[Whereupon, at 10:52 a.m., the meeting resumed.]

Dr. Howell: As you know, we've been concerned and discussing the issue of the use of residual dried blood spots for quite a long time. And as you know, the May report on residual dried blood spots was posted for public comment.

There were a large number of public comments received. And today, Alissa Johnson is coming back having been through all those comments. And matter of fact, I've read all the comments also, and I'm sure others have. And she has basically analyzed the public comments and has looked at those, worked with other various members of the staff to try to incorporate those as appropriate into the report.

And so Alissa's going to tell us about the public comments and how she has put those -- and I think the group knows Alissa, she's been with us a number of times. She has a lot of experience in public policy research and so forth. And so we are delighted to have you back Alissa.

Ms. Johnson: Thank you for having me back. And first I will say that probably Lisa Vasquez and Michele did much delving through all of the public comments and Lisa sorted them out for me. And she has put together a few slides that I'm going to run through first on exactly some statistics about the comments.

And then we'll go through subsequent changes that were made to the paper based on those public comments, based on two

lengthy calls with the residual dried blood spots working group. So I want to thank them for their input. And based on you know, the thoughts of HRSA staff.

So as far as the public comments, approximately 550 individuals submitted email comments and responses and reactions and 13 organizations submitted comments.

Lisa has put together some specific concerns and interpretations from some of the individual comments. Number one reaction is recommends the Committee simply develop national guidance for consent or dissent for the secondary use of specimens. And we did have individual as well as organizational comments about consent and dissent options so we'll discuss that further later.

Number two, asserts a public claim on the DNA of newborn citizens. And I think there were numerous comments similar to that. Claims that newborn blood is necessary for population surveillance. Number four, claims that newborn screening test development is not research.

Number five, claims that state screening programs are charged with stewardship of newborn DNA samples ensuring appropriate use rather than charged with simply testing each newborn. Number six, fails to recommended informed written consent requirements for the storage and use of newborn DNA for research and other purposes.

Number seven, does not support the 22 state genetic privacy laws and the five state genetic ownership laws that may or do require consent. Number eight, does not include public opinion data from the University of Michigan study regarding unconsented storage and research. And number nine, recommends parent education instead of informed parent consent requirements that will enforce such education.

Just summarizing the general tone of that. The interpretation that the recommendations for the storage and use of newborn DNA do not acknowledge the consent, privacy, parent and DNA property rights of the individual. There was a tone that the belief that the Committee is advocating for the expansion of government power over the individual's most intimate property.

Opinion that the recommendations advocate for the reduction of Constitutional rights of individual citizens and as proposed do not comply with the legal individual rights and informed written consent requirements as secured by the 4th Amendment privacy and property protections.

And lastly, perception that the Committee seeks to establish and support government banking and ownership of citizen DNA at birth through the creation of 50 state government DNA warehouses for nationwide genetic research on the American public without the informed written consent of citizens.

And so we did try to take the tone of those comments into account and we did make some efforts to reorganize an rename sections of the paper to try to highlight the area of the paper that do address those kind of issues as I will show you later.

These are the organizational comments that we received. If you want to just take a look, I won't bore you with reading through all of those. And we'll go ahead and start through the edits to the paper. If you do have the briefing book up on your computer, those of you that have one, I do have the page numbers on there and it should match the page number that you have in the briefing book copy of the paper.

And I also wanted to point out, we've been having some issues with passing the document back and forth. And again, when the briefing paper was converted to this PDF format, there are some oddities. For instance, there is some bolded text that's bolded and italicized in the recommendations. That's not intended emphasis. And there's some boxes that appear.

So I ask you to please disregard that. When the paper does go to the Secretary, I will be spending the day at HRSA meticulously going through it and making sure that it's not converted to another format. So all of that will not appear in the final format.

To start with, for the introduction the -- we did some rewording there. The Secretary's Advisory Committee on

Heritable Disorders in Newborns and Children encourages an approach to the guidance that -- and this is the change that I'd like to highlight, maintains the standard uses of the residual blood specimens by newborn screening programs and upholds the core principles of benefitting infants, families and society, etcetera.

We did in several places in the paper as we'll discuss further later, add language referring to standard uses of residual blood specimens. And made an attempt to lay out what that the standard uses were versus other uses. And I think that this comment is in part in line with some of the concerns that March of Dimes had also. That these recommendations wouldn't harm the regular program activities of newborn screening programs.

Also in the introductions, the recommendations related to the retention and use of residual dried blood spots specimens are intended to work in concert with and not to weaken long standing and highly effective state newborn screening programs.

And that change, again, was made based on comments we had received from the March of Dimes. And we did, as I mentioned earlier, go through these comments with the Residual Blood Spot workgroups and get their input.

There were some sections that were renamed as I stated earlier and reordered just for what we felt was better

organization of the paper. So now there are sections on international policy, federal policy and state policy under the ethical, legal and social issues.

And there were sections that were renamed on engaging the providers and the public and engaging the public trust through empowerment. And we thought that might highlight areas where the paper responds to public concerns or comments around those issues.

On pages six and seven of the briefing book you can see the standard newborn screening program uses of residual dried blood specimens that we laid out. Program evaluation and quality assurance is one. Treatment efficacy, test refinement and result verification. And I don't know if at this point it's fine -- if anyone has any comments on that. Do we want to hold to the end or -- okay.

Dr. Puryear: No, I --

Ms. Johnson: Go ahead and --

Dr. Puryear: No, ask for comment.

Ms. Johnson: Yeah, does anybody want to go ahead and comment on that?

[No response.]

Ms. Johnson: No, okay. And then as laid out, other uses. New test development, population surveillance, parental request for other testing, family requested identifications of remains,

and research. And particular the parental request for other testing, right now we have that under other uses. We want to make sure that you want it there and not under standard uses.

[No response.]

Ms. Johnson: Then on page 6, we also outlined the two principle purposes of the paper. And that was based on a comment from NIH. I thought that would be helpful. So now the language states, the first purpose is to review the issues facing state newborn screening programs related to the retention and use of residual dried blood spots specimens.

And after that it had said, research -- it had initially said research use, or including potential research use. And after talking with the Residual Dried Blood Spot working group we decided to remove that and just say retention and use generally. And then the second purpose is to lay the foundation for developing national guidance to states in this area which is similar to what we had previously.

