SECRETARY'S ADVISORY COMMITTEE
ON GENETICS, HEALTH AND SOCIETY

Twenty-First Meeting

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I N D E X

P R O C E E D I N G S

OPEN REMARKS

CHAIRMAN TEUTSCH: Good morning, everyone.

Yesterday we had a productive day and we're starting again early this morning. Hopefully, we will spare all of you more time in Washington than you bargained for and get everybody out safe and sound before too late today. So thanks, everyone for that.

We have several agenda items that we do need to cover this morning. We'll start with the gene patents. We'll have some public testimony and then we have a couple of important presentations from our companion committee and from the Office of the National Coordinator of Health Information Technology.

So, a bit to do.

I think, Rochelle, are you on the phone?

MS. DREYFUSS: Yes, I am.

CHAIRMAN TEUTSCH: And Mara I heard earlier. So I think we have a good quorum and we'll get going.

OVERVIEW OF REVISED SACGHS REPORT GENE PATENTS AND LICENCING PRACTICES AND THEIR IMPACT ON PANTIENT ACCESS TO GENETIC TETS

CHAIRMAN TEUTSCH: So we'll begin with a discussion of the gene patents and licensing reports. This was sent out to the committee in January so I hope that all of you have had a chance to review it.

Before we get into that I did want to let all of you know that we did have an opportunity to brief the Office of the Secretary, the U.S. Patent and Trademark Office, and the Office of Science and Technology Policy on the conclusions and recommendations on the revised report.

At our last meeting in October we voted on the recommendations individually and then collectively with a collective vote of 12 to one in favor. There was one abstention. We were advised to form a small subcommittee to work on the report to take care of a number of important issues. One of—and I want to go over those with you now because those represent the major changes that were in the report.

The subcommittee itself was composed

myself, Jim Evans, Gwen Darien, Rochelle, Sheila and Paul. I think I got everybody, right? That's the group.

And this group did an incredible amount of work since the October meeting. You will see that the report was substantially revised and a dissent was incorporated since we could not get to unanimity on all the issues.

But the major things that we were asked to do were to strengthen the rationale and conclusions. Paul had advised us that somehow we weren't—we had a lot of material in there but we had not pulled it all together as strongly and coherently as we did, so you'll see that the conclusions and rationale that precede the recommendation has been added.

Paul Wise advised us that the timing of the report was not as tight and coherent as it should be with our main agenda item to enhance patient access and the quality of tests that are available. So thanks to Paul W., who undertook the task of making sure that we got that framed properly, that was then done.

The body of the report was changed substantially, too. At the October meeting and really throughout the process we knew that there

were substantial differences of opinion, and that we needed to incorporate as many of those perspectives as possible in the report, and so this report was substantially revised to do that. And I have got to say that that was a product of the subcommittee but the subcommittee could not have done this without the unbelievable writing, re-writing and re-writing again of Darren Greninger and the staff.

So the report that you all have had a chance to review is substantially changed and, I think personally, substantially better than the report that you saw in October.

So that's where we are.

I must say that although there is a dissent here that people who worked on that dissent did us all a tremendous service because it helped sharpen the points that needed to be made though, as I said, we could not bridge all of the differences, and hence the dissent is there. I think we should recognize that without that prompting and prodding and pushing we would not have the report that we have today.

So I want to express thanks to the dissenters, particularly Sheila and Paul, but I also want to acknowledge the incredible work that the

other members of the subcommittee, particularly Gwen, Jim and Rochelle, did because I cannot tell you the number of calls, emails, nightmares that we have had over the last couple or three months to get all of this together.

So, the report is complete. It's here.

Our task this morning is to move it forward to the Secretary.

COMMITTEE DISCUSSION

CHAIRMAN TEUTSCH: With that, I will open it up for comments or motions on the draft report.

MS. SHEILA WALCOFF: Steve?

CHAIRMAN TEUTSCH: Yes, Sheila?

I just wanted to point out that you are the only one that I can tell that has a chocolate heart in front of you this morning.

(Laughter.)

And I'm wondering who came in early to put it there for all of your dedication and hard work on this because it certainly wasn't lost on me and I think on the rest of the folks that worked on this for years and years and years before I got here and then certainly in the last few months, and I just wanted to thank my colleagues on the committee for doing such a great job and working so hard because

it was an interesting process but I think one that it's a better place now and I'm the only commenter, and you can eat your chocolate.

I will move to close the report and move it forward.

CHAIRMAN TEUTSCH: All right.

MS. ASPINALL: This is Mara and I'm going to shorten this. While I was involved in the second part of the report—the second part of the report more intensively than the first part of the report and the initial piece. I believe the process was one that we came to was appropriate, effective, and we should move on to more important—the additional new work from the committee that will be important in the future, and look to have this as now a representative report of the majority of the committee and to have the dissenting opinion.

I am very much appropriately really want to thank Steve and Jim and Sheila and Paul, and everyone for the opportunity to have in their representation of the other perspective but I think the process itself was one that was critical to acknowledge.

DR. EVANS: I just want to second that in the—from the atmosphere of this love fest here—

I want to second what everybody has just said. I think that the--while difficult at times--the dissent and the emergence of some degree of controversy really did sharpen all of our thinking about this. And I think it shows how good the process can work; how well it can work; and I also do want to second what Sheila said and really give an incredible thanks to Steve who remained incredibly calm during all of this and was able to keep everybody's passions channeled in a productive way. So thank you, Steve.

And I want to thank Darren who was unbelievable.

CHAIRMAN TEUTSCH: Thank you, all of you. It was a group process for sure.

So we have a motion on the table and that is a motion to move the--basically to approve the report as it is so we can move forward to the Secretary. Is there any further discussion on that?

DR. : There will be more chocolate hearts at the end for everybody else.

(Laughter.)

CHAIRMAN TEUTSCH: There will be more than chocolate hearts.

MS. WALCOFF: I didn't know—

(Simultaneous discussion.)

MS ASPINALL: I was just thinking that he's the only one who didn't eat it yesterday.

(Laughter.)

MS WALCOFF: I ate yours, Mara.

MS ASPNINALL: Okay.

(Laughter.)

CHAIRMAN TEUTSCH: All right.

Hearing no one else, all those in favor of moving the report forward, please signify by raising your hand.

(A show of hands.)

MS. ASPINALL: Aye.

CHAIRMAN TEUTSCH: That's Mara.

How about you, Rochelle?

MS. DREYFUSS: Aye.

CHAIRMAN TEUTSCH: I think we have a unanimous vote of all of those who are here. So we will—

--approve the report to move forward and I again want to express my gratitude. This has been a long process. I think we've learned an incredible amount about the patents and licensing process, more than I ever imagined I would ever learn.

DR.EVANS: Or wanted to know really.

CHAIRMAN TEUTSCH: And I really want to thank the task force for all of its work again and for all of those of you who have spent an enormous amount of time and energy and really high level thinking to bring this to completion.

So thanks again to everyone.

UNKNOWN: Thank you.

CHAIRMAN TEUTSCH: All right. Terrific.

I am going to move to some public comments.

Oh,let me just say the process from here on the report. What happens now is that staff will do a copy edit without any substantive changes. Sarah is going to—because there has been a fair bit—a lot of interest in this report, Sarah is going to see whether we can post it on our website in advance of finalization but if any of you have any additional edits, not substantive comments but edits, so things that you need to wand in there, please get them to Sarah by February 10th.

So let’s move then to the public comment and we do this at each meeting. I’m delighted we can do it this morning. And we have two.

MS. CARR: One.

CHAIRMAN TEUTSCH: We have one and possibly a second person who expressed interest in speaking to us.

The first individual is Ashley Stephens with the Association of University Technology Managers.

Dr. Stephens?

Behind me, okay. Please, welcome.

PUBLIC COMMENTS

DR. STEPHENS: Thank you, members of the SACGHS, for providing this time for public comment.

I am Ashley Stevens and today I represent the 3,500 members of AUTM, the Association of University Technology Managers, as their president-elect.

