DEPARTMENT OF HEALTH AND HUMAN SERVICES

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of the

SECRETARY'S ADVISORY COMMITTEE ON GENETICS, HEALTH, AND SOCIETY (SACGHS)

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CONTENTS

CONTENTS *(continued)*

PROCEEDINGS

[8:36 a.m.]

Opening Remarks

Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: Good morning, and welcome to the meeting of the Secretary's Advisory Committee on Genetics, Health, and Society.

It seems like if we're having the 20th, we should have some sort of a celebration and it's nice to be in this lovely venue. It's a change from the Humphrey Building. So hopefully everyone will have a chance to enjoy that, and I can tell you it's a delight for me to be talking about H1N1 all day. So this is a welcome change.

The public was made aware of this meeting. Three notices in the Federal Register as well as announcements on the SACGHS Website and Listserv. We want to welcome all of the members of the public who are in attendance as well as those of you who are tuning in via the webcast. Thank you for your interest in our work.

We will have scheduled public comments at 11:45

this morning and tomorrow again at 10:15 in the morning and, as always, we look forward to input from the public.

We have a full agenda for this meeting and several topics before us and some decisions we made to make. We'll begin this morning with an Update on Implementation of GINA, the Genetic Information Nondiscrimination Act. We are really pleased to have all the agencies that have been involved with the implementation process here today to report on the status of their efforts to promulgate the rules needed to implement the law's protection.

The rest of today's meeting will be devoted to review and discussion of the Committee's Final Draft Report on Gene Patents and Licensing Practices.

We've also set aside tomorrow afternoon for this issue, if we need it, and our goal is to come to agreement on the recommendations and approve the report for transmittal to the Secretary. So it will be an important discussion and I am counting on a lot of interest from the disparate views on this topic.

Tomorrow, we'll consider a proposal related to the ethical implications of genomic data-sharing, discuss

the Findings and Draft Recommendations of the Genetics Education and Training Task Force, and review the Revised Draft Paper on Direct-to-Consumer Genetic Testing.

Our goals are to decide on next steps for our priority topic in data-sharing, approve the DTC paper to send to the Secretary, and provide input on the Draft Recommendations for the Report on Genetics Education and Training. So we have a lot to accomplish.

Before we move to our first agenda item, I would like to inform you of a couple of items.

First, I want to report that last month I met with Dr. Francis Collins. Given NIH's role in managing SACGHS, I thought it would be important to brief Francis in his new role as the NIH Director. As those of you who have been on this committee know, Francis was the NIH Ex Officio to this committee until his departure last year. So our meeting was really an opportunity to update him on our work and on the priority issues we've decided to take up.

It also gave us a chance to get his perspectives on the critical issues within genetics and genomics and how we could be helpful to the department's

priorities.

Francis emphasized that we should continue to be forward-looking and to anticipate issues that will arise as -- oh, I see my name. I've become Barbara, but we can fix that. There's got to be truth in advertising here.

He asked that we anticipate issues that will arise as genomics moves forward, particularly whole genomic sequencing and how it is integrated into healthcare and public health.

He suggested that it would be fruitful to focus on the implications of the affordable genome, comparative effectiveness and the economic value of technological innovations and was pleased that we were already taking up the comparative effectiveness issue and thought it was important to consider the meaning of the word "benefit."

With regards to the implications of the affordable genome sequence, you'll recall that during last year's priority-setting process, the Committee identified this as a high-priority issue but decided to incorporate it as part of the study area on genetics and the future of the healthcare system.

The sessions we held earlier this year on the healthcare system focused on issues of a more immediate nature, such as coverage and reimbursement of genetic technologies and barriers to access in genetic services.

I would like us to consider addressing the implications of an affordable genome as a discrete topic and, finally, Francis encouraged us to publish a paper highlighting prior SACGHS recommendations to help gain recognition for the Committee's work.

If we have time at the end of the meeting, we will begin a discussion of these items before we adjourn.

In September, we finalized our letter to Secretary Sebelius on genetic-related priorities that support healthcare reform. These priorities included ensuring that health information systems are capable of securely storing, transmitting, and receiving genomic data, that comparative effectiveness research recognizes that the effectiveness of interventions may vary among genetic subpopulations, and that Centers for Medicare and Medicaid Services use a transparent and evidence-based process for the coverage and reimbursement of genetic tests, and that the value of genetic services is

recognized as changes are considered to remunerate primary care and cognitive services.

The NIH Director has transmitted the letter to the Secretary's Office.

I also want to report that the Committee's Clinical Utility and Comparative Effectiveness Research Task Force held its first teleconference in late July. The members discussed two reports on comparative effectiveness research, one prepared by the IOM and one by the Federal Coordinating Council for Comparative Effectiveness Research. The Task Force also discussed NIH and AHRQ activities in the area of comparative effectiveness.

The Task Force is awaiting public release of the Secretary's Fiscal Year 2009 Operating Plan for the $700 million in funds for comparative effectiveness research allocation under the American Recovery and Reinvestment Act. After review of this plan, the Task Force intends to identify and discuss particular policy issues the Committee could explore in the area of comparative effectiveness research.

In the meantime, NIH has issued $360 million in

ARRA grants to support CER, Comparative Effectiveness Research. A number of them are focused on genomics, and I thought since many of you may not have heard of what was funded, I would give you a few examples.

Scott Ramsey at the University of Michigan received funding for his Center for Comparative Effectiveness Research in cancer genomics. Katrina Armstrong at the University of Pennsylvania was funded for comparative effectiveness in genomic medicine. David Fenstermacher at Moffett Cancer Center and Research Institute was funded for developing information infrastructure focused on cancer comparative effectiveness.

John Finjue at Wake Forest will be doing work on clinical validity and utility of genomic targeted chemoprevention of prostate cancer. Jeff Ginsburg at Duke will be working on programs in clinical effectiveness of cancer pharmacogenomics, and Katrina Goddard at Kaiser Foundation Research Institute will be looking at comparative effectiveness in genomic and personalized medicine for colon cancer.

I also want to take note of developments of

interest at our ex-officio agencies. Last week, we learned that the Federal Trade Commission investigated two companies, the General X Corporation and Sayona, for their promotion of a direct-to-consumer neutrogenetic service called Myself Program, which involved the analysis of specific genetic variations.

The companies claimed that the test results could significantly affect consumers' health outcomes and enable consumers to achieve long-term or permanent weight loss. According to FTC letters to these companies, which were sent in August and posted about two weeks ago on the FTC website, General X is no longer marketing the Myself Program and Sayona has ceased operations all together.

We appreciate the FTC's actions and hope that investigators will examine other DTC tests with questionable claims. We also hope that FTC's actions will serve as a reminder to other companies that claims must be substantiated. Copies of the FTC letters are in your table folders and available for members of the public. We'll hear more about them in tomorrow's session on DTC Testing.

I also wanted to applaud the efforts of the

Centers for Medicare and Medicaid Services for its progress on proposed rulemaking for laboratory proficiency testing programs that are required under the Clinical Laboratory Improvement Amendments or CLIA.

This effort addresses one of the recommendations of the SACGHS Oversight Report. CMS plans to re-evaluate the current list of analytes and mandated proficiency testing for laboratories that use these analytes and identify scientifically valid mechanisms to select new analytes and update the analyte list periodically as the environment and technologies change. Genetic and molecular tests will be included in this evaluation, as well.

CMS will utilize the CLIA Advisory Committee or CLIAC in the process of convening an expert working group for this effort. It has gathered a working group of outstanding individuals and who represent proficiency testing programs, laboratories, accrediting agencies, government agencies, and subject matter experts in laboratory specialty areas, including genetic testing. The first CLIAC Working Group meeting is planning for early 2010.

Finally, the National Human Genome Research Institute held a State of The Science Conference in August on Family History. The conference panel included in its draft statement that, while family history plays an important role in the practice of medicine because it may motivate positive lifestyle changes, enhance individual empowerment, and influence clinical interventions, substantial research will be needed before a systematically collected family history for common diseases can become an evidence-based tool in primary care.

The panel recommended research in the following areas: the structure or characteristics of a family history, the process of acquiring a family history, and outcomes of family history acquisition, interpretation, and application.

Committee members can find the Draft Statement in the briefing books under Tab 8. For attendees from the public, there is a handout with information where to find the Draft Statement on the NIH website, as well.

A number of meetings are taking place this month that are of interest to SACGHS. Information about

these meetings is in your table folders and provided in the handout for the public.

On October 15th, the Office of The Secretary is sponsoring a workshop entitled Identifying Opportunities to Maximize the Utility of Genomics Research Data Through Electronic Health Information Exchange. That's an awful lot for this early in the morning for someone from California. The purpose of the workshop is to discuss data standard requirements for clinical genetics and obstacles to their development and adoption. Andrea Ferreira-Gonzalez and Charmaine Royale will be attending this meeting on our behalf.

The next meeting of the Health Information Technology Standards Committee is October 14th, and the Health Information Technology Policy Committee meets the end of the month, the 27th and 28th. The public can participate in these advisory committee meetings by web conference.

On the 26th and 27th, the American Association for the Advancement of Science and the Food and Drug Law Institute are co-sponsoring a two-day Colloquium on Personalized Medicine in an area of healthcare reform.

The agenda includes presentations on policies associated with comparative effectiveness research, health information technology and research and clinical practice and the status of biomarker discovery and use in clinical practice.

I also want to highlight a new CDC/NIH initiative called Genomic Applications in Practice and Prevention Network, GAPNET, one of things William's been working on of his many nets, which is a collaborative effort initiated by CDC's Office of Public Health Genomics and the National Cancer Institute, Division of Cancer Control and Population Sciences, and includes partners across the health sector.

The aim of GAPNET is to accelerate and streamline effective and responsible use of validated and useful genomic knowledge and applications in clinic and public health practices.

Over the next two years, GAPNET will be working to develop models for synthesizing and disseminating evidence-based information on genomic applications, enhance development of evidence-based recommendations, accelerate translation research, and implement genomics

translation programs at clinic and community levels.

The inaugural meeting is October 29 and 30th and Marc Williams will be participating in that.

Lastly, I also want to introduce a new member of the SACGHS staff, Dr. Symma Finn behind me. Symma was awarded a fellowship from the American Association for the Advancement of Science and will be serving her fellowship year at the NIH Office in Biotechnology Activities as part of the SACGHS team.

She has a Ph.D. in Medical Anthropology from the University of Florida at Gainesville and her doctoral studies were focused on patient empowerment and health literacy in genetic disease and patient-physician communications.

She also has a Master's in Environmental Anthropology that focused on the social impacts of ecosystem management. She informs me that she's been following our work for a long time and will be a great addition to the staff. She'll be working on genomic data-sharing, genetics education, and public health genomics. So welcome, Symma.

And now for the highlight of the morning, we

will hear from Sarah about our ethics rules.

MS. CARR: Thank you, Steve, and good morning, everyone.

I'm going to just review a couple of rules that you have to follow as special government employees.

First, Conflicts of Interest. Before every meeting, you provide us with information about your personal, professional, and financial interests which is information that we use to determine whether you have any real, potential, or apparent conflicts of interest that could compromise your ability to be objective in giving advice during committee meetings.

While we waive conflicts of interest for general matters because we believe your ability to be objective will not be affected by your interest in general matters, we also rely to a great degree on you to be attentive during our meetings to the possibility that an issue will arise that could affect or appear to affect your interests in a specific way.

We've provided each of you with a list of your financial interests and covered relationships that would pose a conflict for you if they became a focal point of

committee deliberations. If this happens, we ask you to recuse yourself from the discussion of the Committee and leave the room.

I also want to remind you about lobbying. Government employees, special government employees are prohibited from lobbying, and thus, we can't lobby, not as individuals or as a committee. If you lobby in your professional capacity or as a private citizen, it's important for you to keep that activity separate from our work. Just keep in mind that we are advisory to the Secretary of Health and Human Services, not the Congress.

As always, I thank you for being so attentive to these rules. We appreciate your conscientiousness.

DR. TEUTSCH: Thank you, Sarah. Because we are already in a large room, it's important that we identify ourselves. Our note-taker doesn't know all of us by name. Try and identify yourself if whoever is introducing you fails to do so, so we can get it properly recorded.

So let's begin. We will have an update on GINA, the Genetics Information Nondiscrimination Act. Genetics discrimination has been a longstanding priority

issue for this committee, and we celebrated the enactment of GINA in May of 2008. Now we want to learn about the progress in implementing this important law.

First, we'll hear several presentations on the implementation of the provisions of Title I, which applies to group health plans, health insurance issuers in the group and individual markets, and issuers of Medicare Supplemental or MediGap policies.

Title I generally prevents health insurance plans and issuers from collecting genetic information, adjusting premium or contribution amounts for a group or an individual based on genetic information, or using genetic information as a condition of eligibility for insurance coverage.

Amy Turner, who is a Senior Attorney and Special Projects Manager from the Department of Labor, and Ross Weinheimer, Senior Counsel with the Internal Revenue Service, will report on the Employment-based Group Market Provisions.

They will be followed by Jim Mayhew, Director of the Division of Private Health Insurance at the Centers for Medicare and Medicaid Services, who will

address Individual Insurance Market Provisions.

Robinsue Frohboese, the Principal Deputy Director in the Office of Civil Rights, and Christina Heide, Senior Health Information Privacy Policy Specialist in that office, will report on the proposed regulations implementing the Privacy Provisions in the law.

Then we will hear from Kerry Leibig, Senior Attorney Advisor in the EEOC Office of Legal Counsel, who will review the proposed regulations implementing Title II Provisions which prohibit discrimination in employment based on genetic information and limits the acquisition and disclosure of such information by employers and other entities covered by Title II.

Although Kerry presented on the proposed rules at our March meeting, we thought it would be good to hear from her about the EEOC proposed regulations again in the context of the other regulations.

So we will begin with Amy.

Update on the Implementation of the Genetic Information Nondiscrimination Act

Amy Turner, J.D. and Russ Weinheimer, J.D.

MS. TURNER: Thank you very much. It's nice to be here.

For years, I've had the pleasure of participating as the Labor Department's alternate ex-officio member to some of these meetings. I feel like I've listened, for years, to people asking people who came from Congress, why can't we get this GINA legislation passed, why can't we get this GINA legislation passed.

I had the luxury of not being in the hot seat and thought, not my turn yet; I'll just listen and hear what these congressional staffers have to say. Then GINA was passed in May 2008, and I heard that some of you were asking, where are those regs, where are those regs. I skipped those meetings, not because I was avoiding answering your questions but because we were actively working on writing those regs.

So I am happy to announce that, yesterday, those regs were published. I don't know if they are in your materials, but I'll give you a site in case.

DR. TEUTSCH: They should be in your folders.

MS. TURNER: Excellent, fabulous. So you'll

have them. So you can enjoy them tonight with a glass of chablis in your wonderful suite upstairs at the Park Hyatt. They are fine reading, those regulations.

I thought I would start, just in case you're wondering, geez, why are there so many government bureaucrats sitting up there, I might just take a few minutes to explain why there are so many government bureaucrats sitting up here.

GINA is a far-reaching law; it does a lot. Sections 101 through 104 deal with nondiscrimination in health coverage. Russ from the IRS, myself from Labor, and Jim Mayhew from CMS, all worked together, and also collaboratively with the states, to administer the health coverage nondiscrimination provisions.

GINA Section 105 deals with privacy and that is HHS's Office of Civil Rights, that is why Robinsue and Christina are here. Then Title II deals with the employment discrimination provisions which is the EEOC.

So if you're wondering why there are so many of us up here, it's because GINA does a lot, and we're all here to administer it and enforce it.

So what I'm going to focus on, with Russ and

Jim, are the health coverage nondiscrimination provisions. I'm going to subdivide those, as well, because my brain works in outline format. There are group market provisions, individual market provisions, and Medicare supplementary policy provisions.

The group market provisions are administered jointly by Labor, IRS, and CMS. If you're wondering, again, why so many government bureaucrats, I think not only does that inform the interpretive process but it's to make sure that GINA is enforceable.

Those group market provisions, what that means is that is for individuals who get their health coverage through their employer. That is the group market. You're put into a group. So if I work for Russ's widget company, we're all in an employment-based group and we have group market coverage.

There are lots of different employers out there. There are private employers, there are state and local government employers. The employer is responsible for making sure that his health coverage complies, but the employer may choose to do what is called a self-insuring the plan, particularly if he is big.

I don't want to pick on a particular employer, but let's say it's IBM or something like that. They may choose to self-insure, but your smaller employers may tend to go to an insurance company, Aetna, Cigna, something like that, and buy an insurance policy. Those insurance companies are also responsible for complying with GINA.

So to make sure that the insurers and the employers, whether they are private employers, or state and local government employers, or church employers, to make sure that they are all complying with the law, and that the government can enforce against all those different types of entities, and that, essentially, individuals can also enforce on behalf of themselves, that they have private rights of action, what GINA does is it amends all these different laws.

It sounds confusing. You probably don't have to worry about it too much. I can give an hour presentation on the GINA enforcement structure. If people have questions, I would be happy to answer them, but suffice it to say, I think the main message I wanted to send on that is, it may seem complicated at first but

that is to ensure that it works and that people get what they're entitled to. So that is the group market.

The individual market is a little bit more simple. That is administered solely by HHS and the states. Jim is going to talk about that. The individual market is an individual who just calls up BlueCross/BlueShield and says, I want a policy for me and my family unrelated to employment. The IRS and the Labor Department have nothing to do with those individual policies. We're only involved when people are getting their coverage through their employers. Then there are also Medicare supplemental policies, which Jim will mention.

So let's zone in and focus on the group market. Yes, I'll tell you one more quick joke I just thought of 30 seconds ago. Russ is here from the IRS. We've worked together for a long time. He is wonderful to work with. If you're afraid of talking to Russ because he is from the IRS, I can tell you that I've worked with him since 1996 and I have still yet to be audited.

So you don't have to feel like you have to give him a fake name or something. Feel free to share your

business card if you have some questions afterwards. I am not guaranteeing you won't be audited, but again, you don't have to feel like you have to use a fake name or something like that.

The group market provisions that Russ and I are going to focus on build on some protections that were already enacted as part of HIPAA, namely, if an individual has their health coverage through their employer, that health coverage cannot impose a pre-existing condition exclusion, based solely on the fact that an individual has certain genetic information.

Let's say that they have a mutation on their BRCA1 or BRCA2 gene. They are predisposed to getting breast cancer or ovarian cancer but it's not manifested yet, they don't actually have the disease.

Already in the group market for years, since HIPAA has been effective since 1997, an individual can't have a pre-existing condition exclusion imposed upon them, based solely on that genetic predisposition, in the absence of a diagnosis of a condition, an actual diagnosis of breast cancer or ovarian cancer, for example.

In addition, in the group market already under HIPAA, the individuals within the group -- let's say we all work for Russ's widget company, so we're all one employment-based group -- we can't be charged different premiums and we can't be kept out of the plan, denied access to the plan, denied eligibility or [dis]continued eligibility, or have our benefits changed between us based on any health factor, including genetic information.

So let's say we all work for Russ's widget company. I can't be charged a higher premium than Russ or Christina, based on the fact that I'm the one with those bad genes. All similarly situated individuals within that employment-based group all pay the same premium, they get the same benefit package, they have the same rules for eligibility, regardless of any health factor, including their genetic information.

Then GINA comes in, and GINA adds some protections. I'm going to turn it over to Russ. There are three main protections in the group market and we are going to tag team and go back and forth a little bit, but I'll just mention that before we did these regulations

that were published yesterday, we did do what we call an RFI, and that is because we're government people and we love acronyms and we drop acronyms every time we can.

An RFI is a Request for Information. We published one in October of 2008 that was open for 60 days, I believe, where we got comments from the public, both consumer groups, the regulated community, which is essentially employers and insurance companies, a wide variety.

The Medical Information Bureau commented, a wide range of commenters gave us some information in response to specific questions we asked, and also generally on the statutory provisions, before we issued these regulations yesterday.

The regulations were actually made available to the public on October 1st. I know, at least on the Labor Department's website -- and I'm sure HHS has stuff, too -- but on the Labor Department's website, if you go to www.dol, as in Department of Labor, .gov/ebsa, as in Employee Benefits Security Administration, we also have, in addition to the regulations, some fact sheets and press releases and Q&As, and a little bit more plain-

English summary of what is going on. So that may be helpful information, as well. That was made available October 1st.

And with that, I think I hit all the preliminaries. I'm going to turn it over to Russ to start.

MR. WEINHEIMER: Thanks, Amy. We're going to talk about the three substantive rules that GINA adds to what Amy already summarized with existing HIPAA, and has been the requirement for the past 12 or 13 years, that you can't discriminate in certain respects on the basis of genetic information. That was principally based on an individual.

The three rules that are added are, you now can no longer discriminate on the basis of the group rate. An insurance company can't charge a group a higher rate based on genetic information in the group. Insurance companies and plans cannot request or require an individual to undergo a genetic test, and insurance companies and plans cannot request, require, or purchase genetic information for underwriting purposes, or prior to or in connection with enrollment.

Now we're going to go into a little bit more detail about each of those rules, but I wanted to mention three other things that GINA does specifically that differs from the HIPAA framework that Jim, Amy, and I have been operating under for the past 12 or 13 years.

There are these three agencies we have been dealing with, the Health Insurance Portability and Accountability Act, pre-existing condition rules, special enrollment rules, nondiscrimination requirements, the mental health parity rules, both the '96 ones and the ones that were enacted last year, the one on Women's Health and Cancer Rights Act, and the Newborns' and Mothers' Health Protection Act.

So we have shared on all these provisions. There are certain provisions that apply across all of those laws that we share, and there are three specific rules that are special for GINA that go beyond that general framework. I just thought this audience would be interested in those.

One is there is a general exception to all of these HIPAA requirements. I'm going to call them HIPAA, but it is HIPAA and related legislation, that if on the

first day of a plan year, a plan has fewer than two participants who are current employees, they don't have to comply with any of those requirements.

Now, how many plans have fewer than two participants who are current employees? Well, for active employees, there probably aren't going to be many plans. This is essentially a retiree plan exception, and that exception does not apply for GINA. For GINA, not only does it apply to plans of active employees, it also applies to plans covering only retired employees. So that is one difference.

The other two differences, I can mention, but I'm going to invite Amy and Jim to chime in because they are specific to their departments. The one for Amy's department is the Department of Labor.