On page seven, because newborn screening specimens are usually the first blood specimen drawn in a baby's life, they represent a unique time frame where, and this is what we changed based on the working group's comments, most influences, whereas before it said where influences, on the contents of the blood are in utero exposures.

And moving on to page nine, the section on GINA. And this

was based on comments from the Genetic Alliance. And we added a sentence, greater public understanding of protections mandated by GINA could mitigate parents' -- I'm sorry, there seems to be a problem with the apostrophe there, concerns about possible risk of genetic discrimination if their children's blood spots are retained. And that I think responds in part to some of the individual public comments as well.

On page 11, this section was on the voluntary national repository was expanded. The new language includes, one method for establishing voluntary repository under discussion that could be accomplished without the collection de novo specimens involves the use of a newborn screening -- of newborn screening biobanks to develop a national newborn research biobank.

There are challenges to the establishment of any non-newborn screening repository comprising residual newborn screening specimens and significant issues would need to be addressed including variations in state law, regulation and policy. And I think it's the latter sentence that you would want to focus on more. And that was done also with help with Anne Como. We talked to her a significant bit about that issue.

Also on the section on voluntary national repository there was a sentence removed with reference to the National Children's Study. And that was done based on the working group discussion that there may be some question of where things are at there as

far as whether that was good example to put as the National Children's Study providing the impetus for a U.S. national biobank based on similar hypotheses. So that sentence was removed.

The section on national IRB. A locally structured IRB lacking public health expertise may not suffice to serve a national bio-repository being used for public health research. That sentence was added, also based on our discussions with Dr. Como.

On page 13, the section on state laws and regulations. There was a reference added to the new table that is in the paper on state statutes and regulations on the storage and use of residual dried blood specimens. And the reference was removed to examples of state forms.

If you recall, we had a few examples of forms in there from various states, I think South Carolina was one. We decided to remove those examples and add the statues and regulations. And so a search for that was done in July and we were going to update the table again before we send it to the Secretary.

And I can mention here, we also did, in response to the comments, go through some of the consent or opt in and opt out forms. We looked at Denmark, we looked at Michigan and tried to develop possibly sample opt in and opt out forms and have put together something to add to the appendix.

And then we did have a conference call with the working group and at that time it was decided that providing these sample opt in and opt out forms in the absence of educational materials really was not that useful at this time. But we -- there has been some work done related to that issue and obviously there were many comments received related to that issue.

And the working group at one point did suggest the possibility of maybe there should be an ad hoc group who can go ahead and start looking at these consent and dissent issues. But that it wasn't work to be done necessarily in this paper.

Dr. Howell: Right.

Ms. Johnson: That it's something that can be done at a later date.

Dr. Puryear: Can I say something?

Ms. Johnson: Sure.

Dr. Puryear: This was a really strong recommendation to have those kinds of model policies from NIH. They really have two times asked for this within this briefing paper. So the Committee and the NIH representative or member is not here today but I think the Committee should be cognizant of that and be ready to respond to NIH.

Ms. Johnson: Yes.

Dr. Skeels: I'm not sure if this is the right place to

bring this up but it occurred to me as I was reading this section last night. I really like what's been said about the ownership of the original samples themselves. But something that comes up frequently is what about the amplicons from the samples.

Ms. Johnson: Mmm-hmm.

Dr. Skeels: When you take somebody's DNA and you're now doing nucleic acid amplification tests like PCR, you are duplicating, replication millions of copies of a piece of the patient's sample. So at some point we're going to need to address whether ownership of the original sample extends to amplicons and derivatives of those nucleic acids or not.

Ms. Johnson: Right. And we did have on a -- and I agree with you and that's not something that we've talked about at all at this point. And actually, one of the comments that we had from Vanderbilt was to get away from the whole ownership issue.

And we did have a discussion and in the working group conference call there was a suggestion to remove the title ownership entirely and just change it to authority over decision making.

That ownership might be you know, sort of a -- not the best way to word it. And the working group just said that we should put that out to you all and see what you would like to do. But that raises --

Dr. Puryear: Ask the Committee.

Ms. Johnson: That raises a good point but I don't know if --

Dr. Howell: Alan, you have a comment on that?

Dr. Fleischman: My comment actually was back to Michele's request for clarification about the NIH's request. And I think that in the recommendation seven, which relates directly to this issue, there's a request of the Secretary to improve efforts to facilitate a national dialogue among federal and state stakeholders and develop some models.

It's not that we have neglected their concern. The question is, is it right for a prescription. And I think that's the -- that we have not done the necessary work to give the states those recommendations even though they'd like them and we'd like to have done that work but we haven't.

So there's going to be the need for additional work in order to clarify this area. It's not that we disagree with the need for that outcome.

Ms. Johnson: Thank you Dr. Fleischman. And that was the discussion during the working group call that everyone agreed upon. And as I just alluded to on the section on ownership, we did make some changes there referring to who has the authority to make decisions. Changing that from ownership previously.

So it said uncertainty about ownership before but we

changed it to who has the authority to make decisions. But we kept the section titled ownership. So if you'd like to remove reference to ownership for that as well, please let me know.

[No response.]

Ms. Johnson: I mean you can see that the individual comments, the feelings about the word you know, ownership were quite strong.

Unknown Female Speaker: The Committee needs to discuss this now.

Dr. Kus: One of the comments is it says ownership and then it doesn't mention it in the rest of the part.

Ms. Johnson: I'm sorry, on the section about --

Dr. Kus: When you look on the section on ownership --

Ms. Johnson: Right.

Dr. Kus: -- and the rest of the discussion doesn't even touch ownership. It talks about --

Ms. Johnson: Well --

Dr. Kus: -- authority and things like that. So I think you --

Ms. Johnson: I think -- well -- it's in -- that's -- right now the section is titled ownership --

Dr. Kus: Right.

Ms. Johnson: -- and this sentence is in there. And before it said, prior to this change, nonetheless potential uncertainty

about ownership with regard to specimens. And we reworded it as suggested to say, potential uncertainty about who has the authority to make decisions. Because ownership is clearly an issue in some states in that they do have genetic privacy laws that include personal property rights to DNA.

