as apheresis to produce a  
4 double group or a red cell unit with platelets or an AB  
5 plasma units with platelets and not collect the red cells.

6           Now, I think some of these trans impact the  
7 inventory management comments that you heard yesterday.  
8 Platelet supply is a special case -- the supply is  
9 vulnerable to sustained collection shortages. The shelf-  
10 life is 5 or 7 days depending on whether or not bacterial  
11 culture is done and participation in a program that  
12 includes bacterial testing.

13           Platelets apheresis are now 85 percent of the  
14 platelets supply an increasing. What are the implications  
15 for that and for emergency planning? It probably would  
16 not be easily possible for a blood collection  
17 establishment to suddenly revert to making platelets from  
18 whole blood collections because there is now such a  
19 dependence on apheresis that the collection site distance  
20 from the processing lab, the trend toward downsizing of  
21 the component lab and other factors may not necessarily  
22 keep this as a reverse -- reserve capacity for platelet

1 production.

2           In the meeting that we held with the Pandemic  
3 Task Force I asked about, you know, the ability to  
4 increase platelets for ESA's collection and the blood  
5 community responded that probably that could be boosted  
6 from 40 to 50 percent by doing off hours collections and  
7 using the apheresis equipment 24 hours a day if need to be  
8 to boost that capability, but that was probably the extent  
9 to which that could be increased with given equipment and  
10 supplies.

11           It's important to recognize there are a lot of  
12 interdependencies in providing safe and available blood  
13 supply. It's a complex network, it involves availability  
14 of donors, trained collection staff, supplies, infectious  
15 disease test kits, immunohematology reagents, centralized  
16 testing labs, controlled storage facilities, blood  
17 establishment computer systems and transportation.

18           There was a manuscript in the June transfusion  
19 which addressed this issue of some of the  
20 interdependencies and how a break in one of the systems  
21 could ultimately impact the availability of blood  
22 components and that particular publication emphasized the

1 blood establishment computer systems and the  
2 immunohematology reagents and in talking to our staff  
3 about some of these concerns.

4 Well, the sentiment was raised that world blood  
5 bankers generally know their field well enough that they  
6 can, you know, figure work around as to try to work with  
7 the Beck system or use, you know, a slightly modified  
8 immunohematology reagent, but it came out that if a  
9 machine calls for a reagent that carries a certain barcode  
10 and you're not using that same reagent, you created a  
11 glitch in the computer program that ultimately results in  
12 a label that enables you to release the blood product.

13 So just little glitches like that can in fact  
14 put a stop to the whole system and I urge you to take a  
15 look at that paper. It kind of developed some of the  
16 scenarios that could take place by a seemingly simple  
17 break in this complex chain. I also want to stress the  
18 blood shortages at the local level, even if blood is  
19 available 50 miles away that can very quickly become a  
20 safety issue.

21 And that's going to form a basis in a lot my  
22 talk that absence of blood, when you need it itself

1 becomes a safety issue, so that becomes a risk benefit  
2 calculation. And I think it's a tribute to our current  
3 system, our current blood community that this really has  
4 not happened and in general the blood supply through the  
5 years has been sufficient to maintain public health at its  
6 high level.

7           A few comments about the FDA, the FDA has  
8 limited ability to influence the overall supply or  
9 movement of blood supplies. What we can do is whenever an  
10 intervention is under consideration, we try to target that  
11 intervention to preserve critical supplies and again to  
12 the extent data are available or modeling can be done that  
13 risk benefit assessment is done to try to create --  
14 preserve supplies to the greatest extent possible, but we  
15 really don't have any control at the FDA over production  
16 volume or distribution.

17           If a test kit manufacturer suddenly decides it's  
18 no longer profitable to make a certain test kit, they can  
19 cease production and although we can try to work out the  
20 problems that might be associated with that overall we  
21 just do not have control over manufacturing. FDA does  
22 have an active outreach program in many areas and

1 particularly with emergency planning.

2           We have liaison to most of the AABB groups, but  
3 specifically to the AABB Disaster Taskforce and the  
4 Pandemic Flu Committees. FDA communicates and  
5 collaborates actively with the PHS agencies and with  
6 Department of Health and Human Services. And we actually  
7 developed a few years ago and I believe presented to this  
8 committee a blood shortage monitoring program known as  
9 TRANS-Net that would actually identify transfusion  
10 services that had shortages and assign a impact value to  
11 that shortage.

12           And I'm going to say a little bit more about  
13 that later because I think that's potentially one of the  
14 triggers that could be put to use in managing, supplying  
15 and emergency. We also have several regulatory databases.  
16 One of them is our Blood Establishment Registration  
17 Database. We supply data from that to DHHS to help them  
18 in their emergency response capabilities at the  
19 Secretary's Operation Center and we've recently developed  
20 related to that a GIS system actually, using Google Earth  
21 Professional and we're going to share that in the next  
22 week or so, also with DHHS.

1           What you see here is a -- just the integration  
2   for Manhattan of the integration of our blood  
3   establishment registration database, the blood collection  
4   centers on Manhattan. The wild factor comes from the  
5   aerial photography, that's part of Google, but the real  
6   utility of this and if you look at the green cloud there,  
7   I mean, this could represent a chemical event, it could  
8   represent a radioactive plume. On a much larger scale, it  
9   could represent a hurricane.

10           It has that capability to draw this free form  
11   indicator around any event that is occurring and see right  
12   away what potential manufacturing sites that's affected --  
13   affecting and there are public databases available that  
14   also can put hospitals and similar facilities on the map.  
15   One of the additional benefits of using the program is  
16   this uses a -- what's known as a KML programming language  
17   so that a central facility like CDC or the Secretary's  
18   Operation Center could simply transmit by e-mail, the KML  
19   data on a half-hour or hourly basis and one can update on  
20   one's own PC where the event is actually occurring and  
21   who's being affected. So, this is actually fully  
22   functioned in our shop and we're going to be sharing this

1 with HHS and we've always used our databases and GIS  
2 systems in the Top Off exercises and whenever we've had to  
3 deal with some sort of emergency response.

4 The AABB Interorganizational Disaster Task  
5 Force, you've heard about, so I won't dwell on that. The  
6 FDA participates in the level one calls as a liaison to  
7 the group and it's been active in each of the Top Off  
8 exercises and in proactive planning for major collections  
9 of the population and the way this works is at the first  
10 call.

11 Generally, it involves the involved blood  
12 organization as well as the level one members and there is  
13 an immediate assessment of available supplies and an  
14 assessment of what blood might be needed. I would have to  
15 say in a multiple scenario situation or a very large  
16 situation, the ability to monitor that level where blood  
17 is needed and what's available is untested.

18 Now that -- not that it couldn't be done, it's  
19 simply untested and I think that's something that needs to  
20 be considered. Generally, by the second call, this  
21 disaster task force, if it's something like Top Off  
22 exercise, the question comes to FDA, "Okay, what's your

1 recommendation for how to deal with this event?" So it  
2 keeps it on our toes in terms of anticipating potential  
3 disasters.

4 I wanted to say a few comments related pandemic  
5 response planning and it showed some differences with  
6 respect to planning for overall emergencies, but also some  
7 crossover areas, so I'm using this as a context for some  
8 additional thoughts. We've been interacting now for over  
9 two years as an agency, as members -- liaison members of  
10 the AABB Pandemic Influenza Task Force.

11 And this task force has been very active in  
12 helping AABB members with checklists and advisory  
13 information for preparing for a pandemic, but specific to  
14 the FDA, what they did is basically challenge us as an  
15 agency to consider how regulatory policies might be made  
16 to accommodate a blood shortage situation, such as a  
17 pandemic.

18 And they presented with us a rather sizable list  
19 that you see here of potential accommodations which they  
20 think would -- thought would be appropriate, and these  
21 included reduced interdonation intervals of red cells,  
22 modified hemoglobin, values, travel deferrals, weight

1 limits and some reflecting the fact that blood center  
2 staff would undoubtedly also be reduced in the event of a  
3 pandemic.

4           Some accommodations with respect to frequency of  
5 quality-control testing, timing of audits, reporting  
6 requirements for biological product deviations and so  
7 forth. And this task force also urged that FDA be  
8 transparent regarded, you know, its attentions not have a  
9 sealed envelope so as to allow planning by the blood  
10 community. We held a, I think, a very productive meeting  
11 in June of this year with several of us from FDA and a  
12 Pandemic Task Force and tried to pin down some of these  
13 areas a little more closely and the FDA did convey  
14 information to the task force at that meeting.

15           Some of the information is that in our view the  
16 best preparation is for blood establishments to anticipate  
17 pandemic related disruptions and prepare backup plans for  
18 their key manufacturing steps. This would include staff  
19 training, regulatory approvals that might be proposed in  
20 advance, supply management, Beck's override options,  
21 recording keeping in an adverse environment and factors  
22 such as that.

1           Also it's been recognized at search collections,  
2           early in a recognized pandemic would help to maintain red  
3           cell supplies for at least the first 6 weeks which might  
4           cover most of the first wave of a pandemic, and also as  
5           discussed here practice guidelines for the triage of blood  
6           components used electively in times of emergency would  
7           greatly facilitate the optimal use of available supplies.

8           Some comments on regulatory flexibility in a  
9           time of emergency. Most importantly, FDA is committed to  
10          following its own statutes, regulations, guidances and  
11          SOPs. Now, FDA just doesn't have the ability to say,  
12          "Well, here's your situation, why don't you go ahead and  
13          do this?" It really does have to have a regulatory basis  
14          and that's at considerations of regulatory flexibility,  
15          typically we're encountered to most of the measures that  
16          have been established to prevent deviations from  
17          established standards.

18          The statutes or laws, they're not flexible. FDA  
19          can't violate them -- nor can manufacturers. Regulations  
20          carry the force of law, but there are provisions for some  
21          exceptions and alternative procedures built into the blood  
22          regulations that can be invoked particularly in an

1 emergency situation. Guidance, it's not required if they  
2 are recommendations and alternative procedures can be  
3 proposed, but some of the recommendations, if they become  
4 used throughout the collection community can themselves  
5 become CGMP.

6 Our voluntary industry standards are also in  
7 place. They are not FDA required, but FDA is certainly  
8 considers voluntary industry standards as important and  
9 tries to harmonize with those standards. Also important  
10 is that emergency in pandemic response issues are FDA  
11 wide. Decisions can be made certainly within the office  
12 of blood or at receiver level because they might have  
13 implication agency wide, so there is a large area of  
14 consideration.

15 Inherence to the standards that are in place is  
16 a critical foundation of the current blood collection  
17 system. FDA is not totally opposed to relaxing standards,  
18 but any relaxation of standards would have to be dependent  
19 on recognition of shortages as an imminent public health  
20 threat, IEA safety concern in itself and would be  
21 considered in the context of any supporting data that  
22 assesses the risk benefit to the greatest extent possible.

1           At the same time FDA is actively seeking  
2 mechanisms that will help to preserve critical blood  
3 supplies in a pandemic or other disaster and as Jay  
4 mentioned FDA did show flexibility on 9/11 through the  
5 guidance process. At the June 26 meeting with the AABB  
6 the discussions narrowed on several potential  
7 interventions that appeared to have the most favorable  
8 cost-benefit relationship.

9           There was negotiation or agreement made at the  
10 meeting, just that these were potential targets for future  
11 discussion and consideration. The first being that  
12 probably the most bang for the buck is it were -- would  
13 occur by considering the reduction of a 56-day red cell  
14 inter donation interval, but this would be in the context  
15 of a predonation hemoglobin determination.

16           In other words, a donor who would be eligible  
17 other than the 56-day time period, that is, is in the  
18 regulations. This would be projected to provide a large  
19 increase in the red cell supply with likely minimal to no  
20 safety impact, although this is still under discussion.  
21 Second would be that a minor reduction in the weight  
22 requirements for double red cell apheresis, something on

1 the order of 5 pounds reduction would potentially also  
2 increase the availability of donors for double red cell  
3 collection.

4 There is a lot of emphasize from the blood  
5 community on relaxing travel deferrals, particularly areas  
6 like malaria and some of the variant CJD or BSC related  
7 travel deferrals. This was estimated to potentially add a  
8 1 to 3 percent increase in accepted donors, but blood  
9 establishments generally seem to feel that they would not  
10 go back to deferred donors and recruit them in an  
11 emergency situation.

12 The benefit would only apply to incoming donors  
13 and to the extent that the change in policy would be made  
14 known, donors might not self defer prior to coming to the  
15 blood collection. There is consideration of relaxing of  
16 internal QC frequency and FDA reporting timelines. This  
17 is an area of -- that potentially would help keep staff  
18 focused on the collection activities, but at the same time  
19 one certainly doesn't want to compromise your QC activity  
20 at a time when the manufacturing process is stressed.

21 So again, considerations need to be further  
22 discussed. So these potential flexibilities are a

1 conceptual start. There are in need of more sophisticated  
2 assessments. Questions like what would be the gain in  
3 donors and in donations, what would be the impact on  
4 safety, if the standard were to be modified temporarily,  
5 donor safety and product safety.

6           Importantly, what organizational entity, would  
7 it be community or government would declare the need and  
8 accept a responsibility for an intervention. And from the  
9 blood establishment perspective, if FDA were to provide  
10 flexibility, what mechanisms would produce the most  
11 deficient pathways for FDA to provide this flexibility.  
12 Perhaps having more than a thousand blood collection  
13 establishments, submit variance request, might not be the  
14 most efficient way to put something in place.

15           We did want to say a word about Walking Donor  
16 programs. We at CBRA had a meeting in mid-June with the  
17 Boston Fresh Whole Blood Group. The Walking Donor concept  
18 isn't new, but I think FDA involvement in some of the  
19 recent discussions really grew out of that meeting and Dr.  
20 Brinsfield presented some of the characteristics of that  
21 program and I won't repeat those here.

22           I think one of the key areas, one of the first

1 steps is to make the determination as to whether this type  
2 of program hasn't potentially a unique niche in emergency  
3 response, if that's the case then, you know, discussions  
4 can start regarding some of the regulatory hurdles, some  
5 of the logistic hurdles which are large. But probably the  
6 first question is -- is this a necessary program to really  
7 make sure that at a local level the response can be  
8 adequate.