Generally, the IRS has enforcement authority to impose an excise tax, and the excise tax is $100 per day per beneficiary for each day that the plan isn't complying with whatever one of those HIPAA laws is with respect to that beneficiary for each day. The Department of Labor has enforcement authority but it isn't any monetary one, like a $100 per day in general.

Do you want to go into what it is, or should I mention it?

MS. TURNER: I'll just mention generally, like Russ said, under the HIPAA enforcement framework, the Secretary of Labor can sue if there is a violation of HIPAA, GINA, mental health parity, any of those laws, to bring a plan into compliance.

Also, under ERISA, which is the law that we administer, individuals have a private right of action, so they can sue, themselves, to get what they're entitled to, or the Secretary of Labor can.

We traditionally have not had civil monetary penalty authority against plans or issuers. GINA changes that. In addition to the excise tax authority that IRS has, the Secretary of Labor also is authorized to impose an excise tax against a plan, which is, again, an employment-based plan, kind of like, picking on GM, if GM is providing health coverage to its employees, there is a separate legal entity that is created called the GM Plan.

GM realizes -- its small employers don't necessarily realize it -- but there is a separate legal entity created called "The Plan". That plan is

responsible for complying with ERISA as amended, including these GINA provisions. Now the Secretary of Labor can impose a civil monetary penalty against the plan administrator if GINA isn't being complied with.

Also, the Secretary of Labor can impose a civil monetary penalty against insurance companies. We call them issuers. It's insurance companies and HMOs that sell policies to employers if they fail to comply.

So again, if you have the small widget company, and Russ says, I've got 20 employees; I just bought a policy from BlueCross; what did I know about GINA, we can go to BlueCross and say, but you guys knew better, and impose a civil monetary penalty against the insurance company or HMO for failure to comply with the GINA provisions in the group market.

MR. WEINHEIMER: It looks like we have a question.

DR. ASPINALL: Have there been any lawsuits filed, or any penalties levied since GINA has been enacted?

MR. WEINHEIMER: Well, we should tell you the effective date of GINA is plan years, beginning on or

after May 21st, 2009. In general, that means for calendar-year plans, they're going to have to start complying January 1st, 2010.

So there may be some plans that, if they have a July 1st to June 30th date, are currently subject to GINA. It's just too early. I don't think that your agency has taken any enforcement action yet.

MS. TURNER: Most plans are calendar-year plans, so it will start becoming effective 1/1/10.

MR. WEINHEIMER: Okay, I mentioned two of the three special provisions for GINA that vary from the general HIPAA structure, the exception for very small plans of fewer than two employees, which basically affects retiree plans and special enforcement authority for the Department of Labor.

Then under the authority for Centers for Medicare and Medicaid Services, the HIPAA laws generally apply to state and local governments, but there is also a provision -- this may be because of unfunded mandates or some other reason, I'm not sure what the basis for it was -- but state and local governmental plans generally can opt out of any of the HIPAA requirements if they wish to.

I don't know if you want to go into detail about that, Jim, or if you want me to just go ahead and talk about it.

MR. MAYHEW: Good morning. What Russ is talking about, there is a group of plans called "non-federal governmental plans," and these are essentially plans for state and local governments, local counties, municipalities, sheriffs offices. There are thousands of these plans that are just throughout the United States.

When HIPAA was enacted in '96, Congress dictated that these plans could affirmatively opt out of the major HIPAA provisions, and they do that by filing a notice with CMS on an annual basis, and then they have to notify their enrollees annually that they continue to opt out.

These major HIPAA provisions that they can opt out of are the nondiscrimination, the special enrollment provisions, the pre-existing condition exclusions. If they opt out, they don't have to follow these rules.

In order to opt out, they have to be self-funded. If they buy insurance for their health coverage, they can't opt out because the insurance carrier has to

follow HIPAA, but fortunately GINA created an exception to this. So under GINA, all non-federal governmental plans have to comply with GINA. They do not have the opt-out option.

That is an exception created by GINA to the opt-out provision. So GINA, all non-federal governmental plans, whether they are insured or self-funded, have to comply with the GINA provisions.

MR. WEINHEIMER: Thanks, Jim. So now we're going to dive into a bit more detail [about] the three substantive rules that we have already mentioned. The first one is that the plans and insurance companies -- we say plans, too, and maybe this is being overly technical but you can have a situation where a plan actually covers the employees for more than one employer and they could charge a different rate to different employers.

So it technically applies to both plans and insurance companies, but there is a requirement that plans and insurance companies and HMOs can't charge a higher rate to a group, based on genetic information of anyone in the group. As we said, HIPAA rules already prevent that on an individual basis; now it's prevented

on a group basis.

The statute provides an exception or a clarification, that if somebody has been diagnosed, if a disease or a disorder is manifested with respect to an individual, then they can rate them up based on the manifestation of the disease, but they can't based on just having the genetic variation that increases their susceptibility or their likelihood of developing the disease.

In the regulations that we issued, we wanted to make clear -- they just came out yesterday -- that even though the plan can rate up, based on the manifestation of a disease, or an issuer can for the group -- they can't do it, still, on an individual basis -- but they can rate up a group on the manifestation of the disease. They can't rate up additionally based on the greater likelihood of family members of that individual developing the disease.

So let's say we have a family-owned business, and you have adult children that are involved in the business, and one of the parents has Huntington's disease. Either there is a greater likelihood that the

children will have it, or maybe we even have knowledge that some of the children have markers for developing Huntington's disease.

So the insurance company can rate up for the one parent that has Huntington's disease that has been diagnosed with it, but they can't rate up additionally for the children that are almost assured to develop Huntington's at some point during their life. They can't rate that up, even though it's a virtual surety. They can only rate up for the one individual with respect to whom the disease is manifested.

That's about all I am going to say about the group rates. I am going to turn it over to Amy to talk about the second rule.

MS. TURNER: The second rule is that plans and issuers can't request or require that an individual undergo a genetic test, and there are three exceptions to that. All three exceptions are statutory exceptions. What we did in the regulations is just provide some examples on how that works and some additional clarifications.

So the first exception is for a healthcare

professional who is providing healthcare services to an individual. That person can request that an individual undergo a genetic test. Here is the example. Kaiser Permanente, an HMO, is subject to the rules. They are an issuer.

So if I'm an employee who works for Russ's widget company and Russ buys an HMO contract from Kaiser, I go to my doctor. My doctor might say to me, hey, Amy, I'm looking at your medical history and your mom has a history of breast cancer. You're getting up there in age; I would suggest that you go get a genetic test to see if you are predisposed to getting breast cancer.

My doctor just requested that I undergo a genetic test. He's an employee of Kaiser but he is my doctor; he is actually providing healthcare services to me. There is an exception for that to make sure that my Kaiser doctor can request that I do that, in the best interests of my health and all that good stuff.

We have some examples, though, that clarify (1) this exception only applies if the healthcare professional is actually providing services to the individual. That wouldn't include a claims reviewer,

somebody who is deciding afterwards, doing some sort of concurrent review, a retrospective review, for the plan to try to figure out whether or not they're going to pay the claim for the plan. It has to be somebody who I actually see and receive healthcare services from. So that is one clarification.

Another clarification that we made is that the exception is not limited to physicians. It could be someone other than a physician, a physician's assistant, an RN. There could be some other healthcare professional that may suggest that I go for a genetic test, who also may be a Kaiser employee. We clarified that that exception is not limited to physicians. So that's the first exception from the general prohibition against plans or issuers requesting or requiring that an individual undergo a genetic test.

The second is that plans and issuers can obtain and use the results of a genetic test to make a determination regarding payment of a claim, but we clarify that that is limited. They can only ask for the minimum amount necessary to pay the claim. Here is an example.

I think we have an example in the reg where an individual wants to get a test -- I think it would indicate whether or not they're likely to get celiac disease -- and the person submits a claim to their plan or their insurance company and wants to get it paid.

The plan may seek some sort of verification that the test was performed if they're going to be asked to pay for it, but they can't ask for the results of the test. That would go beyond asking for just the minimum amount necessary.

So if they want some sort of statement from a lab that says, yes, we did perform this test before they'll pay the claim, that's fine, but they can't say, and by the way, can I have the results of that test. That would go beyond the minimum amount necessary.

Also, we clarify that there may be certain circumstances where it would be medically appropriate. I think probably any plan says, we only pay for items and services that are medically appropriate.

So if I just walk into my plan and say, I decided I want this battery of tests because I'm feeling, today, a little under the weather, it doesn't mean that

the plan is going to pay for it. They only pay for things that are medically appropriate.

Sometimes it may be that if a plan is going to pay a claim, they might need to request that an individual undergo a genetic test in order to make sure that it is medically appropriate to pay some other claim. If your head is swirling, like, what are you talking about, here is the example that we have in the reg.

We worked closely with NIH. I don't see any of those people here, but I'm sure we worked closely with them. NIH told us that sometimes individuals, after they've had breast cancer, after it's gone into remission, may be put on Tamoxifen, just to try to prevent the reoccurrence. There are some studies that have shown that Tamoxifen may not be helpful in up to 7 percent of breast cancer patients if they have a variation of the CYP2D6 gene.

So a plan may say, look, we are willing to pay for your Tamoxifen, but first I want you to undergo this genetic test and show me that you don't fall in that 7 percent, because if you fall in that 7 percent and this isn't going to help you at all, then I'm not going to pay

for the Tamoxifen. It's up to you, if you want to submit claims to me for the Tamoxifen, you need to undergo the genetic test to show me that it is medically appropriate for you to take Tamoxifen. If that is what the tests bear out, then we will pay for it, but if the tests bear out that it is not likely to help you, then we are not going to pay for it.

So the plan can't require it, but they certainly can request it, and they can make contingent payment of the claims based on an individual undergoing that test and showing that, yes, I don't fall into that 7 percent, and therefore it would be medically appropriate for me to take Tamoxifen.

So that is another example that we have in the reg to illustrate an exception where plans may request that individuals undergo a genetic test if they want a claim paid.

The third statutory exception that we provide some additional clarification on in the regulation is the research exception. This is a statutory exception. My understanding of the legislative history is, it was something that was added kind of late. I think it was

something Kaiser was doing in northern California, where they were essentially doing some genetic research and they had this pool of people sitting there, all these Kaiser members, and they wanted to just ask them, do you want to participate in this genetic research.

Because Kaiser is an issuer, Kaiser can't ask individuals to undergo a genetic test, so an exception was added in the legislation. We provide some additional clarifications on that exception in the regulation that essentially describes when that genetic exception can be claimed.

I'm not sure we provided a ton of additional guidance. We repeat the statutory criteria, which is that the research has to comply with 45 CFR; Part 46, and any other applicable state or local laws that are for the protection of human subjects. Those include informed consent requirements. There are also disclosures that need to be made to make sure that people who are being asked to undergo this genetic test understand that it is completely voluntary and that any information gathered won't be used to discriminate against them.

The plan or issuer actually can't discriminate

against them. They can't take that information and then use it for underwriting purposes. Also, if a plan or issuer wants to claim this exception, they are supposed to file with the government, and we have a form available on the Labor Department's website that is the form that someone would use to file before they could claim the research exception.

So those are the three exceptions to the general prohibition against the plan or issuer requesting or requiring that an individual undergo a genetic test. If there are no questions now, I'm going to send it back to Russ.

MR. WEINHEIMER: Thanks, Amy. Unlike Amy, I haven't been participating in these meetings for a dozen years. Looking at the agenda, we're supposed to go until 9:30, and I know Christina and Jim still want to talk.

Do we have five or 10 extra minutes? If not, then I'll just try to rush through what I have.

DR. TEUTSCH: Take a couple-three more, and then we'll move on. We have some time for discussion at the end, so we have some flexibility.

MR. WEINHEIMER: Okay. Under the third market

requirement is that a plan and an issuer cannot request, require, or purchase genetic information from an individual for underwriting purposes, or prior to or in connection with enrollment.

I think the things to be aware of there are, "underwriting purposes" in the insurance market generally is fairly narrow, and it just means we're going to rate someone up or maybe refuse somebody coverage because of their health risks.

In GINA, it is a much broader definition of "underwriting purposes," and if you change their benefits, if you try to give them any kind of incentives, if you lower their co-pays, if you raise their co-pays, if you change the benefits that are available to them, say, as part of a disease management program not based on genetic information but based on their responding to a request for genetic information, then that would implicate the underwriting purposes, and it would be a violation of the rules to request or require someone to provide that genetic information in order to get a greater benefit under the plan, not only just to get a higher contribution rate or to be denied coverage

overall.

The other rule is that you can't request or require genetic information, or purchase it -- we end up using the term "collect" as a summary for request, require, or purchase -- collect information prior to or in connection with enrollment.

The timing of that may be important in some instances because people will sometimes have to re-enroll in a plan every year, so if a plan does collect genetic information but is not using it for underwriting purposes, it's not going to affect your benefits, it's not going to affect the amount that you're charged, but they just want to do that; are you a good candidate for our disease management program, for example.

Then what they can do in that instance is, they can advertise, we have this disease management program. You can enroll if you want to, but they can't start enrolling, they can't offer the person additional benefits for enrolling. All they can do is say, we have this disease management program.

Getting back to the collection requirement, if they are doing that after someone has already enrolled in

the plan and then they're saying, okay, we are going to request some genetic information. You don't have to provide it, it's totally voluntary, but if you respond to our request, we may find out that you're eligible for some of these disease management programs or additional benefits that we do have.

If they provide it, then we said that you determine whether someone is requesting or requiring genetic information prior to enrollment at the time that they are collecting it. This time they are doing it after somebody has enrolled and it is not going to affect their enrollment status.

The fact that they may change plans, they may switch options in one plan and then get back to that option later so it ends up being, in a strict time sense, prior to the time that they later re-enroll in that benefit, doesn't mean that it was genetic information collected prior to or in connection with the enrollment.

I can see baffled looks on people's faces, but go ahead, ask a question and maybe I can clarify it.

DR. BILLINGS: So I have a health and wellness program at my employer's -- this is hypothetical -- and

that health and wellness program is more effective in people with a risk for some disorder, and that risk might be my medical history or might be some aspect of my family history.

Can the employer make, or the health insurance company, make a determination of my risk based in part on my family history, and can they offer any incentives for me to participate in that health and wellness program?

MR. WEINHEIMER: Okay. They can't offer incentives for someone to participate. Let's say that they have a diabetes disease management program and they can't offer incentives. They can give you greater benefits. They can reduce your co-pays, they can reduce your co-pays for diabetes-related claims. They can give you those kind of incentives to join it.

What they cannot do is scour the plan and find out, do we have any people that are at greater risk for diabetes. We can't start asking people, do you have diabetes, does a family member. They can ask if you have diabetes as an individual, have you been diagnosed with a condition, because that is not genetic information.

The definition of genetic information includes

not only the results of genetic tests but the results of genetic tests of family members and medical conditions of family members.

So they can't start asking about family members having the disease. They can't ask about the results of genetic tests for family members.

I can see Amy leaning up to the mic. If you have a clarification, feel free to add it.

MS. TURNER: Well, here's the thing. I see your look of consternation and I feel like you're troubled.

DR. BILLINGS: To put it mildly.

MS. TURNER: I think maybe I can try to provide a little bird's eye perspective. You still might be troubled, but I'll try to give you a little perspective of what we dealt with when working on these regs.

One is that HIPAA already prohibited individuals from being discriminated against. The discrimination provisions were already in HIPAA. I know that when I came to these SACGHS meetings before -- and am I the only person that calls it SACGHS? -- when I came to the SACGHS meetings before GINA was passed and I

listened to the debate about whether or not GINA was needed, one of the things that was debated and talked about was there weren't necessarily a lot of actual cases of discrimination in health insurance in the group market that people were able to find, but there was this fear that people would be discriminated against.

They wanted to keep their genetic information private, and people felt like if they knew that it was private and they wouldn't be asked for it, and they could keep it private, they were more likely to go get genetic tests, get them with their doctor under their real names. So it could be coordinated, and good things would happen.

So what Congress did in GINA, in the group market, is, it really didn't write a nondiscrimination rule so much. There is a small piece Russ talked about, about how the whole larger group can't be rated up by the insurance company, but it had these prophylactic rules to say plans and issuers can't even ask for this stuff.

Doctors can get it, all sorts of other people can get it. There are all sorts of reasons why people need it, but people are afraid of their employers and

their insurance companies having it, because they don't trust that their employers and their insurance companies aren't going to use it to discriminate against them.

There already was a nondiscrimination rule. GINA adds this prophylactic rule and, to be honest, sometimes it's hard to prove why you were fired or why your insurance rate went up. It can be hard to prove, but putting that aside, and I see you're really unhappy, Congress added these prophylactic rules to say plans and issuers can't request it, they can't require it, they can't collect it, they can't purchase it. All these words were thrown out to say they shouldn't even touch it.

There was a wellness exception that was debated in the legislative history and exists in the Title II provisions which are the employment provisions, but in Title I it didn't make it into the final legislation. So we don't have a wellness exception.

So what you have is, if it's a healthcare professional, again, going to my Kaiser example earlier, if they actually hire a doctor who is providing services, there can be discussions about genetic information and

genetic tests.

If the idea is that they're just going to send out a piece of paper and say, tell me your whole family medical history, while that may be used by some plans to do good things, like run it through the computer system and figure out what they might be at risk for and say, hey, you don't even realize that I know your parents are living but they both had heart attacks before age 50 and that puts you at risk, and you might not even know it, go talk to a cardiologist.

I understand they may use it to do good things, but they also may use it to do bad things, and that was the fear, and [that is why] that wellness exception didn't end up in the final legislation.

So where we're at, and I'll turn it back to Russ to go over some of the details, what we tried to do is, essentially say there are ways that plans can still ask for this information, but we are sort of walking a fine line.

They are going to have to be careful and they are probably going to have to make some changes to how they do it, because the statute says what the statute

says. To be honest, although I would like to say that we did all these great things and had all these great ideas on how to handle it, the statute is self-implementing on this point, and I don't think that we really used any regulatory discretion at all. If we hadn't published the regulations yesterday, I think that is what this statute says.

So I think what we really tried to do was issue some examples that would help plans that were trying to do good things to say, you can still do good things if you make some modifications and set it up this way, like Russ is going to talk about. But there is this prohibition that says, you can't just hand people a piece of paper and say, we want all your family medical history and if you don't fill it out, your premium is going to be 50 bucks higher; if you do fill it out, your premium is 50 bucks lower.

Even if the plan is going to use it for the "good purpose," we have this prophylactic rule, and you have these people saying, so I have to turn over my family medical history or my premium goes up 50 bucks a month? I thought this is what I didn't have to worry

about anymore after GINA.

MR. WEINHEIMER: Well, I'm going to try to do this quickly, but there is a fine line that we have drawn, and the sequence is the plan can't ask for genetic information, including family medical history, if it's conditioning any benefit or if it's paying you to provide the information, it can't do that.

It can ask for genetic information, it can just say, if there's nothing connected to it. It can say, we can ask for genetic information.

So they could have a separate medical questionnaire that they send out to people, apart from one that they may provide some incentives for, that says, this is our genetic information questionnaire. You don't have to complete this one if you don't want to, but if you want to, feel free to complete it, and it may help you understand. We may be able to identify certain benefits under the plan that are better for you if you do complete it, but we aren't going to pay you for it. You don't get any greater benefits for completing it. All it is is additional information for us.

Then once they have done that, they can ask for

that information. Then if they get that information, the plan can advertise what programs it has to them without telling them that they need to enroll or something like that. They can just advertise what programs they have, what benefits they have that may be beneficial for that individual, based on the family medical history and genetic information that they provided to them, and if the individual then seeks to enroll, they can provide enhanced benefits within those programs.

They can have enhanced benefits if someone enrolls in a diabetes disease management program, but they can't send out a medical questionnaire saying, listen, we'll give you additional benefits for diabetes if you complete this genetic information questionnaire. They cannot do that. So it's a fine line that we're drawing.

We also have some exceptions for some incidental collection under the statute and that is, basically, if a plan is seeking information from someone, let's say they just, on an annual basis, say, we want you to verify that this is your home address still and these are the people that are enrolled in the plan.

If that's all they are doing, and somebody provided genetic information and somebody said, oh, well, my dad just died of colorectal cancer and I'm sorry, it took me awhile to get back to it. I know I'm late. I didn't meet your deadline for verifying this, but that was why, well, that would be family medical history that the father had colorectal cancer, but that would be subject to the incidental collection exception.

Well, they weren't asking for it, just asking for a verification of who's in the plan and what your address is. It's just unreasonable to expect that they would provide genetic information there.

If they are sending out a general medical questionnaire and it only applies to the individual, they just say answer this for yourself but they say, is there any other additional information, at the end of the questionnaire, that you would like us to know, well, it is reasonable that someone might start talking about their family history there.

So we've said, if you have general questions that solicit [information], well, a reasonable person might answer by giving genetic information, that's not

going to be subject to the incidental collection exception, unless you specifically say, do not provide any information related to family members and do not provide any information relating to the results of genetic tests.

I think that's pretty much it. So we'll turn the time over to Jim for the individual market.

DR. BILLINGS: Can I just ask one follow-up question on this issue?

My concern is that the healthcare system be able to identify people at high risk for things, particularly when you can do something to prevent the later development of disease, and the burdens of that, and the costs of that, and can we spend the money on something better than that.

MS. TURNER: I think the healthcare system can, if you're talking about healthcare professionals. When you're talking about the payers, there are some limits.

I think, as Russ described, plans can ask for that information if they don't provide an incentive and if they do want to provide an incentive for people turning over their family medical history. They have to

do it a certain way, like he described with the disease management program.

DR. BILLINGS: So is genetic information or family history information being treated as a special class of that kind of information for this particular kind of thing?

MR. WEINHEIMER: Yes.

MS. TURNER: Yes.

DR. BILLINGS: Thank you.

DR. TEUTSCH: Sam?

DR. NUSSBAUM: Sam Nussbaum from Wellpoint. So this is something that is very significant to health insurers and employers, because then I wonder if you've thought this through. I imagine you have seen the various consequences, to build on Paul's statement.

Today, literally millions of people fill out what are termed "health risk assessments," and as you know, this is a well-evolved science in terms of, what are the intended consequences of filling out that health risk assessment. In part, it is to help people be far better informed about risks for them, their potential chronic illnesses and how they can engage in health

improvement and avert some of the long-term consequences.