And it is an issue in that some state newborn screening programs you know, have declared that they own the specimens. And the related genetic privacy laws have come out and lawsuits and so forth. So it's a matter of whether you want to steer clear of that ownership language or not.

Dr. Howell: Michele has a question.

Ms. Johnson: Sure.

Dr. Puryear: This is to the Committee so that we're not deciding things ourselves. So Alan for one, the reason why he brought up the issue of the NIH recommendation, the Committee needs to decide. We made this decision, the workgroup made this decision. Does the Committee agree with that decision not to have any model policies. I think it is addressed in the recommendation.

But as for ownership, we need to decide now whether or not that title is appropriate. In fact, that paragraph does talk about ownership issues and ownership is mentioned three or four times in that paragraph. If you read the brief, and some program state statutes or regulations define ownership of the

specimen. But it ends with this last sentence. And the brief does give some examples of different laws.

Nonetheless, potential uncertainty about who has the authority to make decisions, that's the end. So it is talked about, ownership, and there's several other areas under that section that talk about ownership. The point is, between ownership and stewardship the public health community, of those that provided input, thought framing the role of the state public health programs who have oversight responsibility of newborn screening program like the word, the term, the concept of stewardship.

Although their state laws may define ownership, that they feel they have a stewardship responsibility, all programs do fill that responsibility to take care of the newborn screening programs.

Dr. Howell: Gerry.

Dr. Vockley: I think it would be a mistake to remove the word ownership from this policy paper because that's the word that's out there and we're addressing not only a commonly invoked piece of public perception, but also direct language in several state statues. So I think to ignore it is to ignore the elephant in the room.

But I do like the way it ends up being redefined to authority to make decisions because I think that's the more

correct ultimate piece that we're getting to. And so I would just leave the title of that section ownership and continue moving it to try to be a little bit less inflammatory which I think ownership inflammatory. Authority to make decisions brings it down to what we really want to say.

Dr. Howell: I think that's well put. Jeff.

Dr. Botkin: Yeah, I want to agree with that and perhaps just suggest that I think the main problem is people look at the concept of ownership and think that that means you can do anything you might want with the sample. So the qualifiers that are included here about the authority to make decisions I think highlights the fact that ownership is a complicated term, it means a variety of different things depending on the context.

So maybe that sort of qualifier phrase ought to move up to the front of the paragraph here so that readers understand at that point that ownership, we understand ownership to be a complicated phenomenon. But we don't want to avoid the word because it's so commonly used in this --

Dr. Howell: So you would begin the paragraph with this document? Take out nonetheless, but start with potential? Start with potential uncertainty and then have the section on the state laws and so forth?

Dr. Botkin: Yeah, and we might even simply say right at the very beginning, the word ownership is a complicated term

that means a variety of things. What we're concerned about is who has the authority to make decisions about the management of these samples. Something to that effect.

Dr. Howell: I think that's the sense that I get. Sharon.

Ms. Terry: I would take it a little farther and say, not only is it complicated term but that actually its legal ramifications vary from state to state and the contractual arrangement between the state and the individual is different. And it certainly doesn't have to be as complicated as I just said it. But I think more than just saying it's a term, I think we should also allow that it's associated with a legal connotation. And that should be explicit so that we're not later challenged to say, that actually has legal meaning.

Dr. Howell: Right, right. That sounds sensible. Any further comments for Alissa on that point?

[No response.]

Dr. Howell: I think -- you got the -- I think the sense of the Committee --

Ms. Johnson: I got it.

Dr. Howell: -- about what we want.

Ms. Johnson: Yeah, and I think that just starting out that way will be good. And ownership is one way in which to handle --

Dr. Howell: Yeah.

Ms. Johnson: -- who has authority to make decisions.

Dr. Howell: Yeah.

Ms. Johnson: Okay.

Dr. Howell: Very good.

Ms. Johnson: With reference to the section on the Michigan Biotrust for Health, pages 14 and 15 and then in the appendix, changes were made and that was based on information that was provided by the Michigan Department of Community Health.

And the discussion of the Denmark Biobank, that was not changed it was just moved into a text box which is called Denmark an International perspective. And that was placed in the sections on state policies on the storage of residual dried blood specimens. It just seemed to be the most appropriate fit there.

Dr. Howell: Yeah. I like that.

Ms. Johnson: Okay.

Dr. Howell: It sits in a box, it has the information there but it kind of segregates it --

Ms. Johnson: Right.

Dr. Howell: -- as information that's independent of the discussion.

Ms. Johnson: Yeah, it didn't fit well into international policies.

Dr. Howell: I think you're correct.

Ms. Johnson: The section on consent and dissent we did add a few sentences there in response to the comments. And like I said, we did put forth some examples that we decided to hold off on and not put in the appendix at this time.

A new paragraph was added, page 18. Newborn screening programs may utilize several methods to provide parents or guardians with alternatives regarding specimen storage and use. The alternatives involved an opt in or opt out process whereby individuals are informed of the potential storage and use of specimens and either one of the following occurs.

First, a newborn specimen is not stored or available for allowable approved uses after screening is complete unless the parent opts into the biobank. Parental consent is sought and possibly formalized through a signed document.

Or number two, a newborn specimen is stored and available for allowable and approved uses unless the parent/guardian objects or indicates dissent. And we did add a reference. The decision to opt out also may be formalized through a signed document. Longitudinal studies of children who eventually transition to adulthood should retain some degree of flexibility to account for the decision making authority of children as compared to adults.

So that's all language that you have not seen before. Does anybody -- anyone have any comments on that?

[No response.]

Dr. Howell: No.

Ms. Johnson: Okay, moving to the conclusion. There were some sentences that were reworded on page 23 of the briefing book. Nevertheless, aspects of the current public policy environment including differing or lacking state policies on the need for explicit consent. And that refers to the explanation that was earlier in the paper or dissent.

Potential uncertainty about authority over decision making with regard to residual newborn screening specimens in state without a well defined policy and minimal public awareness of newborn screening send an unclear message to the public about the purpose of storage and use of residual blood specimens.

And I think in particular we added the language regarding consent and dissent and changed the end of the sentence to say, that this does send an unclear message to the public. And I think that maybe that's apparent from the individual comments that were received on the paper.

Does anybody have any thoughts on that?

[No response.]