I am also executive director of the Office of Technology Transfer at Boston University. Before entering the technology transfer profession I was a cofounder of GenMap, the first company founded specifically to work in genomics. I initiated the discussions with Eli Lily that led to Lily funding the cloning of the BRCA1 gene and Myriad Genetics spun off of my company to perform that work.

Then while I was at the Dana Farber Cancer Institute immediately afterwards, I managed the

HMPCC genes cloned by Dana Farber, Yale, the University of Vermont and the Oregon Health and Sciences University. I established the nonexclusive licensing program for these genes.

So I have been on both sides of this issue.

AUTM members manage and license innovations resulting from academic and nonprofit research. We make these innovations available to the public through commercial development and we are strongly committed to the advancement of science and ensuring that public funded innovations benefit the public.

I also remind the committee hat AUTM and some of its individual members submitted comments to SACGHS report during the public comment period last year and we continue to stand by these comments.

I would like to reiterate our appreciation for the great deal of research that accompanied the committee's report. The case studies provided were excellent and are a valuable addition to previous studies by the National Academy of Sciences, the Organization for Economic Cooperation and Development, and others that are cited in it.

Having been so intimately involved in all

aspects of the committee's first case study, the test for breast and colon cancer, I can personally attest to its accuracy. However, as scientists, we find it alarming however as scientists we find it alarming when there is no connection between these excellent research results and the policy options offered in the report. The policy options address the potential problems that the committee's studies and studies by others show are no longer issues.

With regard to the recommendations made at this committee's October 2009 meeting I'll spend my remaining time on one issue in particular. Our primary concern lies with supporting the creation of exemptions from infringement liability.

Intellectual property protection has been a crucial element of American innovation since the drafting of the constitution in which the rights to both patents and copyrights are enshrined.

Today corporations are motivated to invest in nascent technologies because novel technologies are protected.

When corporation license technologies from universities, technologies that are normally truly nascent, they make significant investments in product development and their clinical trials, and

often get close to final production, only to have the product fail. Time and again corporations will take and suffer this risk.

If we weaken the protection for novel technologies we also weaken the potential for commercial development of those technologies. This will result in significant delays and fewer products reaching the public. Fewer jobs will be created in the companies supplying these products.

The data in the reports I listed demonstrate the success our universities have had in partnering with corporations to get innovations to market. Remember, neither universities nor scientists commercialize their research, companies do. Whether this is through established companies or start up companies especially formed to develop a new technology, protection from infringement is vital to justifying the investment risk involved in developing new technologies.

Without this protection, companies can't and won't take that risk. The United States cannot afford to take this risk either. Without strong patent protection, jobs won’t be created at existing companies and new start up companies won’t be formed to commercialize these technologies.

This recommendation would decrease the amount of taxpayer supported science that reaches the public. Since the goal of this committee is to improve, not impede, the delivery science to the public, we ask that you consider the unintended consequences of this recommendation. Licensees will evaporate and university technologies will again sit on the shelf much as they did the pre-Bayh-Dole era when academic technologies were only licensed nonexclusively.

The last time a proposal was made to amend patent laws as they apply to human genes, the infamous 200-word statement issued by President Clinton and Prime Minister Blair on March the 10th, 2010, as the successful conclusion of the genome initiative was in sight, it started a secular decline in the biotechnology industry's capital markets that has not been reversed to this day, despite their remarks being retracted almost immediately.

AUTM supports continued research on the impact of gene patents and an advisory board on the health impact of gene patenting and licensing practices. AUTM remains committed to partnering with the American College of Medical Genetics and

the Association of American Medical Colleges to develop successful practices that reflect our collective learnings from the 20 years of the genetics revolution.

AUTM would also be pleased to participate in research efforts and any advisory boards created or deemed necessary by the Secretary.

Thank you for your time.

CHAIRMAN TEUTSCH: Thank you, Dr. Stephens. We really appreciate AUTM's input. I know this has been an area of a lot of controversy but we do very much appreciate the input of AUTM and various members of your organization.

DR. STEPHENS: Thank you.

CHAIRMAN TEUTSCH: Thank you.

Dr. Trampage, Albert Trampage is the other name I had.

Is there anyone else who wanted to make a public—yes, ma'am?

DR. CAPESI: My name is Christina Capesi from Duke University, Center for Genome Ethics, Law and Policy. We worked on the case studies.

I would like to say this morning that point two of the nine points, the Nuffield Council, the OECD guidelines and the NIH best practices all

address diagnostic licensing. The nine points are most explicit and precise.

It notes that exclusives should be reserved for when they promote getting a test available.

In our case studies there were seven clinical conditions in which exclusive or restrictive licensing came up as a problem, HFE, APOE, BRCA, STA, Canavan, Long QT and hearing loss. It was not reported as a problem for colon cancer, cystic fibrosis or Tay Sachs, all of which were patented but none of which was exclusively licensed.

In five of those problem cases the patents are held by academic institutions. Of the other two problem cases, BRCA patents are jointly assigned to a university, NIH and Myriad. In HFE the patent was assigned to Mercader and two subsequent private companies. Of those academic institutions doing exclusive licensing, only one, Duke, for APOE, has signed on to the nine points as of one month ago. Minnesota, Utah, Baylor, Hopkins, Institut Pasteur have not signed on and have exclusively licensed method or sequence patents identified as having been raised to shut down testing labs.

In no case did the exclusive licensee introduce a genetic test that was not already available. So exclusive rights did not lead to new availability of testing for any condition we studied. In HFE, APOE, Long QT and BRCA, it is quite clear that others were already on the market when the exclusive license entered it.

In the case of Long QT there was a year-and-a-half period where there was no test available from a CLIA certified lab because DNA Sciences sent cease and desist letters which led to market withdrawal but never got their test on the market.

In the Evan Overall (ph) study in *Nature Genetics* there were blocking patents in 15 of 22 clinical conditions. Two-thirds of the patents studied were from academic institutions. The two largest being Baylor and Hopkins, which, as noted, have not signed on to nine points.

Exclusive licensing has not stopped. Hopkins and Myriad announced exclusive licensing of PALB2 testing for familial pancreatic cancer testing several weeks after the draft SACGHS recommendations were approved and after AUTM’s public comment that SACGHS recommendations were based on practices that are no longer prevalent. Moreover, Ambry already

offered full gene sequencing that would include the relevant mutations the day the deal was announced. So it simply cannot be the case that exclusive rights were needed to get the test on the market. The Hopkins license deal is, therefore, unequivocally a deviation from the nine points.

In sum, it appears that most of the academic research institutions that have exclusively licensed for diagnostics have not endorsed nine points. Exclusive licensing is continuing and several papers have pointed out that in the majority of clinical conditions studied these are problems with exclusive licensing that will only get worse with a multi-allele testing and full genome sequencing.

Thank you for your time.

GOODBYE AWARDS

CHAIRMAN TEUTSCH: Thank you very much.

Are there other public comments?

If not, I would like to move on to actually one of the sadder parts of this task, and that is the time we have to say good-bye to dear friends.

So, first, we say aloha to Sylvia Mann Au, who has been--preceded me here on this panel and she

has been a sunny part of this group all along. She has provided us wise counsel, involved in--I can't imagine—you were involved in virtually all of our panels in one way—

She missed Gene Patents, I think.

(Laughter.)

Oh, you were on that, too, weren't you?

DR. AU : (Not at microphone.)

CHAIRMAN TEUTSCH: Yes. That's one of the problems when you come from Hawaii.

But she chaired our task force on DTC genetic testing. She served on patents, genetics education, clinical utility and comparative effectiveness, and the policy issues surrounding the large population cohort study of genes, environment and disease. So, you have been there and you are not escaping now.

As she knows, we will continue to call on her as we do call on former members. We also won't forget that she initiated the well-appreciated practice of bringing macadamia nuts covered with chocolate to each of the meetings but I understand that you have passed the baton and Adam is taking on that task for which I want you to know we are also appreciative.

And so, Sylvia, we'll bid you adieu, and we have a certificate, for you, of appreciation.

(Applause.)

CHAIRMAN TEUTSCH: There's no check.