9           So rather than go, you know, in-depth into some  
10 of the regulatory concerns and hurdles, what we've done,  
11 first make the statement that FDA neither -- currently  
12 neither endorses nor dismisses the potential value of  
13 Walking Donor programs. I think, you know, this is an  
14 active area of discussion, I think there are other  
15 considerations which can be brought to bear.

16           For instance, one set of ideal characteristics  
17 for Walking Donor program would be to hone in on Group O  
18 donors, but preserve the capability to rapidly express  
19 plasma. It doesn't that long or take, you know, high-tech  
20 equipment to take off plasma. If you can do then you can  
21 focus on a Group O inventory or a Group O Walking Donor  
22 program.

1           There is considerable regulatory concern about  
2 who would collect the blood and under what training  
3 conditions, what regulatory conditions are -- ideally are  
4 a fresh whole blood are collected under GMP by experienced  
5 blood collectors is what would be the ideal one could  
6 envision that this might be better done by, you know,  
7 someone who is part of a licensed or registered only blood  
8 collection community.

9           Anyhow, so whether it should be a blood  
10 collection establishment versus a transfusion service is  
11 an area for discussion. Use of rapid tests was mentioned,  
12 if there is time and availability that would help create  
13 an ideal situation. There are some rather I think  
14 important advantages to the concept if a program could be  
15 sufficiently designed.

16           Sufficient supply of Walking Donors and this is  
17 looking at a nationwide level combined with the  
18 appropriate collection capabilities E-supplies, blood  
19 banks et cetera, where they could address any blood  
20 shortage or crisis. I mean, if this system could be made  
21 to work, it would be very powerful.

22           On another note, donors interested in being

1 Walking Donors might be more likely to donate more  
2 frequently to retain their Walking Donor status. And what  
3 I'm getting at here is we heard yesterday this sort of  
4 disconnect between, if there is a disaster event, donors  
5 line up on the sidewalk to want to help and make a  
6 difference, versus asking six times in a normal situation  
7 to get a donor to come in.

8           There has got to some sort of bridge between  
9 those two considerations from a behavioral standpoint that  
10 can be identified and brought to motivate donors and  
11 potentially something like being part of an elite group  
12 that's an emergency response blood donor group might have  
13 that impact, it's hard to say totally untested, but it's  
14 potentially a benefit to having a program like that.

15           And as mentioned the military has a lot of  
16 experience with Walking Donor programs. What are some of  
17 the hurdles? It remains to be documented, whether Walking  
18 Donor programs have a unique niche that can't be met by  
19 other supply mechanisms. The logistic hurdles of  
20 maintaining a viable Walking Donor program particularly  
21 when it's not being used for a period of years are  
22 probably huge.

1           The current regulatory paradigm for blood  
2 precludes many aspects of a Walking Donor program so that  
3 would entail a lot of discussion and there needs to be  
4 determination of feasibility of hospital versus blood  
5 center mobile Walking Donor collection sites. One of the  
6 potential areas, here emergency response kind of crosses  
7 over with pandemic response is that the risk, assuming  
8 blood is collection under GMP conditions.

9           The use of untested Walking Donors basically  
10 mimics the same risk that one would have in a pandemic  
11 situation, where there is a break in the test kit supply  
12 system. One would probably emphasize repeat donor -- use  
13 of repeat donor blood, but would not have the ability to  
14 test it because one wouldn't have test kits available,  
15 very similar scenario with different -- with similar risk  
16 assessments.

17           So, just to wind up, what I've done is, is put  
18 together four different characteristics of -- that might  
19 be incurred for blood shortages and crisis and you will  
20 see this goes a little more toward the philosophy of hope  
21 for the best prepare for the worst, because the first area  
22 is a concern about shortage, a large scale extended

1 shortage that we have experienced, but the other three  
2 scenarios as a nation we have not experienced.

3           This would be a local crisis that's short lived,  
4 a large scale crisis that's short lived, a large scale  
5 crisis that's extended in time. I did put a couple of  
6 definitions up here. The shortage definition came from  
7 the statement by Louis Katz at the AABB pandemic task  
8 force meeting. He defined shortage as "don't have it,  
9 can't get it."

10           Crisis again sort of a new concept, this is  
11 defined by eminent patient morbidity, or mortality due to  
12 an absence of blood. So the first situation, a shortage  
13 large scale extended, this examples would be severe  
14 seasonal shortages, they do happen several times a years,  
15 typically holidays and summers and every few years it's  
16 severe enough that there is a need for a national appeal.

17           Potential interventions in that situation are  
18 alternate supply sources and donation appeals, where a  
19 adequate transfusion triage program available that would  
20 help also and to mitigate seasonal shortage. Some of the  
21 other factors here that are in grey probably would not be  
22 invoked some of these involve changes in standards that in

1 the absence of a -- really a crisis situation probably one  
2 would not consider as mitigation for a shortage event.

3 The second consideration is a local crisis short  
4 lived, similarly, to the situation that Dr. Brinsfield  
5 mentioned. This would be a severe trauma or BTCT event  
6 requiring blood, local supplies exhausted. Frequency of  
7 occurrence, it was actually anticipated on 9/11 as I will  
8 show you in the next slide, but in fact there's never been  
9 observed actually, in the U.S.

10 In this situation because it's local there would  
11 be alternate supply sources available, but these would be  
12 subject to a transportation time lag. There maybe an  
13 indication for modified blood establishment SOPs to be  
14 able to sustain local blood supplies. A Walking Donor  
15 program may be inappropriate response and again  
16 transfusion triage as it will appear on virtually all of  
17 these situations would help mitigate blood shortage.

18 On 9/11 the midday reports coming into FDA out  
19 of New York indicated a potential for thousands of severe  
20 traumatic injuries and then later -- a little later in the  
21 day also from the Pentagon attack. So, we were planning  
22 for a potentially thousands of injuries that might require

1 blood and the FDA issued same-day guidance which included  
2 provisions for training and certification of emergency  
3 staff members, a release in unit -- and use of units that  
4 were not fully tested with appropriate labeling as being  
5 "For Emergency Use Only," with an indication of the tests  
6 not completed.

7 A provision for enforcement discretion, for  
8 interstate shipment by registered only facilities with,  
9 again, labeling that a unit would be unlicensed and "For  
10 Emergency Use Only," and recommendation for adequate  
11 product identification and record keeping.

12 By 9/14 it was evident that the extra blood was  
13 not needed for attacked victims and FDA issued revised  
14 recommendations through guidance that discontinued, the  
15 collection by emergency trained staff --

16 (Tape interruption)

17 -- are in great -- probably would not be invoked in some  
18 of these involved changes and standards that in the  
19 absence of a really a crisis situation probably one would  
20 not consider as a medication for a shortage event.

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22 short-lived similar to the situation that Dr. Brinsfield

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2 requiring blood, local supply is exhausted. Frequency of  
3 occurrence, it was actually anticipated on 9/11 as I'll  
4 show you in the next slide. But in fact it has never been  
5 observed actually in the U.S.

6 In this situation, because it's local, there  
7 would be alternate supply sources available but these  
8 would be subject to a transportation time lag. There may  
9 be an indication for modified blood establishment SOPs to  
10 be able to sustain local blood supplies, Walking Donor  
11 Program may be an appropriate response, and again  
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13 these situations would help mitigate blood shortage.

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15 of New York indicated a potential for thousands of severe  
16 traumatic injuries, and then later -- little later in the  
17 day also from the Pentagon attack. So we were planning  
18 for potentially thousands of injuries that might require  
19 blood. And the FDA issued same day guidance which  
20 included provisions for training and certification of  
21 emergency staff members releasing -- and use of units that  
22 were not fully tested with appropriate labeling as being

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6 emergency use only, and recommendation for adequate  
7 product identification and record keeping. By 9/14 it was  
8 evident that the extra blood was not needed for attack  
9 victims and FDA issued revised recommendations through  
10 guidance that discontinued the collection by emergency  
11 training staff and recommended a quality assurance  
12 investigation to be reported to FDA within 72 hours and to  
13 discontinue use of any non-tested units.

14 In fact on 9/11 the only testing problem that  
15 occurred had to do with a centralized testing program for  
16 NATs and that was very minor. But the transportation  
17 disruptions potentially threatened the ability to provide  
18 NAT for platelet units. So, some of the lessons from  
19 9/11, the quality assurance assessments done following the  
20 event indicated that in fact much of the blood collected  
21 under emergency conditions was not suitable for inclusion  
22 in the non-emergency community supply.

1           So, again that was a trade off on risk benefit.  
2       Had there been thousands of injuries probably there would  
3       have been more blood available. But the injuries were not  
4       there and the blood was lost.

5           The experience identified the need for  
6       consistent public messaging regarding adequacy and safety  
7       of the blood supply and the need for interested donors to  
8       schedule future donation rather than simply line up down  
9       the sidewalk to try to help shortly after an event.

10          And this experience led to the formation of the  
11       AABB Inter-Organizational Task Force on disasters which I  
12       will add as a, you know, one of the long term  
13       participants. It is a very effective mechanism for  
14       everything that has been encountered to date.

15          The third situation is large scale crisis which  
16       is short lived. This would be the situation for something  
17       like a multi-focal BTCT event creating a critical supply  
18       disruption. This has never been observed in the U.S.  
19       There would be some alternate supply sources available  
20       from sites that were not affected but this would be  
21       subject to availability and time lag.

22          Modified donor eligibility considerations and

1 appeals probably wouldn't produce donations in sufficient  
2 time period to be responsive. So these would not be  
3 potential -- effective potential interventions. On the  
4 other hand, Walking Donor Program or transfusion triage  
5 again potentially would help to sustain critical supplies.

6 And then the fourth type of situation is a  
7 large-scale crisis for an extended period. And this would  
8 be the severe pandemic situation. Never observed in the  
9 U.S., virtually all of the potential interventions would  
10 help somewhat in helping to preserve supply but the  
11 alternative of bringing blood in from elsewhere in such a  
12 broad based event may not provide meaningful support.

13 So, you know, some of the local facilities might  
14 be, you know, a little more on their own than normal to  
15 help try to preserve supply and again an area where some  
16 regulatory flexibilities, transfusion triage and  
17 availability of walking donors may help to preserve  
18 things.

19 I title the talk intervention triggers and  
20 pathways in the final slides just to talk about what some  
21 of the current status is, particularly with respect to  
22 pandemic planning. In terms of defining candidate

1 interventions including the risk benefit assessments, I  
2 think through the work with the AABB pandemic taskforce  
3 and the blood community some of the candidate  
4 interventions are coming into focus and are entering the  
5 stage of going through some formal risk benefit analysis.  
6 We have a pandemic modeling program through our office of  
7 Biostatistics and Epidemiology at CBER, and this will  
8 provide a good framework for assessing some of these  
9 interventions on a formal basis.

10           The second step is to defining appropriate  
11 triggers to put an intervention into place. And this is  
12 an area that really has proven to be much more difficult  
13 than originally anticipated. And these triggers even  
14 despite a lot of discussion remain largely undefined and  
15 also include the levels at which implementation decisions  
16 will be made, who bears responsibility, and the role of  
17 the public versus the private sector. This was discussed  
18 at our June meeting with regard to a pandemic and really  
19 could not reach conclusions. Inventory figures both at  
20 the blood center and the transfusion service level are  
21 difficult to interpret.

22           One of the elements proposed in the TransNet

1 program was the proposal that used -- potentially useful  
2 trigger for invention -- intervention might be to assess  
3 the impact on blood shortages at the local transfusion  
4 service level, while transfusion service do guard their  
5 inventory information and don't want to be, you know,  
6 shown as not potentially available to the community needs.  
7 If in fact there is a shortage one would anticipate, I  
8 think, that any hospital put out, you know, a cry for help  
9 if they were potentially compromising patients because  
10 there wasn't blood available.

11 So the concept here is that it would be a  
12 shortage reporting inventory rather than a daily reporting  
13 inventory with indication of what the impacts of that  
14 shortage would be ranging from a cancelled elective  
15 surgery to use of Rh+ blood to Rh- patients, the need to  
16 triage transfusions internally, and in a severe situation  
17 the concept of imminent patient morbidity or mortality.  
18 If one had those data then one could potentially decide  
19 where to move blood in a meaningful way and provide an  
20 intervention. This was discussed and in fairness I think  
21 I want to reflect that the discussion from the blood  
22 collection community at the pandemic taskforce meeting

1 felt that these measures in the transfusion service would  
2 be unreliable simply because transfusion services would  
3 still tend to preserve some of their internal data.

4           Within FDA we've had to consider some of the  
5 appropriate regulatory pathways that might be appropriate  
6 to a situation. We have taken the first step which is to  
7 strongly encourage proactive contingency planning by the  
8 regulated manufactures, not only blood collection  
9 community but plasma and other areas.

10           There are other regulatory pathways which can be  
11 brought to bear. I'm not going to go into them at this  
12 time, but probably the most reliable way to transmit  
13 regulatory recommendations is through the issuance of  
14 guidance and there is act of consideration of trying to  
15 put out advanced guidance that might help anticipate  
16 emergency needs and create regulatory flexibilities to  
17 help address those under defined conditions and set  
18 triggers. And the final consideration, and I think you  
19 began to hear it today, is in the planning realistically.  
20 There is certainly general agreement about the plan, about  
21 the value of proactive planning regarding measures to  
22 sustain the blood supply in the face of a disaster.

1           But there should be caution in basing these  
2 plans solely upon the parameters that pass disasters with  
3 no contingency plan for larger scale events. They haven't  
4 been experienced but they could be anticipated to result  
5 in severe disruptions at multiple levels to a fragile  
6 blood supply chain and that could occur at numerous  
7 locations. Thank you.

8           THE CHAIR: Thank you, Dr. Williams. We will  
9 entertain questions or comments from the committee. One  
10 thing that resonated with me is the notion of donor  
11 management that you mentioned which is a positive  
12 attribute of the Walking Donor Program. It appears to me  
13 that in smaller scale settings people have used this  
14 approach to cover some of their local shortages. But  
15 there are truly a number of people that are -- that want  
16 to be heroes in a sense, and it's the resource I think  
17 that really needs to get tapped.

18           DR. WILLIAMS: I think also presented  
19 historically to the committee has been the concept that,  
20 you know, funding for behavioral research in this area may  
21 well help to get at that large component of the general  
22 population as eligible to donate and doesn't, you know,

1 what are the barriers to those folks from coming in.