Ms. Johnson: Also in the conclusion were a couple of sentences that were reworded. This has engendered some public concern about the storage of residual newborn screening specimens even for standard newborn screening program uses. And

that just refers back to the standard uses that we laid out earlier in the paper.

And the storage and use of residual blood specimens for non-standard uses such as research may not be adequately addressed in current state laws or policies. So the emphasis there is on standard uses versus non-standard uses.

Also in the conclusion, policies developed for the storage and use of residual dried blood specimens for research should not harm longstanding and highly effective state newborn screening programs including their ability to store and use specimens for program activities.

And that's in partial response to the March of Dimes' comments as well. Rather, these policies should strengthen these -- and we should take out a these there. I see, I feel like that's too many these. These policies should strengthen these well established public health programs through increased public education and engagement.

I think at this time maybe we can move on to the recommendations. So on page 24, the more detailed explanations of the recommendations that were under the initial -- the first sentence of the recommendations. We did remove those from the executive summary. So you just have one brief sentence about the recommendations in the executive summary now. And then the further explanation is in the body of the paper.

As far as recommendation one, the explanation of that recommendation was shortened and a sentence about access to policies was added. And it was shortened and the explanation was shortened based on the HRSA felt it was a bit repetitive. And then the sentence about access to policies was added based on comments from the Genetic Alliance that we emphasize that these policies should be accessible.

And in recommendation two, standard uses provided in -- and the sentence, that doesn't make sense to me. Regarding access to policies added to recommendation two. I'm not sure what the provided is, but we did add standard uses and access to policies.

Recommendation three, potential use for research was changed to potential uses because we were concerned about all potential uses perhaps in the recommendation not necessarily focusing on research. Educational programs should focus on prenatal care providers as the primary target. Education of postnatal care providers should instruct them to follow-up on prenatal educational efforts, etcetera.

So the new -- the changed language is that which is italicized and bolded there. And that was also based on comments from the Genetic Alliance that we should emphasize that the prenatal care providers are the primary target although the postnatal care providers definitely have a role to play.

And that -- actually it's a duplicate slide but there's -- if you just look at the last item on there. The first two are duplicates to the previous -- reference to prenatal care providers being primarily responsible for parental educate was also added to recommendation 5.

On recommendation six and seven, those were separated and reworded to explain the goals of the recommendation and make those the primary focus. So those were improved education and facilitating a national dialog rather than requesting funding to support these activities.

If you recall before, it stated the Advisory Committee recommends that the Secretary provide administrative funding and support for education. And then to facilitate a national dialog. And we separated those out to try to better explain ourselves for why we thought that should be the case.

And then recommendation eight is an entirely new recommendation. And this recommendation states that the Secretary of Health and Human Services should explore the utility and feasability of establishing a voluntary national repository. And the comment with regard to the repository, those were received from the Secretary's Advisory Committee on Genetics Health and Society.

Unknown Female Speaker: And NIH.

Ms. Johnson: And NIH, okay. Further explanation of

recommendation eight. It states, to implement this recommendation the Committee recommends that the Secretary instruct and provide additional funding for NIH and CDC in consultation with OHRP and other relevant federal agencies and non-governmental organizations to draft policies and guidelines addressing the support and maintenance of the repository.

Issues to be addressed include stewardship of the collection, establishment of oversight systems, and a national human subjects review structure, access and retention policies, and how legal and ethical issues would be addressed including variations in state laws.

So do we want, before we move on to this, do we want to discuss that?

Dr. Botkin: I'm wondering whether the voluntary term needs more discussion here. Is it clear enough that it's voluntary with respect to the parents of the kids as opposed to voluntary with respect to state programs?

Dr. Howell: I'm not completely clear about your question Jeff.

Dr. Botkin: Well I guess the rest of the explanation doesn't really describe what we mean by voluntary. And I assume what we mean is that parents have agreed to have their samples included in a national repository. Is that what the voluntary term means?

Ms. Johnson: I think that was the intent. And I see what you're saying, not voluntary by the state newborn screening programs to opt in everybody in their state --

Dr. Howell: Oh, okay.

Ms. Johnson: -- it's voluntary on the part of the parents.

Dr. Howell: That should be clarified. Certainly, I think it was clear the intent that it's voluntary on the part of the parent or the guardian. So maybe that can be clarified. Good. Jane.

Dr. Getchell: Alissa, I noticed that APHL is not listed in the organizations that provided comments on the paper. And I know that we did, in fact, provide like five pages. Were those incorporated? What became of those?

Ms. Johnson: We did have APHL comments several rounds --

Dr. Getchell: Right.

Dr. Puryear: But not during the official public comment period. So they're first --

Dr. Getchell: So they were --

Dr. Puryear: They were.

Ms. Johnson: They were -- yes, they were. And I have -- I think I have an email from you that we exchanged laying out how it is. So I'll find it and send it to you just to make sure. But they were, that was one or two meetings ago and that was done.

Dr. Puryear: But they didn't come back with comments, or we didn't receive them if they did.

Dr. Howell: We have a comment from Jelili about that question.

Mr. Ojodu: I just wanted to be clear Alissa, we did provide comments to you, five pages worth in January during the --

Ms. Johnson: Right.

Dr. Howell: Yes.

Ms. Johnson: And those were all addressed at that time.

Dr. Howell: Right.

Mr. Ojodu: But it wasn't -- have they been addressed in the particular document up here? The recent revised document.

Dr. Puryear: Well we sent out the revised document before this one for public comment in May. And we did not receive any public comments from APHL at that time as an organization.

Mr. Ojodu: Okay.

Ms. Johnson: But I don't know that the paper would be so different at this time then when you had commented on it in January.

Mr. Ojodu: Okay.

Dr. Puryear: We addressed them in May.

Ms. Johnson: Right, right. So you provided comments but I don't think the paper changed that significantly since they

provided the comments.

Dr. Howell: But the point is, the comments were provided --

Ms. Johnson: Yes.

Dr. Howell: -- before the May document ad so forth.

Ms. Johnson: Right.

Dr. Howell: And we're delighted that Jelili is here and not being held hostage as his partners across the street were recently. Please.

Ms. Johnson: Okay. So if we have --

Dr. Puryear: Wait.

Dr. Howell: Oh, Mike has some questions.