Now, it has also been part of the practice of, as you say, creating incentives to get people to fill out health risk assessments, because when people fill them out they can become much more involved in these programs and others, and we all wish we had a perfect healthcare system where all of us got recommended care 100 percent of the time, but we don't; we only get it about half of the time.

So the question that I have is, as you've thought through these regulations, that you're dealing with changes for millions of people, and many of the unintended consequences could be far less knowledge, involvement, and preventive activities related to chronic illness.

Certainly, we understand what the intent of GINA was, and the intent of this regulation, but have you actually looked through how many employers encourage and in fact provide incentives for filling out these health risk assessments, and what the long-term consequences might be?

MS. TURNER: I guess I would say -- and Russ,

feel free to jump in -- this was the number one issue, health risk assessment, that we heard about in the comment letters that we got in response to the RFI.

Also, this regulation, like every regulation that the government does, has an economic analysis where we discuss the costs and benefits attributable to the statute, and attributable to exercises of regulatory discretion.

As far as unintended consequences, I'm not sure I can answer that question, because I go back to what is an unintended consequence of all the members in Congress who voted for this overwhelmingly or not. I don't know. There was an exception for wellness programs in Title I, in versions of the bill as they moved through, and it was taken out.

Whether it was an unintended consequence or an intentional decision, I don't know. It all goes back to what Russ was saying, a plan is not allowed to request genetic information for underwriting purposes. There is a statutory definition of "underwriting purposes" that is probably broader than you and the insurance industry would have thought "underwriting purposes" meant.

To be honest, we probably would have interpreted it differently if there wasn't a statutory definition. The statutory definition says that any change in eligibility, benefits, or premiums is an underwriting purpose. So as soon as you're giving people incentives, cash, return on premiums, any sort of penalty if they don't comply, it's an underwriting purpose.

So if you're affecting eligibility, benefits, or premiums based on whether or not they fill out that health risk assessment and turn over the family medical history, there is no statutory authority for us to have come out any other place, to be honest.

I think what we tried to do in the regulations was recognize this point, which we heard loud and clear in the comment letters, and say you can have two separate HRAs. You can have the first one and you get 50 bucks if you fill out that one. Then there is the second one, which is right behind it, and we explain all the same good reasons for filling it out, but whether you fill that out or not, you don't get 50 bucks.

A lot of people might very well fill them both out. When people use the word "incentive," I feel like I

always smile a little bit inside, because one person's incentive if they participate is another person's penalty if they don't. That is how we viewed it in wellness programs, going back to HIPAA in 1996.

If I get 50 bucks and you don't, that is a $50 incentive to me but it is a $50 penalty from your perspective. What GINA very clearly says is, you can't vary individuals' eligibility, benefits, or premiums based on whether or not they respond to a request for genetic information.

We had some ideas for how you might be able to make it part of a disease management program and still offer incentives, but there are some statutory limitations there. I think we tried to do the best we could to preserve what I referred to before as the good things that we recognized that insurers and plans are doing, and just tried to draw this line.

When you talk about a health risk assessment from Wellpoint, I know what you're talking about, but there could be fly-by-night insurance companies sitting in some chair over there that also have their health risk assessment, which looks very different from yours, and

there is no way under the statute to distinguish the two.

So I think, again, we tried to use the idea of, just separate your health risk assessment into two: one has a reward; one doesn't. Rely on your healthcare professionals, use the disease management program, and try to keep doing the good things that you are doing without running afoul of the statute that says what it says. It is sort of this fine line we tried to walk.

DR. TEUTSCH: Why don't we move on to Jim?

Individual Insurance Market Provisions

James Mayhew, J.D.

MR. MAYHEW: I'm going to talk, very briefly, about the individual market.

As Amy said, the individual market, the individual health insurance market is exactly what is says. It's when the individual goes directly to an insurance company to purchase health coverage for themselves or for themselves or their family.

So GINA was really very groundbreaking in the individual market because, unlike the group market, up to the point when GINA was enacted, there was no protection in the individual market in terms of rating based on

health status. So in the individual market, if anybody applies for coverage, the insurance company can have them fill out a health form and get medical information from their provider and it would rate them, rate their premiums based on their health status, and also with the exception of a very limited class of individuals called HIPAA-eligible individuals, there was also no protection against basing eligibility or pre-existing condition exclusions based on health status.

So GINA is really the first type of this protection for most people in the individual market. What GINA does is say that insurance companies cannot base eligibility, it cannot impose pre-existing condition exclusions, nor can they rate premium based on the genetic information of an individual. They can still do those things based on manifested conditions of an individual, but they cannot do those things based on genetic information.

And so we call these provisions the catch-up provisions for the individual market to sort of get them up to speed or same level of protection as there is in the group market in terms of genetic information.

In terms of the prohibition against requiring genetics test and collection, they're virtually the same as in the group market, so I won't go into those because what Amy and Russ said about the rules against collection and requiring genetic tests also apply in the individual market as does in the group market.

So what we simply did in the regulations was we basically reiterated the three new protections, the prohibition against imposing pre-existing conditions exclusion, basing eligibility and rating premiums based on genetic information, and then in terms of the prohibitions against the testing and the collection, we basically cut and paste what was in the group market, shifted it over to the individual market and just made some just minor changes to make it more relevant to the individual market.

And that's essentially what the individual market regulations do. I just wanted to just talk about one instance about collection. Amy and Russ talked about the health risk assessments in the group market in terms of the wellness programs.

Well, that's not very common in the individual

market. What you're going to see more in the individual market in terms of collection is an individual basically applying for individual coverage and they fill out a release to the insurance company for them to get their medical records from their providers and because when they request a medical record from a provider, it can be reasonably expected that there's going to be genetic information in that medical record, what the insurance companies have to do is put a disclaimer in that request saying please do not send me any genetic information, including family history, and so when the provider gets that, hopefully what they'll do is they'll purge the medical records of any genetic information, any reference to family history or any information on genetic tests or genetic services.

Even if the provider fails to do that and the insurance company receives it, well, as long as they put that disclaimer in there and as long as they don't use that information for underwriting purposes, the insurance companies will be fine because that falls under the incidental collection exception.

If they didn't put that disclaimer in there in

the request and they get that information, then they would have violated GINA. So we make that really clear in the regulations and we give the insurance companies specific language they can use for that disclaimer so that they can remember to put the disclaimers in those requests for medical records.

The only other thing I wanted to point out about the individual market is the enforcement. The states are the ones that really have the primary enforcement authority over insurance companies. States regulate insurance. So each state has a Department of Insurance and so basically in terms of GINA, the states will be the primary enforcement authority, the state Department of Insurance, for the GINA protections in the individual market.

CMS has the authority to step in if a state substantially fails to enforce any HIPAA provision, including GINA. So we've been in the past year and a half, ever since GINA's been enacted, we've been working very closely with the state Departments of Insurance, making sure that they have the state laws so that they can enforce the GINA provisions and we're working with

them on an individual basis. We work with them through the National Association of Insurance Commissioners and it seems like at this point most states are on track to get those statutes in order, regulations in order, whatever authority they use to be able to enforce these GINA provisions.

The only other thing I wanted to talk about briefly was the Medicare Supplemental Insurance, also known as MediGap, and these are supplemental coverage that people and fee-for-service Medicare can purchase to help pay the deductibles and co-pays in Part A and Part B and also some of these MediGap policies cover additional services that Medicare doesn't cover.

Now, I think it's Section 104 of GINA really imposes the same protections as far as people with MediGap policies. It prohibits MediGap insurance companies from discriminating based on genetic information in terms of rating the premium, based on eligibility, or imposing pre-existing condition exclusions, and it has the identical prohibitions against collection and requiring genetic tests.

Now, the MediGap piece is not addressed in

these regulations. Instead, the National Association of Insurance Commissioners has what we call a MediGap Model Regulation and it basically incorporates all the federal standards to the MediGap Plan and the states are required to adopt these model regulations in order to be able to regulate MediGap policies in their state. If they don't do that, then CMS is supposed to step in and regulate the MediGap policies in that particular state.

The NAIC amended their MediGap model on September 24th of 2008 to incorporate the GINA provisions. What they essentially did was they cut and pasted the GINA statute and they put it right into the MediGap model and so the states were required by July 1st of this year, 2009, to incorporate those GINA provisions and most states have done so and the remaining states are on track to get those into their regulatory structure soon.

So that's basically the high-level overview of the individual market and MediGap, and I'm happy to answer any questions.

DR. TEUTSCH: I'm sure there will be some as we get into the discussion period.

Robinsue and Christina, want to talk about Privacy and Confidentiality?

Privacy and Confidentiality

Robinsue Frohboese, J.E. and Christina Heide, J.D.

MS. FROHBOESE: Thank you, Steve. Good morning, everyone. I'm Robinsue Frohboese, the Principal Deputy of the Office for Civil Rights at HHS, and like Amy, I've had the privilege of serving as an ex-officio on this committee since it was created in 2001, and I well remember the early days because, as luck would have it, we were seated alphabetically and I sat next to Francis Collins who, at that point, had not completed the human genome sequence but did shortly thereafter and actually yesterday was at the White House receiving a National Medal of Science for his incredible efforts in this area.

I remember Francis speaking very passionately about the need for nondiscrimination legislation for genetics information. And so, I just wanted, at this midpoint in the panel, for us to just step back from the bureaucrats, as Amy has said, and to just recognize the importance of this moment and the fact that back in 2001

this committee took on passage of the Genetic Information Nondiscrimination Act as its number one priority. As a result, the Committee held public hearings, did gather testimony about, both, actual discrimination as well as the chilling effect of the fear of use of genetic information. It really was the concerted effort of this committee that, although it took seven years, resulted in the significance of GINA finally being passed.

I think, in your packages there are the press releases that HHS issued with the publication of our GINA regulations, and there you see in the quote from Secretary Sebelius, who invokes the memory of Senator Ted Kennedy as well as his words, that GINA is the first major civil rights legislation of this century.

So I'm so pleased that the Office for Civil Rights is part of this effort. Our involvement is that Congress wanted to add the extra protection of ensuring that there are HIPAA privacy protections for genetic information, so it directed us to do two things in amending our HIPAA regulation.

First, to make it clear that protected health information does include genetic information and, second,

to ensure that genetic information is not used or disclosed for underwriting purposes, and so for the past year, we have been involved in very intensive coordination with our partners at Treasury, Labor, CMS, and EEOC to ensure consistency in our approach in the suite of regulations and in our definitions.

Our Deputy Director for Health Information Privacy at Civil Rights, Sue McAndrew, regrets that she couldn't be here today, but we're fortunate to have the principal author with us, Christina Heide, as well as I would like to recognize in the audience two other members of our staff, Ileana Peters, who will be sitting in during this meeting, as well as Jennifer Weisman, who came to us first as a AAAS fellow to work on this regulation and we're very fortunate that now she is a permanent employee with us.

So with that, let me turn it over to Christina to give you the broad overview of the HIPAA provisions.

MS. HEIDE: Thank you, Robinsue, and thank you for the invitation to be here today. We are very pleased that our proposed rule was published just yesterday, along with the other Title I regulations, and our rule

deals with a different HIPAA, different piece of HIPAA.

We like to think of our HIPAA as the big HIPAA, but I know DOL might think differently.

MS. TURNER: What am I? Chopped liver?

MS. HEIDE: So when I talk about HIPAA, I talk about Title II of HIPAA which includes privacy provisions and under which the Privacy Rule, the HIPAA Privacy Rule was born, which regulates the uses and disclosures that covered entities, certain healthcare providers and health plans may make with individuals' personal health information, what we call protected health information.

And one thing I do want to note, our rule is just a proposal, so we have a 60-day public comment period that closes December 7th, and we encourage public comment on all aspects of the proposal. The instructions for submitting comments are in the proposed rule itself upfront and I do want to underscore one thing that Robinsue mentioned which was we coordinated heavily with the other agencies, particularly the other Title I agencies, to ensure that the definitions and other cross-cutting issues were the same and you'll see that the definitions are substantially, if not completely, similar

across the Title I regulations and we also, as well, consulted with NIH on the technical aspects.

So we have a small piece of GINA, Section 105 in Title I. Congress recognized a distinct privacy interest in the use of genetic information by health plans, distinct from the nondiscrimination aspects of Title I, and Section 105 requires us to amend the HIPAA Privacy Rule to do two things, as Robinsue briefly mentioned.

One is to clarify that genetic information is indeed health information and thus protected under the rules and, two, to then prohibit certain health plans from using or disclosing that information for under-writing purposes. Our section also includes that broad definition of underwriting. So the definition of underwriting purposes across the regulations is the same. Our regulation does not deal with what information can be requested. We deal with uses and disclosures once the health plan has the information.

So just a couple of points. The proposal goes ahead and does those two things. [There are] two things I would like to point out and draw your attention to.

The GINA statute required that we prohibit group health plans, health insurance issuers, including HMOs, and the MediGap issuers, to prohibit those plans from using or disclosing genetic information for underwriting purposes.

However, under the Privacy Rule, we cover a number of other types of health plans, as well, including certain public benefit plans, such as Medicare, state Medicaid agencies, the VA Program, the Military Health Program, long-term care insurers, excluding nursing home fixed indemnity policies, and certain accepted benefits, such as limited scope, vision, and dental plans that are separate from group health plans.

And so our definition of health plan is broader than the plans listed in GINA and under the Privacy Rule currently, an individual's privacy interests are protected, the individual's information is protected without regard to which type of health plan holds the information, and so pursuant to our general HIPAA authority to regulate the uses and disclosures of health plans, we expand the prohibition on using or disclosing genetic information for underwriting purposes to all

health plans covered by the HIPAA Privacy Rule to maintain an individual's uniform protection across all plans that we currently have today in the HIPAA Privacy Rule, and also in recognition that we do not expect that all health plans today use or disclose genetic information for underwriting purposes, and certainly most of the public benefit plans may not do underwriting at all in terms of eligibility and determinations of benefits.

So we certainly welcome public comments on that, but I did want to point out that we do have a broader scope in the Privacy Rule.

The other one item I wanted to note is that under the Privacy Rule, an individual has the right to receive a Notice of Privacy Practices of covered entities, including health plans, and for those health plans that do underwriting, the proposal would require that the plans amend their Notice of Privacy Practices to explicitly state that even though they may do underwriting, they may not use or disclose an individual's genetic information for those purposes, so that individuals are put on notice or made aware of this

important new right that they have and this limitation, this change in privacy practices for the plans.

Other than that, we do on our website have the proposed rule. We have a separate page for genetic information now and we do have the proposed rule, links to the other rules, as well as some press releases and related matters. So we encourage you to visit our site. I believe it's listed in the press release that the agency's put out on these rules.

Thank you.

DR. TEUTSCH: Liz, did you have a question?

DR. MANSFIELD: Liz Mansfield, FDA. Is all genetic information considered medical information, and if it's not, where do you draw the line?

MS. HEIDE: The department has always considered that genetic information is protected health information. We say to the extent it otherwise meets the definition.

So what Congress said was please clarify that it is health information. So now we have an explicit reference to genetic information in our definition of health information. Not all health information, however,

is protected by the Privacy Rule. It needs to do two things.

One, it needs to be maintained by HIPAA-covered entity, a health plan, HIPAA-covered healthcare provider, for example, and, two, it needs to be individually identifiable in order to be protected by the rule. So we've clarified that it's health information.

The Preamble also goes on to state that it still must meet the definition of protected health information to fall under our Privacy Rule.

DR. TEUTSCH: Could I ask you a follow-on question to that because this committee is very interested in direct-to-consumer testing, as well, and has been and we've actually had substantial discussions about whether the information that's gathered there is health information. You've made clear what you consider health information.

To what extent are those laboratories, many of which are CLIA laboratories and subject to the rules that you're just describing?

MS. HEIDE: They would be a healthcare provider, but we don't cover all healthcare providers.

By statute, the HIPAA rules only apply to those healthcare providers that conduct certain transactions, financial and administrative transactions electronically. For example, billing a health plan.

So it could be in some cases that these independent labs that do not, for example, bill health plans for the services that they provide to individuals may not be HIPAA-covered entities, but to the extent that they do, they would be covered healthcare providers and subject to the Privacy Rule and they can use and disclose genetic information for treatment purposes. Obviously GINA does nothing in that area to prohibit providers from using the information for treatment purposes.

But it would be dependent -- it's a two-part test for healthcare providers. One, you need to be a healthcare provider and meet our definition. Two, you need to be doing one of the transactions electronically.

DR. TEUTSCH: Marc.

DR. WILLIAMS: Marc Williams. One of the other issues that this committee has been looking at is the issue of the identifiability of DNA samples, and I assume at the present time that the definition of identifiable

health information does not quite go to the level of weighing in on the identification of a DNA specimen.

MS. HEIDE: That's correct. We have not opined to date on to what extent or how much of the genetic sequence, if that's all that's there, is identifiable. Obviously, if there are analyses or other identifiers attached to it, that would be a different story.

I mean, we would certainly, before we would do something like that, need input on what to say from you all and the industry, but to date we have not made a determination.

DR. TEUTSCH: Great. Thank you all. Hopefully you can stay for the rest of the discussion.

Kerry Leibig, you want to carry on, talk about Title II?

Title II - Prohibiting Employment Discrimination on the Basis of Genetic Information

Kerry Leibig, J.D.

[PowerPoint presentation.]

MS. LEIBIG: Okay. Fancy. All right. I went ahead and provided some PowerPoint slides because I have

been traveling around talking about Title II, which is the employment discrimination provisions of GINA, to EEOC personnel, to some employers who've asked for sort of a preview of what the Title II regs are going to look like, and I went ahead and just modified it.

Usually this takes about an hour and a half and I modified it, so I'm hoping it's going about 20 minutes. So give a wave, Sarah, Steve, if I'm going over.

Title II becomes effective on November 21st. We are in the home stretch now of issuing our final regulations, but we haven't done so yet. So today, we're going to be talking about our proposed regulations and I will be pointing out topics on which we got a good deal of comment sort of so that you can be aware of where it's likely that the final regulation is going to be a little bit different.

And on this, I think everybody has handouts that parallel the slide show here and you'll see that I've put in regulatory sites for the various topics, but on my way over here, I realized that I didn't put in the whole site because I'm so used to talking in shorthand. But when these regulations are issued, they will appear

at 29 CFR 1635 and on your slides, you'll see reference to 1635 point something or other to point you in the right direction and that's 29 CFR 1635.

Okay. So we're just going to jump right in. Feel free to ask questions as I go along or you can wait until the end, but basically we have three rules under Title II. It prohibits the use of genetic information to make employment decisions, it restricts the acquisition of genetic information by employers and other entities covered by GINA, and it requires that covered entities keep genetic information confidential, subject to limited exceptions.

I can't move because I don't have a microphone attached to me, so I'm feeling a little awkward here, but that's why I'm standing right here.

In any case, in a moment I'll give a definition of genetic information for purposes of GINA, but the important thing to see here when we're talking about the three basic rules is that the first rule, which prohibits the use of genetic information, is an absolute rule.

Under no circumstances can an employer use genetic information to make an employment decision and

this is intended to operate pretty much like Title VII of the Civil Rights Act of 1964's prohibition on using race or sex, for example, to make employment decisions. You can't use genetic information to decide to hire someone, fire someone, promote someone, give someone a raise, make any decisions related to terms, conditions, or benefits of employment, and that includes a prohibition against harassment based on genetic information and an anti-retaliation provision. If someone takes protected action under GINA, they can't be retaliated, for example, for filing a charge of genetic information discrimination. So it's very broad. It's also pretty simple to understand because there are no exceptions.

The second two rules, in particular the second rule, which restricts the acquisition of genetic information, has six exceptions and therein lies the complication and that's where we got most of our comments and I'm going to talk more about that in a moment.

And then the third rule is just a basic confidentiality rule. Genetic information, like all medical information, must be kept confidential. There's six limited exceptions that are very similar to the

exceptions we have under the Americans With Disabilities Act for confidential medical information and we'll talk about that in a moment.

Very briefly, obviously usually I'm giving this talk to EEOC investigators or employers and they have no idea what we're talking about when we say genetic information. Obviously that's not a problem here, but I did want to go ahead and make sure we're all on the same page and know what we're talking about under Title II here on genetic information.

First, obviously an individual's genetic tests, the proposed rule gives a specific definition of this based on the statute and also some examples of things that are genetic tests and some examples of things that are not genetic tests.

This is an area where we got a lot of comments, where people wanted more examples and they wanted the examples to appear in the regulation as well as the Preamble, and you can expect to see some of that in the final reg, but obviously an example of a genetic test would be a test to determine if someone had the gene that predisposed them to breast cancer. That would be a

genetic test, but a drug or alcohol test is not a genetic test. A test for the presence of non-human DNA, RNA, or virus, like an HIV test, is not a genetic test. So we're talking about genetic tests, not other kinds of medical tests.

Genetic information also includes genetic tests of family members and family members is very broadly defined. It includes not only your children, spouse and husband, adopted children, but also all of your relatives up to the fourth degree, so your great-great-grandparents and your first cousins once removed, which means the children of your first cousins, information about them, genetic tests about those family members is also genetic information.

Very importantly, genetic information includes the manifestation of disease or disorder in family members. In other words, your family medical history, and this is important and this is where we're expecting that we're going to get the charges that we get because this is an area where employers do have family medical history. It's probably not that current right now that employers would get your information about your genetic

tests or genetic tests of family members, but family medical history is the kind of information that employers often have.

And finally, genetic information includes the request for or receipt of genetic services by an individual or a family member. That includes genetic tests, genetic counseling, genetic education, and the genetic information of a fetus carried by an individual or family member or of an embryo legally held by the individual or family member using assisted reproductive technology. So that's what we mean when we say you can't use genetic information.

Okay. Did I see a question? Yes?

MS. ASPINALL: I just have a quick question. When you talk about, I think I heard it right, non-human samples, like you used the example of AIDS virus, I'm assuming you mean sort of AIDS virus genotyping where you're --

MS. LEIBIG: HIV tests.

MS. ASPINALL: HIV tests. Where you're getting the information on the virus itself and therefore not considering that human testing. Is that --

MS. LEIBIG: That's right. That's correct. An HIV test and all of these examples where we're talking about genetic information, genetic tests, this is not an area in which EEOC has any expertise or experience. So these all came from experts we consulted at NIH.