2 But I was struck by this gap between the lined  
3 up donors in response to an event versus the difficulty in  
4 recruiting in a normal situation that could there be some  
5 messaging that might bridge that.

6 THE CHAIR: Thank you. Additional comments from  
7 the committee. Thank you. Our last present for the day  
8 will be an update on BASIS. And Dr. Holmberg will make  
9 that presentation.

10 DR. HOLMBERG: What I've learned from this job  
11 is to be flexible and you were really supposed to have a  
12 presentation by Dr. Lelkens from the Netherlands to talk  
13 about frozen blood. Unfortunately, yesterday he sat on  
14 the tarmac for numerous hours in Amsterdam and was never  
15 able to get out of Amsterdam, so we will reschedule some  
16 time later on to talk about some of his activities in the  
17 Netherlands because he does have a total frozen blood bank  
18 and with frozen platelets and also frozen red cells and  
19 plasma. But this really gave me an opportunity because  
20 there was a lot of discussion yesterday concerning BASIS  
21 and what it is and the participation that we have.

22 And I really felt that after talking to Dr.

1     Bracey and others that it was probably necessary to give  
2     an update on where we are with BASIS and let people see  
3     the capabilities of it.

4             I also have to say that early on in the planning  
5     we did consider a lot of the features of the TransNet  
6     program that Dr. Williams just mentioned, and I'll try to  
7     show you some of those capabilities. First of all, I do  
8     want to go back and just show this graphic again because  
9     it was referred quite a bit yesterday and I just wanted to  
10    spend a few minutes on this.

11            I think that we really focused on the gap here  
12    and, you know, the possibility that maybe we're doing a  
13    better of job of managing the inventory. Definitely here  
14    is a surplus, like Dr. Bianco said, you know, during 9/11  
15    there was about a half a million units of blood collected  
16    as a result of 9/11.

17            But I also want to draw the -- your attention to  
18    this right up here and that is the difference between  
19    collections and available collections. And so I think  
20    that yesterday in the discussions I think some of things  
21    that people maybe overlooked was that the increased number  
22    of deferrals that have taken place here.

1           And I just wanted to draw that to your  
2 attention. The other thing I wanted to draw to your  
3 attention is a comment that I believe Dr. Epstein  
4 mentioned yesterday concerning our transfusion ratios here  
5 in this country. Up above is our collection ratio, that  
6 is the number per 1000 population and this is an age group  
7 of 18 to 65 and we run about an 85 -- in 2004 it was about  
8 85 per 1000.

9           Over here on transfusion, we've run about a 49  
10 per 1000 and this is for an all age group consideration.  
11 But I believe that as Dr. Epstein mentioned yesterday  
12 there are other countries such as Canada, France, the UK  
13 that do a much better job as far as reducing the amount of  
14 transfusions. And definitely as Dr. Williams mentioned in  
15 the presentation just a few minutes ago in each one of the  
16 strategies it was really, you know, taken advantage of,  
17 transfusion, restricting transfusions and maybe doing away  
18 with elective surgeries that would free up a lot of blood.  
19 But you can see that we probably could do a better job in  
20 the amount of blood that we do transfuse. I also just  
21 want to quickly go through ESF 8. Matt Payne explained a  
22 little about ESF 8 this morning. And I just want to

1 mention that the current version of ESF 8 has blood  
2 mentioned three different times.

3           There are quite a few support agencies; the  
4 American Red Cross is there but as a member for the  
5 disaster response. The ARC as far as blood is part of the  
6 AABB taskforce. ESF 8 when activated is coordinated by  
7 ASPR through the HHS secretary's operation center, and it  
8 very clearly states in there that the blood support is the  
9 responsibility of the Assistant Secretary for Health.

10           Coordination is with the AABB taskforce, talks  
11 about the levels of participation and also makes a  
12 clarification that ARC is for disaster response and that  
13 their participation in blood activity is coordinated  
14 through the AABB taskforce.

15           The wording here, I just want to read this to  
16 you because it's very clear as far as what is expected.  
17 The one area that really draws a lot of people's attention  
18 is the monitors. HHS monitors blood availability and  
19 maintains contact with the AABB taskforce and it's  
20 necessary as individual members to determine the need for  
21 blood, blood products and the supplies used in the  
22 manufacture, testing, and storage, the ability of existing

1 supply chain resources to meet these needs and any  
2 emergency measures needed to augment or replenish existing  
3 supplies.

4           Yesterday, there was some discussion about,  
5 BASIS may not -- doing both the daily preparation or the  
6 reports, determining whether there are shortages, and also  
7 in the response to a crisis. What BASIS really is, is one  
8 database and the reason we have one database is so that we  
9 have a baseline when an event happens. So we have the  
10 ability to determine the shortages on a daily basis, but  
11 then when an event happens we already know what the status  
12 is of the blood supply.

13           Just quickly to go through some of how we are  
14 activated in a disaster, of course hospitals are  
15 activated. The event happens at hospitals and the  
16 effective blood centers are activated. We also have a  
17 starting BASIS data point. And we also are encouraging  
18 visibility at the state level. The secretary's operation  
19 center is activated. We internally are coordinating  
20 activities with FDA, CDC, NIH, HRSA, CMS, and we are  
21 looking at the critical infrastructure such as supplies  
22 electricity, communication, water, and has also --

1 supplies, that would include fuel in there.

2 We also coordinate very heavily with the DoD and  
3 the Department of Veterans Affairs. This is the AABB  
4 taskforce straight down the blood center would then call  
5 AABB, the level 1 taskforce members which is AABB, the  
6 Armed Services Blood Program, Blood Centers of America,  
7 America's Blood Center, American Red Cross and then  
8 messaging going out to the affected blood centers and then  
9 if as needed the level 2 taskforce which would also  
10 include some of our participants such as the AATB, the  
11 tissue bank people, the medical device people, American  
12 Hospital Association, CAP, PPTA and also HRSA.

13 One of the things that was learned right after  
14 9/11 was that we needed to have common messaging and that  
15 is one reason why the ESF 8 says that the Assistant  
16 Secretary for Health is responsible for blood. That  
17 messaging goes through the secretary of HHS and one of the  
18 things that we really agree upon is that there will be a  
19 common message. There may be 12 to 24 hour delay before  
20 that message goes out. But once we all agree upon it, it  
21 is in concert. They can go out and talk to the blood  
22 community. But it is in concert and it is in agreement

1 with what the secretary is going to say.

2 Just throwing everything together you can see  
3 how this thing gets little bit confusing, but it is  
4 complicated and it also just emphasizes that we are  
5 bidirectional interacting with the taskforce and also with  
6 the SOC and so that this is where HHS and the task force  
7 comes together.

8 One of the things about BASIS is that it  
9 monitors both supply and demand and I have to emphasize  
10 this quite a bit. I think we've heard in the last day-  
11 and-a-half a lot of concern about what would the  
12 government do with the data. And one of the things that  
13 we are every emphatic about is that we are not to  
14 interfere with day-to-day operations and decisions with  
15 local centers, hospitals and/or community transfusion  
16 centers.

17 What BASIS does is it tracks the quantitative  
18 data of blood supply and demand, the quantitative data on  
19 platelet supply and demand, and qualitative data on the  
20 supply chain and also the demand chain. The basis system  
21 uses weighted values. The hospital considers the day of  
22 supplies, the platelet therapeutic doses and that is

1 entered into their profile just as the blood center's days  
2 of supply is also weighted.

3 And then also the statistical sampling is such  
4 that we've gone out with random sampling and for our  
5 recruitments efforts in order that we can get a  
6 statistical significance in our sampling. The BASIS is  
7 the design being -- is being evaluated by the national  
8 blood collection unitization survey and also it does have  
9 the capability with the GIS.

10 Some of the qualitative data that is asked for  
11 within BASIS as Dr. Williams referred to as was surgery  
12 delayed, was an order not filled completely, was blood  
13 products purchased from an alternate supplier, was a non-  
14 standard protocol used in patient care because of the  
15 shortage, was a routine transfusion practice ignored, or  
16 was surgery or therapy cancelled.

17 I know this is busy, but I did want to read to  
18 you the -- what is said on the front homepage. I think  
19 that it tries to dispel a lot of the concerns that  
20 especially some people may have, and that is the BASIS  
21 program is designed to be a tool for local blood centers  
22 and hospitals to track their inventory while providing a

1 unique ability to monitor the supply and demand by states,  
2 emergency operation centers and public health regions  
3 during a disaster.

4           Each facility's identity is secure and not  
5 visible by other participants enrolled in the system  
6 unless designated by a local memorandum of understanding.  
7 Your participation in BASIS is critical to the State  
8 Department of Health and the Department of Health and  
9 Human Services to monitor that nation's blood inventory in  
10 light of national disasters and patient donor safety  
11 policies. Accreditation and certification of data  
12 maintained in BASIS is pending protection under the  
13 protection of the Critical Infrastructure Information Act,  
14 and then you can contact HHS for information.

15           I must stress that we are undergoing right now  
16 the accreditation and certification process. Once we get  
17 the PCII certification we will then have that data secure  
18 and that under the PCII Act it frees up for many  
19 litigation and it is protected. I know that this screen  
20 is little bit difficult. This is the blood center's input  
21 and there are quite a few fields here. The amount of  
22 collections, the inventory, the production, distribution

1 to the hospitals, wastage outing, updating returns,  
2 exports to other locations and imports.

3           What we have decided at the June meeting that  
4 Alan referred to just a few minutes ago is that we think  
5 that we can in working with the blood community, the AABB  
6 taskforce we think that we can narrow down the data fields  
7 -- some of these data fields and that it may not be  
8 pertinent on a daily basis to collect this information.  
9 Shortages -- shortage days, was delivery delayed, were  
10 inventories of blood products below minimum established  
11 levels, was an order not filled completely and was blood  
12 products purchased from an alternate supplier.

13           The hospital side, I apologize I pulled this  
14 together last night and also could not find the screen or  
15 the screenshot for the hospital, but the hospital side  
16 actually asks 25 questions, 25 data elements and then  
17 there are the questions that I read to you just a few  
18 minutes ago as far as the qualitative information. The  
19 data can be downloaded either manually through the web or  
20 it can also be downloaded by an Excel spreadsheet or CSV  
21 comma separated file. The reports of course we can get  
22 various specific reports out of here. Again, the hospital

1 can get their own individual report, at our level we can  
2 look at and aggregated national, regional, east west,  
3 public health regions, we can look at all of that and this  
4 is just tabular reports with some of the qualitative data,  
5 was delivery delayed, with surgery delayed and we can get  
6 that information.

7 We only track group O blood cells, O+, O- and  
8 also platelets both random and apheresis. Here is another  
9 national report, tabular report. One of the things that  
10 we do have on the home screen, and again I didn't have a  
11 screen shot of this, it is that we have incorporated what  
12 Alan was referring to also of shortages, shortage report.

13 We have the capability of a non-participant to  
14 report any type of shortage, whether it is a shortage of  
15 supplies, blood bags reagents, you name it they can add  
16 the information. They get an account and they have to  
17 provide their name in the account, but they don't have to  
18 identify the facility or the address and they then go to  
19 another screen to give exactly what the shortage is.

20 Where we are currently, blood centers, you can  
21 see the blood centers were quite far behind. Our goal was  
22 to have 85 blood centers. We only have 10 percent of that

1 goal. The 156 is the number that new need on a national  
2 basis to have weighted value so we can have some  
3 confidence, 95 percent confidence limit on -- with the  
4 status of the blood supply within the nation.

5 As you can see we have 101 facilities as of last  
6 Friday onboard, I'll get another report tomorrow, and so  
7 we're at about 65 percent of what we need for hospitals.  
8 Now, as I go out and talk to the various states and the  
9 states wanting their visibility and the regions want their  
10 visibility the number will definitely go up on the number  
11 of blood center that we have participating. So we almost  
12 will need every blood center -- information from every  
13 blood center and whether that is provided through ABC,  
14 BCA, Red Cross, you know, that's yet to be determined and  
15 we may be able to pull the information from their systems  
16 if we can work those relationships out.

17 But then also for the hospitals, especially at  
18 the state level, we're going to have to increase the  
19 numbers so that it is more significant for the state  
20 medical officers. So that's a quick overview of where we  
21 are currently with BASIS and you can see that we're almost  
22 there as far as the hospitals, but not completely. So --

1           THE CHAIR: Thank you. One question on the  
2 hospital side, sometimes it may be unknown to the folks in  
3 the transfusion service about the extent of surgical  
4 delays. The hospital transfusion services generally tend  
5 to know but it's not bullet proof. Is there any -- what  
6 are your thoughts, what are your instructions to the  
7 members in terms of gathering that information?

8           DR. HOLMBERG: Well, again, you know, as  
9 anything training is necessary with the system and one of  
10 things that -- of course we also know that the transfusion  
11 service may be the last person to know or the last part of  
12 the hospital who that surgery -- you know, the surgery is  
13 scheduled, although they should know the surgery is  
14 scheduled.

15           But if surgery is cancelled, I mean, think that  
16 most medical directors would know that information. We  
17 also, at least in my personal experience when I was at a  
18 hospital setting that also had a blood center, we had a  
19 quality assurance person that actually picked up  
20 information like this on a daily basis and tracked the  
21 surgeries that were cancelled because of blood and also  
22 the utilization of blood products. So I think that there

1 is several ways that this could be handled whether  
2 internally within the blood center or the -- I'm sorry the  
3 transfusion service or maybe by a quality assurance person  
4 within the hospital.

5 THE CHAIR: Yeah, because -- one of things I  
6 guess I was kind of trying to get at in an indirect way  
7 is, you know, the AABB and it's members have a very  
8 extensive quality program, and I don't actually know if  
9 this is one of the elements that they emphasize in their  
10 program that might help the --

11 DR. HOLMBERG: One of the things that we have  
12 really -- a very strong comment that we have gotten back  
13 from a lot of the hospitals, and this may be a shock to a  
14 lot of people and that is that we all think that hospitals  
15 are very highly automated. And, you know, it was a real  
16 shock to me in the early '90s when we started doing  
17 surveys that only 40 percent of the hospital blood banks  
18 were actually computerized. And so there is a lot of  
19 facilities that are still managing their inventory by the  
20 3X5 cards and this really has given some of the hospitals  
21 little bit more capability to be able to do some nice  
22 reporting, especially to their transfusion committee. And

1 so we've gotten some good feedback. But the amount of  
2 data, the 5X5 or the 25 data elements seem to be very  
3 minimal at the max 10 minutes to put in, but most of the  
4 time it's 5.