Dr. Skeels: I'm sorry, I was asleep at the switch when you went by page 11. Did somebody catch the omission of the word improved under CLIA on page 11? It says the clinical laboratory amendments of 1988, CLIA. It should be, the Clinical Laboratory Improvement Amendments.

And then under the CLIAC the word improvement was also eliminated or omitted in the name of the --

Dr. Howell: Oh.

Dr. Skeels: -- Clinical Laboratory Improvement Advisory Committee.

Dr. Howell: Okay, so if you'll get that improvement in there.

Dr. Skeels: Yeah, I just happened to notice that last night.

Ms. Johnson: Sorry about that.

Dr. Howell: We always want to improve the laboratories any way we can.

Ms. Johnson: Like I said, I will be going through this with a fine tooth comb before -- at HRSA before the paper is submitted. And also we will -- this section that I'm going to talk about now, we will be updating it again. So do we want to go ahead and move on to the state statutes and regulations?

Dr. Howell: Yes.

Ms. Johnson: Okay.

Dr. Howell: Yes.

Dr. Kus: Can I just make a --

Ms. Johnson: Sure.

Dr. Howell: Well Chris has a comment.

Dr. Kus: If you put the one up where you said primary target of education as opposed to focus educational efforts on the prenatal care. Primary target bothers me, but if it doesn't bother other folks.

Dr. Puryear: Focus?

Dr. Kus: Yeah, focus educational efforts on them. Primary target just --

Dr. Puryear: Yeah, belligerent.

Ms. Johnson: So just end at providers.

Dr. Puryear: Yeah, we can just end at providers.

Dr. Kus: No I --

Dr. Puryear: Educational program to focus on --

Dr. Kus: Focus on --

Dr. Puryear: -- prenatal --

Dr. Kus: No, as long as you say you should focus on primary --

Unknown Female Speaker: It's the word target.

Dr. Kus: It's target, primary target. Just --

Dr. Puryear: So we could just end at providers, period.

Ms. Johnson: Primarily focus was the suggestion here. Does everyone like that?

Dr. Puryear: If you put primarily --

Dr. Kus: It's still primary target.

Ms. Johnson: It's primarily should focus. And I do that and then people don't like it.

Dr. Puryear: I know, yes.

Dr. Howell: We've converted that to a less belligerent statement.

Ms. Johnson: Okay.

Dr. Howell: Okay.

Dr. Kus: But it's going to keep the primary target?

Ms. Johnson: I've got that.

Dr. Kus: Target's going to go out? Primary target's going to go out?

Dr. Puryear: We're going to say educational programs primarily should focus on prenatal care providers, period.

Dr. Kus: That's good. I like that.

Dr. Puryear: Is that okay Mary?

Unknown Male Speaker: Mary did you like target?

Dr. Kus: And that's why do debate here.

Ms. Johnson: Okay, so we will go on to this. So you have the table, lays out all of the state statutes and regulations on storage and use. And I will -- if you see the asterisk there, the table is merely on state policies that refer to storage and use of information or test results only without specifically discussing specimens -- what is up with this.

State policies that refer to storage and use of information or test results only or without specifically discussing specimens and genetic privacy law is not included. I don't like how that's worded. But the intent is, we actually worked through this, Brad and I after, so thank you for helping me. But we worked through -- we want to be sure that people understand that if the policy merely says that you can store a specimen for 21 years, it's not included.

Only if it says how you can use that specimen in addition is it included. And this is no -- this is not intended to cover

genetic privacy laws that may apply. So we will reword that.

Dr. Skeels: If we know of others that you don't have listed do you want us to tell you later about those?

Ms. Johnson: That are on the table?

Dr. Skeels: Yeah, I mean you can add Oregon. We do have a law that relates to this.

Ms. Johnson: Now see this has happened to me with Oregon --

Dr. Skeels: Actually it's been on the books for a long time.

Ms. Johnson: -- with you before.

Dr. Skeels: It was brought forward by the Catholic Conference in the late 19 -- I think about the mid 1990's and it just says that you can't use these to do complete genetic testing of everyone. It actually relates directly to --

Ms. Johnson: Well is it -- now see are you talking about though the genetic privacy law?

Dr. Skeels: No, I'm talking about a rule in the newborn screening -- actually, it's a statute, part of the newborn screening statute. I'll tell you later about it.

Ms. Johnson: Okay. But I've read -- so I did read through all the newborn screening statutes. So I definitely would be interested. Yeah, and the regulations. And that's why I tend to, based on my experience at NCSL always put, at least. But

yeah, you'll always be foiled.

And as you can see there, there is a brief that was prepared for the IOM. And as an example of what happens, I read through all the statutes of regulations in late April and we read the brief in early May and sure enough, a bill that had passed one chamber of the Oklahoma legislature in that time, by the meeting had passed the other chamber and was signed by the Governor.

And since that meeting there's also been another new regulation in Indiana. So as of August 2010, and that was early August, state statutes or regulations were found in 19 states, and I'll discuss with you Oregon later, that discuss storage and use issues to some degree. And you have a list there of the states that I found.

And I'm sorry, I had said Indiana, it's Idaho in July 2010, these are some just recent changes that have occurred in the last three months, has a new regulation now that states, use is limited to routine calibration of newborn screening lab equipment and quality assurance. And for other uses, the express written consent of parent/guardian is required. The storage period is up to 18 months. And retesting a specimen in the event of a symptomatic diagnosis or death is permitted.

And another example of a recent change, the Governor signed a bill in May of this year in Oklahoma that a laboratory,

medical facility, hospital, or birthing place is prohibited from the unauthorized storage, transferring, use, or databasing of DNA of any newborn child without expressed parental consent.

There was actually already a regulation there that said that the health department had authority over storage and use of the form kits. So this really just changes it that there has to be parental consent to do so.

And I actually did confirm with the program there because I think it's interesting to note that this doesn't actually state newborn screening blood specimens in the text. So I went and called to be sure that was the intent was to address this.

I wanted to give some examples of some state websites on storage and use policies. Because we did add to the paper in the recommendations that people should be able to access these policies.

And if you want to take a look, maybe -- I don't know if I can click on it here at the Minnesota website, but they do layout newborn screening studies that have been done; no, it's not going to let me do it, and non-newborn screening studies. So they have a pretty informative page there. And then also in Texas there is information available on studies from dating back to 2001. So you may want to take a look at that as well.