The other member of our committee who we'll be losing is not here today. I hope he is watching over the Webinar because this meeting is actually occurring at a good time for him. He's in Melbourne, Australia, and that's Julio Lucinia. Julio, as I said, Julio has moved to Australia so he is not here today but he provided us wise guidance all the way along. He's a researcher, teacher, author and clinician extraordinaire. He has provided us insightful comments that were on target, down to earth, practical, and he has always been a voice of reason in our discussions. He served on task forces on policy issues, the large population study cohort, and pharmacogenomics, as well as the DTC testing.

So, Julio, if you are listening, we wish you well. We will call on you as well. And we thank you for all your service.

We have a certificate for you but that will be coming by mail. Unfortunately, they did not allow me to deliver that in person.

So, thank you, Julio; all the best.

All right. So let me move on. We have a couple other reports.

Is Dr. Hunt here?

Oh, good. That was Rodney.

Dr. Hunt isn't here yet, is he?

So, Dr. Howell, we'd like to go ahead then and proceed with that.

Dr. Rodney Howell chairs our companion committee, the Advisory Committee on Heritable Disorders in Newborn and Children. We have had the pleasure be of his visit here on prior occasions and I was delighted to see him here.

He is going to brief us about his committee's efforts to develop a national policy recommendation for retention and use of residual dried blood spots after newborn screening and is also going to talk to us about a proposal for a joint ACHDNC and SACGHS task force on carrier screening, which they've given a great deal of thought to.

So, Rod, thank you very much.

ACHDNC EFFORTS TO DEVELOP NATIONAL POLICY RECOMMENDATIONS FOR THE RETENTION AND USE OF RESIDUAL DRIED BLOOD SPOT SPECIMENS AFTER NEWBORN SCREENING AND PROPOSAL FOR A JOINT ACHDNC-SACGHS TASK FORCE ON CARRIER SCREENING

DR. RODNEY HOWELL: Steve, thank you very much.

(Slide.)

And I do have two areas to comment about but I will be mercifully brief and will appreciate any questions you have.

I think that most of the people in the room are aware of the fact that there has been considerable discussion in recent months during the past year about what happens to the dried blood spots once newborn screening is completed. We won't go into the details of how those are handled but, suffice it to say, that most states retain these dried blood spots, some indefinitely, and some states, such as California, have literally millions of these spots on hand.

They have historically been used for quality assurance programs and importantly they have been used when a new test is to be developed. If

one has a new enzyme assay, such as for Krabbe disease that you would like to develop, what has historically happened is those spots that are stored in their own hand are anonymized, they're run through the lab so you can get the test working before you actually introduce it.

(Slide.)

In view of the fact that there has not been any national policy on the storage and retention of residual blood spots, our committee has been looking at this and has drafted a document, and it's still very much in preparation, and I will comment to you about what our committee has thought about it. And, again, I will simply go through this briefly to show you what our bullet recommendations are.

(Slide.)

One is that we feel that all state newborn screening programs should have a policy in place that has been reviewed by the state attorney general or appropriate legal authority addressing the disposition of these dried blood spots remaining after newborn screening.

I might point out some of these recommendations you will say, well, gosh, that seems

like a very simple recommendation but let me point out that very few states have these recommendations.

(Slide.)

We also feel the state newborn screening program should have a policy in place that has been reviewed by the state attorney general or other legal authority that specifies who may access these dried blood spots, and once they arrive at the state newborn screening laboratory and further access as the newborn screening is completed.

(Slide.)

And important one is that we feel that the state newborn screening program should work to ensure that families receiving prenatal care are educated about newborn screening. Although newborn screening is done on 4.3 million babies in this country, it is amazing how few parents really understand about newborn screening and it's not uncommon to find families that do not know that their baby has been screened. And so we think the newborn screening program should maintain and distribute education and culturally appropriate information that includes basic information about the potential use for dried blood spots.

(Slide.)

And I think that one of the issues that has come up in the storing of these samples, and some of the families have been concerned about this, is that they learn after the fact that certain things have been done, such as QA things that they didn't know were going on. And so I think informing the families is important.

(Slide.)

If the spots are to be available for any other purposes other than the legally required screening process for which they were obtained, an indication of the parent’s awareness and willingness to participate should exist in compliance with federal research requirements. In other words, if the spots are to be used for true original research, we feel that that should not be done unless the persons are aware of that and have agreed.

(Slide.)

We also feel that the Secretary of HHS should provide administrative support in funding for the state program to develop model consent and dissent procedures for the residual dried blood spots, national data on the utility of any additional consent or dissent processes, model

educational programs for the general public, and educational materials for the use of such programs with facts about potential use of residual newborn screening both for consumers and prenatal healthcare providers.

(Slide.)

It is very important when one is doing newborn screening to have a process in place that will permit normal newborn screening to go forward and that you don't have to become encumbered with an informed consent process that would impair ordinary newborn screening.

(Slide.)

Now, I might point out that this draft report has been sent around fairly broadly and the committee has gotten a variety of comments back, and we would anticipate that this committee--your committee would want to comment about this formally in the future.

The NIH group made a variety of comments that our group felt were very worthwhile. The NIH urged the committee to become an advocate for research on these spots, setting forth recommendations for the states to consider, and the committee proposed voluntary national standards for

broad research use that each state could consider.

(Slide.)

Again, recommend that Secretary provide resources to facilitate the national dialogue with relevant stakeholders, and incorporate fuller discussion of the education in the two audiences, and we have incorporated that already in some, consider the potential benefit of suggesting the creation of a National Repository for Blood Spots into which parents could voluntarily opt their children.

Let me comment about what that means. Let’s assume that you live in a state that does not retain the spots at all. In other words, after the immediate newborn screening program is done the states will voluntarily discard all the samples. Some states do that simply because they don't want to deal with the legal aspects that have to do with retention. The NIH has suggested, and I certainly personally agree with it, there ought to be a mechanism whereby you could say, well, I would like my baby's spot to be retained because there are a variety of issues, which we won't go into today, but these spots have be extremely valuable in a variety of circumstances, sometimes many years later. And

so some families who are well-informed would want their baby's spot saved and we think there should be a place that that could be done.

(Slide.)

The NIH committee--there was a pre-discussion that some of the recommendations that were actually incorporated into the document that was reviewed, and that added some ethical/legal issues. The ownership of these spots, who owns these spots, and simply case law was added. And as far as privacy concerns, we accepted the formal comments from the Office of Civil Rights that had commented on the document.

We also wanted--we added already awareness and education, and the role of providing education to parents, and so forth in the prenatal setting was added.

(Slide.)

We are working with the Office of Research Policy to put comments into the paper and add text boxes explaining what anonymized, unidentified and link identifiers are to these spots and how they might be used and how they are de-identified.

(Slide.)

But, fundamentally, I simply wanted to

apprise you of the fact that this draft paper is coming along. We have gotten a variety of comments back on the paper and we would look forward to hearing from this group.

(Slide.)

The public controversy over the retention of these spots, we think, is a very critical area because if parents and so forth become extremely concerned about how the spots are handled, the newborn screening program could be jeopardized because folks would be concerned about how the spots are retained and opt-out procedures could be a major problem in that area.

I would be glad to answer any questions or comments. I'm sure some of you have seen articles in the paper about this but I have gone over this very hastily and I realize you might have more questions.

Yes?

DR. BILLINGS: Rodney, is the committee going to take a position on the--given the fact that some of the collected samples that have been retained were not consented in a traditional sense, whether the currently saved samples should be retained under some exemption from go-forward rules

about how you will consent these things going forward?

DR. HOWELL: Let me comment about the samples that are currently saved. At the current time there are very few samples that have been stored that have been stored with consent. Very, very few states have a consent process. Virtually all states have an opt-out but not all states have opt-out procedures and so forth. So the samples that are on hand have not been consented and so forth.

I think that the committee will make a recommendation about what might happen with those spots. In other words, what would be appropriate for those spots to be used for. And I think it basically will point out that they have a variety of uses and so forth that if you were to use them for research I think the committee will make a recommendation that that would not be an appropriate use of a non-consented sample.

Let me--I won't go into great details about it but, for those of you who are not in this business, what are some of the things that have been done with these tried blood spots.