5 Now, the problem is that -- what we realize is  
6 that -- and one of the goals that we put behind BASIS was  
7 that it had to have a minimum amount of data elements so  
8 that we did not create reporting fatigue. And as Dr.  
9 Benjamin mentioned we also really stressed that hits  
10 reported at the same time on a daily basis.

11 THE CHAIR: Questions or comments from the  
12 committee for Dr. Holmberg? Dr. Epstein.

13 DR. EPSTEIN: Yeah, thank you Jerry. You  
14 mentioned the numbers of enrolled centers but are they the  
15 right ones? In other words, in order to be able to  
16 project from a statistical sample you need the appropriate  
17 distribution of centers in every region, and are you  
18 succeeding at that level as well, at least with the  
19 hospitals?

20 DR. HOLMBERG: Good question. We have actually  
21 gone out on two random selection process. The first one  
22 was a random selection of 300 facilities and these were

1 randomized through different -- all 10 public health  
2 regions. We have had some states like the state of  
3 Georgia. We have great participation in the state of  
4 Georgia.

5 But -- and so we really, as far as the weighted  
6 value we don't really need to recruit anymore. However,  
7 if the State Medical Officer of Georgia would like to have  
8 -- to be able to use this, obviously, we have to increase  
9 the universe within Georgia. But what we've done is we've  
10 done two 300 hospital samplings. At the present time  
11 we're working on our second sampling to go out there and  
12 get the facilities to participate.

13 But we all -- and the reason for that is -- and  
14 this is all weighted. So based on the size of the  
15 hospital and also the geographic location it is weighted.

16 THE CHAIR: Okay. If there are no more  
17 questions we will move to the public comment section. We  
18 have, I believe, one person to present a public comment  
19 and that is Lori Williams who is from MD Anderson, and she  
20 has a comment on the use of ESA, she was not able to make  
21 it yesterday. Ms. Williams.

22 MS. WILLIAMS: Good afternoon. Doctor --

1 THE CHAIR: Bracey.

2 MS. WILLIAMS: -- Bracey already introduced me.  
3 I work in -- I'm Faculty Member and Neuroscientist in the  
4 Department of Symptom Research at MD Anderson right now.  
5 And I'm actually here today on behalf of the Scientific  
6 Advisory Board of the patient advocate -- National Patient  
7 Advocate Foundations, and I'm here to address you about  
8 some concerns that we have about the recent CMS changes in  
9 coverage determination for Erythropoiesis-Stimulating  
10 Agents.

11 We are concerned that this may have a  
12 significant impact in blood usage and availability. We  
13 are concerned that this may result at least for cancer  
14 centers in shortage of packed red blood cells because of  
15 the increased demand.

16 CMS -- you've discussed this yesterday and I'm -  
17 - so I'm just going to give you a -- just a very brief  
18 overview. Because of some concerns in studies where the  
19 targeted hemoglobin was greater than 12 grams per  
20 deciliter of hemoglobin, and in these studies patients who  
21 were receiving these ESAs and getting these increased  
22 levels of hemoglobin they either had increased occurrence

1 of their cancer or increased mortality. And so because of  
2 this CMS restated what they would cover ESAs for Medicare  
3 beneficiaries, and the stated premise of their new policy  
4 essentially is that the patient's hemoglobin will be  
5 maintained above a level of 8 grams per deciliter and the  
6 administration of ESAs is allowed only up to 10 grams  
7 deciliter.

8           The FDA approval for ESAs right now allows ESAs  
9 to be given in the 10 to 12 range grams per deciliter of  
10 hemoglobin. So we are concerned -- very concerned about  
11 the safe and appropriate use of ESAs and we are concerned  
12 about the safety of these. But we also are concerned that  
13 maintaining hemoglobin at between 8 and 10 grams in these  
14 patients will result in an increased demand for blood cell  
15 transfusions and impossible shortages of these products.

16           I work in symptom research and I'm very aware of  
17 the importance of hemoglobin and how that affects symptoms  
18 in patients with cancer. Several years ago I had a  
19 colleague Dr. Shelley Wang who led a study of a cohort of  
20 over 200 patients with Leukemia and Lymphoma looking at  
21 the causes of fatigue in these patients. And she  
22 correlated directly fatigue with hemoglobin level. All of

1 the patients were asked to rate their fatigue on a scale  
2 of 0 to 10 with 0 meaning they didn't have any fatigue at  
3 all and 10 meaning they had fatigue that was as bad as  
4 could be imagined.

5 This is a very well established reliable and  
6 valid method of measuring symptom severity in patients  
7 with cancer and other chronic illnesses. And previous  
8 research by the symptom research group at MD Anderson has  
9 show that patients who reported fatigue level of 7 or  
10 greater according to this method are experiencing what we  
11 would call severe fatigue.

12 Our research has further show that fatigue at  
13 this level interferes with patient's ability to work,  
14 perform general activities, enjoy life, maintain their  
15 normal mood, relate to other people normally, walk, and  
16 even think.

17 Correlating fatigue to the hemoglobin levels in  
18 this cohort of patients we found that approximately 65  
19 percent of patients with the hemoglobin level of 8 will  
20 report severe fatigue. At a hemoglobin level of 9, there  
21 are still 55 percent of these patients reporting severe  
22 fatigue. At a hemoglobin of 10 it's a little over 50

1 percent who report severe fatigue. At 11 grams per  
2 deciliter 40 percent have severe fatigue, and finally at  
3 12 grams it drops to about 25 percent of patients who  
4 report severe fatigue. Hemoglobin of 15 grams per  
5 deciliter was the level at which no patient reported  
6 severe fatigue.

7           So this research, I think, really dramatically  
8 illustrated the increased symptom burden of cancer related  
9 fatigue that each gram of hemoglobin causes. And I think  
10 we should remember that this decrease in hemoglobin is not  
11 just in the fatigue it causes, it's not just a matter of  
12 quality of life for these patients, they are not able to  
13 work.

14           And while -- these are Medicare beneficiaries  
15 and they may not be working fulltime. Many of them are  
16 still working part time. And even more importantly many  
17 of them are providing resources within their family such  
18 as caring for children so that younger adults in their  
19 family can work or possibly caring for an even more  
20 disabled relative such a spouse. If these patients, if  
21 their hemoglobin drops and they are experiencing severe  
22 fatigue not only will they not be able to do these jobs,

1 but they are probably going to become dependent on family  
2 care givers. So, although the new regulations on the use  
3 of ESAs are really too recent for you to know for sure, I  
4 spoke with the blood bankers at MD Andersons and at this  
5 point they are thinking that they might see up to a 25  
6 percent increase in the demand for blood products which  
7 would mean it would be almost a 1000 units a month for MD  
8 Anderson.

9           Several of the solid tumor clinic departments at  
10 MD Anderson such as the melanoma, sarcoma, and the medical  
11 breast departments in the past have managed their patients  
12 during therapy completely without blood products, they  
13 have only used ESAs. And now with the new regulations  
14 they probably will not be able to do this anymore.

15           So we are -- they are extremely concerned that  
16 this will mean an increased usage in blood products and we  
17 also are concerned too that we're going to see an increase  
18 in other side effects of blood products that have not been  
19 -- we had not been seeing before, such as transfusion  
20 related lung injuries, iron overload and fluid overload in  
21 general. So we seem to be entering a new era in the  
22 management of cancer related anemia and fatigue and I

1 think it's vital that we determine what is appropriate for  
2 the use of both ESAs and blood products. What is the  
3 correct mix that we have that allows patients to function  
4 with the greatest level of safety. And so I would just  
5 urge this committee to be sure that you think about this  
6 and think about the impact of drops of hemoglobin on  
7 fatigue in patients and their functionality. So, thank  
8 you.

9 THE CHAIR: Thank you for your comments. We --  
10 as I mentioned before, yesterday we did spend a  
11 significant amount of time on the issue and we have  
12 recommended that the impact of these new directives be  
13 assessed.

14 MS. WILLIAMS: And I think we're very interested  
15 in actually seeing what does happen. Thank you.

16 THE CHAIR: Any additional questions or comments  
17 from the committee? Thank you. We'll take a 10 minute  
18 break and then we'll reconvene at 3:00. Thank you.

19 (Recess)

20 SPEAKER: -- but we don't really know the extent  
21 of that elasticity, and that there are some steps that can  
22 be taken on the part of HHS to help improve our ability to

1 understand exactly where we are. And those are sort of  
2 listed as sub-elements one, two, and three.

3           So, I would -- I'll read it off just to -- I  
4 know you are reading it. But it basically will say,  
5 "Whereas, the blood supply is a critical part of the  
6 nation's healthcare infrastructure emphasizing the  
7 importance of the blood inventory." The HHS ACBSA  
8 believes that detailed, and that can be changed in some  
9 way, ongoing analysis of national blood inventory is  
10 essential so that we understand what we actually have.

11           In the August 22nd and 23rd meeting the  
12 committee heard from blood centers -- variety of people  
13 and we can fix that. Blood centers, blood recruitment  
14 representatives, or at least one, government threat  
15 response representatives, better term can be used,  
16 regional -- well, that needs to get fixed and BASIS,  
17 government representative responsible for monitoring the  
18 blood supply. Committee finds that blood center data is  
19 extensive, which, I think reflects what the ABC and ARC  
20 presentations showed us -- where is that? It's extensive,  
21 but hospital data actually should be -- hospital data, I  
22 guess was -- it's limited. I guess we could make that

1 hospital data -- the data -- we can fix the plurality  
2 later. The blood supply is elastic, but the extent of the  
3 supply and demand variation so that -- in other words  
4 understanding both what the supply is and the demand on  
5 that supply needs better definition.

6           The committee recommends that as step A or one,  
7 HHS takes steps to expand hospital participation and  
8 inventory assessment so that a weighted sample can be  
9 obtained. We're two-thirds there, but actually it would  
10 be better to even have more. We can discuss that.

11           And two, HHS developed models to address and  
12 respond to the elasticity of the blood supply in a variety  
13 of surge -- getting at greater demand, donor depletion and  
14 other threat conditions to accurately cover blood needs or  
15 perhaps predicts blood needs.

16           And sub item three, HHS work with the blood  
17 community to define shortages that would require  
18 implementation of alternative blood collection  
19 contingencies, techniques, you name it. So we'll use that  
20 as a starting point.

21           SPEAKER: Excellent.

22           THE CHAIR: Is that a reasonable starting point?

1 SPEAKER: Yeah, very good.

2 THE CHAIR: Mr. Matyas.

3 MR. MATYAS: So, kind of, going back to what  
4 Jerry was talking about with BASIS, and he is waiting to  
5 see this to -- is a weighted sample sufficient?

6 THE CHAIR: That's a key point, because, you  
7 know, when I was -- I did brackets at first and my idea  
8 was to move towards the majority, if not the ideal 100 --  
9 you know, so that's something we need to discuss.

10 MR. MATYAS: And -- I'm sorry.

11 SPEAKER: No, go ahead.

12 MR. MATYAS: Therefore --

13 THE CHAIR: -- okay.

14 MR. MATYAS: -- I mean, first of all, take steps  
15 to expand is, no disrespect, very wishy-washy.

16 THE CHAIR: Okay.

17 MR. MATYAS: It doesn't do anything for us. And  
18 I think you've -- we've already had. You know, voluntary  
19 isn't getting you enough of what you need as opposed to  
20 even require we could have, you know, HHS -- the committee  
21 recommends that HHS establish incentives for participation  
22 and the reason that I'm even thinking that is from a CMS

1 payment methodology with moving more and more to pay for  
2 performance, one of the indicators for pay for performance  
3 could be performance in -- this is one of factors, because  
4 again the comment that I heard from yesterday was, yeah,  
5 but there is no money to pay for it.

6 Well, again it could just be a factor that if  
7 you do participate, it can otherwise be a factor to  
8 increase, if you don't, it otherwise could decrease.  
9 Again, it's just within the realm of what CMS is otherwise  
10 working on to get hospital participation in performance  
11 indicators.

12 THE CHAIR: You know, to be honest with you I  
13 had spent a lot of time thinking about what you just  
14 talked about in terms of CMS performance standards and  
15 that was my, you know, bias initially and I guess I was a  
16 little sensitive to getting too prescriptive, you know, in  
17 terms of HHS would make that -- make it happen, so that's  
18 why I got wishy-washy. But -- we need to talk about that.  
19 Ms. Finley.

20 MS. FINLEY: Thank you. I really think that  
21 this may not be the appropriate time to raise the issue,  
22 but that -- or you may not want to do this in this

1 recommendation. But in order to get the information that  
2 we will need for some of the scenarios that we've  
3 discussed they have to get down to the unit level in all  
4 the hospitals.

5           And I think we may want to recommend that that  
6 be a serious consideration whether you want to do it by  
7 incentives is one thing, but you don't -- in setting up  
8 these threat assessments you can't drag this out five or  
9 ten years, you know, for people to get onboard. It's just  
10 something to think about.

11           The second, I have a suggestion on number three  
12 as well just HHS worked with blood community to define  
13 shortages in a variety of scenarios that would require  
14 blah, blah, blah. And I think that gets to the point that  
15 -- or my personal concern is that the presentations that  
16 we heard are very much reactive to the expectations and  
17 the experiences that these groups have had which is fine  
18 as far as it goes. But there are other scenarios out  
19 there that will seriously challenge their past experience,  
20 and I think it would behoove us as a country to, you know,  
21 get on top of that before it becomes an issue.

22           THE CHAIR: So that's a good insert and we've

1 got it in. In terms of that first recommendation, the  
2 issue of how do we move in that direction, do we -- so  
3 what's the rest of the committee's thought about  
4 toughening up the statement? Tying to pay, you know,  
5 performance incentives. So the --

6 DR. ROSEFF: Can I say something?

7 THE CHAIR: Yeah, okay, but Dr. Roseff has a  
8 comment.

9 DR. ROSEFF: I don't know about this pay for  
10 performance. I think there have to be (inaudible), yeah,  
11 but this is such a complex issue. When you get down to  
12 the level of individual blood banks having to supply data  
13 of unknown quantity and unknown -- you know, we don't know  
14 how it has to be presented, we don't know the format, and  
15 then to start penalizing people, different hospitals that  
16 have different capabilities and different staffing levels,  
17 I get worried about that, especially if you look at pay  
18 for performance in a larger scope and what pathology and  
19 clinical pathology is going to gain or not gain by pay for  
20 performance and also, you know, people who already do it  
21 may have an advantage versus those who don't, but I would  
22 -- they probably do need to be (inaudible), but I don't

1     like the idea of reimbursement being tied to that  
2     necessarily, so I would not advocate that.