And that, I believe, covers it.

Dr. Howell: Kelly has a comment.

Ms. Leight: Yes. If we could go back to the section about education. I just wanted to question as to -- question why the education's going to be focused on providers and not expectant parents? And that the primary target should indeed be the people who are going to be consenting or not consenting to storage and use.

Ms. Johnson: Well we have the --

Ms. Leight: Yeah, educational programs should focus on prenatal care providers and patients.

Ms. Johnson: There's a separate recommendation for -- let me read back for consumer education.

Ms. Leight: Okay, but that's not what it says in the section. So that's -- it's a little confusing.

Ms. Johnson: Okay.

Ms. Leight: Thank you.

Ms. Johnson: Thank you.

Dr. Howell: A general question and that is, is that you have gone through the public comments with a fine tooth comb. And are there any substantive comments from the major organizations such as the March of Dimes or the NIH, or the CDC that were felt not appropriate incorporating the document?

Ms. Johnson: I think the biggest issues would be what we've gone back to about whether there should be a model consent or dissent included in the paper. And I think --

Dr. Howell: And can you tell us the comments about that from the various agencies? What were the specific recommendations --

Ms. Johnson: Sure.

Dr. Howell: -- from the organizations?

Ms. Johnson: Sure I can hold on. I can bring them up right now. I can read them to you. Hold on just one second.

Dr. Howell: Many of the public comments that I read came from a similar geographic area --

Ms. Johnson: Right.

Dr. Howell: -- and were very similar in content.

Ms. Johnson: It would be -- so referring to consent and dissent?

Dr. Howell: Yes.

Ms. Johnson: It would be, these are from NIH. It would be helpful to provide a more complete discussion of opt in/opt out approaches to consent, discuss mechanisms to ensure privacy and confidentiality. They also make reference human subjects, further discussion of human subject regulations. But we thought that we did do that and had run this by OHRP.

And people would also benefit from the use of standard definitions and consistent terminology. We did at standard uses explanation, and we do have some definitions in there as far as types of information. It just said it would be a more

useful educational tool.

Dr. Puryear: I'm going to address the CDC comments before Roger talks.

Dr. Howell: And Michele is going to make some comments about the CDC.

Ms. Johnson: Right.

Dr. Puryear: We received CDC comments about three weeks before this meeting. Coleen is that about right?

Dr. Boyle: Yes.

Dr. Puryear: So we included in the briefing book and right after the briefing paper and I can go through them. One is to consider the IOM -- if you remember, the Committee had, or the Chair and the roundtable had encouraged the Institute of Medicine to conduct, hold a workshop on the use and storage of residual blood spots for translational research.

And this was an effort to have wide public comments received -- organizational, but more importantly public comments. We were interested in that, to have a forum for that. And it's out now, we have a -- in your supplement briefing package the pre-publication copy of the summary from the IOM workshop is included. Jeff Botkin actually was one of the editors.

I spoke with Alissa now before this presentation and said we should go through it and see if we can include some of the

parts from that workshop. I would like to include, for example, Anne Como's presentation gave a really detailed example of how she used residual blood spots to develop a test for SCID within the state.

We mention that, but the detail I think is in the workshop summary is good to include if everybody agrees. And we need to agree now for some of this stuff so that we don't have to come back in January.

CDC recommends that -- includes a recommendation that all newborn screening programs should have policies addressing the disposition, access and use of residual dried blood spot specimens as an urgent need for federal guidance. And through partnerships -- I'm going to skip over the entire statement from CDC.

Through partnerships CDC has partnered in formulating model menu best practice provisions for legislative aspects of other public health programs and could partner with stakeholders to develop the guidance and they were already included in the last recommendations so we thought we had addressed that recommendations. Coleen, if you don't think so, we need to hear now.

CDC also has extensive experience in producing and implementing health communication, education campaigns to inform the public. CDC would like to join HRSA and MCHB in this

effort. To provide this flexibility we suggest that specific references to funded agency in recommendation seven be deleted. We deleted it in the recommendation but we included -- we kept the explanation -- we didn't change the explanation.

Discussions of potential uses of residual dried blood spots specimens often lump activities that have a diverse set of issues. For example, the label research which can evoke concerns and privacy, particularly inappropriate disclosure of medical information may be applied to the use of dried blood specimens for program development and she's going through what we would consider standard program uses.

We thought we addressed this by actually defining what standard program uses are. More distinctly, by having that box and distinguishing between standard program uses, other uses, and research uses.

Dr. Boyle: So just one comment there Michele.

Dr. Puryear: Uhh-huh.

Dr. Boyle: And as I'm going through it on page 7.

Dr. Puryear: I can't go back and forth.

Dr. Boyle: Oh, sorry. But on page 7 where you have the uses, other uses. I thought it might be useful to say which ones could be done within the context of anonymized samples versus not. I mean because the examples that you actually give are those. I mean there's many uses of dried blood spots.

Dr. Howell: Coleen, we can't hear you clearly.

Dr. Boyle: I'm sorry.

Dr. Puryear: Yeah, can't hear you.

Dr. Boyle: I said there's many uses of dried blood spots that don't require identifying information. So that was really more -- it was the issue of the purpose for surveillance.

Ms. Johnson: Right.

Dr. Howell: That's a worthwhile comment.

Dr. Puryear: Okay, so you want us to do what to that?

Dr. Boyle: You could even just mention it as a sentence.

Ms. Johnson: Just point out that those activities can be done --

Dr. Boyle: Exactly.

Ms. Johnson: -- using anonymized.

Dr. Boyle: Exactly.

Ms. Johnson: Right, okay.

Dr. Puryear: And that's also I think the issue in comment number five from the CDC. So if we make that change to -- on page 7, will that help?

Dr. Boyle: Yes.

Dr. Puryear: Okay. And that's it from the CDC.

Ms. Johnson: Thanks Michele. I couldn't even find that in the briefing -- that big briefing book.

Dr. Howell: Yeah, any more comments from the -- this is

obviously a very important document. It's been percolating through the system for a very long time. And so I think that having gotten the public comments and so forth, and we want to be certain that people are comfortable with it but we need to get it out. We need to send it to the Secretary and we also would want to publish this obviously.