MS. ASPINALL: So did you talk at all about information on the tumor in a cancer patient in the same way as you're talking about information on the virus in an AIDS patient? Did you use any examples in looking at the tumor itself as opposed to genetic basis of the individual?

MS. LEIBIG: We certainly don't have anything on that in the proposed rule. The final rule is going to add some examples. What exactly those examples are going to be, I can't say right now. It's still in the process of being discussed, but anything that we did add or any definitions that we clarified from the statute, we did so because of NIH and other experts because EEOC doesn't know anything about that. Does that make sense?

MR. WEINHEIMER: Yes. I would just like to add to what Kerry said. The Title I provisions, we share the same definitions, and we relied on NIH to tell us what

constitutes that.

But I'll take a stab at your question when you talk about cancer. I think the tumor is part of the individual -- has the individual's DNA in the tumor. So I don't think that it would be excluded the way that HIV is which is some other organism, if a virus rises to the level of a full organism, but, anyway, I mean, it is separate DNA for the virus, whereas the tumor, I think, would have the individual's DNA.

MS. ASPINALL: That's what I was trying to understand, the subtlety, and then the second question was are all the Title I provisions in terms of definition consistent with Title II?

MR. WEINHEIMER: We have minor differences, but they're mostly consistent, I would say.

MS. LEIBIG: That's right. We did work together and they're mostly consistent. There are a few differences when you're talking about what a family member means in terms of dependent due to some provisions in ERISA, but essentially we did sit down together and try to make sure they're going to be the same.

Okay. So the first rule prohibited use,

absolute rule.

The second rule has to do with acquiring genetic information. Covered entities shall not request or require or purchase genetic information of an applicant or an employee and here there are six exceptions and there's sort of six situations where employers are permitted to acquire genetic information and, as you'll see, they sort of take into account the legal framework that already existed as well as just how the employment life works.

So the first one is intended to protect the supervisor who is walking down the hall one day and overhears a subordinate on the telephone saying, oh, I had a terrible weekend, my son was diagnosed with asthma. That is family medical history about that employee because that's a manifestation of a condition in a family member. The employer has now acquired genetic information.

Similarly, if an employer says or a supervisor says, oh, how are you doing today, how was your weekend, and in response, an employee says, oh, it was terrible, my sister was diagnosed with breast cancer, they've just

acquired genetic information.

Does that violate Title II? No. The statute and the regulation anticipated this problem and we have our first exception which is no liability for inadvertent acquisition. This protects covered entities that unwittingly receive otherwise prohibited genetic information. You'll see some examples there. The unsolicited e-mail message, the how are you, or documentation to support a request for reasonable accommodation or other lawful request for health information that employers do under various laws or policies.

Now, this is an area that we got quite a bit of comments on, mostly having to do with situations where employers are lawfully requesting medical information, and we had some civil rights groups who were saying, look, any time an employer's requesting medical information, be it in response to reasonable accommodation requests or fitness for duty, post-offer exam, they should know that they're probably going to get genetic information.

It's reasonably likely they're going to get

that information and they shouldn't be able to take advantage of the inadvertent exception, and then we had employers who were concerned that their HR departments were going to be responsible for telling doctors who were doing these exams for them how to do the exam and they wanted the rule to say no matter what, employers can't get the information but doctors can collect it.

So this is an issue that we're going to be -- you should expect some changes in the final regulation. We're going to be fine-tuning it, but the general rule still exists that it is a violation of GINA for an employer to request, require, or purchase genetic information.

It's interesting because, I don't know how many of you know this, but under the Americans With Disabilities Act, which EEOC also enforces, employers may conduct post-offer medical exams and inquiries or fitness for duty exams, as long as they meet the ADA requirements, and for example, under the ADA, once you make a job offer to an employee, you can condition it on a medical exam and that medical exam can include any kind of medical inquiries that you'd like, any kind of exam,

as long as you treat everyone entering for that same position in the same way.

And as you can imagine, most of these post-offer exams, as well as fitness for duty exams, which are what we call the exams that an employer sends a current employee to under certain defined circumstances, but these exams usually involve questions about family medical history. All right.

Under GINA, as of November 21st, 2009, an employer that asks for genetic information as part of an inquiry or medical exam will not be considered to have acquired the information inadvertently. That's obvious. If you ask for it, it's not inadvertent when you've receive it.

So GINA changes the landscape here. Under the ADA, this kind of questioning was okay in a post-offer fitness for duty exam. It no longer is okay under GINA. Covered entities are prohibited from obtaining genetic information through any type of exam required of employees.

Again, we got a lot of comments about this. We are definitely going to have some more examples in the

final regulation trying to clarify how this is going to work, but just keep in mind there's no exception for an employer doing a post-offer exam to obtain family medical history or any other kind of genetic information.

Okay. What about employer-sponsored health services and here where we get into the issue of wellness programs. As Amy said, although Title I does not have an exception for wellness programs, Title II's exception for employers obtaining genetic information through wellness programs did survive. It is in the statute.

An employer may request genetic information as part of health or genetic services, such as a wellness program, as long as specific requirements are met and this is what was said in the proposed rule. The wellness program must be voluntary. That means the employer must not require participation nor penalize employees who refuse to participate. You have to have a written request, knowing authorization. The information goes only to the healthcare provider and the individual with the employer getting the information in the aggregate.

In the proposed rule, we specifically asked for comments on the scope of the term "voluntary," and we got

a lot of comments and these comments ranged from groups that were of the opinion that in order to be considered voluntary, a voluntary wellness program and therefore a wellness program that was permitted to collect genetic information, there should be no financial inducements.

So we got a number of comments that suggested that approach, and we got a number of comments on sort of the other side of the line there that wanted us to adopt the HIPAA 20 percent rule, meaning as long as any inducement was limited to 20 percent of the cost of group or individual health insurance, then it would be considered voluntary.

This is an area in the final regulation. We will go through the comments we have received. We'll discuss them, and we will have an answer, but we don't have one yet because the final regulation isn't out there yet.

Questions on that? I think probably some of you in the audience are people who submitted comments on this proposal and you will see that we'll address those in the final reg.

Okay. Number 3, I'm going to certainly do a

little more quickly here because these are pretty obvious exceptions.

Under the FMLA and other similar state and local laws, individuals requesting leave often have to provide family medical history because, if they're asking for leave to care for a seriously ill relative, they have to describe the relative and the illness. That's not going to be a violation of GINA. Asking an employee to fill out the general FMLA Certification Form that requires that they give the information about their relative is not a violation. Of course, any information that an employer does get has to be kept confidential, treated as confidential medical record.

Exception Number 4. This was intended to cover the supervisor who's reading the newspaper one day and comes upon an obituary of an employee's father and it says they passed away after a long struggle with lung cancer. They've just acquired genetic information.

Really, this is sort of a subset of inadvertent acquisition, but Congress created a separate exception, and it says that it's permissible for an employer to acquire genetic information through commercially and

publicly available documents such as newspapers, periodicals, magazines and books, also information obtained through electronic media, such as television, movies, or the Internet. The exception does not apply to medical databases, court records, or research databases available to scientists on a restricted basis.

This exception is another area where we got a lot of comments having to do with, what about Facebook, what about the websites, blogs, all these sorts of 21st century media sources. Again, you're going to see when the regulation comes out at 1635.8(b)(4), there is going to be a lot more detail of how Title II works in relation to those kinds of sources.

We had, again, the range of comments from civil rights groups who were very concerned that an employer who was searching for the information, purposely looking for genetic information but happened to find it in the newspaper, wouldn't be able to take advantage of this provision because, really, it's supposed to be the type of inadvertent acquisition, not the employer who is trying to get this information.

Then we also had employers who were very

concerned because they use the Internet as a tool when they are doing the application process. They do Google searches. They want to look at people's Facebooks to determine if they are going to be someone they want to hire. So we had a broad range of comments, and we will be addressing them.

The fifth exception. It's permissible to acquire genetic information through genetic monitoring. Again, that monitoring has to meet specific requirements and this is dealing with employers that, either because they have to under OSHA or Mine and Safety Health Administration rules, they have to monitor the biological effects of toxins in the workplace or employers who are voluntarily monitoring the effect of some toxin that their employees are exposed to, and GINA has carved out an exception, saying yes, this is okay again, as long as you notify your employees, they give knowing authorization, they voluntarily comply with the genetic monitoring.

Of course, if the genetic monitoring is required by law, you don't have to make it voluntary, and again the information is protected. It only goes to the

employee and the healthcare provider, the covered entity getting the information in the aggregate.

And the last exception is very limited. It only applies to employers that engage in DNA testing for law enforcement purposes as a forensic lab or for purposes of human remains identification. These employers may require genetic information from employees to the extent that genetic information is used for analysis of DNA markers for quality control to detect sample contamination.

We didn't really get any comments on this. We did get some sort of informal comments from people who say this kind of DNA marker isn't even genetic information, but we are not experts on that and this is an exception that's in the statute, so obviously we're putting it in the regulation and this is an exception to the general rule against acquisition.

So to sum up all of that, I just want everyone to keep in mind that the rule is employers cannot acquire genetic information. They are not permitted to acquire it.

There are six circumstances in which they're

allowed to get the genetic information, despite the general rule. If they get it outside of those six exceptions, it's a violation of GINA in and of itself, even if they don't use it. Okay? This works very much like some rules under the Americans With Disabilities Act that says you're not allowed to ask certain questions, certain disability-related questions, we call them, even if you don't use the information. You're not allowed to have it in itself. Acquiring it is a violation.

The third basic rule, again beginning November 21st and thereafter, genetic information that an employer has must be kept confidential and must be placed in a separate medical file. ADA file is okay. It means that this has been a rule about medical information under the ADA and before that under the Rehabilitation Act for years. You can keep your genetic information in the same file that you keep your ADA information, but it must be kept separate from personnel records.

There are six disclosure rules. They're going to be listed at 29 CFR 1635.9(b). I don't have time to get into them, but they're things like you can disclose genetic information to government officials who are

investigating compliance with GINA. You can disclose genetic information in response to a court order that specifically asks for genetic information, and there are four other rules that I won't get into.

There's a specific section of Title II that addresses the relationship between Title I and Title II and we call it The Firewall. In the proposed rule, we basically say this is -- the basic point of this rule is to prevent double liability. It's to ensure that a health plan or insurer provisions or actions are addressed and remedied through ERISA, Public Health Service Act, Internal Revenue Code, while actions taken by employers and Title II-covered entities are remedied through GINA Title II.

The example we give is an employer who fires an employee because they get some genetic information and they anticipate that this will increase the person's health claims in the future, so they fire them. That's an employment action. The fact that it involves health benefits does not remove it from Title II liability because health benefits are a term, condition, or privilege of employment, and taking an action based on

genetic information that's an adverse action having to do with terms, benefits, or conditions of employment violates Title II.

At the same time, health plan or issuer provisions or actions that have to do with decisions about pre-existing condition exclusions or health premiums, those types of decisions made by health plans are subject exclusively to Title I and The Firewall is an attempt to make that clear.

Now most of the comments we got about our Firewall discussion were we need more examples. We don't understand how this is going to work. We need more real-life examples, and the final regulation is going to have more examples and hopefully clarify some of the questions that were raised in the comments.

And that's it. So feel free to ask questions. Okay. Yes?

DR. WILLIAMS: Marc Williams. So just to make sure that I understand the statute and the one exception. So if we imagine a situation where we have information that a specific genetic variant would increase the risk of an adverse health outcome in an individual that's

exposed to something in a workplace environment, in other words, a toxin or something of that nature that they would reasonably be expected to come in contact with if they had a specific job, the employer could not use that information on the front end, either in a hiring decision or in a decision about where within the company that individual could work, but they would be able under a monitoring program to be aware -- well, in the sense that whoever they have designated to do the monitoring, i.e., the healthcare professional, would be able to access that information and do health monitoring for toxin outcomes related to that.

Is that a --

MS. LEIBIG: Right.

DR. WILLIAMS: -- fair interpretation?

MS. LEIBIG: Yes, because you can't use genetic information to make an employment decision, even if your intent is to protect someone. You certainly want to -- first of all, if it's required by law, OSHA or something, you're going to be doing your monitoring program that's allowed.

The only example that ever came up of a totally

voluntary genetic monitoring system, there's only one, I actually can't remember what the toxin was, but most of the employers who are doing this are doing this because they're required to do so by OSHA.

So the way Title II works is that, yes, obviously you could still do this. You get the person's authorization and you obviously -- if they end up being someone who is likely to be harmed by this, the healthcare provider would explain that to them, but it has to be voluntary and so if you, in response to the monitoring that you did, fired them or made them take a different job, that would make it involuntary and that violates GINA because we say you can't use the genetic information, even in the situations when you're allowed to acquire it.

So hopefully the person, if they were educated properly, that, look, you're going to die or you're going to get some terrible disease if you continue in this position, they will voluntarily choose to not operate in that position.

DR. TEUTSCH: So following up on that question, so what happens if a person presumably has that

information, decides to keep the job, the employer obviously does not know about this particular enhanced risk because of the genotype? Does the employee then -- if the employee suffers harm subsequently, can they come back at the employer or is the employer protected?

MS. LEIBIG: Well, we don't address that in the proposed rule. There was a comment that raised this issue and the problem is if an employer takes action -- I'm speaking as myself here. I don't know what the final -- I can't say what the final regulation is going to say, if it's going to address that, but when you think about how GINA works and what the acquisition exception is, if an employer took action against the employee, they would be retaliating against them --

DR. TEUTSCH: Right.

MS. LEIBIG: -- or else using genetic information and they're not allowed to do that.

GINA doesn't speak to -- I assume you're talking about an employee who then sues the employer for wrongful death or some --

DR. TEUTSCH: Right. Presumably they've accepted this because they've been informed of it, right?

MS. LEIBIG: You know, GINA doesn't speak to that. So I imagine there could be a situation when an employer is faced with this situation -- although, of course, remember the employer doesn't have specifically identifiable genetic information. So they're not going to know who has it.

DR. TEUTSCH: They don't know.

MS. LEIBIG: But whatever. That doesn't always work out so well. So let's say there's a situation where the employer gets it.

I suppose they would be in a situation where having to decide do they want to violate GINA or do they want to risk a lawsuit, I don't know what the courts would do with that. One would hope that they would look at the provisions of GINA and see that this is a requirement that the employer was following, but I can't say whether that's the case or not, and GINA itself doesn't speak to what would happen.

DR. WILLIAMS: So carrying that on one step further, again assuming that an employee then develops a healthcare condition related to an exposure for which they have a predisposition, are there any comments

specific to unemployment benefits, disability insurance, or any protections around those types of things from this type of information? Does that make sense?

MS. LEIBIG: I don't --

DR. WILLIAMS: So the individual has a genetic predisposition to develop a health consequence from an exposure at work. They develop the health consequence and they become disabled as a consequence of that. Can the disability insurance say, well, you shouldn't have been doing that, we're not going to be paying your disability?

MS. LEIBIG: I actually don't know. GINA Title II doesn't speak to that and EEOC actually doesn't have any authority over how disability social security works. I don't know of anything in GINA that deals with that. Perhaps there are already existing social security rules on that that someone else can speak to, but I do not know.

MS. ASPINALL: On the incidental acquisition of information, understanding in the rules you described, is there an obligation by the employer to document that in the separate medical file or once they -- is there

anything they have to do, employers have to do or not do with the incidental acquisition?

MS. LEIBIG: Okay. We call it inadvertent acquisition. I think under Title I, it's call incidental.

Obviously any genetic information that an employer receives in writing has to be kept in the confidential medical file. Any genetic information they receive has to be kept confidential, but an employer -- and again this is not something we say specifically in the proposed rule, but we did receive some comments and my sense is that our position is going to be an employer need not reduce information they receive orally into writing. So they need not do it, but there could be a situation where employers want to do it just for their own record, say okay, we're going to have it written down somewhere that this information was received, here's why it was inadvertent just for the purposes of defense at a later point, but the regulation doesn't require them to do it nor does it make it unlawful to do it. So it's sort of up to individual employers.

DR. TEUTSCH: Julio.

DR. LICINIO: I have a question about the acquisition of the information. So you said that if it's available, it's okay, but let's say you go to a site that's specific to researchers or to medical professionals, then it's not.

But let's say if you just do a general like you do a web search and come across information, that's one, and then also if the information is available on social networking sites, how is that kind of permissible to get that or not?

MS. LEIBIG: Well, in the proposed rule, we didn't address that. We asked for comments about what people thought about the social networking sites, other sort of Internet-based information that is out there, and we got a great number of comments.

We are going to be addressing and explaining the position of Title II in our final regulation, but because the final regulation isn't issued yet, I can't get into specifics, but I can tell you a lot of people raised a concern about the employer who just wanted to Google applicant A. They Googled them, that's part of their regular employment process, a bunch of websites

come up, and they start clicking away. Are there websites they have to avoid? What actions should they take? We will be addressing that in the final regulation.

When it comes out, hopefully prior to November 21st, I'm happy to come back at the next meeting and talk in detail about the decisions that were made, but I'm not allowed to talk about it until then.

DR. LICINIO: Is that also going to cover like if I put some genetic information in my Facebook page --

MS. LEIBIG: Yes.

DR. LICINIO: -- and is that --

MS. LEIBIG: That will be discussed. We discussed -- we're going to be -- we got comments about Facebook, MySpace, LinkedIn, websites, blogs, everything you can imagine, and we will be talking about that and hopefully answering all of those questions.

DR. TEUTSCH: We just have a few minutes, and I want to make sure we get back to the other panelists, as well.

Are there any other questions you want to direct to any members of the panel? Yes, David.

DR. DALE: Yes, I just have a general question. I think that in many ways in this discussion we're dealing with old versions of what might be regarded as genetic information, that is specific tests or test results, whereas when you begin to link clinical information with likelihoods of genetic disease or poly-genetic disorders, it becomes more complicated.

I just wondered how -- because in this area of discrimination, it's so likely that, although you don't have a specific test, in fact it's genetic information that's the basis for discrimination, I wonder how broadly you reviewed the issue in the public law where it defines genetic information and genetic tests.

MS. LEIBIG: Well, what I can say about EEOC, and I think this is probably the case for all of us, is that none of the Title I or Title II agencies are experts on medicine or genetics or any of that. So we took what the statute said and we brought in experts from NIH and basically did what they said.

MR. WEINHEIMER: Well, let me come in. It seems to me you aren't asking about family medical history here. You're talking about an individual's own

conditions and because of either the way that they manifest certain symptoms that they have, certain collections of conditions that they have, that you can discern from that a genetic condition. Is that what you're --

DR. DALE: Well, I would include family history but also having a genetic phenotype and a clinical phenotype. There are a lot of other things that are involved in determining the genetic aspects of the outcome for illness or health.

MR. WEINHEIMER: Certainly, it's going to be protected under both Titles I and II, to the extent that family medical history is relied on because family medical history is defined as genetic information.

If it's something else with an individual's own medical condition, I don't know. I'm stumped there. I don't know if anybody else has anything else to add.

MS. LEIBIG: Well, if it's a condition, as Russ said, that's manifested, even if there's proof that it's a genetic basis, let's say you have breast cancer and you took a genetic test and it shows that you have the gene that was likely to lead to breast cancer, once you have

the manifested condition, once you have breast cancer, at least in terms of Title II, you're no longer protected by GINA.

If you have a manifested condition, you're protected from employment discrimination because of the Americans With Disabilities Act, if that condition rises to the level of a disability. So even if the manifested condition you have has a genetic component or genetic basis, once it's manifested, Title II is no longer at play.

MR. WEINHEIMER: Well, and similarly, you could say GINA doesn't apply but that's because the HIPAA nondiscrimination requirements already prohibit that kind of discrimination based on a manifested condition. So it's as if there was no need for GINA to take care of the manifested conditions. It's only when they haven't been manifested that GINA had to step in.

DR. TEUTSCH: First, let me thank Robinsue, specifically, for reminding us how important this legislation was and how far we've come and now we're talking about a lot of the refinements of all of this and so thank you for that and thanks to all of you for all

your work in bringing this law to practical reality with all the implementation. It's obviously extremely important and we do appreciate it.

Obviously there are many issues and I'm sure we'll be talking about this in the future again, but we sincerely appreciate it.

We're getting to a break. One of the advantages of being here is we have lovely facilities. One of the disadvantages is we don't have coffee at every break. So in your notebooks you'll see that there's breakfast and coffee available at a couple places nearby. The Starbucks is at 24th and M and the Bread and Chocolate at 23rd and M.

So I realize that some will want to scamper quickly for their morning dose, but we will meet again in 15 minutes.

So thank you all and thanks again to our entire panel. We really appreciate it.

[Applause.]

[Recess.]

DR. TEUTSCH: We're going to now begin with the next topic on Gene Patents. All right, so let's now turn

to our session on Gene Patents which will occupy us for the remainder of the day and the importance of gene patents and their impact on patent access to genetic tests.

Our last discussion of this issue was in December when we approved the Public Consultation Draft Report for release to the public. We received extensive comments and diverse comments, as you'll hear from Jim Evans.

Jim has been chairing the Patents Task Force, and is going to discuss the comments we received. You have a summary of them in Tab 4, and he is going to walk us through the content of the final draft before we break for lunch today. So this is our time, mostly, to listen to the results of the deliberations of the Task Force. They were extensive.

Needless to say, this has been a topic where there has been strongly held feelings on multiple sides, where stakeholders have really very differing points of view, and then after lunch, when we convene, we have two individuals who have signed up to provide public comments, and if others would like to participate in that

process, please sign up at the Registration Desk.

After the Public Comment Period, we're going to put the committee to work and begin an in-depth discussion of the recommendations. Hopefully we can get through them today. We're prepared to keep us all here until late in the day, but if we don't, we do have a little bit of time tomorrow, and at the end we need to come to some agreement on the recommendations and approve the report for transmittal to the Secretary.

So before I turn this over to Jim, I think everyone needs to know the extraordinary work Jim and his colleagues have done, and particularly Jim, in leading this Task Force. It's been an extraordinary process in terms of the depth of the investigation, the differing points of view that needed to be understood and digested and synthesized.

So Jim, we really do appreciate all your work to bringing it to fruition, and now it's your opportunity to bring it to completion.

DR. EVANS: Don't thank me yet.

Gene Patents and Licensing Practices

James P. Evans, M.D., Ph.D.