3             THE CHAIR: Ms. Finley.

4             MS. FINLEY: Thank you. I think that's a valid  
5     point. If I can make a suggestion here, it's already 3:30  
6     we may lose our quorum in a little while. I think our job  
7     as a advisory committee is to set the expectation or make  
8     the recommendation. And I think we should seriously  
9     consider making the recommendation that we need the  
10    information down to the hospital blood bank level.

11            It's really the secretary's responsibility to  
12    find a way to do it. You know, you ask who is going to  
13    pay for it, that's a very logistic, you know, very serious  
14    logistical matter. But it's not our problem. So, you  
15    know, I think our job is to give the 30,000 foot level and  
16    let the secretary workout the details.

17            THE CHAIR: So, if we just take -- eliminate --  
18    take steps two and just make it expand hospital  
19    participation.

20            MS. FINLEY: I think -- I personally would like  
21    to see it reflect what I think we need, which is expand  
22    hospital participation and inventory assessment, not

1 expand it, but down to the level where we are able to get  
2 an accurate inventory at all times of how much blood we  
3 have in the system.

4 THE CHAIR: Okay. So, expand hospital  
5 participation, and -- well, one thing that we actually  
6 missed, and that is what the data -- I believe one of the  
7 slides showed was that it should be hospitals and blood  
8 centers, because it's -- right now it's hospitals, but  
9 really there are only 10 percent, so hospitals and blood  
10 centers.

11 MS. FINLEY: I'm not suggesting that we expand  
12 their participation. I'm saying that we get a system that  
13 gives us that information completely.

14 THE CHAIR: Okay.

15 SPEAKER: So you mean -- so instead of expanding  
16 you mean like ensure.

17 MS. FINLEY: Or develop a system, you know, and  
18 there are I'm sure many ways to do it, none of which we're  
19 going to solve today, but --

20 THE CHAIR: Although there is a system which is  
21 BASIS.

22 SPEAKER: Right.

1           MS. FINLEY: But it's, you know, it doesn't give  
2 us the information that we need representative -- and --  
3 you know, and it's a representative sample. If ultimately  
4 what you want to do in a threat -- to respond to a threat  
5 scenario is to be able to identify the amount of blood at any  
6 given time in the country, then you have to get all of the  
7 information from all of the data points, not a  
8 representative sample.

9           THE CHAIR: So --

10          MR. MATYAS: So that's -- so then that would  
11 advocate for just ending after the word assessment in the  
12 first line.

13          THE CHAIR: Right. That we --

14          MS. FINLAY: Yeah.

15          MR. MATYAS: Hospital, blood center  
16 participation, and inventory assessment.

17          MS. FINLAY: I don't know whether you -- I mean,  
18 I can go either way, if you want to go all the way and  
19 say, so that we get a system that gives us a national  
20 inventory for a national resource at any given time and  
21 let it go with that.

22          THE CHAIR: So expand hospital and blood center

1 participation and inventory assessment to allow accurate  
2 determination of inventory.

3 MS. FINLAY: Yes, of national inventory.

4 THE CHAIR: Of national inventory to allow  
5 accurate determination of national inventory.

6 MS. FINLAY: Yeah, that's right.

7 THE CHAIR: Accurate determination of national  
8 inventory.

9 SPEAKER: Mention the BASIS.

10 SPEAKER: Of the whole universe?

11 MS. FINLAY: Of the United States. We're only  
12 interested in our country. We only have jurisdiction in  
13 this country.

14 THE CHAIR: Expand participation and we -- so  
15 since we have a system which is BASIS it would be  
16 participation in BASIS.

17 MS. FINLAY: I -- well, no, I would leave it up  
18 to the secretary to decide how he would like to handle  
19 this. I trust him to address it.

20 THE CHAIR: Everyone else okay with that? All  
21 right, so HHS expands hospital and blood center  
22 participation and inventory assessment to allow accurate

1 determination of national -- should we say blood  
2 inventory?

3 MS. FINLAY: Yeah.

4 THE CHAIR: National blood inventory. Okay.

5 SPEAKER: Or platelets, sir.

6 THE CHAIR: Would that just be product versus  
7 products? Okay.

8 SPEAKER: You have to change that on line two as  
9 well, all the way up.

10 THE CHAIR: Dr. Duffell.

11 DR. DUFFELL: You got that comment there. Mine  
12 actually are -- I've got two comments, one is in the  
13 opening paragraph. We imply there, to me, something that  
14 sounded like it wasn't true from what we heard, kind of  
15 testimony about, and that is blood centers have extensive  
16 data, but it's not openly shared, and the way the  
17 statement reads, it's -- I think it gives the reader the  
18 perception that information is available. It is extensive  
19 I'm sure, but due to competitive reasons these centers are  
20 not necessarily coming forth with that data in a very open  
21 way. So I'm wondering if clarification of that is needed  
22 just to highlight some of the difficulties that are

1 involved. So that's my first comment.

2 And my second comment deals with point two, and  
3 the thought there is we need to possibly weave into this  
4 the fact that it's not only to cover the blood needs, but  
5 we need to cover the supplies, the equipments, the right  
6 reagents, the disposables that are also necessary to meet  
7 those needs. So it's two different comments, two  
8 different.

9 THE CHAIR: Okay. So elasticity of blood supply  
10 and --

11 DR. DUFFELL: I would identify it -- just my way  
12 of thinking is equipment, reagents and disposables.

13 THE CHAIR: So blood supply, equipment,  
14 reagents, and disposables.

15 DR. DUFFELL: And disposables, yeah.

16 SPEAKER: "Critical materials," is the phrase  
17 that's been used in that context. I -- critical -- the  
18 phrase, "critical materials."

19 DR. DUFFELL: And that would capture --

20 MS. FINLAY: Yeah, that would capture.

21 THE CHAIR: Yeah.

22 DR. DUFFELL: Okay. So, I don't know if anyone

1 else feel the way I did, I guess, about that first in the  
2 first (inaudible)

3 THE CHAIR: Oh, yeah, well, let's have some  
4 discussion on that. I --

5 SPEAKER: Yeah, I actually, don't know if the  
6 second and third sentences are needed.

7 THE CHAIR: Are needed? Well -- yeah, the  
8 second one is basically saying that well, you know, --

9 DR. DUFFELL: I mean, the record itself --

10 SPEAKER: Yeah, reflects that --

11 DR. DUFFELL: -- reflects what we heard and the  
12 agenda reflects that. I think you can go right into the  
13 blood supply is elastic and the Committee recommends.

14 But -- but is it worth pointing out to the secretary  
15 that the available data from the blood centers is limited,  
16 that is my point, isn't that a material piece to this  
17 whole thing is that we don't really have access to that  
18 information. It is there, but it's not openly shared.

19 SPEAKER: Well, could you --

20 DR. DUFFELL: It complicates dealing with this  
21 whole subject matter is the point. So I guess it's kind  
22 of one of the premises to your logic of where we need to

1 go on your conclusion and what we need to do. It's a  
2 factor that has to be considered, so -- I mean, that's  
3 what -- I would agree with the first sentence. Yeah, if  
4 the record shows, where itself the second sentence I'm  
5 thinking, well, it's information for you to keep in the  
6 back of your mind as you pursue these recommendations.

7 THE CHAIR: So how about the Committee finds  
8 that the blood center data is a extensive, but not widely  
9 shared?

10 DR. DUFFELL: Yeah, that would do --

11 THE CHAIR: And hospital data is limited or  
12 extremely nonexistent.

13 THE CHAIR: No, no --

14 (Laughter)

15 THE CHAIR: -- limited, it's limited, it's  
16 limited.

17 DR. DUFFELL: It's limited, yeah.

18 THE CHAIR: There actually, is more hospital  
19 data and basis than there is -- then you just pointed that  
20 out, than there is blood center data. I'm just thinking  
21 of the in, because there are 3,000 hospitals.

22 SPEAKER: Only at the present moment it is not

1 representative.

2 THE CHAIR: Correct.

3 SPEAKER: Can you reread -- Dr. Bracey, what you  
4 were reading off of?

5 THE CHAIR: Okay. Oh, yeah, I'm sorry. The  
6 Committee finds that blood center data is extensive, but  
7 not widely available?

8 (Discussion off the record)

9 MS. FINLEY: I think that should be  
10 "accessible."

11 THE CHAIR: Accessible. And then hospital data  
12 is -- and then hospital data is limited.

13 DR. DUFFELL: How about instead, "but not openly  
14 accessible," because it's -- I mean, that's just the issue  
15 of transparency that I think we're after.

16 THE CHAIR: Okay. and then hospital data is  
17 limited.

18 SPEAKER: That is limited, yeah. It's  
19 nonexistent.

20 SPEAKER: Are limited.

21 THE CHAIR: Are limited, yeah, sorry. Now, do  
22 we want to put those sentences up before this "supply is

1 elastic" or does it -- is that the right place?

2 SPEAKER: I think they should. Yeah, they  
3 should go up --

4 SPEAKER: Yeah, your right that -- you should  
5 put it back. Yeah.

6 SPEAKER: You all say, is it fair to say blood  
7 center data to say that it's extensive, I mean, it seems  
8 patchy, right, it was presented yesterday from American  
9 Blood Centers, and not all the centers contribute to that,  
10 you know, warning light they have.

11 THE CHAIR: Yeah, they're different  
12 methodologies that --

13 SPEAKER: The data is there, it's just that the  
14 institution.

15 THE CHAIR: Ms. Ashton?

16 MS. ASHTON: Oh, I -- could you say that it's  
17 not widely disseminated so that it's -- it is accessible  
18 to plenty of people, but it's not disseminated publicly?

19 SPEAKER: Or you could just say that, "not  
20 publicly available?"

21 MS. ASHTON: Right.

22 SPEAKER: Or you could say the data is not

1 complete and that maybe the best way to --

2 SPEAKER: Yeah, unless pejorative.

3 THE CHAIR: So blood center data is extensive?

4 SPEAKER: No.

5 SPEAKER: No, not -- blood center data is not  
6 complete.

7 THE CHAIR: It's not complete?

8 SPEAKER: I would argue that it is complete for  
9 them. They've got all the data that you can --

10 THE CHAIR: If you put it altogether from the  
11 different systems?

12 SPEAKER: Right -- no, but --

13 SPEAKER: And it's --

14 SPEAKER: Yes, sir, that it's not, they don't  
15 have at least --

16 SPEAKER: Each institution has every bit of data  
17 that they need and that we need, but it's at the  
18 institution level.

19 SPEAKER: But -- so it's not standardized?

20 SPEAKER: And not coordinated.

21 THE CHAIR: No, standardized is -- it's not  
22 standardized yet. Its not standardized, yeah, yeah.

1 That's I guess the --

2 SPEAKER: So he blood center data is not  
3 standardized?

4 THE CHAIR: It's extensive, but not  
5 standardized.

6 SPEAKER: Right.

7 SPEAKER: It's extensive, but not standardized.

8 SPEAKER: Or inconsistently maintained. It's  
9 not maintained in the same way. I mean, it's all reported  
10 differently.

11 SPEAKER: It's not centrally maintained.

12 SPEAKER: Or centrally maintained, yeah. And  
13 then to your point, it's not publicly available, but  
14 that's the key point to me.

15 THE CHAIR: No, not centrally maintained, that  
16 are publicly available.

17 SPEAKER: That's right, we can't get to it.

18 SPEAKER: -- that term was "openly accessible."

19 THE CHAIR: Okay, so there is -- so do we prefer  
20 openly accessible or -- oh, no, that was good, but --  
21 centrally maintained, but not centrally maintained --

22 SPEAKER: And accessible?

1 SPEAKER: And publicly available.

2 SPEAKER: Yeah, I think the "publicly available"  
3 is a good way to say it.

4 THE CHAIR: Okay, we had a vote over here for  
5 "accessible," but "publicly available" is good. This is  
6 about the public health we're talking about. Okay, so the  
7 Committee finds the blood center data as extensive, but  
8 not centrally maintained, -- with that centrally  
9 maintained or -- or an --

10 SPEAKER: Or.

11 SPEAKER: Or.

12 SPEAKER: Nor.

13 SPEAKER: Nor.

14 SPEAKER: And but what about -- we don't  
15 necessarily -- it doesn't have to be publicly -- I don't  
16 need to know what that blood center down there has someone  
17 centrally. I think that would people think that we're  
18 saying, everyone needs to know what every inventory is.  
19 The inventory needs to be available to people who are  
20 making decisions about --

21 THE CHAIR: Yeah, so "publicly" might be  
22 overstating the need.

1           SPEAKER: I think so. I think it would scare  
2 some people in that kind of situations.

3           SPEAKER: Nor "readily available" maybe.

4           SPEAKER: Well --

5           THE CHAIR: Readily.

6           SPEAKER: Government (inaudible)

7           DR. BIANCO: Yeah, it scared me doctor --

8           THE CHAIR: Oh, Dr. Bianco has a comment from --

9           DR. BIANCO: No, it's the ABC data in terms of  
10 this stoplight is publicly available, is on the website of  
11 Americas Blood Centers. I would say that the basis data  
12 is not publicly available.

13           THE CHAIR: Okay, so the Committee finds the  
14 blood center data is extensive, but ARC data is not on the  
15 web.

16           SPEAKER: Right.

17           THE CHAIR: But is it publicly available? Wait,  
18 ARC -- is Dr. Benjamin here?

19           SPEAKER: No.

20           SPEAKER: ARC is sharing data with us at the  
21 national aggregate level using the stoplight system.

22           DR. EPSTEIN: I think --

1 THE CHAIR: Dr. Epstein?

2 DR. EPSTEIN: I think what's missing is the data  
3 are not comprehensively aggregated.

4 THE CHAIR: Right.

5 DR. EPSTEIN: They're not comprehensively  
6 aggregated, they're not centrally maintained.

7 THE CHAIR: So that would it be centrally  
8 maintained nor comprehensibly -- comprehensively  
9 aggregated.

10 DR. EPSTEIN: Right.

11 THE CHAIR: Okay.

12 DR. EPSTEIN: I think because they -- if they  
13 were comprehensively aggregated, we would care less about  
14 who maintains it.