Roger.

Dr. Eaton: Thank you. My question may have just been addressed by Coleen's comment but I just want to be sure. The one thing that really jumped out to me as a surprise in the new changes was the listing of development of new tests as an other rather than a standard use. The use of anonymized residual blood specimens in the development and validation of new test, in my opinion, is a very standard use.

And if for some reason listing that as an other use had implications that interfered with the growth and development of new tests, I think that would be a concern. So I just wanted to point that out. But it could be that when you addressed this concept of anonymized that it was -- then my concern will be fine.

Dr. Howell: Are there further comments about the paper for Alissa?

Dr. Boyle: Can I just ask one further question? And this was on number four in the recommendation on page 25. And I'm

going to ask this of Jeff and Alan in terms of just our ethical, legal issues here.

When I read the actual recommendation, particularly the latter part of it, and I'll read it out loud for everybody. Is if residual blood specimens are to be available for any purpose other than the legally required newborn screening process for which they were obtained, all state newborn screening programs should document parents' wishes, awareness, and willingness to participate in compliance with federal research requirements.

And then the explanation, I guess the second part of that explanation, the second sentence, I mean maybe I'm missing the point here. It doesn't feel like it supports that, the latter part of that statement.

It says, once the use of residual newborn screening specimens moves beyond the state mandated and related standard program uses, each state should consider whether separate or blanket consent/dissent processes for approved studies is required from parents, legal guardians, or individual screened for the use of residual newborn screening specimens.

I feel like those say two very different things. And maybe I'm just not getting the last part of that recommendation, in compliance with federal research regulations or requirements. And maybe it's just me.

Dr. Puryear: Because federal research regulations wouldn't

always require consent if they're anonymized for example. If you go back to the briefing paper the Office of Human Research Protections actually defines when consent would actually be needed. And if your samples are anonymized -- that was one of their points they made to us in their earlier comments where they made those distinctions.

I think that's why the recommendation was written the way it was. Because it's a thoughtful process for the state to decide you know, is this a case where research should be -- I mean consent should be obtained. Or, after looking at federal regulations, do we need to obtain consent.

And even if federal regulations might not require, you know would it be politically best to go through a process of consent. So it becomes the individual state and/or researchers sort of weighing some of those issues in the context of what is required I think. That's why we worded it the way we did.

Dr. Boyle: Well if other people feel comfortable with it, I'm okay. It just feels a little bit --

Dr. Howell: Alan.

Dr. Fleischman: I think that both Coleen and Michele are correct.

[Laughter.]

Dr. Fleischman: In that we could word this better so that we could clarify --

Dr. Boyle: I hear what she's saying but it doesn't read that way to me.

Dr. Fleischman: -- because I think it can be read as Coleen is concerned. But it should be read as Michele has argued. So I think perhaps Jeff and I over lunch could quickly try to just fix that a little. I mean without changing the intent at all.

Dr. Puryear: Okay, thank you.

Dr. Boyle: That would be great.

Dr. Fleischman: Or if Jeff has already done it. Maybe he's got it done.

[Laughter.]

Dr. Botkin: Well quick comment. I think I see the problem and I do see this, the body of the recommendation itself is setting a higher standard then what the federal regulations require.

Dr. Fleischman: Right.

Dr. Botkin: And if we wish to do that, that's fine. But we should be aware that that's where this is going.

Dr. Puryear: It's to allow some -- because you may want to do that.

Dr. Fleischman: Right. I think what we need to do is craft language which says it must be consistent with federal research requirements at a minimum. It must consider whether or

not it's appropriate to document parents' wishes. And the state has the right to make that judgement. And an awareness and willingness to participate. I mean I think we -- we just need to craft the language so that the states will know that they have to be consistent, at a minimum, with the federal regulations, but they have the option then to discuss these concerns and adjudicate how they want to do that. Is that, Jeff, consistent with what you're saying?

Dr. Botkin: Yes.

Dr. Fleischman: So I mean I think that's where the clarification needs to occur.

Dr. Howell: Aside from this one point of clarification, is the Committee comfortable with this document as it now reads? Jeff you have additional comments?

Dr. Botkin: Well just real quick. One of the things I think the document does pretty well but the IOM roundtable does a little bit better is just talks about the benefits of research. And we're doing a study now talking to lots of folks around the country about this specific issue. And one of the striking outcomes so far is that members of the general public cannot describe what the benefits are of research.

They can tell you what the risks are, they can make stuff up and they come up with a list of risks. But they can't tell you what the benefits are. So I think having an opportunity to

really tell folks why this is important. And again, I think it's pretty good now so it's just a general comment. If there's ways to strengthen that a little bit --

Dr. Howell: Do you have specific suggestions of how to do that?

Dr. Botkin: Well and again I think IOM document is -- I think it's Anne Como's work there that's very impressive. So maybe just a reference or -- I don't have a specific recommendation so I apologize, it may be late in the game for that then.

Dr. Puryear: Well we just received the summary from the IOM. So that's what I said in the beginning when I spoke that Anne's comments in particular I thought we should try to incorporate because she gives some detailed examples of that state specifically used them. So I wanted -- I did want to -- if the Committee agrees, expand on that section using some of the specific comments from the IOM study, I mean workshop summary and reference that.

Dr. Howell: Well the NIH recommendations were quite specific in trying to emphasize the value of research in these -- with this material and so I think that --

Now do we have too many changes to vote on this at the current time? What's the sense of the group? Most of the changes I've heard are wording changes.

Denise.

Dr. Dougherty: Well I had one more question and I don't know if it was included in changes. So I guess the answer to your first question is yes, it would be nice for us to see the changes in a single document. But there was a recommendation that the Committee facilitate a dialogue among all the relevant stakeholders on this issue.

And I guess if I were the Secretary or the Secretary's staff, what I would be looking for is some outcome from that dialogue or some time frame around doing that so that the issues at least have a chance of being resolved to the extent that they can.

Dr. Puryear: Can you suggest changes to that specific recommendation, number seven?

Dr. Dougherty: Let me see. Do you know what page it's on?

Dr. Howell: It's on page 26.

Dr. Dougherty: Okay.

Dr. Howell: While Denise is contemplating her changes. Sharon, do you have a comment?