One of the more common uses that provide a

great deal of value is with children who die suddenly without a known cause and the so-called metabolic autopsy has been done with some frequency.

In other words, the dried blood spot would be sent to a laboratory after a child dies at age three or four and the child has been discovered to have, for example, medium chain Acyl-Dehydrogenase deficiency, so a metabolic autopsy.

They have also been used for identification of children who have been lost in fires and things of that nature, and so forth. They have routinely not been used in any legal thing.

I would assume that you understand that lots of people are interested in these spots. For example, the police would like to get them and things of that nature. And they historically have not been available at all. However, a court can order a spot to be released but that's a legal issue, and so forth, et cetera.

But—yes?

MS. ASPINALL: This is Mara. I just have a quick question about that. Does that mean that despite the fact that in this repository they will be de-identified, that if an individual family has a

need to retrieve the information from their spot in the future to make a health-related decision for the child, they will indeed be able to do that more effectively? And I know there have been many discussions but in several states today, while that, in theory, exists, has not been practical in reality.

DR. HOWELL: The spots, by and large, are identified when they stored in the state. In other words, the identification is known only to the state laboratory, et cetera, but they are identified at the state level. However, they are not released to anybody in an identified fashion and so forth, et cetera.

Let me point out one of the--the public, interestingly enough, is very concerned about these spots for reason that really come down to lack of information about genetics. Some--there's one advocate for destroying these spots who is convinced that you can do something quite remarkable with it and that you could take a dried blood spot and just out of the blue identify someone, and of course you can't do that.

The second thing they are concerned about, you know, if you have my DNA you can do evil things,

ranging from cloning on down.

So the perception of what you can do with these is really a very, very interesting problem.

CHAIRMAN TEUTSCH: So we sent out the draft report to all members of this committee.

DR. HOWELL: Yes.

CHAIRMAN TEUTSCH: I don’t know if you received comments from folks but we’d obviously be interested in addressing—you’ll be sending the next one out for public comment—

DR. HOWELL: Yes.

CHAIRMAN TEUTSCH: --after you’ve done your revision.

DR. HOWELL: Yes. And we would greatly appreciate people's comments because this is an extremely important document about recommendations to the states so the states do have some organized method of handling these.

CHAIRMAN TEUTSCH: Do you know the time frame when that report will be out? Because the problem with us the last time was we didn't convene again so it was hard to get a group.

DR. HOWELL: We would probably some modifications from our previous meeting taking into account the report—the comments we had and that

should be out certainly within the month.

CHAIRMAN TEUTSCH: Within the month.

So you're talking about between March and April having—

DR. HOWELL: Yes.

CHAIRMAN TEUTSCH: --comments.

DR. HOWELL: It should be. And we will provide that to Sarah to distribute if you would like.

CHAIRMAN TEUTSCH: Yes. I am thinking more about the process that we have because we will not be convening over that timeframe.

DR. HOWELL: Yes, right.

CHAIRMAN TEUTSCH: But we will definitely get it out to individuals.

DR. HOWELL: This process is not going to be an immediate one so I think that you probably will have time to be very thoughtful in your comments and so forth.

CHAIRMAN TEUTSCH: So if we actually discuss this at our June meeting that would still be timely?

DR. HOWELL: Yes.

CHAIRMAN TEUTSCH: That would be helpful. That's—

DR. HOWELL: Let me make one comment that I want to be very clear. These non-consented spots have in virtually no circumstance that I'm aware of, and I'm really aware of most things that have happened, been used for research. And it has to do with what people consider research. For example, if I am running a laboratory and I'm setting up a new test and I use the anonymized blood spots, we would consider that laboratory quality assurance and quality control not research. In other words, you are simply establishing a technology to use these spots and that's the overwhelming use that these spots have been made.

DR. BILLINGS: Will the document be explicit about this problem with the potential use of these spots for forensic purposes and the threat to the newborn screening program that you commented on?

DR. HOWELL: I think that we will certainly try to incorporate that and so forth.

The newborn screening—the reason it has ordinarily been mandated by the states is as a mandate it does not require consent, and so that's the history that we come against. However, increasingly states are asking people if they would

be interested in having their sample be used for certain kinds of research, et cetera. And so I think that we will have model documents of that so that they can be available for things that come to the table.

CHAIRMAN TEUSCH: I just want to return—so what I'm hearing from Rod is we will have a chance to comment. I'd like to form a little group that can take the report that should be out here in the next month or so and comment on it so that we can then discuss it in June and then decide, you know, collectively how we might wish to respond. Obviously people can do that individually as well. So who would be interested in doing that?

Everybody!

MS. ASPINALL: I will.

CHAIRMAN TEUTSCH: I've got Mara, Paul, Janice, Alberto, Paul, Andrea, David. My god. Wow!

(Laughter.)

MS. ASPINAL: Wow!

CHAIRMAN TEUTSCH: I'll tell you folks—

UNKNOWN: How about those that don't want to be on raise their hands.

(Laughter.)

CHAIRMAN TEUTSCH: Wow! Hey, I think you—

Rod, do you want to take over this committee?

(Laughter.)

DR. HOWELL: Wait until we get to the next subject.

CHAIRMAN TEUTSCH: Did you get all of those people because we've got Charmaine, and Muin, and Paul, David, Andrea, Adam, Alberto, Janice, Paul and Mara, I think.

MS. ASPINALL: Is that your definition—Steve, is that your definition of small?

(Laughter.)

CHAIRMAN TEUTSCH: Yes, I was going to say—all right. Rod, why don't you tell us about the carrier screen?

DR. HOWELL: Let me go back and make one final comment, and that is that there have been a variety of studies done about parents' perception about these spots, and so forth. And the basic issue is that when folks have been concerned, they have been concerned because they didn't understand what might be done. And, as a corollary, to that if you explain that these spots are saved and they're retained for quality assurance, the vast majority of people are perfectly comfortable with that.

And if you are doing straight out real

research on the spots people would want to be asked. I think that's totally appropriate.

And the situation that has really been a problem is one of information.

(Slide.)

I want to talk just briefly about carrier screening with you. Our committee has focused very heavily on newborn screening but the charge to our committee is broader than that, and would include genetic testing in children for other purposes.

There has been a considerable discussion among members of our group at the NIH and otherwise about carrier screening has been going on for a very long time with certain genetic conditions among the Ashkenazi Jewish community, for cystic fibrosis as a recommendation that it made be available after an NIH consensus conference about a decade ago, and there has been considerable interest among certain people that carrier screening be adopted for spinal muscular atrophy, and there was a conference at the NIH sponsored by several institutes in the past year looking at carrier screening broadly but, more specifically, at spinal muscular atrophy.

(Slide.)

Our committee has been interested in

looking at some of the issues and there's been a very specific issue that has been brought to our committee that I would like to tell you about very briefly that has to do with carrier screening for sickle cell disease.

(Slide.)

In newborn screening all states for many years have screened for the hemoglobinopathies. And as a part of the newborn screening for hemoglobinopathies one identifies carriers for sickle cell disease. They are routinely identified. And states have handled this in a very different way. Some states do nothing with it. Some states have a rather formal mechanism of informing people that an infant has been identified as a carrier for a hemoglobinopathy.

I don't know whether it has changed but one of the more interesting systems that I have been aware of is that which used to exist, and probably still does, in Georgia. They send a letter out that says we have information that might interest you and, if you are interested, call us. And so about half the people do call and say, “What do you know that I would like to know,” and it has to do with carrier screening.

But at our recent meeting we had a very nice presentation by Lynetta Jordan, and I am using her slides this morning. Dr. Jordan is the chief medical officer of the Sickle Cell Disease Association of America. And the question she addressed that had been brought to our committee had to do with carrier screening for sickle cell disease. Now, one might say, “Well, goodness, you already screen all people with sickle cell disease.” But the point is that, number one, most people don't know about it and, if they did know, they forget so, by the time you get to the young adult that we’re going to be talking about this morning, you don't know.

(Slide.)