15 THE CHAIR: Yeah, right. Yeah, right.

16 DR. EPSTEIN: So I think the problem here is,  
17 we're trying to create the linkage between inventory  
18 monitoring and preparedness, and what we're saying is when  
19 there is a crisis we don't really know the inventories, so  
20 we don't know how prepared we are.

21 SPEAKER: Yeah.

22 DR. EPSTEIN: And so the real problem here is

1 that the data are not comprehensively aggregated nor are  
2 they centrally maintained or readily accessible.

3 SPEAKER: Right.

4 THE CHAIR: So but not -- so this would be as  
5 extensive, but not comprehensively aggregated nor  
6 centrally maintained?

7 DR. EPSTEIN: Well, nor -- now, is the key point  
8 that they're not available to HHS?

9 THE CHAIR: Nor available -- yeah, yeah. Yeah,  
10 right. Right, because we don't want it to -- it's not  
11 necessary that the public know.

12 DR. EPSTEIN: That's right.

13 THE CHAIR: Okay.

14 SPEAKER: Or available to --

15 THE CHAIR: Now, Dr. Epstein for the --

16 DR. EPSTEIN: Well, I have -- I'm not sure I  
17 quite understand the function of this second sentence, "To  
18 state that the blood supply is elastic," well, that's a  
19 finding of this Committee, but we aren't commenting about  
20 how elastic which is really what we're being asked to  
21 advise about and the ultimate question is whether it's  
22 efficiently elastic. So, is the point of this sentence

1     that the degree of elasticity is in relation to potential  
2     need is not well understood.

3             THE CHAIR:   Right, that's the point.

4             DR. EPSTEIN:   Because simply if one would better  
5     monitor current supply and demand variation, we might be  
6     no better off understanding how elastic it might be in a  
7     disaster scenario.

8             SPEAKER:   I think this is where you might be  
9     able to split the two concepts up because I think we heard  
10    a lot about seasonal shortages and it seems like, it's  
11    elastic enough to handle that but for crisis that's where  
12    we don't know whether it's efficiently elastic.   So I  
13    don't know if we can -- the Committee agrees with that and  
14    can make that distinction, that for -- what the wording  
15    would be, routine shortages the blood supply maybe  
16    sufficiently elastic, but has -- but is -- has -- but has  
17    -- but it's unclear whether sufficiently elastic for a --

18            SPEAKER:   I thought yesterday we said we didn't  
19    know if it was elastic.   I thought we made that -- we drew  
20    that conclusion that we didn't have the data to decide  
21    that?

22            SPEAKER:   Well, for a disaster.

1 THE CHAIR: Well, for a disaster.

2 SPEAKER: What -- right --

3 SPEAKER: So I'm (inaudible) drawing a  
4 distinction between day to day shortages and a disaster  
5 that's -- but I don't know if --

6 THE CHAIR: Well, what -- you know, we -- let's  
7 -- Dr. Epstein's wording would be a starting point because  
8 I think it kind of got at the critical issue being is it  
9 adequate to meet --

10 DR. EPSTEIN: Whether it's efficiently elastic  
11 to address disaster situations.

12 SPEAKER: Yeah.

13 THE CHAIR: And that would cover -- I mean, that  
14 would sort of be a cover up so --

15 SPEAKER: That's right. Yeah.

16 DR. EPSTEIN: So although the blood supply is  
17 elastic and I think we might want to play a little bit  
18 with just a bold statement that it's elastic because it  
19 begs the question of how elastic? But leaving that for  
20 the moment, although other blood supplies are elastic, it  
21 is unclear whether it is sufficiently elastic to meet  
22 needs in times of disaster or to address potential

1 disasters --

2 SPEAKER: I lost you.

3 DR. EPSTEIN: -- to address potential disasters.

4 And then I would strike the rest.

5 THE CHAIR: Yeah, that's fine. I mean, that  
6 really hits the point.

7 The piece about hospital data seems to be  
8 hanging out there. Sort of understated, but I mean its --  
9 any thoughts about whether --?

10 SPEAKER: I thought you were going to put the  
11 second sentence the end of the paragraph because didn't --  
12 the -- I thought the, what is currently the last two  
13 sentences --

14 THE CHAIR: You're right, you're right, we were  
15 thinking about putting the second sentence as the end  
16 statement because that's really sort of the 'take home  
17 message.'

18 SPEAKER: And I think in the first sentence when  
19 we say, "analysis national blood and blood product  
20 inventories essential," essential to what? It's essential  
21 to preparedness planning or essential to preparedness?

22 THE CHAIR: Yeah, right, it's essential for --

1 what is the process of preparedness planning called? It  
2 is essential for --

3 SPEAKER: To --

4 SPEAKER: Contingency --

5 SPEAKER: Contingency planning?

6 THE CHAIR: Contingency planning.

7 SPEAKER: Yeah.

8 SPEAKER: Preparedness.

9 THE CHAIR: Or would preparedness because that -  
10 -

11 SPEAKER: Preparedness.

12 SPEAKER: Well, that terminology -- isn't the  
13 terminology "medical countermeasures" or --

14 SPEAKER: Medical -- yeah, yeah.

15 THE CHAIR: Oh, yeah.

16 SPEAKER: Essential for medical --

17 THE CHAIR: For -- essential for --

18 SPEAKER: Medical preparedness?

19 THE CHAIR: -- for --

20 SPEAKER: No?

21 THE CHAIR: -- for projecting medical -- there  
22 is something missing. Is essential for assessing medical

1 --

2 SPEAKER: Or for meeting the needs of medical  
3 countermeasures?

4 SPEAKER: This is getting at the point of what -  
5 - of what is the reason for this I think.

6 (Laughter)

7 SPEAKER: Its emergency preparedness and  
8 response.

9 SPEAKER: Yeah.

10 SPEAKER: I think that's the term, that's  
11 knowledge --

12 THE CHAIR: Yeah, that's emergency preparedness  
13 response?

14 SPEAKER: Emergency, preparedness and response.

15 SPEAKER: Yeah, that's good.

16 THE CHAIR: Yeah, that's good, that's good.

17 SPEAKER: Yeah, and also detailed ongoing  
18 analysis, that troubles me, isn't simply the concept that  
19 we need to know the inventory, that knowledge of the blood  
20 inventory --

21 THE CHAIR: Oh, well, one of the --

22 SPEAKER: -- and its dynamics?

1           THE CHAIR: One of -- its dynamics is the peace,  
2   in order words, the whole -- the point is that one needs  
3   an ongoing -- you don't need a static picture, you need a  
4   running picture.

5           SPEAKER: Right.

6           SPEAKER: So you see, what I think -- right, the  
7   knowledge of the national blood and blood product  
8   inventory and its dynamics is essential.

9           SPEAKER: Real time knowledge.

10          SPEAKER: Speak up here.

11          SPEAKER: You want in front of knowledge -- he  
12   had real time knowledge?

13          SPEAKER: Yes, I think --

14          THE CHAIR: Yeah, that's a good point.

15          SPEAKER: I think -- oh, I see --

16          THE CHAIR: Real time.

17          SPEAKER: Real time, sure.

18          SPEAKER: Real time knowledge.

19          SPEAKER: After dynamics it's "R."

20          SPEAKER: Do you mean real -- oh, is the  
21   knowledge real time or is it the --

22          THE CHAIR: Well, I mean, if you had a system --

1 well, really that's what you would desire, real time  
2 knowledge.

3 SPEAKER: Yeah.

4 THE CHAIR: Yeah.

5 SPEAKER: Right, I think real time knowledge or  
6 knowledge of real time national blood and blood product  
7 inventory is that we need the real time inventory and  
8 dynamics.

9 SPEAKER: Yeah, that's what I was --

10 SPEAKER: Yeah.

11 SPEAKER: Okay. Yeah, okay.

12 SPEAKER: What was said about hospital?

13 SPEAKER: Hospital data -- essential -- are  
14 essential and limited or essential and --

15 THE CHAIR: So here on the hospital data are --  
16 that would be essential and limited -- but limited or -- ?

17 SPEAKER: But limited.

18 THE CHAIR: But limited would probably be  
19 better.

20 SPEAKER: Yeah.

21 SPEAKER: Well, is it the data that are limited  
22 or the reporting of the data?

1 THE CHAIR: Hospital data reporting, yeah.

2 SPEAKER: Right.

3 THE CHAIR: Yeah, because the data are there.

4 SPEAKER: Data we think are there. Every  
5 transfusion service knows its inventory everyday.

6 THE CHAIR: Yeah, right. They just don't --

7 SPEAKER: It's just -- we don't have reports.

8 THE CHAIR: Right.

9 SPEAKER: They haven't told us.

10 (Laughter)

11 THE CHAIR: Okay, so --

12 (Discussion off the record)

13 SPEAKER: I think we also need to get at not  
14 just the inventory that's in the hospitals and blood  
15 centers, but the inventory that's walking around. What is  
16 the real donor pool?

17 THE CHAIR: That's an interesting -- yeah. That  
18 would be another sub, yeah.

19 So the available donor pool, knowledge of the  
20 available -- would it be accessible donor pool, no,  
21 available.

22 LAURA: Maybe it's more of what John Armitage

1 was talking about this morning, about there being some  
2 centralized best practices response to donor availability,  
3 I'm thinking of shortages as he talked about as more of --  
4 you know, if you could apply best practices or some areas  
5 that have been able to manage, in having more constant  
6 inventory and using more professional marketing and we've  
7 talked about the past about how we communicate with the  
8 public about disasters and maybe this can be tied in,  
9 messages to donors.

10 You know, and again national strategies to  
11 improve our readiness as, you know, regarding the donor  
12 base.

13 THE CHAIR: So improved donor management  
14 strategies. I'm trying to think improved donor management  
15 and strategies --

16 SPEAKER: Maybe to collect the best practices  
17 and disseminate them or something.

18 THE CHAIR: How about implementation of best  
19 practices for donor management in emergent and/or shortage  
20 or emergent and/or blood shortage situations? That's kind  
21 of starting --

22 DR. HOLMBERG: But I think that one of the

1 questions that Laura (phonetic) was making was -- her  
2 comment was that we don't --

3 SPEAKER: Can you use the mic Jerry?

4 DR. HOLMBERG: -- pool is --

5 SPEAKER: Use the mic?

6 DR. HOLMBERG: I think Laura's comment was that  
7 we don't know what the donor pool is.

8 SPEAKER: I think one of the points that was  
9 brought up was that we don't know the -- we need to really  
10 find out the demographics of the available donor pool,  
11 target the messages towards that demographic --

12 THE CHAIR: Right, yeah, yeah, good point, so --

13 DR. HOLMBERG: I think, what we are asking --  
14 the question is, what we are asking HHS to do -- I think  
15 what we are asking HHS to do is to support the operations  
16 research that could best characterize the potential donor  
17 base and establish strategies to draw those donors in.

18 THE CHAIR: Yeah, that's -- that is what HHS  
19 would do, because right, the implementation of best  
20 practices would be with the industry rather than --

21 DR. HOLMBERG: Right.

22 THE CHAIR: -- than HHS.

1 DR. HOLMBERG: And I'm just also harking back to  
2 what Dr. Williams said that there is a need for behavioral  
3 research to understand the barriers to donation.

4 SPEAKER: Right.

5 DR. HOLMBERG: So it's the two things together,  
6 it's what Laura is saying, what's the demographic of the  
7 candidate donor who is not now donating and what are the  
8 strategies to encourage donation by that demographic?

9 THE CHAIR: So this would be support operations  
10 research to characterize and attract --

11 DR. HOLMBERG: Right.

12 SPEAKER: I think it's, characterize existing  
13 donors and attract new, isn't it?

14 DR. HOLMBERG: No, I think what we are talking  
15 about is the gap.

16 THE CHAIR: Yeah, we want to find out who's out  
17 there.

18 DR. HOLMBERG: We want to compare the  
19 demographic of potentially eligible donors to the current  
20 demographic of who's donating.

21 SPEAKER: Okay.

22 DR. HOLMBERG: And then try to close that gap

1 with the right behavioral tools.

2 THE CHAIR: To characterize and attract  
3 potential donors?

4 DR. HOLMBERG: Potential donors who do not now  
5 routinely donate.

6 THE CHAIR: Yeah.

7 SPEAKER: Are you trying to attract them or  
8 recruit them?

9 SPEAKER: Recruit.

10 (Laughter)

11 THE CHAIR: Yeah, good. We want to Shanghai  
12 them, no I'm just --

13 (Laughter)

14 SPEAKER: So now that we will start with HHS  
15 (inaudible)

16 THE CHAIR: Yeah, we will start with HHS.

17 SPEAKER: Do we need to state here why we made  
18 this statement? I mean, is it intuitive, I guess, maybe  
19 from the above -- because you had in there before that it  
20 was -- for it to be able to respond to an emergency  
21 requirement.

22 THE CHAIR: Well, I think it supports -- what

1 you have the -- the paragraph above.

2 SPEAKER: Okay.

3 THE CHAIR: Okay, a read through?

4 SPEAKER: No, I -- if we can go through  
5 paragraph 2 and 3, recommendations 2 and 3?

6 THE CHAIR: Okay.

7 SPEAKER: HHS worked with the blood --

8 (Tape interruption)

9 SPEAKER: So now we will start with HHS --

10 THE CHAIR: Yeah, we will start with HHS.

11 SPEAKER: Do we need to state here why we made  
12 this statement? I mean, is it intuitive, I guess, maybe  
13 from the above -- because you had in there before that it  
14 was -- for it to be able to respond to an emergency  
15 requirement.