Ms. Terry: [Indicating.]

Dr. Howell: Okay.

Dr. Puryear: What if we add at the end, it says administrative support and funding should be provided to this Committee to facilitate this dialogue and develop this guidance.

This activity should be, because it's dependent on funding it's hard to put a time line. But we could say that reports should be delivered to the Secretary --

Dr. Dougherty: Within two years.

Dr. Puryear: -- within two years.

Dr. Dougherty: Yeah.

Dr. Puryear: Okay.

Dr. Howell: Okay.

Dr. Dougherty: But I thought there was another change that got rid of this request for funding and just said that the Committee should do it.

Ms. Johnson: It was reordered to make the request for funding not the focal point. To make the focal point that there should be a dialogue.

Dr. Dougherty: Okay.

Ms. Johnson: And then add the funding request after that. And that was just -- NIH thought it might be more --

Dr. Howell: We need to move this document along. And I guess the question is, does the Committee feel as Denise, that you would like to see the final wording of these? Are you comfortable that Alan and Jeff can make these changes and we can put the IOM stuff in there and you would be comfortable with that without seeing how it actually looks?

Gerry.

Dr. Vockley: I would. I think these are minor changes and they're word smithing only. They're not going to change the intent, we all agree on the intent.

Dr. Howell: Is the sentiment similar from the Committee?

Dr. Dougherty: I guess it would be nice. I agree, but it would be nice if when those changes are made we could at least an information copy.

Dr. Howell: Oh, well you clearly will. The bottom line, these are minor changes. They will incorporated some data form the really very nice IOM report that Adam, as we mentioned earlier, provided the Committee. And we'll make those changes, they're -- and Jeff and Alan will be able to make theirs promptly and the IOM stuff can be added and so forth.

Having heard that, there are two issues here. One is to send the report to the Secretary and the second is to have it published as a report of the Secretary and submitted likely to Genetics and Medicine.

Can we have a motion for the first part of that? And that is to accept this and send to the Secretary?

Dr. Vockley: So moved.

Dr. Buckley: Yes.

Dr. Howell: Gerry and Becky. Those favoring that say aye -- raise your hand. Any opposition?

[No audible response.]

Dr. Howell: And did anybody --

Dr. Boyle: Can I just ask a question.

Dr. Howell: Yes.

Dr. Boyle: Can we see it before it goes to the Secretary?

Dr. Puryear: Sure.

Dr. Howell: Sure.

Dr. Boyle: Okay, thank you.

Dr. Howell: Yeah it would -- I would think that these changes should be made promptly and they could sent to you electronically. And you'll have a very brief period -- one of the problems that when things go to you electronically, most people's email seems to be down for the month when you get it.

[Laughter.]

Dr. Howell: But anyway, if you have a comment it'll have to be done promptly and so forth, etcetera.

Dr. Bocchini: Just give a deadline --

Dr. Boyle: Yeah.

Dr. Bocchini: -- and basically -- one that basically says that if we don't hear from you in --

Dr. Howell: Within a week.

Dr. Bocchini: -- whatever time you need -- a week.

Dr. Howell: A week after you get the thing electronically.

Dr. Bocchini: We assume your consent.

Dr. Howell: We assume that you're comfortable with the

wording and so forth. So we've had a motion -- you've had a motion and a second to accept and send forward the Secretary, and I saw no opposition to that.

Now the second is to publish the document as a report from the Committee. Is there a motion for that?

Dr. Vockley: So moved.

Dr. Trotter: Second.

Dr. Howell: And those favoring it?

[Hands raised.]

Dr. Howell: Any opposition?

[No response.]

Dr. Howell: Any abstentions?

[No response.]

Dr. Howell: Thank you very much our --

Dr. Puryear: Can we ask --

Dr. Howell: -- we're delighted that this document is in English. It' been around so long that it might have been introduced in an ancient tongue.

[Laughter.]

Dr. Howell: But anyway, I think it's a good document and it will, I think it will very helpful in forwarding the dialogue and so forth.

Ms. Johnson: We did translate some Danish in this last round.

Dr. Howell: Oh, good. Excellent.

Dr. Puryear: On the phone.

Dr. Howell: Excellent. Ben Peterson's very good with his English. Michele has some burning issue.

Dr. Puryear: Sorry. Could Brad Therrell actually speak to the -- or actually Alan could, either one, to the workgroup's proposed design for this publication? Because it isn't going to be -- they're proposing not to have a duplication of the actual briefing paper sent forward to the Secretary. But to actually do some analysis of the recommendations. Right?

Dr. Therrell: We are?

Dr. Puryear: Well that's what --

Dr. Therrell: We work at the prerogative of the Committee. So the discussion had been with the Committee, with our working group writing something a little bit more condensed that would be more amenable to publication. But either way you want to go. I mean the group -- the working group, two members are here, Sharon and Alan on the group and then there's more of us in the audience. So whatever you want to do, we'll do.

Dr. Puryear: Well on the phone you had some specific recommendations. For instance, with the recommendations you wanted to do an analysis of why those recommendations were being put forward. That was Don Bailey's suggestion.

Dr. Therrell: Yeah, I don't recall that so -- but Don was

--

Dr. Puryear: It's in my notes.

Dr. Therrell: Don is happy to work with us and do whatever we want to do.

Dr. Howell: Here comes one of the historical workers on this document, Harry Hannon.

Dr. Hannon: Don's suggestion was that we take each of the recommendations and go back into the document and pull the information that supported those recommendations and the aspect of constructing a condensed document so that the reader could understand the information that went or contributed to the creation of each recommendation.

Dr. Therrell: So it's more of a formatting thing than it was an analysis.

Dr. Puryear: Well it's a content.

Dr. Howell: It is lunch time and let me make a comment about lunch and that is that those of you who remember having lunch in this hotel before, the audience went upstairs to the restaurant which overwhelmed the restaurant and folks did not get served before 3 in the afternoon.

[Laughter.]

Dr. Howell: So at the front desk they have a list of some of the area places nearby where you're more likely to get served briskly and get back for our 1 o'clock time frame.

So let's go to lunch and we'll start talking about CLIAC at 1 o'clock. Thank you.

[Whereupon, at 12:00 p.m., a lunch recess was taken.]