[PowerPoint presentation.]

DR. EVANS: So while we're giving thanks, though, I do want to say this has been a five-year project really, as you'll see in a moment, and I want to highlight the contributions of the staff. I think that Sarah Carr, Darren Greninger, and Kathi Hanna have been absolutely indispensable, as they are regularly in these endeavors.

I also want to thank the members of the Task Force, who, in spite of having day jobs, were able to hang in there through interminable conference calls.

A note at the start here. We were never so delusional when we started this out as to expect unanimity in regard to this topic. This is an inherently contentious issue, and different stakeholders will understandably and naturally have different opinions. It's been a challenge to my conflict-averse personality, but I think that throughout our deliberations, we always tried to keep foremost in our minds the stakeholder that we ultimately all represent, and that is the patient.

In spite of some degree of, at times, very strong dissent, the arguing and the vociferous debate was

invaluable in shaping our conclusions. None of us got everything that we wanted, but it is fair to say, I think, that as a whole the Task Force is in firm support of the report and its recommendation.

So I am going to run through these slides at this point. We will have, it appears, ample time for discussion after public comments and lunch. So bear with me as I go through this rather rapidly, because we only have about 40 minutes now to get you to lunch.

This is the current composition of the Task Force with members, ad hoc experts, agency experts. I would give a special nod to Debra Leonard, who was the original chair of the Task Force when this first started, but her tenure came up a couple years ago and I took over.

The timeline is such that it was, again, about five years ago, or more than that, when we identified gene patents and licensing as a priority issue, but there was a National Academy of Sciences report that was in the works, and we deferred activity until after that report.

We formed a small group in the Fall of '05 to review that report, and in March '06, we endorsed the

report's general thrust, but there were significant limitations in terms of relevance to patient access. That was not their major focus. We felt that, from the standpoint of our charge as a committee, that more information regarding patient access was needed.

In June '06, we decided to move forward with an in-depth study. We established the Task Force, and in December of '06, Duke's Center for Genome Ethics, Law, and Policy was commissioned to assist in carrying out a variety of components of the study, most importantly the case studies.

In March '07, we organized a primer on gene patenting and licensing practices to establish a foundation of knowledge among members and in July '07, we had a Roundtable on International Perspectives and Gene Patents and Licensing Practices.

The Task Force continued the information-gathering process and began developing the report. About a year ago, we approved, after public consultation, a draft report for release and the public comment period went the standard time, this was from March 9th to May 15th, and we will hear some of the comments throughout

this report to you now.

The overview of this session, this next 40 minutes or so, is that we want to familiarize you with the process for having reviewed the comments and for creating the final draft report. We want to give you an overview of the report, a presentation of the proposed recommendations, and then we will, in the afternoon, have a discussion of findings and conclusions.

I would urge you all to read as much of the report as you can, especially the recommendations with the rationale that follows those recommendations towards the end of the report.

So we did receive a number of reports, some of them extraordinarily extensive, some with tables of contents and indexes, and there were 77 total reports. They came from a wide variety of different sources.

The review process for these public comments was extensive. Some of us read every single comment in detail, but the binder containing all of the comments was sent to each Task Force member for their review. Members of the Task Force were assigned comments to present for group discussion during the teleconferences and all

comments were discussed during conference calls, no matter how short or no matter how involved and lengthy.

The public comments were a critical supplement to case studies and literature. I think this is always an instructive process. I know that, for example, with the genetic discrimination process, the public comments were instrumental in forming our thinking and I think that, at least for many of us, the same can be said with regard to the public comments.

I would add that I think many of us on this Task Force very much started and ended the process in somewhat different places or very different places. It was very much a learning experience and the public comments were instrumental in that learning experience.

It was of note that the public comments confirmed that patient access issues that had been identified in the case studies were not isolated problems. These came up over and over again in public comments from a variety of sources, and the access problems appear to be the most problematic for the Medicaid population, as you'll see momentarily.

The public comments highlighted the problem of

exclusively-licensed sole providers and limitations on their ability to offer, for example, population-wide recommended carrier newborn screening and there were many comments that called for more discussion in the report and more discussion among the committee regarding the impact of patents on whole-genome sequencing, multiplex testing, and other emerging testing innovations.

After receiving all of the comments and going through them, I was actually pleasantly surprised to see that there were critical comments from really both ends of the spectrum, those that advocated dramatic and extensive changes and felt that there was extraordinarily problematic activities going on and those who felt that things really were great and that there should be no changes whatsoever.

I feel like we have tried to walk a balanced approach here, though I'm sure people, especially on the ends of the spectrum, will not agree with that.

Many that submitted public comments discussed their opinions and their perspectives on patents and that's certainly extraordinarily valid to do so. This is a subject that people have strong opinions and

perspectives on. We especially appreciated, though, comments that had concrete examples of benefits or harm, not platitudinous, not principle-based, but concrete examples.

Some of these concerned the impact, for example, of patents on test development. Some commentators thought that patents are not needed for test development, others thought that patents are needed for test development, and again we sought wherever we could to find evidence that illuminated those issues.

Regarding the process for producing this revised report, you'll notice, perhaps, that this report is much tighter. It's much shorter than the original report, and that was intentional. After reviewing and discussing the comments, we revisited our preliminary conclusions, and you'll remember that we took a somewhat unorthodox approach in our draft report, giving a range of possible recommendations to consider for recommendation to the Secretary.

What we were hoping and, indeed, I think, transpired was that following the public comment period and the extensive discussions we engaged in, we could

then sort through those comments and decide as a task force which ones we felt were most appropriate to include in the final report.

We revised the conclusions after considering all the evidence, the case studies, the articles, public comments, previous informational sessions, and public comments during meetings.

I would also point out that there was a wealth of expertise on the Task Force itself, people who do these tests, people who order and perform these tests, as well as those who deal with the consequences of them.

We discussed which policy options made sense as these final recommendations. The background sections of the draft report were revised to reflect the Task Force discussions, and the considerations, and it was reorganized according to the key questions that we addressed.

So here Is the summary of the report's main points.

First, we had to tackle what types of patents, or, more precisely, patent claims, are associated with genetic tests. It's important that we all be on the same

page as we consider these issues. So there were patents claiming isolated nucleic acid molecules, and these in many ways are the oldest type of what is generically referred to as "gene patents".

These patents claim an isolated nucleic acid whose sequence may correspond to a gene, to a mutated gene, to intergenic DNA, for example. These patents are sometimes called, loosely or colloquially, "gene patents," and for the sake of simplicity and accuracy, the report refers to these patents as "patent claims on genes."

There are other types of claims that really accomplish, in many ways, the same thing but have subtle and important differences. Patent claims to the act of simply associating a genotype with a phenotype is something that has gotten much, much activity and interest in recent years.

For example, a patent might claim "a method of determining a predisposition to disease X, comprising testing a body sample of a human for the presence of a mutation in gene A, wherein the presence of a mutation in gene A indicates a predisposition to disease X."

So what you can see with this type of claim is that, inherent in it is that association of genotype with phenotype. For the sake of simplicity, the report refers to these patents as "association patent claims." Again, these are very much in the news now because of recent court rulings and pending court rulings.

There is another type of claim that is important to define so that we understand the different mechanisms for attempting to patent this type of information, and that is patent claims to processes for detecting specified genetic sequences.

So "a method," and I put that in quotes for important reasons, or process of detecting a particular sequence, including a particular mutation, using specific probes, specific primers, et cetera. In essence, this type of patent is attempting to claim a specific sequence, but you can see that it jumps through certain hoops to do so.

I think it's extraordinarily important to emphasize that this type of patent should not be confused with patents on innovative methods for general DNA analysis. What we are not talking about here at all

today are methods patents. For example, PCR, a new type of sequencing, et cetera.

We are talking about laying claim, in some way, to a sequence through different avenues or to an association. Also, there are patent claims to test kits for conducting a specific genetic test. So patents lead to exclusive rights. That is the intent of the patents. That is why we have patents in the first place.

Well, how a patent's claim can give exclusive rights to a genetic test is a multi-pronged mechanism. In addition to claiming an isolated gene molecule, these patents may claim, for example, primers for amplifying a gene and/or nucleic acids that are complementary to the gene. So that would be one way.

Because the typical methods of testing for a gene in a diagnostic setting involve either patented primers or complementary probes in such a situation, these methods, then, require the patented molecules in order to function. The patent holder's ability to exclude others from using the molecules, then, gives the patent holder exclusive rights to testing.

An association patent is a little different.

It gives somebody exclusive rights to a test, but with an important, subtle difference. A patent of this sort does not claim the molecule itself, it claims the method -- again, I would put air quotes around that -- of testing humans for a particular genetic sequence and associating that genotype with a phenotype. That "which" should not be there, and that "and" is very important.

So an association patent says we own the process for testing for this and associating it with a genotype, that thought step. The patent holder has exclusive rights to that process or method which involves the testing and the association of, for example, sequence A with disease X. Because genetic testing for disease X or its predisposition, for example, necessarily involves the patent process, the patent holder has exclusive rights to genetic testing in that setting.

There is another way that this can be done. Patent claims over a process for detecting a specific mutation through probe hybridization, primer-driven amplification and sequencing, or some other means. The patent holder then has exclusive rights to any genetic test that detects that specific mutation through that

patented method.

So it's very important to keep in mind, as we go through this, the purpose of the patent system, and this goes back, of course, to the U.S. Constitution. Article II; Section 8, says that patents exist to promote progress in the science and the useful arts.

There is a long history in U.S. legal tradition, founded originally in the Constitution, that the patent system has, very much, a utilitarian purpose in our country. Patents in the U.S. are not awarded as natural rights. They have a very utilitarian function in mind.

Patents are designed to stimulate scientific progress through a variety of mechanisms by offering the inventor an exclusive time-limited rights to use, make, or sell the invention. In other words, it grants a limited monopoly, and this is a trade-off.

Society has decided that this trade-off is a good thing for us, as a whole, and the trade-off is between benefits of patents and stimulating scientific progress, because as part of the deal when you receive a patent, for example, you divulge that information and now

others are free to use it to build the next mouse trap. It has to balance that with the harms from the patent holder's ability to exclude others from an invention.

The report, from the outset, was intended, and we were charged with very clearly, the charge of examining both sides of this trade-off. So we were not charged initially to, for example, just go out and find harms from patents. That would have been a presumptive and an unfair type of activity.

Not only would it have been presumptive and unfair, but it wouldn't take into account the basic, underlying rationale for patents in this country. Therefore, it was important that we kept in mind throughout the process that we were looking for both benefits and harms where we could find them.

So let's look, for a minute, at examination of benefits of patents in the genetic testing arena. The patent system, as I've said, is intended to promote scientific process, and economists recognize three main mechanisms for how such progress can be promoted in the scientific arena.

One, patents can promote progress by

stimulating research for the purpose of making discoveries or inventions. This is what we think of, oftentimes, as the most overarching benefit to patents, but they also are meant to promote progress by stimulating disclosure of new discoveries and of adding to public knowledge.

Finally, patents promote progress by stimulating investment in post-discovery development, especially in the realm of healthcare, as for example as Bayh-Dole recognized, we're not interested in just having discoveries, we're interested in implementing those discoveries.

So we want to drill down, and I think it's important to remember that our task force and this committee is charged with looking at a very narrow slice of patents, and that is in the realm of genetic diagnostics. So we want to frame these questions in the realm, in the context of gene testing.

So one question that we have to ask is, do patents stimulate genetic research leading to diagnostic tests. Regarding disclosure, we need to ask, do patents stimulate the disclosure of genetic discoveries that then

lead to diagnostic tests; and finally, does stimulation of investment needs to be focused on whether patents stimulate investment and develop the discovery of a gene-disease association, for example, into a test.

Taking a look, for a moment, at this idea that we want to stimulate research and discovery for invention, the case studies were instructive here, and they revealed that patents stimulate some private investors to fund genetic research.

However, there was also abundant evidence that academic scientists conduct research not because of patents but because of other motivations. In fact, academic researchers are oftentimes almost willfully ignorant of the patent situations.

Government provides vast amounts of funding for basic life sciences research, and this is an important piece of the equation when we're thinking about the stimulation of research in this field. There were no consistent findings, by case studies or public comments, that patents were necessary to stimulate research leading to the availability of genetic tests.

There were weak indicators here that there was

never strong evidence that patents were necessary. In fact, many, many genetic tests exist out there in which patents were a complete side issue or non-existent as a consideration.

Disclosure is another issue which, of course, we are interested in. Researchers have, we felt, sufficient existing incentives to disclose genetic discoveries. Academic ethos encourages open science and rewards publication of its first discovery, and the individual investigator in the academic environment where most of these discoveries are made is after other things that do not include patents in a typical situation.

Patents and genes, in fact, by some criteria, would appear to diminish public knowledge because they result in less follow-on research. In a study by Huang and Murray, we quote in the report that strict interpretation of our results suggest that follow-on genetic researchers forego about one in 10 research projects or, more precisely, research publications, hence, disclosure, through the causal negative impact on the gene patent grant.

Regarding the stimulation of investment to

develop genetic tests, although patented discoveries are developed into tests, unpatented genetic discoveries are routinely developed into clinical genetic testing services, and I can't really emphasize this point too strongly.

The empirical data around this issue was a very persuasive point for many of us on the Task Force. What one sees in example after example, with regard to development of genetic tests, is that the role of IP was primarily used to narrow the offerings out there for genetic testing.

Prior to the granting or implementation of patents and exclusive licenses for, again, example after example, many labs offered the tests, in that, there were numerous laboratory options for an individual to have a genetic test.

After IP was enforced, after exclusive licenses were negotiated, what one sees is a clearing of the market. This phenomenon is likely due to the fact that clinical need is sufficiently high and developmental costs are sufficiently low, so that genetic tests can be implemented when the knowledge is out there, and that

therefore patents and IP considerations do not seem to play an important role in developing tests. In fact, again, what they seem to do in example after example is narrow the market.

Thus, the conclusion of most of us in the Task Force was that patents are not needed for the development of testing services. I think there was an instructive public comment from a director of a laboratory who specializes in rare disease, in which he very poignantly said that when they are considering what new tests to develop, as soon as they see that there is IP, especially exclusive IP that is surrounding a particular test, it moves to the bottom of the list, in his quote.

Again, we will have plenty of time to talk about this in the discussion period. This was not a unanimous feeling among the Task Force, as I mentioned at the outset, but it was certainly the feeling of the majority of the Task Force.

So our overall conclusions concerning patents benefits are that patents do not serve as a powerful incentive to conduct genetic research, to disclose genetic discoveries, or to invest in the development of

genetic tests. There exists sufficient incentives and funding for research and development and, as such, the benefits of patents in the area of genetic testing are limited.

We then turned to examining the costs, and when I say costs, I would always insert in your mind a slash "harms." We're not talking about just financial issues here, we're talking about harms or costs, in the universal sense, to patents in the genetic testing arena.

So the Task Force examined whether patents on genes, on genotype/phenotype associations, on methods of detecting specified sequences, are causing (1) limitations on the availability of genetic tests at reasonable prices, and this could be through, for example, the combination of sole providers and a multipayer system; (2) limitations on the ability of researchers to develop new tests; and (3) whether one was seeing problems in the quality of genetic testing, because it must be remembered, of course, that access to genetic testing doesn't just mean access to any test, it means access to a quality test that is of the highest possible quality that we can reasonably expect.

We wanted to interject a quick licensing refresher here, because the issue of licensing is an important one when one discusses these issues.

So to evaluate the costs of patents and licensing practices, there is some background information that is required and a license is an agreement through which a patent holder agrees not to exclude a specific licensee from using the invention, and there are different types of licenses that exist.

On one hand and on one end of the spectrum, one has exclusive licenses. This creates a sole provider of a genetic test. That is, only that licensee has the right to practice the invention.

There are less exclusive forms of licensing. There are, for example, non-exclusive licenses that are extraordinarily broad, co-exclusive licenses that permit multiple licensees to use the patented molecule or method to offer testing.

So one of the most surprising features or outcomes of the case studies was the impact on price for genetic tests, because I think most of us assumed at the outset that there would be some patent premium associated

with the holding of a patent and exclusivity in the realm of a genetic test, and that did not turn out to be the case.

So there was not a pattern of overpricing for tests that were patented and exclusively licensed when compared with tests that were either unpatenteded or non-exclusively licensed. There were a number of instructive and interesting kind of experiments of nature here that focused, for example, on the BRCA testing. So Myriad Genetics, for example, as we all know, holds the patent on the BRCA test and excludes others from doing it.

When you compare the unit price for that test with either tests that they offer that are not exclusively owned by them or with tests that are performed by other entities, one does not see a patent premium.

Now, there is evidence or suggestion of a patent premium in the test for Canavan disease versus Tay-Sachs, which is a reasonable comparison that could reflect a patent premium, but overall, we did not see a pervasive increase in costs.

There was a public comment that was

instructive, suggesting that Athena, who owns the exclusive licenses on a number of spinocerebellar ataxia-responsible genes is needlessly expensive, not because of a patent premium, per se, but because it necessitates bundled testing in some circumstances. So one has to think about the fact that we deal frequently with genetically heterogeneous diseases.

It may well be that a clinician would like to test gene A or gene B or gene C. If an exclusive licensee or an exclusive provider of such testing doesn't allow that type of testing and says no, you have to get the whole panel, that obviously can cause an increase in prices, is of a somewhat different mechanism than a traditional patent premium.

So clinical access to genetic tests was judged by trying to review articles, case studies, public comments, and these indicated that overall patents and exclusive licenses have certainly limited the ability of clinical laboratories to offer genetic testing. This is a non-controversial statement, in that, one can show over and over again, of course, that laboratories are prohibited from doing testing when IP is invoked against

them.

Now, licensing practices that limit the number of clinical labs that can offer a test do not necessarily result in patient access problems. However, patient access problems were certainly reported and arose when licensing creates a sole provider as, probably, the major type of context or situation in which problems occurred.

So going on to look at this process, these access problems have generally not occurred for patent-protected tests that are broadly licensed. Most problems seem to occur when tests are exclusively licensed and create, then, a sole provider.

For example, the case study of the Long QT syndrome. The Long QT syndrome is a lethal disorder in which individuals have a genetic predisposition to lethal dysrythmias. Over a period of about 18 months, excessive exclusive licensees enforced patent rights, even though they were not yet offering a test, which, in the judgment of the case studies, "probably had a small but tangible negative effect on patient access."

So looking at the issue, an issue that was, again, highly instructive in the realm of public

comments, and in talking to clinicians as well as patients who have dealt with these issues, is the issue of how the sole provider interacts with health insurance and how that changes or affects patient access.

What we saw over and over again and again, again, in the public comments, is that the combination of exclusive licensing to create a sole provider, combined in the context of a multiple payer system, like the U.S. healthcare system, often results in patient access problems. The meat of this type of scenario is the following.

Sole providers oftentimes fail to secure coverage from some major payers. This includes, for example, out-of-state Medicaid programs. As a result, some patients can't obtain the covered testing and, of course, it's indigent patients, covered by Medicaid in particular, that do not obtain testing. The way this works, for example, is that a laboratory with exclusive rights to do this test, for example, doesn't have a contract with MediCal, the Medicaid program in California.

MediCal has numerous contracts with

laboratories who have said, we would like to do this test; you have a contract with us, we would like to do this test. But they can't do it because of the exclusivity engendered by the patenting and licensing situation.

In the hearing loss example for Athena, which has exclusive license to a number of the genes that are involved in hearing loss, they have not been able to secure coverage from MediCal for Connexum-26 testing. Now Connexum-26 mutations account for the bulk of non-syndromic recessive hearing loss cases, and this quote is from the case studies:

"Access for these consumers, therefore, depends on the availability of additional providers who may have contracts with Medicaid, or entails direct out-of-pocket payment by consumers. Uncertainty surrounding whether these alternate providers will face enforcement or will stop testing creates an unstable situation."

So there are many different ways of dealing with this. If you're a lab and you have a contract with a state Medicaid agency, and yet you are prohibited from

doing the test, one choice is, we won't do the test. That, of course, is what your legal counsel would tell you, typically, not to do. Other laboratories say, well, we're just going to do the test and hope that nobody enforces. So, as you can see, it's a rather unstable situation.

There are similar problems for SCA testing, which we have mentioned before. Sole providers offering testing for Alzheimer's disease and Long QTS have had problems, for example, securing coverage from particular payers.

Myriad Genetics had this problem at the outset but now has secured wide coverage from Medicare with very reasonable types of regulations about when it applies as well as private insurers, but it should be noted that Medicaid patients still cannot obtain such testing in at least most, if not all, states.

The information from public comments again highlighted this issue. It arose in Georgia. We got several comments regarding this same issue going on in Georgia as going on in California with "the end result is that access to genetic tests can be largely influenced by

patient's socioeconomic status and geographic location." In one state where there is a contract, you might be covered. If you're in another state, you won't.

A healthcare provider complained that some sole providers have not secured coverage and by this same mechanism there were problems in Montana. A parent complained of insurers not covering genetic testing for hearing loss. An advocacy group complained that Athena, the sole provider for dystrophin genetic testing, has not secured coverage from some payers, again resulting in access problems.

So observations from the public comments include that when there's a sole provider, patients can't obtain second opinion testing. So this is another issue that came out in the public comments and have actually been in the news of late because of the ACLU-orchestrated lawsuit against Myriad Genetics.

This issue of second opinion testing is seen as a particularly-troubling one when one is in the context of a sole provider.

Recommended carrier and newborn screening is not possible at times when only one lab offers the test

and it's thought that multiple labs are oftentimes needed to handle the kind of volume of testing as well as the temporal factors that are important in newborn screening in which this has to get done quickly in order for interventions to be enacted.

So our conclusions regarding patient access are for the most part patents covering genetic tests and related licensing practices do not appear to be causing wide or lasting barriers to patient access and this sentence is lifted out in a number of comments, that sometimes what is not lifted out is the subsequent sentences which are, "However, the case studies and public comments document several situations in which patient access to genetic tests has been impeded for segments of the population, especially indigent patients, when these tests are offered by an exclusive provider or a limited number of providers, a practice directly enabled by current patent and licensing practices."

Now, we struggled for a long time with the issue of quality. Again, as I mentioned, from the outset, our charge was to look at patient access to genetic testing and inherent in that charge was the

genetic testing needed to be of high quality.