16 THE CHAIR: Well, I think it supports -- what  
17 you have the -- the paragraph above.

18 SPEAKER: Okay.

19 THE CHAIR: Okay, a read through?

20 SPEAKER: No, I -- if we can go through  
21 paragraphs 2 and 3, recommendations 2 and 3?

22 THE CHAIR: Okay.

1           SPEAKER: HHS worked with the blood community to  
2 define shortages, but above we're saying HHS developed  
3 models. Aren't those kind of intertwined? Then you first  
4 have to have these definitions in order to develop the  
5 models? And then --

6           THE CHAIR: I would think that it would be step  
7 wise, but I would keep them separated. Yeah, I mean, I  
8 see them as --

9           SPEAKER: But isn't it part of the blood  
10 community to help develop the models too?

11          THE CHAIR: Oh, yeah, that's a good point.

12          SPEAKER: Yeah, I think what I was -- the way I  
13 read three was that we need to work with the blood  
14 community to define HHS's expectations of them as, you  
15 know, partners and emergency response. And more  
16 importantly, I also think HHS needs to get from them a  
17 very clear understanding of what their capabilities are in  
18 a wide variety of scenarios including ones they may not  
19 have considered.

20                 So, I think, I viewed three as getting HHS to  
21 recognize that unlike other countries where the blood  
22 collection organizations are part of the government, we

1 need to incorporate them perhaps more fully, or to define  
2 our expectations more clearly, regarding emergency  
3 preparedness.

4 SPEAKER: So you're saying the HHS needs to  
5 define threats --

6 SPEAKER: I'm not confident based on the  
7 presentations that I've heard that the blood collection  
8 organizations have a full understanding of the kinds of  
9 scenarios that we are looking at in threat assessment.  
10 And, I think, you know, before something happens we need  
11 to express that to them.

12 SPEAKER: We need -- yeah, we need another  
13 threat, then you need to know what your baseline is, what  
14 you have.

15 SPEAKER: Yeah, they're responding with their  
16 vast experience, but the kinds of scenarios we're looking  
17 at that could really cripple them, they've never seen.

18 SPEAKER: Yeah. Then it does make sense. Then  
19 you figure out what your vulnerabilities are and how do  
20 you close the gaps.

21 SPEAKER: Right.

22 THE CHAIR: Okay, so this would then be that HHS

1 worked with the blood community to define shortages in a  
2 variety of scenarios that would require implementations of  
3 -- I mean, this kind of --

4 SPEAKER: I mean, you know --

5 THE CHAIR: I know you want to get away. Well,  
6 what the -- the point of this was really in response to,  
7 if FDA were asked to respond -- you know, change, to give  
8 a variance when and how and where. You know, what  
9 constitutes --

10 SPEAKER: No, that isn't how I viewed it at all.  
11 What I viewed, when they came here and told us that based  
12 on our past experience all we need is -- what, 3,000?

13 THE CHAIR: Two hundred to three hundred  
14 additional units. But they're assuming that the kinds of  
15 scenarios that they're going to see are the kind they've  
16 seen in the past. That's not the case. And --

17 THE CHAIR: Well, yeah, so -- yeah, I see what  
18 you're saying. Yeah, I was thinking about, number two is  
19 really getting at that, but through the models. Yeah,  
20 really what I was thinking -- so, yeah, two and three are  
21 intertwined.

22 SPEAKER: Okay, they may -- HHS may be

1 developing models, but based on what I heard yesterday, I  
2 don't know that those models have been shared with the  
3 critical partners in the blood collections organizations.

4 SPEAKER: And going back -- I'm sorry.

5 THE CHAIR: Okay, yeah, (inaudible).

6 SPEAKER: Going back to what Jerry was talking  
7 about, weren't some of those organizations part of some of  
8 the sub-working groups that are part of BARDA?

9 SPEAKER: No, they're not part of the BARDA  
10 committee and they're not --

11 SPEAKER: Okay.

12 SPEAKER: The working groups in BARDA are all  
13 government. It is strictly government.

14 SPEAKER: With security clearances.

15 THE CHAIR: So in number two, would the models --  
16 within the models there would be definition of what a  
17 shortage is.

18 SPEAKER: I would hope so.

19 THE CHAIR: I was just concerned about the fact  
20 that in the current day, we saw nice definitions in Dr.  
21 William's presentations, but I really saw no other  
22 definitions of what a shortage --

1           SPEAKER: Yeah.

2           THE CHAIR: What is a blood shortage?

3           SPEAKER: Okay.

4           THE CHAIR: So Mr. Benzinger?

5           SPEAKER: Oh, I'm sorry.

6           MS. BENZINGER: Yeah, on number three, I think  
7 you need to define what blood community you're speaking  
8 to. I think about -- when you say blood community, I  
9 think also of the plasma collection centers that are  
10 manufactures and all too, and I think you need to take  
11 them out of that scenario that you're actually asking  
12 about.

13           SPEAKER: Well, you know, the more I think about  
14 it, the real reasons for number three, at least in my  
15 initials thinking, was just to say that we needed the  
16 definition. But the model is done right, the definition  
17 is included in the model, and the response actually covers  
18 the alternative piece. So I don't think you really need  
19 number three, isn't it?

20           SPEAKER: But I think you do. But I think we  
21 may be stumbling on the issue here that we're not really  
22 trying to define shortages; we're trying to define

1 expectations in a variety of scenarios, the ability of the  
2 blood collection and/or plasma organization organizations  
3 to collect and respond in a variety of situations. It's  
4 not enough to define the scenarios. You have to  
5 incorporate them and get them to focus on the fact that if  
6 -- you know, at ARS a situation occurred and they lost the  
7 Southwest and New York and Washington. What could we  
8 expect them to produce under those circumstances?

9 THE CHAIR: So you would put define expectation?

10 SPEAKER: Exactly.

11 DR. EPSTEIN: Well --

12 SPEAKER: Dr. Epstein?

13 DR. EPSTEIN: See, I think we've got two ideas  
14 lumped here. I would just say to define shortage  
15 scenarios, that would require implementation of  
16 alternative collection. I mean, this is -- you know,  
17 what's the niche for reserves, what's the niche for a  
18 walking donor, you know, what's the niche for, perhaps, a  
19 better network of delivery systems.

20 THE CHAIR: Uh-huh.

21 DR. EPSTEIN: I think what this is about is  
22 defining the scenarios that require measures that are not

1 now in place.

2 SPEAKER: It's really to ensure an adequate  
3 supply of blood. I work with the blood community. Maybe  
4 we need to define that, but to ensure an adequate supply  
5 of blood and blood products in a variety of scenarios,  
6 that would require implementation of alternative. And  
7 here it focuses on blood collection, but we're -- the  
8 blood collections is just one part of it. The other part  
9 of it is demand. Talked about that a little bit too.

10 SPEAKER: Yeah.

11 DR. EPSTEIN: So --

12 THE CHAIR: But wouldn't the response in number  
13 two -- in other words, if you have a model to address and  
14 respond to the demand?

15 SPEAKER: Right. Well, then --

16 DR. EPSTEIN: I think --

17 SPEAKER: Oh, Dr. Epstein?

18 DR. EPSTEIN: Well, number two, I think we've a  
19 confusion there because we're not addressing and  
20 responding to the elasticity.

21 THE CHAIR: Yeah, right.

22 DR. EPSTEIN: It's the shortage we're trying to

1 address and respond to, right?

2 THE CHAIR: Right, right, right.

3 DR. EPSTEIN: So to address and respond to blood  
4 needs, or needs for blood and related critical materials.

5 THE CHAIR: So to address and respond to blood  
6 needs?

7 DR. EPSTEIN: Uh-huh.

8 THE CHAIR: And then the scratch the --

9 DR. EPSTEIN: Needs for blood and related  
10 materials.

11 THE CHAIR: And then go to related materials.  
12 Okay? Comments? Dr. Holmberg?

13 DR. HOLMBERG: I think that in number three,  
14 it's alternative blood supply and demand strategies.

15 SPEAKER: Yeah.

16 DR. EPSTEIN: What do you mean by demand  
17 strategy?

18 DR. HOLMBERG: Well, in other words.

19 DR. EPSTEIN: You're talking about triage.

20 DR. HOLMBERG: Triaging, who sets priorities,  
21 transfusing guidelines, you know, dropping elective  
22 surgeries.

1 THE CHAIR: That's a good point.

2 SPEAKER: Right.

3 DR. EPSTEIN: I think that's right, but I think  
4 it's perhaps not a transparent way to say it. May be it's  
5 strategies for blood collection, distribution and use.

6 SPEAKER: Okay.

7 THE CHAIR: So the strategies for blood  
8 collection, distribution and use? Yeah. Okay.

9 SPEAKER: Going back to the meeting when we  
10 talked about pandemic flu and communications, we had made  
11 a recommendation at that time that, you know, there would  
12 be some collaborative efforts at a standard message being  
13 sent out. And I don't know if it's necessary to reiterate  
14 that recommendation because we already made a  
15 recommendation or because I thought that that was  
16 something that was otherwise discussion, which is some  
17 centralized communication.

18 THE CHAIR: Right. I was thinking that that was  
19 -- in your working group, you are covering that currently  
20 or does that need reemphasis?

21 DR. HOLMBERG: Right. I don't know if it needs  
22 reemphasis, but -- I mean, it's like Ruth said yesterday,

1 lessons observed versus lessons learned. And I think that  
2 this is one that we really learned the lesson.

3 THE CHAIR: Okay. Dr. Epstein?

4 DR. EPSTEIN: On number one, is it inventory  
5 assessment we want hospitals and blood centers participate  
6 in or inventory reporting?

7 THE CHAIR: Reporting. Okay, additional  
8 comments? Actually, I think the -- that change in number  
9 three really helped me in terms of this issue of triage  
10 because that was something I was concerned, that's an  
11 important piece and we were losing it; it's now captured.

12 SPEAKER: In number one we're already doing  
13 that. We're expanding at the present time. Do you want  
14 to change the word expand to something different?

15 THE CHAIR: Well, well, you're expanding but  
16 there's -- what we're saying here, I think, is that we  
17 want to get to the number where we can accurately  
18 determine what the inventory is. I mean, we're just kind  
19 of reemphasizing -- what you're saying is you're expanding  
20 now?

21 SPEAKER: We're currently expanding. Do you  
22 want us to do anything different?

1           SPEAKER: Do you want us to compel, encourage  
2 or --

3           SPEAKER: Compel, mandate --

4           SPEAKER: What --

5           SPEAKER: Ensure, we work with Congress to --

6           SPEAKER: Well, you know, this is your  
7 responsibility, not Congress'. I think, what we're trying  
8 to get at in number one is that we need to get a national  
9 inventory.

10          THE CHAIR: Right.

11          SPEAKER: Not, you know, what necessarily  
12 representative sample because that's not going to help you  
13 in some of the scenarios that could occur. It certainly  
14 wouldn't help you in a pandemic situation. So what I  
15 would recommend for number one is not that you expand, but  
16 that you establish a national -- I don't know how you want  
17 to say this, national inventory. One that's -- you know  
18 that gets you. If you feel it's necessary down to the  
19 actual single unit in every hospital in America, you know,  
20 if that's what you need, then that's what you should say.

21          THE CHAIR: So let's say, to allow establishment,  
22 to allow --

1           SPEAKER: We've already established one, it's --  
2 to what degree do you want us to go.

3           THE CHAIR: We've already established.

4           SPEAKER: Well, except, but -- that's correct,  
5 but it's not a representative sample and it's not --  
6 doesn't give you the national inventory. If you want to -  
7 - I think it's the secretary's decision whether or not he  
8 wants to expand basis to include every hospital in  
9 America.

10          THE CHAIR: What if we do this then? You are in  
11 the process of expanding. So if we modified, further  
12 expand -- I mean, it's the same word but --

13          SPEAKER: Well, I guess, the point of having  
14 teeth in this thing, I mean, I actually liked the word  
15 compel before. I know that's a little strong, but is  
16 there another word that -- does that -- what?

17          SPEAKER: Mandate?

18          THE CHAIR: Dr. Epstein?

19          MR. EPSTEIN: Perhaps establish sufficient  
20 hospital and blood center participation. The problem is  
21 it's expanding, but it's not yet sufficient.

22          THE CHAIR: Yeah, right, right, right.

1 SPEAKER: Did you say, expand to full?

2 DR. EPSTEIN: Well, maybe we want that and  
3 that's something that we should discuss. The question is,  
4 whether you really need 100 percent participation. I  
5 mean, established complete or comprehensive reporting. So  
6 I think this is a discussion we have in hand yet.

7 SPEAKER: Okay.

8 THE CHAIR: That's a good one.

9 DR. EPSTEIN: Because what's on the table is  
10 statistically based monitoring, which enables a national  
11 estimate, but does not get down to the granularity of  
12 every hospital or region.

13 THE CHAIR: I mean, if it's sufficient, then it  
14 meets the need.

15 DR. EPSTEIN: Right, and if we say sufficient,  
16 we're leaving it to a judgment call by HHS when it's  
17 enough. If we say comprehensive or complete, we've made a  
18 judgment here as an advisory committee that you're not  
19 going to get what you need until you have 100 percent  
20 reporting.

21 SPEAKER: Okay.

22 DR. EPSTEIN: And I just think we didn't have

1 that discussion. I mean, what is the sense of the  
2 committee?

3 SPEAKER: Yeah. No, I agree, I agree.

4 THE CHAIR: Dr. Ramsey?

5 DR. RAMSEY: No, I think, again, it gets back to  
6 the purpose of this, and I would raise -- and it's made so  
7 late in a meeting, but is this -- is the idea of this to  
8 intervene somehow in terms of seeing shortages and trying  
9 to do something about it or is it a matter of knowing on  
10 September 11th at noon what the total national number of  
11 units is today, right now?

12 And that's two different scenarios. You could,  
13 as a matter of national emergency requirements, you could  
14 consider requiring a some kind of reporting requirement in  
15 a (inaudible) national emergency to -- okay, we got it  
16 now, everybody's got a call in their units, a blood that  
17 they have on their shelf. I don't -- you know, I -- we  
18 discussed that back and forth, but is the purpose to try  
19 intervene on -- in some kind of fashion to improve the  
20 supply or is the purpose to know on the day of an event  
21 what is available?

22 THE CHAIR: The view that I had is to start by

1 knowing what's there. I mean, currently, we just don't  
2 know what's there. If we can get there, then we can think  
3 later about interventions. I would see maybe a step wise  
4 item. Well, one of the things that we have as a challenge  
5 is that we're about to begin losing members. And I don't  
6 want to cut the discussion short, but do we -- on number  
7 one, I mean, on number one what we're saying is that --  
8 and the issue is do we want a mandatory -- I don't think  
9 we're saying we want mandatory. We -- I think what most -  
10 - no, don't let me put words in your mouth, but I think  
11 the discussion is that we would feel comfortable if we  
12 have enough information to make a reasonable decision  
13 regarding inventory, enough reporting.