Now, I might point out that virtually all babies have been screened for hemoglobinopathies for more than a decade and I might point out this is a very effective program. In other words, if you identify an infant with sickle cell disease you can be very effective with lifesaving vaccinations against bacterial meningitis, and so forth. And as I said, states have been very variable in how they report carrier status.

And, of course, there has been a very--

lack of agreement about clinical evidence of health risk of being a carrier for sickle cell disease.

(Slide.)

And this is a timeline, is that the--in 2007 there was discussion among athletic groups about the fact that carriers for sickle cell disease might be at increased risk for certain sudden death in extreme exercise. The Sickle Cell Disease of America Group met in June of 2008 and did not support a recommendation that would have athletes be screened. However, in June of 2009 the NCAA, which is a very important athletic organization in this country as those of you who are in athletics know, they made a specific recommendation that institutions test student athletes for carrier state for sickle cell disease. And that particular problem came to our committee.

A variety of people have been asked to comment about that and there was a commentary in AAP news and in December of 2009 the Sickle Cell Disease Association of America, the NIH, HRSA and others had a meeting on the public health implications of sickle cell trait.

(Slide.)

Let me tell you some--there fortunately is

a considerable amount of data about relative risk of having carrier state of sickle cell disease and the big data come from the military. And they did a retrospective analysis of two million military recruits, a big number, needless to say, and they discovered that African-American recruits with hemoglobin S trait, there were 13 deaths during that period of time, and African-Americans and other recruits with no carrier state had five deaths, indicating there was a considerable difference in the relative risk between these two groups.

However, there was an intervention period brought to bear, again with 1.8 million troops going forth, and basically what was done is they developed a strict protocol to prevent exercise health injury and illness, and so forth. And, interestingly, during that period of time by simply--by having a very—and, again, I don't remember the details of this but this was basically a very specific requirement about fluids and exercise, and so forth. And during that period of time not one of the 13 predicted deaths occurred. So basically the prevention of exercise related death did not require identification of sickle cell trait, such as prevention, et cetera. They concluded, quite

properly, that heat illnesses, as preventable factor, contributed to sudden exercise related death in persons with sickle cell disease.

(Slide.)

And so, fundamentally, the evidence does support that sickle cell trait is increased risk for exertional health illness. However, it does not exclude military personnel in any of the branches listed and very simple preventive methods can be used to prevent this illness.

(Slide.)

Now, what would be the implications of the NCAA recommendation? Number one, there are 400,000 college athletes, eight million high school athletes, Sickle DACS, which is a simple screening test, is not appropriate. It’s not reliable. So you would need to do a hemoglobin electrophoresis on that and it would cost $20 million for the college and $400 million for the high school. So a recommendation of this nature, if it were indeed carried out, is a big and very expensive procedure.

(Slide.)

Now, that was a presentation that we had from Dr. Jordan. And it would appear—I mean obviously there's tremendous concern about screening

high school—among our group about screening high school athletes for sickle cell disease because you would not only identify persons with the condition, you would obviously single out carriers. And I might point out, as this group knows; you are looking at a very significant portion of African-American athletes who would be earmarked as having a special problem and being in a special program.

And our group is just in the early parts of discussing this but it would seem prudent to say that this is probably not a very good recommendation and what you should do is come up with a very sensible program as far as high school athletes.

(Slide.)

Now, the reason—I had two reasons for wanting to present that. As we think about carrier screening and so forth, and we are in the very early phases, I have talked—we have with Steve and with Sarah briefly—is that we think it would be profitable for members, a group from our committee to work with a group from your committee because there are very broad implications as far as legal/ethical issues and so forth when you look at carrier screening of a population of this nature. So I would really invite your interest in

considering some of these issues as we go forth, and we are really literally just starting.

In order to get you out of the snow this morning--I had some other slides which you will be glad I deleted but one of the things I assume that many of you know is that while we were starting to consider this issue the announcement by Counsyl, which is a group in Redwood City, California, was made where they're offering direct to the consumer carrier screening for 100 conditions, and they are quite aggressively advertising that. So carrier screening is emerging as a very big deal.

If you look at the diseases on the Counsyl carrier screening list it will give you hives because I don't know—I mean some of the conditions are breathtakingly rare and so forth but if you have not seen the website I urge you to look at it. It's C-o-u-n-s-y-l. And I urge you to look at the conditions on their screening panel but, again, they are advertising it directly to the public and you get the information yourself.

So we think that the carrier screening issue is becoming a big issue and we would invite you to--I would hope that you would have some interest in having a group work with some group from

our committee to think about these issues.

Thank you.

CHAIRMAN TEUTSCH: Great.

Jim, you had a comment?

DR. EVANS: Yes. Those are fascinating data about sickle cell disease and I just want to be clear. In the intervention was that applied across the board?

DR. HOWELL: Yes.

DR. EVANS: Okay. So—and you said the 13 expected deaths were prevented. Were the five expected deaths prevented in the non-sickle carrier group as well?

DR. HOWELL: I don't know. These are Lynetta’s slides as I told you.

DR.EVANS: Yes, this is fascinating.

DR. HOWELL: But the—I think that one of the problems in the data that has been presented is that high school athletes—and you read in the paper all the time that a very attractive high school athlete died suddenly. I mean you see this all the time.

DR. EVANS: Right.

DR. HOWELL: And one of the things that we don't know, and they tend to identify an African-

American who is a carrier or something, but we don't know about someone else who died—

DR. EVANS: Right.

DR. HOWELL: --who did not carry the traits.

DR. EVANS: Right.

DR. HOWELL: So—

DR. EVANS: And like you say, across the board sensible interventions would probably benefit everyone.

DR. HOWELL: It would. It would—and these are not remarkable interventions. They are simply limiting exercise when the temperature is above 120 and providing adequate water and so forth. They are very simple.

(Simultaneous discussion.)

DR. HOWELL: Only in Tucson where the temperature at times—

CHAIRMAN TEUTSCH: Charmaine?

DR. ROYAL: Rod, I just really wanted to support the importance of that. At Duke I work with the Sickle Cell Center there and they have been approached by the athletic department about this recommendation by the NCAA and the issues that it raises. So it's something they are talking about as

well.

DR. HOWELL: It's—so many people with sickle cell disease and the other people are being contacted around the country, and we think that such a policy has just enormous implications and we think we should move fairly briskly to comment about that.

I might point out that this is a matter of public record but one of our distinguished members of our committee happens to be a distinguished pediatric hematologist and he was to be on the Olympic team for Ghana when he was a student at Yale University. And since the Olympic Games were in Mexico City at the time, they screened him because of altitude issues for the presence or carrier state of sickle cell disease, and he learned at that time he carried sickle cell, that he is a carrier for sickle cell disease. It turned out that he was not barred from the games because he carried sickle cell disease but because Ghana dropped out of the games because of the participation of the apartheid state of South Africa but it was very interesting. Needless to say our committee benefits from somebody who not only is an expert hematologist but has a very personal stake in this game.

CHAIRMAN TEUTSCH: So what I would like to

do is just get a sense of this group.

Rod and his colleagues are going to try to move this agenda forward and come up with a proposal.

What I would like to do is get a sense as to whether folks here would like to be part of that process so that we can take this up in some joint way, yet to be determined, along with Rod's committee.

I say that because I can never remember all the initials, Rod.

(Laughter.)

So general—I see nods around the table.

So, Rod, my sense is that you and your colleagues will look at how that might proceed.

DR. HOWELL: Yes.

CHAIRMAN TEUTSCH: And then in June we will have a chance to—

CHAIRMAN TEUTSCH: No, we won't form a group now. We will wait. Rod will come up with a proposal. We'll hear about it in June and then proceed. We'll discuss that and then proceed to formulate a group presumably.

DR. HOWELL: But I think this is a very interesting and highly relevant discussion. It's

not theoretical but a very practical discussion.

CHAIRMAN TEUTSCH: It's very practical, relevant and—

DR. HOWELL: And as Charmaine mentioned, people are calling about it.

CHAIRMAN TEUTSCH: And overlaps clearly with the interest of both groups.

DR. HOWELL: Yes.

CHAIRMAN TEUTSCH: So thank you so much.