There were recurrent concerns regarding test quality, where a test is offered by a sole provider. Here, we relied to a considerable extent on the expertise of two members of the Task Force, Andrea Ferreira-Gonzalez and Debra Leonard, who do these tests and who are engaged, on a day-to-day basis, in quality control.

It was pointed out that proficiency testing, which undergirds quality control in this country for laboratory testing in general, requires that multiple labs offer a particular test.

In addition, there is concern that with samples becoming increasingly labile and smaller as we use biopsy techniques, for example, that are less invasive and produce smaller amounts of material, more local laboratories are needed to handle testing. Samples sent to a distant sole provider are subject, for example, to degradation.

The competition between multiple laboratories offering a particular test, in addition, need innovation in the testing method for that test. So quality, I think, needs to be looked at from a rather expansive

standpoint. We are not talking about just reproducibility, about did the right answer occur. Those are absolutely critical and are addressed optimally by multiple labs that can share samples and engage in proficiency testing.

In addition, when we think about quality, one needs to think about implementing new innovations in order to improve, for example, the sensitivity and specificity of a test. The most conical example of this that is brought out frequently is the Myriad Genetics example, where deletion testing lagged behind many calls for improved testing.

In the example of CF, which is instructive, you have a lack of exclusivity, and this has led to multiple, both private and non-private, labs, who all compete to offer a variety of things based on innovative testing, quality of testing, sensitivity, specificity, et cetera.

By having non-exclusivity, what one sees is basically a marketplace in which innovation and quality is enhanced. There is legitimate concern that exclusivity undermines that process.

So the existence of a sole provider dictates,

in addition, what method of testing is offered and the testing strategy. For example, bundling is common, as we discussed a moment ago, for heterogeneous conditions, but is not necessarily the most efficient or the most cost-effective way for a patient or a provider to proceed.

Again, in the setting of exclusivity, there is little pressure on a particular laboratory to offer a variety of modalities by which to do that test. Those methods are at the discretion of a single laboratory, and I mentioned the issue with Myriad and deletion testing.

One of the things you might notice, if you were able to get through both the draft report and the final report, is that we have spent more time in the final report discussing the implications of the current landscape in gene patents and licenses for the emerging world of genetic testing.

There were many comments from all across the spectrum that said, you guys need to consider this and that, which was a major driver in our deliberations over the last couple of months.

There is broad consensus, I think, in the medical arena, in the technological arena, that genetic

testing will increasingly involve multiplex technologies. Genetic diseases, common diseases are genetically heterogeneous. That is, there are many genes that go into a predisposition for any given disease, and moreover, we are on the verge of whole-genome sequencing.

There is no question in anyone's mind, who is involved in this, that within the next few years, whole-genome sequencing will be readily available for prices that now certain bundles of testing, for example, SCA, will exceed in cost. So it will be cheaper to sequence the entire genome than to sequence at current costs, say, 11 genes responsible for a single disease.

The advent of multiplex testing is already an issue with regard to gene patents and access. Labs holding exclusive licenses are currently blocking labs that do multiplex testing from reporting full results pertaining to those patented genes, and we heard about this in public comments. The potential for a blocking situation in Long QT testing, we've discussed.

So the Task Force studied not only the costs or harms of patents on existing tests but also the potential of existing patents to block the development of new

tests, specifically multiplex tests, parallel sequencing of multiple genes, and clinical whole-genome sequencing.

I am going to need to go quickly here if people are going to get lunch.

There is no precise figure for the number of genes or associations protected by patents. Suffice it to say that the typical number bandied about is that about 20 percent of the human genome is under patent protection, and concerns have been raised that all of these existing patents on genes and disease phenotype associations have created a thicket of rights. A developer would need multiple licenses to develop a multigene test.

Patents on genes and associations cannot be invented around, an important point, and controversy exists regarding the legitimacy of patents on genes and associations. Some view patents on these as playing in products of nature, and view patents on association as claiming laws of nature.

So would these new methods actually infringe on patents on genes? Well, multiplex testing involves probed molecules that would probably infringe

corresponding patents and nucleic acid molecules. Multiple parallel sequencing typically involves aligo nucleotype molecules that again would probably infringe on patented nucleic acid molecules.

There is interesting uncertainty over whether whole-genome sequencing would infringe on such patents on genes. Association patent claims, on the other hand, are by definition quite broad. We've gone over the definition of an association patent. Claims, such as these, do not specify a particular method of testing, so any method of testing is protected, if one is making that association and, as such, any new form of testing would infringe claims of this breadth, assuming that the test included a gene referenced by the patent which, of course, whole-genome sequencing would by definition necessarily include all genes.

So delving into this a little more, would these new methods infringe patent claims? It really depends on the particular method and process claimed, and I'm going to go to the summary slide here.

New methods would probably infringe at least some association patent claims. For example, parallel

sequencing and multiple testing appear likely to infringe patent claims on genes and the methods for detecting specified sequences. Whole-genome sequencing may or may not infringe on patent claims to genes, and this is a matter of some debate amongst legal scholars in the area.

So test developers nevertheless would need multiple licenses to existing patents to develop most of these new innovations.

There are also challenges to obtaining licenses that has to do with the fact that the human genome has been staked out in many arenas. It is often unclear whether licensing rights are available. One way to learn of this is to look at existing licenses. However, license terms are often undisclosed. Even if one can obtain all needed licenses, all of these licenses can lead to royalty stacking. There are also transaction costs simply involved in having to separately negotiate each license.

A patent thicket may block or hinder the development of new innovations. There's costs involved in researching patents, separately negotiating each license and cumulative license fees that can then

discourage development, and even if these costs can be overcome, patent holders who refuse to license can prevent test developers from using a patented gene molecule or association, diminishing the value then of a multigene test, the blocking problem in which one individual laboratory says we've got this gene, it accounts for 11 percent of cases, and it's not going to be in this panel or that panel, and, moreover, patents on genes and associations, especially simply cannot be invented around.

There have been a variety of proposed solutions to patent thickets, including patent pools which are interesting and innovative agreements among multiple patent holders who license all patent rights as a packet, and those advantages include the ability to retain all the rights with one license. That solves the stacking problem. The disadvantages, however, are that patent pools are voluntary.

In biotechnology, patent holders have no real inherent incentive to join forces because again each holder of a gene can offer a single gene test as opposed to if one owns one necessary component of a chip, all

right, you can't do anything with that, but you actually can do something if you simply own a single gene. A hold-out's refusal to participate can limit the value of the pool and, most instructively, they've not proven useful in the genetic testing arena thus far. So questions remain as to the viability of these solutions.

Clearinghouses are another innovative solution that has promise. Patent holders join a collective that then charges a standard licensing fee for each patent and the advantages, again, are that you don't need to negotiate each license. You have license fees that are considered in bulk.

The disadvantages again are that clearinghouses are voluntary. There is the possibility of hold-outs and they've not proven useful in the genetic testing arena thus far. So again, there's significant questions as to whether this is a viable solution, and I think it would be awfully sketchy to rely on these as solutions.

There are additional challenges to the development of laboratory-developed tests or "home brews," in the colloquial. Research to create LDTs is not entitled to experimental use exemption. The Hatch-

Waxman experimental use provision provides exemption from patent infringement liability for using a patented invention for the purpose of developing and submitting information under federal law regulating drugs. Those using patented molecules during research to develop a CLIA lab-developed test couldn't invoke this exemption because CLIA is not a federal law that regulates drugs.

Conversely, to gain approval for a test kit, developers must submit information on analytic validity, clinical validity, under the FDCA, so any use of patented molecules, associations, et cetera, in a kit would likely be exempt from infringement.

Now, there are a variety of legal developments that are currently in flux. There are various ongoing cases that may well alter the patentability of genes associations and methods of detecting specific sequences.

We all probably know about the ACLU case in which a variety of plaintiffs are challenging the patentability of various claims, including the claim to BRCA1 and BRCA2, isolated gene molecules, the claim to association between BRCA2 and breast cancer, and claims to methods of detecting the mutations in these genes.

Bilski has just been granted certiorari by the Supreme Court and will be heard and may well, it's almost certainly will, affect the patentability of processes for correlating a genotype with a phenotype, even though Bilski is not in its narrow sense about genes.

It was the feeling of the Task Force, however, that it is impossible to predict the outcome of these cases. It's better, then, to address problems that we see as pressing, through recommending policy changes and statutory changes.

We reviewed a few other pieces of material, including the Bayh-Dole Act. This established the uniform policy of allowing academic institutions to retain title to federally-funded inventions and the question arose during our Task Force deliberations over whether law gives agencies the authority to require non-exclusive licensing.

Clearly, even if it does, this is not the norm, and NIH best practices for the licensing of genomic inventions were reviewed. These have been promulgated to promote, for example, broad licensure.

The nine points have been promulgated to

promote many of the same things. The OECD Guidelines for Licensing of Genetic Inventions, the NIH Policy of Sharing Data, et cetera, et cetera. There is no shortage of promulgated suggestions and suggested rules that discourage exclusivity and, for example in this case, discourage genotype/phenotype association. However, these recommendations have existed for a long time and uptake is, to put it mildly, not universal.

Finally, before we get to the recommendations, I want to just remind people of something that I think the Task Force was cognizant of all along, and that is, there is a moral dimension to this question.

There were many comments that pointed out that moral and ethical issues are inherent to the consideration of gene patents and licenses. I think we all understand that at a basic level. You talk to anyone about this subject, people feel strongly about it. There is a moral and ethical dimension.

There is strong sentiment in some quarters that exists that access to one's own genetic information should not be limited or proscribed by patents and, of course, that's what a diagnostic test is doing. It's

achieving information about one's own genetic information, and this is at the root of the recent court case that's been brought against Myriad.

I would also remind us, as we think about making changes to a system, that genetic tests are not equivalent to commodities. We're not talking about consumer electronics or kitchen appliances here. We're talking about human health, and these considerations are important to remember, in that they affect human lives and human health.

So to sum up, the patent system is designed to promote progress. That is the purpose of the patent system in the U.S., going back to the Constitution.

In the realm of therapeutics, for example drugs, strong arguments can be made that patents enable innovation, drive progress, and serve an important role because, for example, of the high, high upfront costs in investment that are required.

In the realm of diagnostics, patent-enabled exclusivity, primarily, demonstrably and empirically results in a narrowing of offering to patients and physicians.

If access, again, to kitchen appliances were the issue, I'm not sure that the situation would be anything more than lamentable, and might not rise to the level which we might advocate change for, but what is at stake is patient access to important medical information and we, the Task Force, in general, with some dissent, felt that this warrants changes to the system.

Now, let me ask Sarah and Steve, since we're running late, do you want me to go through the recommendations, quickly?

DR. TEUTSCH: Yes. Can you briefly go through them?

DR. EVANS: Yes. I'll go through them very quickly, and then you can look at them.

DR. TEUTSCH: It would be helpful for everybody to have them.

DR. EVANS: We're going to go through these in detail afterwards.

So the overarching recommendations are really 1, 2, and perhaps 3. Number 1 advocates that the Secretary supports and works with the Secretary of Commerce to achieve the following statutory changes, and

that would create an exemption from liability for infringement of patent claims on genes for those who make, use, order, offer for sale, sell a test that is developed under the patent for patient care purposes.

What this seeks to do is, it seeks to narrowly dissect the diagnostic use of gene patents from other uses, and exempt that use in the medical context. This can be seen in some ways as analogous to the Ganski-Frist bill which exempts medical providers from infringement claims on a variety of procedures.

So Number 2 is, the creation of an exemption from infringement for those who use patent-protected genes in the pursuit of research. Number 3 is, the Secretary should discourage the seeking, granting, invoking of simple association patent claims, because it was the feeling of most of the Task Force that association patent claims represent basic laws of nature that cannot be invented around and should not be owned.

We are advocating recommendations that promote adherence to norms and we'll need to have a discussion, the major discussion being, should there be teeth put in regulations that seek to get, for example, fundees to

adhere to norms of licensing, et cetera.

Enhancing transparency in licensing is important. Again, it will be a matter of debate whether we want to put teeth [in the regulations] or simply suggest these things.

We have advocated an advisory board that would, in an ongoing way, assess problems in the realm of gene patents. I would add that we tailored these subsequent recommendations after 1, 2, and 3, because we recognize that statutory changes take awhile. The Secretary may not choose to implement them, and therefore we wanted some other recommendations as a fallback, basically.

Federal efforts to promote broad licensing and patient access, we've got recommendations that encourage these things. Again, we can have a discussion about whether this should be more than simple encouragement. Things like exploring whether approaches to addressing patent thickets, like patent pools and clearinghouses, may offer some solutions; whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions is not clear. We've asked for clarification about that particular point.

Finally -- I think this is the end -- it was felt that it might be helpful to the USPTO if an advisory committee were established to advise not only about ongoing dilemmas with the fast clip of technology advancement but how to incorporate the legal decisions that are in the pipeline now into this changing landscape.

So we don't have a whole lot of time for lunch, but we'll come back, and then go through those recommendations and discussion in general.

DR. TEUTSCH: Thank you very much. It's a lot to cover and a lot to think about.

So we're going to break for lunch now. We are running late and it's going to be a little challenging to get everybody back since we're going to pretty much have to scatter to various eating places in the neighborhood, and you have a list in your packet, but we had allowed 45 minutes. That's probably going to be a little tight. So let's plan to start at 1:00. I think the public commenters are able to stay, so we can get all of your input, which we need.

So, why don't we break and see everybody back

at 1:00.

[Lunch recess taken at 12:02 p.m.]

+ + +

AFTERNOON SESSION

[Reconvened 1:02 p.m.]

DR. TEUTSCH: Lovely weather here in Washington. Got a little lunch, and we're ready to go for the heavy lifting this afternoon and to go through all of the recommendations on our report.

Before we get to that, though, as I mentioned earlier, we always set aside time for public comments, to allow time for you to hear different perspectives, for me to hear different perspectives, not only on gene patenting but on other issues. We welcome and appreciate the views of the commenters and the different perspectives that they bring.

In the interest of our full schedule, I ask that the commenters please keep their remarks to five minutes. We should have copies of your full statements, which will be made part of the meeting record. We did have the benefit of many of the perspectives from these same groups earlier, as part of the comment period when our draft report was out, but we look forward to hearing their additional perspectives today.

And to begin, we will start with Jennifer Leib,

who is with Health Futures and is speaking on behalf of the Association for Molecular Pathology.

Do you mind speaking from up here? I know it's a long way away. Welcome. We look forward to your comments.

PUBLIC COMMENT SESSION

Jennifer Leib

Association for Molecular Pathology

MS. LEIB: Thanks. Hi. My name is Jennifer Leib. I'm speaking on behalf of the Association for Molecular Pathology. I'll refer to them as AMP for the rest of my comments to keep it simpler.

This week, your committee is focusing on three areas of policy that has great interest to us and we would like to express our gratitude to the committee for highlighting the concerns and challenges with gene patents, direct-to-consumer genetic testing, and the genetic nondiscrimination bill.

First, as many of you are aware, AMP is a lead plaintiff in the recent lawsuit brought by the American Civil Liberties Union challenging the validity of the BRCA1 and BRCA2 patents.

Let me be clear. AMP opposes the patenting of DNA, of all DNA. While we have concerns about that, our concern does extend beyond that to the negative impact that can occur on to patient access to tests as well as the threat to the quality of testing associated with the exclusive and restrictive licensing practices that we've observed in many cases, including that of the genes with spinomuscular atrophy and the Connexum-26 and Connexum-30 genes.

At the last meeting, we did encourage the committee to continue exploring additional cases of the studies that demonstrate this point and are very pleased to see just before lunch the review of the report's findings that the committee did follow up on our request. We look forward to hearing the additional discussion this afternoon.

AMP completed its position statement on direct access to genetic testing in 2007 and it's posted in its entirety on our website. AMP views genetic testing as an integral part of the healthcare system with a great potential for future test development and use.

However, AMP believes that genetic tests should

be provided in the public only through the services of an appropriate healthcare professional and a properly-certified laboratory.

Additionally, AMP is concerned that genetic tests sold directly to the consumer have the potential to do harm, mislead consumers about the significance of the results and promote the purchase of products not proven to be medically useful.

When considering this nascent industry, AMP requests that the committee review the practices of these companies, including the testing offered, the laboratory certification, the claims made about test results, and access to qualified health professionals throughout the testing process.

Additionally, the committee should solicit feedback from the every-day consumers of these services to learn about any benefits, harms, misconceptions, their genetic literacy, changes in health behavior, and other health outcomes.

Last, AMP has been a supporter of the Genetic Information Nondiscrimination Act, known as GINA, for almost 20 years. We have actively participated in the

long struggle to see these protections enacted by Congress and we're currently working to ensure that GINA's protections are not weakened or otherwise undermined.

Earlier this year in the healthcare reform debate, members of the Senate proposed offering an amendment that would make employer-based wellness programs exempt from complying with the Civil Rights Act, the Americans With Disabilities Act, and GINA.

As we heard this morning, GINA currently allows wellness programs to collect genetic information, including family medical history, if the program meets the criteria voluntary, and as we heard this morning, the interim G&A regulations discussed says that if an employer offers a cash incentive to participate in a wellness program, the program is not voluntary, that incentive is considered not incentive but actually a penalty to those who choose not to participate.

Employers want to offer cash incentives to encourage people to enroll in their programs and instead of attempting to directly address the definition of voluntary in the regulations, they simply tried to

circumvent these important civil rights and privacy protections through the healthcare reform debate.

AMP joined 28 organizations in signing a letter urging the Senate Finance Committee to defeat this amendment and fortunately the GINA advocates won this time.

AMP is hopeful that the regulations currently being finalized by the agencies will eliminate many of the potential loopholes for employers and health insurers to avoid complying with GINA. Recently, we were made aware of the likelihood of genetic testing companies partnering with health insurers to offer tests to enrollees.

While an insurer can inform members about a genetic test without violating GINA, AMP is concerned that the public is not armed with the knowledge they need to know that they have the right to decline testing without any consequences to their coverage.

AMP encourages the committee to explore these ongoing attempts to weaken or circumvent GINA, bring attention to this recent activity and work to educate the public about the protections afforded by GINA. The

amendment in the Finance Committee served as a strong reminder to those that oppose GINA will continue their fights to weaken and unravel its protections and we supporters will have to do the same and continue our fight to protect patients from genetic discrimination.

Thank you.

DR. TEUTSCH: We appreciate your input at these meetings on a regular basis, so thank you.

Were there any questions or comments for Jennifer?

[No response.]

DR. TEUTSCH: Okay. Well, thank you.

Our next speaker is from the Biotechnology Industry Organization. I'm afraid I may get your name wrong. Is it Tom DeLenge?

MR. DeLENGE: That's perfect. You're the first one to ever do that on the first try.

DR. TEUTSCH: I was advised, but I still get it wrong. Anyway, welcome. We appreciate your input. We obviously heard from your organization as part of the public comment period in writing, and we welcome your comments this afternoon.

Tom DeLenge

Biotechnology Industry Organization

MR. DeLENGE: Well, thank you very much. I appreciate the committee letting us have this opportunity today to talk about your report.

I want to start by just talking a bit about bio. We represent mostly start-up companies that are engaged in biotechnology across an entire platform of the industry, so healthcare, but also agricultural, biofuels, industrial applications, environmental applications. We also represent a lot of academic research centers and other people involved in the biotechnology industry, not just companies.

We completely support the mission of this committee. We support enhancing access to patients for genetic tests. That is what our companies do every day, and the partners that we have in the universities. That is what they get up and do every day. They want to create products that people can access. So let's start from that premise, that we completely support that.

There are companies, though, and again, most of them are privately-held, that rely on venture capital,

the private equity markets, to raise the money to do this fascinating and really valuable research that they do. They need to have IP protection. It's the core link. Every study that is looked at this has confirmed that, and this committee also recognizes that important link for the applied research and development work that they do every day. It is critical, it is absolutely critical that we have that link.

This committee's emphasis on securing access and trying to resolve the problems that they have identified is one that we completely agree with, and Jennifer, the prior speaker, we were big supporters of the GINA Act, as well. We are very active in this space and we want patients to get the best access to genetic information that they can get.

We commend this committee's hard work. The case studies that you commissioned were very valuable. They really took an in-depth look at many of these issues.

Unfortunately, what they provide are not really any kind of consistent or broad themes or conclusions that could be based on them, and that is where I think we

part ways with the Committee, [which] is that when you look at those case studies, what you see is that there is some good; there is some bad; there are problems that have been fixed; there is some that seems to work very well.

The idea of trying to tie it back to the patents and licensing is where the committee's report gets extremely weak, to be quite frank. There is just very little evidence that it is the patents or the licensing that are creating these problems.

The emphasis of the committee seems to be more on sole-source providers and suggesting that somehow there is that link between the patenting and exclusive rights and sole-source providers. Of course, that can be true. It's not always true and the notion that somehow we need to attack the patents and the exclusive licenses to cure problems that can occur even without patents and without exclusive licenses seems to be overkill, seems to be overreaching.

We are deeply concerned that the committee would then kind of turn the question around. The initial question was are patents and licensing causing harm? Not

being able to find evidence of that in any broader consistent way, they then say, well, maybe patents really aren't even necessary. So we should restrict them for that reason.

We're very deeply concerned with that. We don't believe that neither this committee's charge nor the methodology that it employed would really support such findings. We don't believe that you can actually look at some case studies and then determine on a broad way whether patents are necessary or exclusive licenses are necessary for innovation in this very diverse area. It may not be true.

I'm not going to say we always have to have patents and exclusive licenses. Many of our companies have non-exclusive licenses, okay, but the idea that we can kind of make generalizations upfront about when and where it might be appropriate, we think, is very misguided.

We don't think it's worth taking that bet that somehow we don't need patents or exclusive licenses, that we can start to restrict those without costs. Quite frankly, we may never know the costs of that, but we will

know who the losers will be and that will be patients, the patients of tomorrow who are waiting for this next wave of innovation from biotechnology.

Before we upset 25 years of largely successful university-industry collaboration, we must have more evidence than this. I would implore you to look at all of the data, including the data that the committee seems to have ignored, even though it commissioned, which was a study that's in your Appendix 2. It gets very little discussion in the committee's report, but I find it absolutely fascinating.

It suggests that the role of patents and licensing in diagnostics is much more complex than the committee's summary conclusions would lead one to believe. We believe that the burden is on the proponents of change, not the other way around. We don't believe that burden's been sustained.