14 SPEAKER: I can live with that.

15 SPEAKER: Yeah.

16 SPEAKER: Yeah.

17 THE CHAIR: Is that -- everybody's comfortable  
18 with that? I don't want to rush it, but we're about to  
19 start losing members in a short period of time. Can we go  
20 back through or read through? Okay, let's go back through  
21 a read through. Okay, so, "Whereas the blood supply is a  
22 critical part of the nation's healthcare infrastructure,

1 the HHS ACBSA believes that knowledge of real time  
2 national blood and blood product inventory and its  
3 dynamics are essential for" -- what's that?

4 SPEAKER: It should be "is".

5 THE CHAIR: Oh, is essential, yeah, in its  
6 dynamics, yeah, yeah, "is essentially for emergency  
7 preparedness and response. The committee finds that the  
8 blood center data are extensive, but not comprehensively  
9 aggregated nor available to HHS. Hospital data reporting  
10 are essential but limited. Although the blood supply is  
11 elastic, it is unclear whether it is sufficiently elastic  
12 to address potential disasters.

13 The committee recommends that, one, HHS  
14 establish sufficient hospital and blood center  
15 participation and inventory reporting to allow accurate  
16 determination of national blood and blood product  
17 inventory. Two, HHS develop comprehensive models to  
18 address and respond to the needs for blood and blood  
19 related critical materials in a variety of surge, donor  
20 depletion, and other threat conditions to accurately cover  
21 blood needs. Three, HHS work with the blood community to  
22 define shortage that would be shortage scenarios that

1 would require implementation of alternative strategies for  
2 blood collection, distribution and use for HHS support  
3 operations research to characterize and recruit potential  
4 donors who do not now routinely donate." Discussion. Dr.  
5 Bianco?

6 DR. BIANCO: I just want to continue on what  
7 Ramsey said. I think it would be very important for  
8 acceptance and participation by the blood community that  
9 you say something about the use of that information. If  
10 it is just data collection, you're going to continue  
11 having the gap between participation or understanding from  
12 everybody and that's my concern.

13 THE CHAIR: Uh-huh.

14 DR. BIANCO: This -- at this point it is just  
15 data collection.

16 THE CHAIR: Ms. Finley?

17 MS. FINLEY: If we threw the phrase after number  
18 one, national blood and blood product inventory for  
19 emergency response purposes, would that -- address that  
20 concern?

21 THE CHAIR: No, you want to go beyond reporting.  
22 Dr. Bianco wants to go beyond reporting, is that --?

1 DR. BIANCO: I want to see the blood banking  
2 community support your effort and in order for them to  
3 support this effort they have to understand why this  
4 information is important because the feeling that we try  
5 to convey is that, at this point, we feel that we have  
6 created a system that responds to those emergencies.

7 What we're hearing here is that there are  
8 (inaudible) sort of things that may put much more pressure  
9 and that we don't know if we're prepared or not. But  
10 again the difficulties -- how am I going to communicate to  
11 the members of my association that this is the  
12 recommendation of the Committee and my recommendation  
13 would be that they participate because -- and I'm missing  
14 the end of this sentence.

15 THE CHAIR: And I guess what Dr. Holmberg  
16 commented upon is that this would be for establishing  
17 emergency counter measures but you feel that is already  
18 done so that's what --

19 MS. FINLEY: Well, if I may? I think the issue  
20 here is we have to give the \$50,000 for DU (phonetic) and  
21 let the Secretary and Dr. Holmberg sort -- and the FDA  
22 sort this out with the blood collection community. What

1 I've heard yesterday and that we discussed is that there  
2 seems to be some feeling that the blood collection  
3 organizations are ready for anything but I think there are  
4 scenarios they haven't considered, based on the  
5 presentations that ABC and ARC made.

6 So, I'm simply pointing that out that now might  
7 be the time to resolve those issues before we actually  
8 need to work together in an emergency preparedness  
9 situation. So, I think it's the Secretary's  
10 responsibility, and Dr. Holmberg's responsibility, and  
11 FDA's, to get to the details. I'm comfortable with this,  
12 I understand the sensitivity but I think there will be  
13 plenty of opportunity to sort that out as they move  
14 forward together to respond to emergency scenarios.

15 THE CHAIR: Dr. Epstein?

16 DR. EPSTEIN: I think the problem that we're  
17 dancing around is whether the federal government needs  
18 daily knowledge of the actual blood inventory in order to  
19 understand the system dynamics and be able to trigger or  
20 not trigger emergency measures.

21 I mean, thinking from the FDA standpoint the  
22 problem that is presented to us is what do we do in a

1 given level of crisis, or it's, how many of our  
2 safeguards, you know, do we relax and we don't -- we're  
3 not going to know that without knowing what the situation  
4 really is. And I think what's troubling us is that not  
5 everyone is convinced that federal government knowledge of  
6 the daily inventory is an essential prerequisite for  
7 taking those kinds of actions and I think what that comes  
8 down to is, what is the expectation of the, you know, the  
9 ASPR the ASH in the disaster scenario.

10 Do they think that it's their job to, you know,  
11 declare an emergency, is it their job to, you know,  
12 authorize a UA (phonetic) -- I'm not putting that forward  
13 as a solution but that's, you know, been discussed; is it  
14 their job to, you know, commandeer resources, is it their  
15 job to redirect distribution of blood, is it their job to,  
16 you know, promulgate advice that day?

17 So, the linkage that we're looking for is  
18 whether knowledge of the daily inventories is a  
19 prerequisite for the federal government to be able to do  
20 the thing we want the federal government to be able to do  
21 namely, provide leadership in a crisis. And I think that  
22 some people are operating from the point of view that

1 that's self-evident, that if we don't have knowledge of  
2 the inventory we're flying blind and other people are  
3 operating from the point of view we have a decentralized  
4 system and it has certain flexibilities and the problem is  
5 essentially a local and that's how they'll get solved.

6 So, I just think that we haven't had a  
7 sufficiently robust discussion about why the government  
8 needs the inventory information in order to really come to  
9 closure on this.

10 THE CHAIR: That's a good point but although, I  
11 mean, in my thinking the points that you made are cogent  
12 and I think that the government really does need to have  
13 that information to make informed decisions.

14 MS. FINLEY: I agree.

15 SPEAKER: I agree.

16 THE CHAIR: And that explains the need.

17 DR. EPSTEIN: But you see, Celso is saying to us

18 --

19 THE CHAIR: The membership --

20 DR. EPSTEIN: -- it doesn't buy that.

21 THE CHAIR: -- buy that.

22 DR. EPSTEIN: Unless I misunderstand you Celso,

1 you're saying a convincing argument has yet to be made?

2 MS. FINLEY: Okay, if I may?

3 THE CHAIR: Yes, Ms. Finley.

4 MS. FINLEY: In a national emergency scenario,  
5 9/11 or much worse -- it's going to be the government  
6 that's making these decisions, not the blood banks and the  
7 blood collection organizations.

8 THE CHAIR: Commander Henry?

9 MS. FINLEY: You know, I don't know why we would  
10 be -- I mean, I understand that's got some sensitivity but  
11 I don't think that can dictate what we're recommending  
12 under the situation.

13 THE CHAIR: Commander Henry?

14 LCDR HENRY: It's my job in emergencies to sign  
15 off on goods and services that the government can provide  
16 the blood community. If they need transportation from  
17 DOT, protection from the Marshals, any other type of fuel  
18 or emergency services, I sign off on it down at the SOC.  
19 I've to have some proof that it was needed; I'm spending  
20 tax dollars on a handshake. You say it's needed, okay,  
21 we'll do it but it would be real nice to have data to  
22 backup my decision to spend money.

1 THE CHAIR: Thank you. Dr. Bianco?

2 DR. BIANCO: But then you can help us by putting  
3 a number five that is the -- those are the reasons why  
4 this data would be useful. It is for regulatory purposes  
5 to see what degree of changes FDA would make. It would be  
6 to command additional resources for transportation fuel --  
7 the things that we've been complaining about in  
8 communications.

9 LCDR HENRY: Isn't that in number three? Right,  
10 because that's just to define scenarios not necessarily to  
11 define data needs.

12 THE CHAIR: But, well, see this gets to the  
13 point though, I think that Ms. Finley was making is that  
14 we're kind of getting bogged down in some of the details.  
15 We -- that is why we need this information and as HHS  
16 works with the blood community, HHS will convince the  
17 blood community exactly why this is needed because I think  
18 that the arguments are cogent and should be -- should be  
19 acceptable. Dr. Roseff?

20 DR. ROSEFF: I think I believe in a national  
21 strategy too because on 9/11, which again was a very  
22 regionalized kind of problem, being in Richmond we had

1 mobilization of resources out of our city that were  
2 unnecessary and actually detrimental to us. And so to  
3 think that locally -- and it was in -- everyone assumed  
4 what they thought was best.

5 THE CHAIR: Uh-huh.

6 DR. ROSEFF: You know, we're an-hour-and-a-half  
7 from the Pentagon and everything was being moved north.  
8 And I think it would have been interesting if there were a  
9 larger -- even the larger state institution at that point,  
10 a larger state agency, some larger entity that could have  
11 helped us mobilize knowing what was where and what our  
12 resources were and what we needed regionally to get  
13 through what we had to get through over the next few days.

14 THE CHAIR: Uh-huh.

15 DR. ROSEFF: So that's probably why I see that  
16 it'd be great to think of someone up above really seeing  
17 what's around and then making better decisions about where  
18 things should move as opposed to leaving it to those of us  
19 in the field thinking, we really need to help, what are we  
20 going to do?

21 That was very uncoordinated and -- again if this  
22 happens in multiple parts of the country, you depend on

1 local areas of different parts of the country to deal with  
2 this, there is going to be a bad distribution of resources  
3 I think.

4 THE CHAIR: Uh-huh. Dr. Holmberg?

5 DR. HOLMBERG: Yeah, I fully agree with you and  
6 also I agree with Dr. Kuehnert. I think that it's also  
7 the statement number three and the way it was reworded,  
8 alternate strategies for blood collection, distribution  
9 and use -- I think that really sums it all up and I think  
10 that it's between you and I and the Red Cross and the AABB  
11 to sit down and work out and develop a message that we can  
12 -- to clarify exactly with these points and definitely  
13 we've heard today the regulatory aspects of potential  
14 medication, you know, commandeering or taking -- getting  
15 additional resources to you. But also at the end of the  
16 day we also need to be able to say, okay, how much is  
17 something going to cost? And we eventually will have to  
18 be accountable also for the financial aspect of it.

19 THE CHAIR: Dr. Williams, comment?

20 DR. WILLIAMS: I'm also bothered a little bit by  
21 number one and I think what's maybe missing there is the  
22 addition of something like and established, efficient

1 mechanisms be they electronic or not, to trigger  
2 interventions. Because you have the power -- if you have  
3 all those data, you have the power in some way to assess  
4 where the needs are and to address them but on a practical  
5 sense, if you have this massive data here and you're in an  
6 emergency situation you just won't be able to deal with it  
7 unless you have some sort of efficient mechanism to do  
8 that for you and highlight where the needs are.

9           We've all seen though the graphs from the data  
10 collection system that are like that and, you know, just  
11 looking at those it's very difficult to pinpoint just  
12 where the needs are.

13           THE CHAIR: That's a good point. So, Dr  
14 Epstein?

15           DR. EPSTEIN: I think -- I don't know whether  
16 this really gets to Celso's need but if number one said to  
17 allow accurate determination national blood and blood  
18 product inventory as a basis for national and state  
19 response in emergencies.

20           MS. FINLEY: Yeah.

21           DR. EPSTEIN: Because the point is that we want  
22 that data so that we're able to respond. And I think

1 Allan's going a step further, he's saying that we also  
2 need an organized system of knowing what we're going to do  
3 but I think that's the essence of item three.

4 DR. HOLMBERG: How about -- how about saying as  
5 a trigger for national -- for local or state and national  
6 response?

7 THE CHAIR: And then as a trigger for getting at  
8 Dr. William's point, coordinated or efficient -- would  
9 that capture -- capture your point?

10 SPEAKER: Mainly in the efficiency area.

11 THE CHAIR: Efficient, efficient.

12 SPEAKER: We don't have time to play with  
13 (inaudible).

14 THE CHAIR: Yeah, so -- so --

15 DR. HOLMBERG: Oh, it's a trigger for efficient  
16 local, state and federal.

17 THE CHAIR: Yeah. Okay?

18 DR. HOLMBERG: And perhaps response should be  
19 plural then?

20 THE CHAIR: Yeah, plural for that response.

21 All right, is the Committee happy?

22 MS. FINLEY: Yes.

1 (Laughter)

2 THE CHAIR: Do I hear a motion?

3 (Laughter)

4 THE CHAIR: A motion from Dr. Duffell?

5 DR. EPSTEIN: If you just go back up to the  
6 intro there's a grammar point I was going to come back to.  
7 The -- can you show the top? Hospital data reporting now  
8 is "is" essential.

9 THE CHAIR: Oh yeah, right, "is" essential,  
10 yeah. I had a second from Ms. Finley, is that -- did I  
11 have --?

12 MR. MATYAS: Second.

13 THE CHAIR: Okay.

14 (Laughter)

15 THE CHAIR: Okay, a second from Mr. Matyas.  
16 Okay, we have a motion approved and seconded. All in  
17 favor?

18 SPEAKERS: "Aye."

19 THE CHAIR: Opposed?

20 (No response)

21 THE CHAIR: Abstentions?

22 (No response)

1           THE CHAIR: It passes unanimously then. Yeah,  
2 great job.

3           SPEAKER: So.

4           THE CHAIR: It's a very challenging area and we  
5 -- you, the Committee did a wonderful job, thank you,  
6 thank you.

7           Is there any additional business? Would you --  
8 if not, a motion for adjournment?

9           MS. FINLEY: Motioned.

10          THE CHAIR: Okay.

11          (Laughter)

12          THE CHAIR: We stand adjourned, thank you.

13          (Whereupon, the MEETING was adjourned)

14                           \* \* \* \* \*