DR. HOWELL: And we appreciate your interest.

CHAIRMAN TEUTSCH: Thank you.

That's terrific.

I believe Dr. Hunt is here now. Is that correct?

CHAIRMAN TEUTSCH: Oh, right behind me. Okay. Great.

Dr. Hunt is here from the Office of the National Coordinator for Health Information Technology and he's in the Office of the Health Information Technology Adoption.

As you know, we heard from Dr. Blumenthal, I believe at our last meeting—

MS. CARR: June.

CHAIRMAN TEUTSCH: In the June meeting and

we provided some comments at that time.

Since then, the proposed regulations on the meaningful use of electronic health records have been disseminated and so we are going to hear an update about the process from Dr. Hunt and then what we will need from this group is to see how we might respond.

So, Dr. Hunt, thank you so much for joining us. If you had been here yesterday, you would have heard keen interest in this topic. There has continued to be--it has been a topic of high interest actually for many years.

So thank you for joining us.

OFFICE OF THE NATIONAL COORDINATOR FOR HEALTH INFORMATION TECHNOLOGY

DR. HUNT: Oh, thank you.

I am thrilled to be here and first I have to give my sincere apologies for running late. As most of you in the area and some of you who aren't from the area know, the mid Atlantic region--we are the official weather weenies of the entire country.

(Laughter.)

So, unfortunately, the red line of the Metro was having their pre-apocalyptic apoplexy--

(Laughter.)

--this morning so I was later than I expected.

CHAIRMAN TEUTSCH: Well, we should say that we have made it particularly difficult for Dr. Hunt. We have moved him all around the schedule and he has been extraordinary in his willingness to adapt to our weather and other challenges.

Thank you.

DR. HUNT: No problem. My pleasure.

I bring you greetings. I know that Dr. Blumenthal spoke here earlier and he sends his greetings also.

I'm absolutely thrilled to be here because the exciting issues you are discussing are really coincident with one of the most transformative moments in American medicine. You see 2010 will be among the most interesting years we have ever seen, we hope, and our office, the Office of the National Coordinator, is really charged to help describe what can make this year and the next five or six hereafter meaningful with regard to health IT.

(Slide.)

Now given that statement, and I know Dr. Blumenthal probably referenced a lot of this material when he was here before, given that

statement, and our office name, I suppose a reasonable assumption is that I'm here to talk about health IT but actually you'd be wrong. That's not the primary focus of our office at all.

(Slide.)

It sounds like I just contradicted myself but I'm sure a great deal of our programs and a huge amount of our resources I will discuss have an obvious association with information technology but a more appropriate way to describe our mandate from the President and Congress is to say that the Office of the National Coordinator has been be given unprecedented resource and authority to effect an improvement in the value and the efficiency of healthcare services through the meaningful use of information technology.

(Slide.)

And the need for that improvement is pretty clear. In 1998 Cyril Chantler clarified it as well as probably anyone. He pointed it out that years ago medicine used to be safe, simple and relatively ineffective. "Today I practice in a world in which my efforts can be very effective but almost everything about the practice is more complex and potentially dangerous."

So understanding at ONC we have a firm conviction that properly applied information technology--properly applied tools can help me as a surgeon be more mindful of my patients and learn new insights into the quality of care that I provide.

But I spend a lot of time managing expectations to make sure that we are careful not to fall into the trap of thinking that everything will be just fine when we get the guys at Google and eBay to apply their skills to our domain. But I think you all, better than most perhaps, appreciate the fact that health IT or technology is really just one piece of a much, much larger solution.

(Slide.)

The compelling solution for 2010 and beyond pivots around the simple question: Can we use information technology as a vehicle to change our culture and in turn our methods in 21st Century American healthcare?

(Slide.)

I mentioned earlier that our President and Congress gave the Secretary and Dr. Blumenthal a mandate and I think it's pretty helpful to look just briefly again at the text of the mandate.

(Slide.)

Here I have taken a section of the text and highlighted some key words and phrases. It starts with “security.” It goes on, “Quality and Cost.” Further along you’ll see that we have a clear direction to facilitate the meaningful use of electronic records nationwide. And we also see throughout that the overarching subtext is to improve the quality of care while making sure that the information remains secure and supports our institutions of public health.

(Slide.)

So, we are talking about improve, ensure, reduce, protect, facilitate, promote. It's a pretty formidable list of challenges but again I ask you to take note that the transcendent goal is not to acquire cool hardware. The point is not to have the latest software. The infrastructure is a means to an end or it is nothing at all but don't let me get too far ahead of myself.

I have it on very good authority that I have to bottom line you. I always recount the public speaking advice my daughter once gave me. She told me, “Dad, don't take this the wrong way but you have to tell your audience very early on, within five or ten minutes, what you are going to talk

about because after that time you have become very boring and tedious."

(Laughter.)

So who could take that wrong at all? I don't know.

(Laughter.)

So the first thing that I want to tell you to take home is that this moment of time, possibly more than any other, is a time for clinical leadership.

(Slide.)

And next, while we lead, I think the essence of this conference and this group actually points to the fact that we must be the very first to acknowledge that this work is a team sport and any success we have is wholly dependent on the strength of our partnerships. You see, our current circumstance is not due to a lack of technology and, therefore, technology alone cannot be the entire solution and, above and beyond all else, we must form strong partnerships in that regard.

(Slide.)

And that brings me to my final point and I always tell my audiences to rest assured that no direction beyond this point will be easy. And while

I can't stand up here and promise you only blood, sweat, toil and tears, you have to understand that the path forward requires a system, tremendous resources and no small amounts of courage.

And with those acknowledgments and looking at all the promise health IT holds, I will say that at ONC our first and steepest challenge is spurring the adoption of electronic health record in clinical practice.

(Slide.)

And here you will see some pretty newly published and very preliminary numbers on the state of adoption. This came out a little less than a month ago from the CDC. Looking at practicing physicians we see that in 2008 only four percent or a little bit more than four percent were using an electronic health record that can do the work that we need, that is handle progress notes, order labs, meds, x-rays and view the results.

Today it looks like we may have increased that number by about two points which still leaves us a long, long way to go.

And why is that?

Why are we still in single digits for adoption?

(Slide.)

Well, the answer is pretty clear.

(Slide.)

Here we see the top six barriers to adopting an electronic health record.

In short, for many, it has not been worth it. Collectively, we in the clinical community have been very clearly saying that to embrace electronic health records, our needs have to be met.

(Slide.)

Now, I use this slide nearly everywhere I go because I find it such a wonderful construct to frame our challenge, as well as our solutions.

(Slide.)

This is a diagram from the work of Abraham Maslow, who, in 1943, described a theory of human motivation. In it Maslow essentially divided our needs into growth needs and deficiency needs. Deficiency needs are physiologic. They have to be met first and, once met, the individual seeks to satisfy the needs of growth.

(Slide.)

Well, we can apply Maslow's hierarchy to our current circumstance in health IT and in doing it we'll assign the foundational need as privacy and

security. Beyond that, moving up the needs of growth, we see the components of usability, basic functions, a strong business case. And, finally, at the top a most fulfilling achievement, one that many of us often gather to discuss, information exchange.

(Slide.)

Now, let's look at how those requirements will translate into action from our office. I mentioned earlier that privacy is the foundation for moving forward and the reason is obvious and you probably, better than virtually any group, understand this. The tenets of privacy are old in my profession and the Recovery Act clearly speaks to this point.

And, fortunately, to help us build the infrastructure that will support that fabric of trust in all of our other programs, Congress provided that we had more than a policy of good intentions.

(Slide.)

I just point this out to say this is a serious endeavor and our intent at HHS is to create durable, measurable, reliable, improvement in healthcare.

So one of the first issues we’re

addressing is how to help providers choose and effectively implement this technology.

Well, a few months ago our department released a framework regarding how we can help give technical assistance to health IT regional extension centers. And within the next few weeks I anticipate we will be able to announce the first of those organizations that will be out of the chute to provide that assistance.

Now, the goal of these centers will be to provide hands-on technical assistance in implementing the technology.

(Slide.)