Your own findings in three-year case studies show that in some cases patents do play an important role in this area and yet the recommendations seem to be all about how do we restrict that, how do we restrict patenting and exclusive licensing.

We believe that when you look at the other main assumption, which is that in this particular area of diagnostics, that somehow patents aren't necessary because most of it's done by the federal goverment or through federal funding.

Again, we're not sure that the data absolutely supports that, and it really, quite honestly, kind of undermines what my members get up every day to go and do. They are the ones discovering, not just academic researchers but for-profit entities and companies, they're out there discovering genes and the gene associations that are helping people cure disease, and to suggest that somehow, well, we don't need to worry about that part of this, we can leave it all to the academic researchers who have no profit motive I don't believe is what the society wants or will lead to the type of innovation that we need.

The only truly broad-based study commissioned by the committee is that Appendix 2, and we need to actually wait for the results of that before we make conclusions.

We are concerned the committee relies on a

series of conflicting anecdotes and theories of possible future harm to propose recommendations that could risk severe unintended consequences not just for biotechnology but for the patients.

We're not saying that every patent that has ever been issued in this area is good or should have been issued. I think the system has evolved over time. We're not saying that every patent has to be exclusively licensed for it to be developed. That's not true. Okay?

All we're saying is that the system that we have today maintain the flexibility so that we can deal with these cases as they arise rather than attempting to set broad rules and federal mandates that people have to work around or get out of, have to prove your way out of a system rather than start with the flexibility that's clearly needed.

The evidence shows that this flexible system seems to work better than the more rigid system that is applied to intramural federal research, although the data is not conclusive on that, and we want to see that data. We want to see what that shows.

Stepping back, when you look at the overall

system, there's no doubt that this is working very, very well ever since we passed the Bayh-Dole Act 25 years ago. The problems that have arisen have been quickly resolved. Your committee has even acknowledged that in your report and working together, we can address any concerns that arise going forward, but my concern here is that these proposals that you're recommending are just going to drive us further apart. They're divisive and unnecessarily so.

The proposals would undermine the enforceability of patent rights, would chill patent private sector investment, throw a monkey wrench into the very successful Bayh-Dole Act, which has fostered technology transfer, spurring economic growth in all of the states, innovation that's benefited patients, the worldwide. This is what Congress intended when it passed the Act 25 years ago. It's working well.

Contrary to the suggestions in your report, your recommendations on exempting certain acts of infringement on the use of patented articles on the sale, on the sale of commercially-infringing products can find no precedent in any prior patent law or act of Congress.

The Ganski-Frist exemption is nothing like what is being proposed in these recommendations.

The research use exemption that you propose is nothing like the Hatch-Waxman research use exemption. Neither of those gives license to the use of patented articles.

DR. TEUTSCH: We just have a couple more minutes. Can you sum up?

MR. DeLENGE: I'll sum up.

DR. TEUTSCH: Thanks.

MR. DeLENGE: For more than 200 years, we have avoided doing down the slippery slope of trying to say certain areas should be patentable and certain shouldn't be or we should restrict this or restrict that as a matter of feat. That's based on our strong belief, borne out by wave after wave of innovation, that patents do spur innovation, even though they do entail temporary costs.

As the editors of "Nature" recently said, specifically on this debate, the fundamental premise of our innovation system "shouldn't be discarded purely because there is a vague hint that harm might one day

occur."

Now I fear it's too late maybe to change some of the members of this committee's mind. The final draft report that we saw this morning seems to even go further than the initial public draft report which received a lot of criticism by many stakeholders in and outside of government. So this process has not been ideal.

I would suggest that there are so many legal implications to what the committee is proposing that this needs another scrub. I don't know what kind of legal advice you received on patents. I would be interested to see what the PTO has to say about your reference to the association claims as being simply laws of nature. I don't think they would agree with that.

I think that they are very valuable, potentially, some of those claims and need to be supported, when appropriate, and I wonder also about the U.S. trade implications in this and whether you've consulted at all with the U.S. Trade Representative's Office. I think they would be very concerned that some of these proposals would violate our international obligations under the Tripps Agreement.

So I do caution this committee that I think these issues are hugely important. They need to be thought through very carefully, and I would urge you to think about that one a little bit more.

If I can make one last comment? The access issues that have been identified are truly a concern of ours. We think, quite honestly, when you look at those access issues, the best way of resolving those are not trying to change the patent system, which is so divisive and is going to take forever, but working with us to make sure that the major insurers who cover indigent populations in this country actually will pay for these diagnostic tests, whether they're provided by sole-source providers or not.

It shouldn't have to be provided by the designated Medicaid lab. Okay? Let's work together to try to improve access because that is where the rubber meets the road here, right. We want to make sure that patients are getting coverage for these tests. That is critical, and I urge you to work with us to get that accomplished, and we will be your partner in that. We cannot be a partner in undermining the patent system.

Thank you very much.

DR. TEUTSCH: Great. Thanks, Tom. Any questions for Tom? Sheila.

MS. WALCOFF: Sorry to keep you up there, Tom.

MR. DeLENGE: That's okay.

MS. WALCOFF: Just on that very last point. I have some familiarity with the reimbursement system, not a huge depth of expertise in that, but could you just comment on behalf of your members about how it is that those tests come to be reimbursed by private or public payers, and is a patent and licensing issue interfering directly with the ability for reimbursement to be covered for these particular tests?

MR. DeLENGE: That's a good question. Unfortunately, I'm not a reimbursement expert, so I don't know. There are some other folks from Bio here.

Darrell, I don't know if you want to come up.

I would think that because the problem really arises in the context of Medicaid for the most part, not so much the private-payer system, what happens with Medicaid, my guess is, there are certain designated laboratories that get the bulk of Medicaid business in a

particular state, and they have contracts with the Medicaid agency. It may be that they are not allowed to use some of these other sole-source providers of diagnostic labs, but I don't know that.

Darrell, do you have any idea about the issue of how those lab tests get reimbursed?

MR. PRITCHARD: Sure. Absolutely.

MR. DeLENGE: This is Darrell Pritchard, who handles this issue for Bio.

MR. PRITCHARD: Yes, I'm Darrell Pritchard with Bio, and I lead on the Diagnostics issue.

Diagnostic tests are reimbursed typically through Medicare through a lab fee schedule and this has been --

DR. TEUTSCH: This is mostly about Medicaid, of course.

MR. PRITCHARD: About Medicaid.

DR. TEUTSCH: Medicaid access is what we've been talking about, not Medicare.

Mara, did you have something?

MS. ASPINALL: Well, I don't know if we want to deal with this issue now because I think there's a

reimbursement issue from Medicare and Medicaid, and also an issue in terms of what is required for the labs to be able to give free access because the access system for drugs and therapeutics are not equivalent and, unfortunately, something that didn't get as much focus in the report as I would have liked which is a key issue in terms of having full access, particularly for these tests.

MS. WALCOFF: I guess, one quick follow-up thing I'm kind of wondering is, are the Medicaid payer policies consistent across all states? Do they vary state by state? What sort of influence does the federal goverment have directly on the payer policies, state by state, for whether or not they would reimburse them?

MR. DeLENGE: Sorry. My guess is you're going to find a lot of variability at the state level and people on the committee actually may have more expertise in that since they've looked at this. In fact, I believe you issued a report a year or two ago that looked at this.

My point, Sheila, really, in raising it was not so much that I know the answer to that, but it seems to

me it's a much more fruitful avenue for this committee -- and particularly since this is an advisory committee to the Secretary of Health and Human Services, not to the Secretary of Commerce, which runs our patent system -- that it would be more appropriate to look at ways that the Secretary of HHS can really use her authority, which is quite substantial, to look at things about CLIA laboratory testing and oversight regulation reimbursement.

Obviously, the Secretary of HHS oversees Medicare and Medicaid, looking at those access issues that Mara mentioned. I think that's a much more fruitful area of inquiry and will have much quicker and more immediate impacts on patient access.

MS. WALCOFF: I appreciate that, and I think that's a lot of where my questions lie today. So thank you.

DR. TEUTSCH: Why don't we take one or two more questions, and then we'll move on?

DR. DALE: I'm just interested in your general position. Is it that every gene and potentially every protein in each component of our bodies should have a

patent associated with it?

MR. DeLENGE: No, not at all.

DR. DALE: Only those with some position or view of opportunity?

MR. DeLENGE: Well, what we want to do is we want to try to explore the human genes to figure out what genes and which gene mutations might actually lead or cause disease, or make some tumors more susceptible to treatments than others. People tend to talk about gene patents as if we've just invented the gene. We didn't invent the gene.

What we're trying to figure out is what that gene does, and that is a critically important avenue of inquiry, because it's going to help with this entire development of biotechnology and biologics, and in fact personalized medicine.

So you think about the products like Herceptin, which is a therapeutic, not a diagnostic, obviously, but grew out of the notion of, we discovered that the Her2 gene provides a susceptibility to this greater, more aggressive form of breast cancer, and then we could target a therapeutic on that.

So I'm not suggesting every gene should be patented. I think someone said about 20 percent of them are, but they also shouldn't be banned.

DR. DALE: You understand that this report, though, just deals with testing.

MR. DeLENGE: Absolutely, but I think if you look at the Appendix 2 study, which is still not yet complete, but if you look at that, what it shows is that you can't tell from the initial patent applications, oftentimes, what the applications of that invention will be. Sometimes, it is the very same patent that fosters diagnostic development that will foster therapeutic development. Many of the diagnostic patents are method patents.

DR. TEUTSCH: Tom, I'm going to ask you to be brief. I know we could go on, but --

MR. DeLENGE: I understand. I'm trying to be responsive to the question, which is that, in Appendix 2, it goes through in some detail how it is very difficult to say we are only focusing on diagnostic patents.

DR. TEUTSCH: I know Jim wants to respond to that. I am going to get Gwen and Julio, and then we're

going to need to move on.

DR. EVANS: I just want to mention to the Committee and the audience the Appendix 2 issue. Bio has placed a great deal of emphasis on the study that is related in Appendix 2. I would emphasize to you that the reason that it was put into the Appendix, and the very good reason that it did not get a lot of play is that it is, by its own admission, highly preliminary data, which has left out a tremendous amount data that has yet to be analyzed.

Moreover, the design of the study is such that it is essentially looking at the generation of royalties as its barometer for the impact of tests. The venue in which the great majority of diagnostic testing is done in this country is in laboratory-developed tests at, for example, university laboratories. There are no royalties associated with that.

Therefore, this study, while I think of mild interest, the effects will be transparent to this study in the realm where most of this testing is done. Therefore, it does not make much sense to put very much stock in this study as any kind of definitive issue.

DR. TEUTSCH: Gwen.

MR DeLENGE: Can I respond to that? Perhaps you might want to author's study to come and respond to that.

DR. EVANS: I've talked about it at length with Lori Pressman, who headed up the study.

MR. DeLENGE: And she agrees with your characterization?

DR. EVANS: It is the case. She definitely admits that where most testing is done, that study is unable to address it.

MR. DeLENGE: The point of her study, if I understand it correctly, is to look at two things. One was, can you tell from a patent what the application of that invention might be, diagnostic, gene-based therapies, otherwise, and I think she concluded you can't.

That is very important, because you're making broad-based generalizations and recommendations about what we call patents on genes, or in the diagnostic field of use.

Those are things that we don't believe are as

simple as the Committee's report suggests to understand which ones we're talking about. That uncertainty is really a problem.

DR. EVANS: That actually is not the point of the study. And again, the metric that was used was the generation of royalties, which is not a metric that is applicable to where most diagnostic tests are done in this country.

DR. TEUTSCH: Gwen.

MS. DARIEN: I would just like to say as a patient and a patient advocate that, and this is just a comment, which is that we are asked, all of us are asked to be open-minded about the issues of patents and about the issues of IP, but I have to say that when patient benefit is just brought up as the justification for a certain line of thinking, I would ask you to think about it in a little more depth than just saying patient benefit.

I know a lot about the Herceptin story, I know a lot about the BRCA1 and -2 story, having been a patient advocate for 15 years working in cancer. So please don't just put out patient benefit to elicit some kind of more

sympathetic response.

Thank you.

MR. DeLENGE: I thought that's what this committee was trying to accomplish.

DR. TEUTSCH: Julio.

DR. LICINIO: I have one kind of comment/question, which is this. As it was said a little earlier, very soon, maybe like within five years, I think, certainly within 10, the cost of whole-genome sequencing is going to be such that individual testing is going to make no sense or is not going to be cost effective.

So, how do you address or deal with the issue of patents for specific genes, for specific genetic sequences that are part of the genome, when someone can just get the whole-genome sequence? And, would such patents prevent whole-genome sequencing efforts in the application of data that comes from that?

Let's say if I have my genome sequenced, and a part of the sequence is indicative of a disease but someone else has the patent on that, can the results be given to me?

MR. DeLENGE: I think what you'll find -- this goes back to the issue I was just referring to -- which is that you don't really quite know. You can't say, what is the gene patent. I think that the answer to your question really depends. It's going to depend on the patents, how they're drafted, what they claim. They're all going to be very, very different.

So I can't give you a short answer, but I can tell you that those issues have been largely worked around in other sectors of the economy. That happens all the time. There are aggregators, if you will, of tests, of Blackberrys, of anything else. They have to work through that. They've got to get licenses, or sometimes people don't enforce their licenses, or they have agreements to not enforce them.

It is complicated. I'm not going to suggest it's not, but I do believe that we've been able to work around those things in other areas. I would see the same types of things developing here that the committee talks about. Patent pooling, we're supportive of that. There are all sorts of things that we could do to try to address that concern, but it's a hard one. I'm not going

to stand up here and say it's easy.

DR. TEUTSCH: I know we'll be revisiting many of these issues over the course of the afternoon.

Tom, we really do appreciate the perspective of Bio and all of the things that your industry does bring to help us accomplish our mission.

MR. DeLENGE: Thank you, and I appreciate, again, the opportunity to be here.

DR. TEUTSCH: Thank you for coming.

We'll turn now to the College of American Pathologists and Fay Shamanski Fay, always are happy to hear from the College. So welcome.

Fay Shamanski

College of American Pathologists

MS. SHAMANSKI: Good afternoon. My name is Fay Shamanski, and I'm here representing the College of American Pathologists, a national medical specialty society representing more than 17,000 pathologists who practice anatomic lab pathology and laboratory medicine in the United States and Canada.

The College has been a leader in developing quality improvement programs for laboratories, including

programs in molecular pathology and cytogenetics. As a medical specialist in the diagnosis of disease, pathologists have a keen interest in ensuring that gene patents do not restrict the ability of physicians to provide quality diagnostic services to the patients they serve.

The College provided written comments on the draft patent report to you in May and today would like to reaffirm our view that human health-related gene patents have an inhibitory effect on pathologists and other laboratory physicians' ability to practice medicine and that this in turn impacts patients' access to important medical testing services.

Pathologists have a long track record of delivering high-quality services to patients through the practice of laboratory medicine and have demonstrated through the introduction of thousands of laboratory tests used daily in clinical practice that the best interests of their patient is the primary driver of innovation in laboratory testing.

For pathologists in particular, it is more often clinical need manifested by the requests from their

clinical colleagues that spurs novel developments in medical testing and not intellectual property.

The College has a clear policy statement in opposition to gene patents which has been in effect since 2000 and that policy states that "The College of American Pathologists believes that patents on genes, genetic variants, and genotype/phenotype correlations, when enforced to restrict diagnostic genetic testing, violate the longstanding prohibition against patenting natural phenomenon."

Moreover, because genes are naturally-occurring substances, we believe that under most circumstances, they should not be patented. Given the existing patents and pending patent applications, the College supports legislation that will protect physicians and other providers of clinical laboratory services from enforcement of any patents on genes and against liability for infringement of patents on genes, regardless of the date of issuance of those patents.

The College believes that gene patents, licensing fees related to those patents, exclusive licensing agreements, prevent physicians and laboratories

from providing DNA- and RNA-based diagnostic services to their patients. They limit access and interfere with medical education and clinical research.

Especially troubling is the fact that under patent protection, the understanding of the utility of the test, as well as the underlying disease processes, can become proprietary, thereby imposing a profound change in how the profession and the public acquire knowledge about these tests and their applications.

In order to address the impact of patents on patient access to medical testing, the College believes that the options in the draft report related to statutory change, as outlined in the report, are the most likely to succeed. These options clearly address the impact of patents and licensing on patient access by addressing the core problem affecting the ability of pathologists and other laboratory professionals to provide medical testing services to their patients.

The College understands the challenges that exist to ensure that the appropriate balance between promoting innovation, ensuring patient access to genetic testing services and is absolutely committed to that end.

However, the College would request that the committee recognize the vast amounts of innovation occurring through the work of pathologists in clinical laboratories who have introduced and improved upon the majority of molecular tests largely without patent protection.

Thank you.

DR. TEUTSCH: Thank you. Any questions or comments for Fay?

[No response.]

DR. TEUTSCH: Great. Well, thank you. We're always delighted to have you here. Thank you.

Our next speaker is Michael Henry from Athena Diagnostics.

Michael, welcome. Look forward to your comments.

Michael Henry

Athena Diagnostics

MR. HENRY: I'm Mike Henry. I'm Vice President of Business Development at Athena Diagnostics in Worcester, Massachusetts.

Athena is a clinical diagnostics lab that performs genetic testing for patient care. Our mission

is to provide the best possible genetic testing services to physicians who treat patients with genetic disease. We perform 200 tests and we license gene patents for many of our tests from universities and in turn we pay royalties to the universities that support further genetic research.

We are a provider of high-quality genetic tests. We make every effort to ensure our tests are widely available. We conduct physician outreach and education to educate them about the benefits and the limitations of our tests and because of the volume of the tests that we conduct, we can be very proficient in the tests that we perform, performing high-quality tests, and we can offer tests for very rare diseases.

And now, I would like to depart from my written remarks and I would like to talk about some factual inaccuracies from the presentation that Dr. Evans presented this morning. Several of them mentioned Athena and I would like to correct the inaccuracies.

One concerned our ataxia testing, also called SCA testing, and bundling. Athena offers testing for 18 different ataxia genes. Each of these tests is available

as a single gene test. There are also a number of ataxia test panels available. Anybody can order -- well, any physician or client can order any one of the single tests or any combination of the tests or they can order the panels. So that is a factual inaccuracy I would like to correct.

Second was on Connexum-26 and there was some mention about the availability of prenatal testing and newborn screening. Athena has sublicensed our Connexum-26 hearing loss genetic test to a company formerly called Pediatrixs which is now called PerkinElmer Genetics. That is the largest provider of newborn screening test services in the United States and they are offering the Connexum-26 test, this newborn screening test, under sublicense from Athena.

Athena is not in the newborn screening business which is a different business from testing older patients.

A third inaccuracy that I would like to correct from today's presentation concerns the dystrophin gene for Duchenne Muscular Dystrophy, and there was also some mention about commercial labs and the extent to which

they deal with indigent patients' and indigent families' ability to pay for tests.

Our dystrophin test, through cooperation between Athena and the Muscular Dystrophy Association, we created a program where the MDA would pay the co-pays for our dystrophin test, thereby making the test more accessible for indigent patients than it otherwise would have been.

Finally, a broad issue I have with inaccuracies in today's presentation. I didn't hear enough about the benefits of exclusive licensing of genetic tests, and I also didn't hear anything about the negatives of non-exclusive licensing.

One of the most widely-known and tragically one of the least-ordered genetic tests in the United States today is the Warfarin Metabolism Test. The FDA has recommended that all patients started on Warfarin, a blood thinner for heart attack patients and stroke patients, be genetically tested with two genes as a Warfarin Metabolism Test.

The patent owners decided to non-exclusively license the Warfarin test. About 10 labs launched the

test two or three years ago. Athena launched a Warfarin test. We discontinued that test because we received no orders and so non-exclusive licensing in the case of the Warfarin test is causing today in the United States perhaps a few hundred Warfarin tests to be conducted when over one million patients in the U.S. are started on Warfarin each year in the United States and there have been cost-benefit studies that suggest that, in addition to patient trauma, millions of dollars could be saved in the system if Warfarin genetic testing was widely done.

This is a negative and a cost to us from non-exclusive licensing. If there was an exclusive license for the Warfarin genetic test, that exclusive holder of the patent rights would have invested in widespread marketing to educate physicians about the test, and instead we do not have that test ordered in any significant way in the United States today.

So returning to my written remarks, --

DR. TEUTSCH: Just to be clear, we only have another minute or two.

MR. HENRY: Yes. Returning to the written remarks, we feel that the policy recommendations of the

report are not in line with some of the conclusions Dr. Evans mentioned. The conclusion thus far patents covering genetic tests and related licensing practices do not appear to be causing wide or lasting barriers to patient or clinical access. That suggests that policy recommendations to improve access do not follow from the research results, and so in the interests of time, I'll cut it off there.

Thank you.

DR. TEUTSCH: Great. Thank you. I think we have your written comments, so we appreciate that.

Liz, did you want to say anything about clarifying what the FDA says about Warfarin testing?

DR. MANSFIELD: The Warfarin drug label was modified in 2007 to recommend genetic testing to be used, the results of which would be used together with consideration of other clinical variables to determine an appropriate Warfarin dose. In the absence of that, I believe doctors have continued to use INR successfully to adjust dose to an appropriate dose.

I don't know that there is existing literature that establishes exactly how those tests should be used

in every patient or evidence that use of the test will necessarily reduce adverse events and until there's more information available, I would suggest that that may not be a good example.

DR. TEUTSCH: We're running kind of short on time, but we've got Paul, Muin, Jim, Andrea, and I'll try and remember all of this, and Mike.

DR. BILLINGS: So I just have a comment. This is Paul Billings. A comment and a question.

My comment is that, as far as the Warfarin test is concerned, there is a clinical need for better management of Warfarin patients. That's quite clear and so whether it's the Warfarin genetic test or others that are going to lead to better management of Warfarin patients, the INR, as we currently use it in this country, is probably not the answer.

But my question about the Athena presentation is for those tests for which you hold an exclusive license and are the sole-source provider, do you have some assessment of how much of the market you are in fact servicing of those people who potentially could use the test?

My impression is that it's rather small, actually a small fraction of the accessible market, which would suggest that your comments about marketing may not be entirely successful.