Now, they will do this for more than 100,000 physicians. Our office is dedicating over $600 million on this assistance. And that assistance will be specifically directed at providers that are least likely to be able to do this on their own.

(Slide.)

Here you can see that those awarded grants must prioritize assistance to those in historically underserved areas with the ultimate goal of reducing health disparities.

(Slide.)

Reducing disparities is a primary goal and clearly our needs in this regard are as acute as ever, which really explains this recent headline that there is becoming ever more evidence of a growing digital divide.

(Slide.)

You see, if we believe that information at the point of care can make a difference in the quality and the value and the safety of that care and, what's more, that this information can go on to support institutions of public health and social priorities, then the imperative of these findings become much more critical and are easily understood.

(Slide.)

So this really begs the question, what is the meaningful use of information technology?

(Slide.)

Well, I have to give a little bit of a disclaimer right here. Right now we just published the rules a little more than a month—a little bit more than a month old, a proposed rule for the meaningful use of health IT and, because of that, we have officially entered a comment period for that proposal which means I can't provide any interpretations of it beyond what is published.

(Slide.)

Now, the good news and the announcement that is of greatest import actually is that we are collecting comments on this. Clearly we believe that the proposal meets the requirements established by Congress in the statute and that statute gives pretty clear contours for the meaningful use. For example, the EHR must be certified and we must be on a trajectory that includes exchange of information of real value to the patient, such as care coordination.

(Slide.)

But let me get back to the most important thing that I can offer, namely that as a published proposed rule we are desperately, desperately asking everyone and anyone who has thought about us moving forward to please submit a comment. So I invite everyone on this panel to submit a comment.

Let me say that again. We are begging everyone to submit a comment because you will see that for many groups, many particularly very interested groups the proposed rule landed sort of flat. We took a tremendous amount of testimony, and obviously we are working on a very, very aggressive timeline, and some were a little bit disappointed

that some of the thoughts and ideas within their testimony weren't fully fleshed out within the proposed rule. There are a number of reasons for that, not the least of which is again the aggressive timeline. Our thought all along was that if we can put up a reasonable proposal that we definitely can perfect this rule with comments, and the comment period lasts from now, and it ends—I believe it's March 13th.

(Slide.)

Well, the gift of this opportunity to speak really—to you really has the price that this is a very brief presentation and doesn't provide opportunity—provide more than a cursory acknowledgement of a lot of the other programs that are being launched for health information exchange, workforce development and beacon communities.

(Slide.)

Now beacon communities are quite interesting. They hold probably the greatest promise because in those communities we are looking to see the full flower of what this technology can achieve. Essentially what we are doing is we are providing grants to about 15 communities and the grants can range anywhere from $10 to $20 million.

And the thought is that these grants will go to communities that are a little further along, a little bit more advanced in terms of their health IT, particularly that they probably have higher adoption numbers already, much higher than the four percent national average that we have, and the thought is that they will provide—the resources will provide a way for them to fill in the gaps and really, really demonstrate the full potential of what health information technology can do in one complete community.

And we all recognize that the essence of that is to see real exchange.

(Slide.)

And, finally, I would be remiss if I don't highlight one other area, and it is not involved in the high tech act at all but I think that this is, along with the beacon community program, probably one of the most exciting areas of all, and that is comparative effectiveness research.

This investment will obviously benefit all Americans but it is clear that some of the greatest value will be in communities and groups that aren’t traditionally included in research protocols.

(Slide.)

Well, I'll wind up and answer any questions that you have, just by restating my central thesis, which namely is that our current circumstance is not solely due to a lack of technology and, therefore, it can't be solved by technology alone. It is no small matter that two of the statutory criteria for meaningful use involve information moving, information exchange. The whole point is to provide a means to facilitate communication, and the transfer of information, and possibly even the transfer of knowledge. In the right hands at the right time, information can be transformative.

The full, complete, rapid and regular exchange of medical information will represent a singular change in our culture and I can think of no better way to increase the value of our services than to make their provision fully informed.

The alternative is equally remarkable.

To continue, each of us in our own silo, putting one new innovation on top of another with no real consideration of how one piece of information informs, supports, or confounds another means that we will keep our current haphazard and dysfunctional method of taking care of patients.

It means that we will recreate the experience of Babel.

So I hope you understand that while necessary, computers are not the whole answer because again the question is not how much technology do we need; the question is how do we improve the quality of care for all Americans and, in turn, effect that elusive, yet supposedly self-evident truth that among our inalienable rights are life, liberty and the pursuit of happiness.

(Slide.)

Now, while I am frequently prone to exaggeration, in this point I am not being hyperbolic because I’ve seen that the pursuit grows slower for our kids who aren’t immunized. Preventable cancers have separated far too many of our people from their right to life, and the full flower of liberty is not as apparent to those that rise every morning with a disability, with Alzheimer's, or with HIV.

(Slide.)

Now, a computer won't make that right but information technology can assure that a pediatrician sees a list every morning of the patients coming that day that aren't up to date on

immunizations, as well as the names of their brothers and sisters who will probably in tow with mom when she arrives for the appointment.

Every man and woman having an electronic record means that our best minds can really ask and answer the question what treatments work best for a 48-year-old Latina with breast cancer or a 56-year-old African-American with node negative prostate cancer? And what are the full portfolio of services they will need to effectively implement that treatment?

(Slide.)

Now, a computer won't rid the world of AIDS but will afford well-meaning people the liberty of having their care coordinated in such a way that every one of their doctors knows the results of all of their tests.

You see nine years ago the Institute of Medicine got it right. Quality care is efficient, effective, safe, patient-centered, equitable and timely but just saying that won't make it real and it only begins to describe what we need to do to reform healthcare.

With information systems we can see the true choices and the balance that must be preserved.

That balance is highlighted in my reality as a 21st Century American surgeon and that reality stands in immediate juxtaposition with the fact that no country, no national enterprise has fully and successfully implemented what we are attempting to deliver.

(Slide.)

Now, I used to end my implementation presentations with a quote from Voltaire that basically said that doubt is uncomfortable but certainty is ridiculous. And while that is very true, and while we stand on the cusp of this new year, I appreciate Mr. Twain's observation even more.

We in the Office of the National Coordinator are willfully and purposefully grabbing this cat by the tail and, in doing so, we are about to understand things that could have been learned in no other way. And essentially everywhere I go I want to point out we are here to ask for your help.

And, with that, I'll answer any questions.

CHAIRMAN TEUTSCH: Thank you so much. Appreciate it.

(Applause.)

Marc?

DR. WILLIAMS: Thanks very much for that presentation.

I have two comments.

One is that our committee certainly was active in providing comments on the first go around of meaningful use and I anticipate that we probably should be involved in the second, and I would propose that.

DR. HUNT: Please.

DR. WILLIAMS: The second thing that struck me as you were going through the presentation and the number of things that you had referenced was that so much of what you are doing intersects with the things we talk about here. And I am interested in the possibility, and I have been told by Sarah that this is not out of bounds, would it be--it would seem reasonable to me to have a liaison from your office that would be an ad hoc attendee of this committee engaged.

DR. HUNT: I think that will be fantastic and I can't step over my bounds, and obviously we have got to clear it through leadership but I think we would be very receptive to that, very, very receptive.

DR. WILLIAMS: I propose that that invitation be made officially.

CHAIRMAN TEUTSCH: We can do that. We will figure out what the channels are.

DR. WILLIAMS: Okay.

DR. HUNT: If you send a note to me, I can forward it on to Dr. Blumenthal, and he will take it under consideration. I am almost sure that it will be favorably—and we are low maintenance. We bring our own water even.

(Laughter.)

CHAIRMAN TEUTSCH: I am sure that we have our own bureaucracy, too, but we will figure out what it is and move it forward because that's—it would be very constructive.

I do want to respond, though, to the draft regulations.

DR. HUNT: Yes.

CHAIRMAN TEUTSCH: And we have just some logistical challenges similar to what we discussed with Rod.

This is out now for a 60-day period or so; correct?

DR. HUNT: Exactly. And the comment period ends on May 13.

CHAIRMAN TEUTSCH: So that's before our next meeting. On the other hand, we do have—

DR. HUNT: I mean March 13th. I'm sorry.

CHAIRMAN TEUTSCH: Yes.

DR. HUNT: Okay. I'm sorry.

CHAIRMAN TEUTSCH: March 13th. But it's before our next meeting. But I do think we would like to get some comments.

I think, Marc, you drafted the—is that right?

DR. WILLIAMS: Yes.

CHAIRMAN TEUTSCH: The comments we sent in before.

DR. WILLIAMS: Yes, I can do that.

CHAIRMAN TEUTSCH: Can you extend those--

DR. WILILAMS: Yes.

CHAIRMAN TEUTSCH: --to be specific—

DR. WILLIAMS: Yes.

CHAIRMAN TEUTSCH: --to that.

I don't know if there are others that wanted to specifically work for you but then we could probably share them with the committee here.

MS CARR: (Not at microphone.)

CHAIRMAN TEUTSCH: Sarah is suggesting that what we do is we basically take what we did and

expand it with other things that we've already done so that it's a bit more complete and more responsive to the needs, and move it forward.

MS CARR: (Not at microphone.)

CHAIRMAN TEUTSCH: We can share it. Yes, we can. That's the problem. We aren't going to reconvene. So we can share it with all of you. Obviously everybody can respond individually and obviously it sounds like we have an open invitation to do that.

DR. HUNT: Please.

CHAIRMAN TEUTSCH: But is what we could do on behalf of the committee.

DR. HUNT: Two things: First is that, you know, the NIH—there is competition within HHS as many of you know. The NIH had been crowing around for I don't know how long that they got 50,000 comments for their stem cell research rule.

We are aiming to top that. Okay.

(Laughter.)

So individually and collectively we really want you to provide comment and I am not stepping out of bounds. I have to be careful. This is not an interpretation of the rule but it's very clear that in the proposal we have three basic periods of

development in the meaningful use. 2011 is first period by which individual practices and individual physicians, I'm sorry, will be able to qualify for meaningful use incentive payments. And as many of you know, 2011, in terms of the federal government is like next Wednesday. So our plans--our thoughts are to have just--to start this off.

The next period begins in 2013, and we are actively thinking on how to really ramp up. In the statute it was very clear that meaningful use—there is an expectation that meaningful use will progress in terms of the requirements.

In 2013 we are looking in terms of a tremendous amount more of process things that can go into place for meaningful use incentives.

And then in 2015, that's sort of the peak literally and figuratively in a number of ways, and that's where we are seeing probably the full flower again of what we can achieve in terms of meaningful use. And that's the peak primarily because after that period you can incur--the statute actually begins to incur penalties for those—for Medicare and Medicaid providers or Medicare providers, I'm sorry, that don't meaningfully use an electronic health record.

So I'm hoping that will help frame some of your comments.

CHAIRMAN TEUTSCH: That's terrific.

Well, these are of keen interest to us.

Obviously there's a flood of information in genomics. There's information that needs to get out.

DR. HUNT: Yes.

CHAIRMAN TEUTSCH: But most importantly it needs to get used and used well.

DR. HUNT: Yes.

CHAIRMAN TEUTSCH: So we are totally in sync with this agenda and we realize that it's not going to happen without an organized system of care that can get this information out in a manageable and intelligible way.

DR. HUNT: And, clearly, very few groups would have a sensibility about the privacy issues around the exchange of information. And so I am sure that thoughts around--because you have grappled with this external to any discussion of health information exchange for are a while and have a tremendous amount of--I know well considered thought on the issues of privacy, and that will be very, very welcome.

CHAIRMAN TEUTSCH: Indeed. It remains a topic of keen interest.

So thank you so much for joining us.

DR. HUNT: Thank you.

CHAIRMAN TEUTSCH: And particularly for your eloquent comments. They were delightful.

DR. HUNT: Thank you.

CONCLUDING REMARKS

CHAIRMAN TEUTSCH: So I think that brings us to the end of our agenda.

I hope I'm right. Sarah, did I forget anything?

So let me try and recap a little bit about what we managed to—

MS CARR: (Not at microphone.)

CHAIRMAN TEUTSCH: Okay. All right.

While they are putting it on the screen, are the any other items anyone would like to bring up that we overlooked?

DR. BILLINGS: Steve, on--

CHAIRMAN TEUTSCH: Oh, there you are.

DR. BILLINGS: Here I am. Are we in some formal way following up on the GINA regulations?

CHAIRMAN TEUTSCH: I'm sorry. On the what?

DR.BILLINGS: GINA.

CHAIRMAN TEUTSCH: We will continue to have some reports from the—

DR. BILLINGS: So we will get updates on the—

CHAIRMAN TEUTSCH: We will get some updates. I gave you some brief updates yesterday on the status but we will be hearing more. I think, you know, there is a part that the agencies are all moving forward to get them done. As we know, there are some residual consequences that were not necessarily fully anticipated.

We may want to revisit some of those in due course.

DR. BILLINGS: Yes.

CHAIRMAN TEUTSCH: As a matter of fact, I'm confident but I think at this moment we're really looking forward to hearing how they're going to be implemented.

(Slide.)

So—okay—to recap:

We began yesterday talking about moving forward with an assessment of the affordable genome and charged Charis and Paul with leading that effort and, hopefully, having a session at our June meeting

that will begin to inform that process so we can decide what our niche might be, and we look forward to that.

We heard from Marc on clinical utility and comparative effectiveness, and have a plan for proceeding with that.

Barbara led us through a review of the draft recommendations of her task force on genetics education and training. We agreed to post those recommendations and put them out, that is, for public comment. So we will look forward to doing that.

These are my—oh, good, notes for me.

Okay.

Let's go on. We'll have that public consultation draft out.

We did not receive any additional comments on the DTC paper so that is going to be completed.

And, Sylvia, it did happen on your watch.

(Laughter.)

So we'll be transmitting that to the Secretary.

Charmaine led us through a good discussion on genomic data sharing. She'll continue to lead that steering group and work to gather some

information about what the experience with these various models is to date but we'll also hear from the Lewin Group as they complete their evidence review and talk at our June meeting then about how we might proceed.

The gene patents report: Thank you, everyone. I probably did not thank Jim enough for all the work he did in preparation for that but we have got a unanimous vote to approve a motion to close it and move it forward. So after a little bit of copy editing it will be on its way to the Secretary.

DR. EVANS: I don't know what I will do with all of my free time now.

(Laughter.)

CHAIRMAN TEUTSCH: We heard from Rod this morning about the Newborn Screening and Advisory Committee and identified a group to comment on retention and use of residual dried blood spots, and we will hear from them in June.

The—Rod's committee is going to be looking at new carrier screening and they will have a proposal for us also to review.

MS CARR: (Not at microphone.)

CHAIRMAN TEUTSCH: Right, a proposal about

collaboration with them on a way to assess and perhaps make recommendations concerning carrier screening.

And then, finally, we heard from David Hunt in regard to the Office of the National Coordinator and Meaningful Use; delighted to hear that there was interest in having them have some representation on this committee.

And Marc is going to help draft some recommendations--a response rather to the regs are out for public comment.

And, of course, lastly, we did hear from our federal partners and all of the great activities that are going on there.

I am sure I have missed a few things but it’s a lot. We did it and we couldn’t have done it without all of you. So many thanks.

MS. ASPINALL: Thank you.

CHAIRMAN TEUTSCH: Thanks for those who hung on there on the phone.

Andrea, do you—

DR. FERREIRA-GONZALEZ: The commentary that we wrote—if anybody has any comments—

CHAIRMAN TEUTSCH: Yes.

DR. FERREIRA-GONZALEZ: --can send it

out—

CHAIRMAN TEUTSCH: Yes, we got comments from Paul. That's the only one I heard. We'll be able to incorporate his suggestions and we're going to send that—we'll then submit it.

Anything else I missed?

If not, safe travels and we look for to seeing you soon.

Thanks so much, also, to the wonderful staff for without whom, we could not do this.

(Applause.)

(Whereupon, the proceedings were adjourned.)