MR. HENRY: I would say that for some of our tests, we have penetrated the potential market. For others, we have not fully penetrated.

A good example would be our spastic paraplegia test. This is a very rare disease. We offer a number of genes for this rare disease, and we feel that with fairly well-educated neurologists that we educate about our test, about our spastic paraplegia testing and we've penetrated that market.

We also offer some tests for other diseases where there's still room to conduct more education and further penetrate the market.

DR. TEUTSCH: Muin.

DR. KHOURY: I would like to come back to the Warfarin story because you used it as an example of how many lives could be saved. You know, you tied it to the patent story, and I think it's a question of clinical utility. It has nothing to do with patent. People are

struggling to know how to use the pharmacogenomics of those two genes. The management of Warfarin therapy, until clinical trials are done, this has nothing to do with the patenting.

So, I mean, I think you should correct that because it's highly misleading, what you just said. I mean, you tied that story to the potentially-damaging effect of patenting and it has nothing to do with it.

DR. TEUTSCH: Jim.

DR. EVANS: Yes. I just wanted to let you know that we certainly want to be correct in any factual errors.

The issue with bundling was a quote from a public commenter and it's good to hear that the bundling is not compulsory, so that's great, and we'll make sure that gets corrected in the report.

With regard to the Connexum, perhaps I didn't communicate clearly, but I think for whatever reason you misunderstood what the comment was. I don't know if you want to show this on the slides, but it was Slide 34, and it had nothing to do with newborn screening. It was as follows.

In the hearing loss case study, it was maintained that Athena had not secured coverage from MediCal. So it was the same issue of reimbursement which is a significant problem with a sole provider of anybody. We're not trying to pick on Athena and so it didn't have anything to do with newborn screening.

Then the other comment about dystrophin, [which] also had to do, on Slide 36, with the fact that an advocacy group maintained that Athena had not secured coverage from some payers. Again, that same issue with the difficulties when there is only a single lab that can do a test. It's very difficult for that lab to secure coverage from all payers.

So I just wanted to clarify that and we'll make sure that the bundling issue gets corrected.

DR. TEUTSCH: Great. Thank you for that. I'm going to get Sheila, Andrea, Marc, and Mara.

MS. WALCOFF: Thanks. Actually, I had a follow-up on that exact slide, Slide 34.

Is the reason that you did not get coverage from MediCal because you're a sole-source provider?

DR. EVANS: No, that's not the issue. The

issue is why coverage isn't obtained. The issue is that when there is a sole-source provider, it is axiomatically much more difficult for all payers to have a contract with that sole-source.

For example, MediCal has contracts with a number of labs, many of whom have expressed willingness to do a variety of tests that they are prevented from doing. So it's not an issue of MediCal not contracting with a sole-source provider, per se. It's the difficulty in getting sufficient payers when there is simply one lab that does the test nationally.

MS. WALCOFF: I guess I'm just trying to make the connection all the way through, that there's a patenting and licensing issue that results in some sole-source lab that results in a lack of access because the lab cannot get reimbursement from everybody, but I don't see how the issue of the patents follows through to the inability to get -- I'm just not -- I'm not an expert. I'm not making the connection with the reimbursement.

DR. FERREIRA-GONZALEZ: If you can do the test locally, for example, what we already have arrangements with Medicaid in our state system for payment of these,

then we can provide another avenue for these tests to actually be done and access to that particular patient. That's the issue that we are driving at.

DR. EVANS: So, for example, when I talk to a clinician --

MS. WALCOFF: The patenting issue fixes the reimbursement, because in terms of CMS --

DR. EVANS: Patenting or licensing will fix it. Here's the deal. For example, MediCal has a contract for certain tests with the Mayo Clinic. The Mayo Clinic is prevented from doing some tests because the sole-source provider prohibits them from doing it. They have a sole-source license. That makes it extraordinarily difficult for payers to have multiple contracts with each sole-source lab to do tests when there is a lab that they have a contract with that's more than happy to do that test but can't do it.

So, clearly, the patenting and licensing situation enables a situation in which we have a significant restriction of the ability to get large populations covered.

DR. BILLINGS: But changing the patents isn't

the only way to change the system.

DR. EVANS: It might not be the only way. It would fix the problem.

DR. BILLINGS: Potentially.

DR. EVANS: It would clearly fix the problem. It would clearly fix the problem. You would not have a sole-source provider. Then Mayo Clinic can say, okay, we'll do the test.

MS. WALCOFF: That's the whole issue of whether Mayo can do it. I mean, can't you ship it to the sole-source provider? The issue is that if California won't pay --

DR. EVANS: Again, if you don't have a contract with them, no, you can't.

MS. WALCOFF: But shouldn't we be telling them that they have to contract with them?

DR. EVANS: Secondly, why do we want to introduce all of these various machinations and complications when you let a lab who can do the test and is willing to do the test do it?

DR. TEUTSCH: I'm going to cut this off. We're going to get into this when we get to the

recommendations.

MS. WALCOFF: I'm sorry. It's a little confusing. I just think there are a lot of reimbursement issues that relate to this that are currently in effect.

DR. TEUTSCH: There are a lot of reimbursement issues.

Andrea.

DR. FERREIRA-GONZALEZ: Well, Muin brought the issue up of Warfarin genotyping. My laboratory is still offering Warfarin genotyping and we have a very good uptake, until there were some reports from coverage reimbursement issues and where there was a decision not to offer the testing until more clinical trials results are made commonly available.

The other issue I wanted to bring up to your attention is that you have a program that helps with the co-pay of the testing for some of these indigent population, but I think the co-pays it not the only issue because you have the co-pay but you also have the cost of the test. When the insurance don't cover the cost of the test, it will be billed back to the patient. So you help with the co-pay but not with the large amount of the cost

of the test. Some of these tests are extremely expensive, in the five thousand and six thousand of dollars.

MR. HENRY: Would you like me to address that?

DR. TEUTSCH: Sure.

MR. HENRY: Athena is in three of the eight case studies. At least two of those case studies mention our patient protection plan, which is our co-pay, where, in exchange for a patient agreeing to pay 20 percent of our list price for a test -- and these are patients with commercial insurance -- we will go for reimbursement with the insurance company, regardless of the outcome. Whether we get paid zero up to 80 percent, there is no additional obligation by the patient.

If we get paid more than 80 percent, we refund the portion up to the full amount of the co-pay back to the patient.

DR. FERREIRA-GONZALEZ: But you don't offer that to every place?

MR. HENRY: These are for patients with commercial insurance.

DR. FERREIRA-GONZALEZ: Exactly. For patients

that don't have commercial insurance, you don't offer that.

MR. HENRY: Well, there's other reimbursement options.

DR. EVANS: I think it's great that you guys are trying to provide some services to allow indigent patients to get the testing.

Unfortunately, as a clinician who deals with patients who need these tests, it's a difficult cumbersome process that is not applicable to many of the patients. So they're still left, in spite of your best efforts, with considerable costs that are simply out of range for them when, if, for example, there was a contract with state Medicaid, it would be covered.

So I think it's a good effort, but it's clearly not the answer to this problem.

DR. TEUTSCH: Marc, and then we're going to get to you, Mara.

DR. WILLIAMS: So at the risk of piling on the Warfarin thing here, there was a third piece of that that needed to be addressed which related to cost effectiveness and it did relate directly to the marketing

perspective.

As noted, the utility argument and having been involved in some of the larger randomized prospective controlled trials has not been answered and the one cited cost effectiveness analysis that showed cost savings, I think, is increasingly being viewed as using assumptions that are not accurate, which has led to basically a bit of a misperception about the value of the test which then brings the issue to -- and again I don't think that this is necessarily a sole provider issue versus a multiple provider issue.

I think extensive marketing of tests without value directly to physicians is not a good thing under any circumstances, that ultimately the evidence base has to be available and anything that impairs our ability to evaluate the evidence base, I think, is problematic.

One of the issues that I would have, that I do support that's within this report and recommendations, is trying to have more transparency about the data that's available, the data that's used in order to really be able to assess what is the utility of this test and is it something that should be recommended or not for those of

us that are in the business of developing guidelines for physicians.

DR. TEUTSCH: Mara.

MS. ASPINALL: So two sets of comments. I actually agree with a lot of what Marc and Jim said but for different reasons.

I think that the additional transparency, which we dealt with in Andrea's committee's report last year about the need to continue to show information on each test out there, to me is something that is important to be done.

A number of different agencies have done it and in having that, it is not at all related to the patent test, but the ability to have that information available for all testing companies and all tests available in any form makes a huge amount of sense and patents doesn't change that.

Secondly, Jim, in your comment about the current system of providing tests for indigent patients is absolutely right. It's an incredibly-cumbersome process, one that is much more difficult for diagnostics.

Athena has talked about this a long time ago

and I'm familiar with it. It is a process for which you've got four individual steps. You literally need to almost go to getting the patient's tax return and going through a process that's cumbersome to anyone.

I think it's unfair to criticize and I know you said it was great that the company's tried to do it, but for any academic or commercial lab to do that, that to me is a key recommendation that should be in the report. Drug companies and therapeutics, it's relatively easy.

Now we have some standards about putting out samples and getting their tests out there. By definition, virtually all therapeutics from their beginning until they get generic are single sourced. We have learned how to deal with that system by either requiring or encouraging the drug companies to get samples out to patients to ensure access.

Some drug companies have sales forces --

DR. EVANS: Are you suggesting that drug samples are a viable way of solving the drug access problem?

MS. ASPINALL: No. I think that is the start of the process and it's one way that has dealt with sole

sourcing, but the drug companies have a much more straightforward way to be able to get access to patients who cannot otherwise afford it because they are by definition pregenerics sole sourcing.

So what I'm suggesting is that we have a process, for which the diagnostic companies have asked for in the past, to say if it's sole sourcing and there is a perception, and in some areas the reality that patients can't get it because of the approval by the payers, that the diagnostic company has the ability to [provide], in a simple and easy way.

The company doesn't need to provide a tremendous amount of burdensome administration to get the patient that test on an expedited basis, because I think your assumption that if there were no patents, lots of people would pick up the test is just wrong.

DR. EVANS: No. Whoa, whoa.

MS. ASPINALL: Nobody else wants it.

DR. EVANS: It's empirically the fact, in case after case after case, there are multiple labs performing these tests, hearing loss, hemochromatosis, BRCA1 and 2, SCA, et cetera, et cetera. Only after IP claims are

enforced and enacted does one see a narrowing of the field.

So, empirically, that's incorrect. We know that multiple labs develop diagnostic tests. That is a fact.

MS. ASPINALL: But I think that it happens for a different reason. It happens because the innovator with the patent on most of the occasions --

DR. EVANS: Mara, it has nothing to do with the patent.

MS. ASPINALL: Well, it's put in the education to do that.

DR. EVANS: Oh, Mara.

MS. ASPINALL: If you look at the smaller market tests, we looked at the major tests, there are lots of tests out there in smaller markets that nobody has any interest in providing, other than a sole-source.

DR. EVANS: And if you talk, for example, to -- we got public comments from the individual who runs Gene DX, a rare disease testing --

MS. ASPINALL: I read the letter.

DR. EVANS: And their point was --

MS. ASPINALL: It's on the bottom of the letter.

DR. EVANS: -- as soon as the IP associated with the test, we move it to the bottom of the list. Over and over, this occurs.

MS. ASPINALL: And I would suggest there are tests that aren't even on their list because the costs of both doing the test and getting to the right physicians aren't even there. We dealt with the ones that are most prominent.

DR. EVANS: The idea that marketing is going to solve this through exclusivity, I think, has absolutely no support, and I think we have to be very leery of marketing driving what tests are done.

DR. TEUTSCH: Okay. We're going to get into this as we get into the recommendations.

Did you have anything else as part of your --

DR. FERREIRA-GONZALEZ: I'll wait.

DR. TEUTSCH: Sheila, last word, a short one.

MS. WALCOFF: I have a question for CMS, just to bring things back.

If there were no gene patents and no exclusive

licenses, would CMS cover every genetic test?

MR. ROCHE: There two different parts of the important chain of issues.

I'm Jeff Roche. I'm the alternate ex-officio for Dr. Straw.

The question of coverage is almost always addressed, and this is based on nearly two years of experience with the agency in that area, on simple facts, like is this a good test, does it measure what it's supposed to measure, does it help actually make a difference for the patient in terms of their outcome, is it something that can be done more cheaply or alternately by a different type of test, is it necessary, and those questions are approached without regard to whether a patent is involved or not involved.

Does that answer your question?

MS. WALCOFF: I think so. I guess you're saying that whether or not we make any changes at all to the patent structure, that doesn't have any effect on how CMS would elect to reimburse under your current criteria?

MR. ROCHE: You've raised a different question. Coverage decisions are made without regards to patents.

However, reimbursement decisions are based on how much CMS will pay for a specific testing service, whether it's based on the CPT code or whatever. Those decisions do take into account price levels and a number of different aspects of the cost that goes into the testing, including other costs of doing the business, such as patent licenses and so on.

However, that is an area that I don't directly work on at CMS, and I can check with Dr. Straw. Perhaps we can get someone here who can talk about that more knowledgeably.

MS. WALCOFF: That would be great because I thought in the report we decided that there wasn't a great difference in pricing because of patents. So if there's not a great difference in pricing that we can identify whether there's a patent or not, that really wouldn't come into play in terms of reimbursement from CMS's perspective. It sounds like.

MR. ROCHE: Again, I wouldn't be able to answer that.

MS. WALCOFF: I'm happy to corner Barry.

DR. TEUTSCH: Mike, thank you for your

forbearance as we've wandered far and wide from the comments that you made. We appreciate your clarifications, your input.

MR. HENRY: Thank you.

DR. TEUTSCH: Clearly, lots to talk about.

Our next speaker is Mike Remington, who is with the Wisconsin Alumni Research Foundation.

Welcome, Michael, and I don't know that we have your written comments. So if you can provide them to us after the meeting, we can have full advantage of your thoughts.

MR. REMINGTON: Thank you. Thank you very much.

Michael Remington

Wisconsin Alumni Research Foundation

MR. REMINGTON: My name is Michael Remington. I am a partner in the law firm of Drinker, Biddle, and Reath. Among my other representational responsibilities, I serve as Washington, D.C., counsel for the Wisconsin Alumni Research Foundation and, no, I'm not here to speak about Warfarin.

As you know, WARF is a non-profit organization

operating under Section 501(c)(3) of the IRS Code, and as a supporting organization of the University of Wisconsin, Madison, WARF was founded in 1925 and is the first organization of its kind to engage in technology transfer associated with a single university.

It has been and is today the designated IP management organization for the University of Wisconsin, Madison, under the auspices of the Bayh-Dole Act through its subsidiary WYSIS which stands for Wisconsin System. WARF also represents the interests of the entire University of Wisconsin System.

WARF has enjoyed a number of technology transfer successes that have had a significant impact on health, patient cures, safety, and so forth. WARF derives no profit from the licensing of its inventions and recycles all royalties back into further research and innovation.

We appreciate the opportunity to present brief oral remarks on the report and we thank you for seeking input of stakeholders, like a representative of a university technology transfer organization to present some input.

We would like to specifically associate ourselves with the comprehensive and insightful comments that were previously submitted by the Council on Governmental Relations, COGR, and the Association of American Universities, AAU, which included three principal concerns which hopefully were addressed or are to be addressed in the final report.

First, lack of support for the policy options; two, lack of understanding that licensing is a complex process, requiring substantial flexibility; and three, too much focus on regulation without consideration of possible incentives. As I said, hopefully the final report will have taken some steps to cure these three principal concerns.

As a personal aside, I spent 13 years as the IP counsel or professor of sorts for the House Judiciary Subcommittee on Intellectual Property under the chairmanships of Peter Rodino and Jack Brooks. Every day in Congress, we had to weigh many of the issues that you're facing.

I just want to leave you with a couple thoughts about your policy options. At one point under the

tutelage of some respected law professors, we even created a Rule of Civil Procedure with a burden of proof for reform proponents to satisfy. We were receiving so many proposals for reform of patent and trademark and copyright law, we thought we had to higher the bar a little bit and we did so. That reform didn't have a long life, but I would like to leave you with the thought that it's very, very difficult to amend the law and we're seeing this today with omnibus patent law reform.

Just a couple cautionary thoughts. I would not have used an economist definition of promoting the progress of science in the useful arts, as I saw in the slide earlier today. There's nothing wrong with that. Intellectual property is an economic proposition. It's an incentive system, but there are other approaches that you could use, like a political utility approach. It's designed to channel certain activities in society for the betterment of the public.

The relationship between the courts and the Congress, generally speaking, there's a rule that Congress likes to wait for courts to finally decide cases because with two independent and interconnected branches

of government, it's hard to draft legislation when there's ongoing litigation without interceding in that litigation and resolving the disputes that are properly pending in the courts.

The three issues that were raised by Tom DeLenge are serious. When Congress interceded to decrease infringement liability, like you're proposing, for the significant societal issue of listening to music in taverns and restaurants, the Irish brought a WTO complaint against the United States and we were found to be in violation of GATT TRIPPS and remember when that happens, the U.S. has to pay a fine or some other segment of our society is punished and in this instance, if you're not WTO-compliant, some patients group or some other area of the medical sector could be punished by our allies.

Besides, we don't like to violate international treaties. We often lecture the rest of the world about respecting treaties.

The evidence of patent thickets appears to be fairly meager, and I would point out to you that there has been a great increase of significant activities in

the Department of Justice and the Federal Trade Commission, with business review letters being forthcoming in various standard-setting organizations and information technology areas. There is no reason why that wouldn't be approved for genetic research.

The enormous successes of the Bayh-Dole Act were given short shrift, and many patient cures have come out of that successful statute. So was collective licensing.

I'm not saying that you can get to collective licensing overnight in genetic research, but I'm counsel to a performing rights organization that licenses several million works in a blanket license for music at universities and in other activities throughout the country for, I might add, a very low price. So that's how you get to listen to your music at football games and in student unions.

These are just a few cautionary notes. You are indeed sitting on a shifting landscape of law, politics, and science, and thank you very much for hearing these remarks.

DR. TEUTSCH: Thank you very much, Mike. Any

questions or comments for Mike? Yes?

DR. ROYAL: We keep hearing about how this violates a treaty.

Now, there's no provision in the TRIPPS Agreement for Irish bars, but there actually are provisions in the TRIPPS Agreement for health. So could you explain in a little more detail how this would violate a treaty?

MR. REMINGTON: I was worried that a professor might ask me a question. I'm raising it as a flag for your consideration. There are health exceptions in our treaties and I'm not saying it's violative. I'm saying that we unwittingly and unknowingly violated the WTO through the enactment of --

DR. ROYAL: I don't know about that.

MR. REMINGTON: -- the law that went all the way through and we still haven't cured it. Twelve years has gone by without a cure by the U.S.

If you have considered this issue internally in great depth, I would defer to your consideration. I was just raising the red flag or, let's say, the yellow intersection, proceed slowly on this point.

Thank you. Yes?

DR. WILLIAMS: Even though your bar-setting review in your previous job has fallen by the wayside, I was curious if you had applied that to this document. And, if you were to look at that from the perspective of, did we hit the level of scrutiny that we needed to before patent reform would be considered, are we well short of that; have we met the threshold; are we above it? Do you have a sense?

MR. REMINGTON: Well, let me just talk a little bit about the standard. In order to elevate something to a policy matter for the Congress, you have to rise to a significant issue affecting society that is appropriate of policy-makers' consideration and, as you know, we have a bi-camera legislature and two political parties in each branch, so it's very, very difficult to get something through. Their first question is, is this is a big issue. So you have to answer that question for yourselves.

The second thing you have to ask is, are you proposing the solution that is the best solution for the policy question at hand.

The third issue is, does it create what we call the law of unintended consequences. For example, if you use the patient health issue as your standard, or the inability of indigent people to pay for these medical tests, then you have to ask yourself the question about what will happen when some other parallel area of medicine comes forward that sits similarly, because people will say, if this passes we should do it for this other area.

We call that the fallacy of analogy. This is the way lawyers think, and it's not necessarily a good thing, I might add. Hopefully, there are many non-lawyers at the table, but lawyers argue by analogy. So once you create an analogy, they will argue by further analogy, and they will use AIDS research, embryonic stem cell [research] to make a similar argument. They will say, one, we should not have exclusive licensing in those areas; two, we should lower prices or not grant patents, accept infringement liability.

So those are questions for you to answer. I am merely suggesting that Congress will ask those questions, whether it has a test or not.

DR. TEUTSCH: Last comment. Paul.

DR. BILLINGS: This is not an analogy question but a question of fact.

What has been the value of the Warfarin patent to your foundation?

MR. REMINGTON: I would have to get that. I'm not in-house at WARF. It is one of the more valuable patents in WARF's purview.

DR. BILLINGS: Can you give me a ballpark?

MR. REMINGTON: No, I can't.

DR. TEUTSCH: Paul, at least in a publication to say that Wisconsin has actually gotten more from this patent than any other single institution has gotten from any other patent by a long shot.

DR. BILLINGS: Yes. That's my impression.

MR. REMINGTON: No, no, no.

DR. BILLINGS: It has derived an enormous amount of support.

MR. REMINGTON: No. WARF's most valuable patent has been Vitamin D derivatives invented by Hector DiLuca, by far, and it's most successful patent was probably the cure for Ricketts, which was invented in

1925. WARF was told by the Attorney General that it -- well, WARF didn't exist at the time -- the university was told that it couldn't even market it because that would be violative of the state constitution. A university can't get into marketing. So the foundation was created and Ricketts was cured in eight years.

I do have a question about the debate about Warfarin, because we call the sequel to Warfarin Coumadin, and it's a separate product.

DR. TEUTSCH: Great. Well, thank you.

MR. REMINGTON: Thank you.

DR. TEUTSCH: Thanks for your comments. We really appreciate it.

Gene Patents and Licensing Practices

Discussion of Final Draft Recommendations

DR. TEUTSCH: I think everybody has now got a clear sense of the diversity of perspectives on these issues. If you haven't, you had too heavy a lunch.

In addition, one of the ad hoc members provided some additional comments. These comments were also provided during the deliberations of the Task Force. They were sent this morning, so they're provided to you

now.

MS. ASPINALL: That's what I wanted to ask. Is Brian here?

DR. TEUTSCH: No, he's not here.

MS. ASPINALL: Is he going to talk through these comments?

DR. TEUTSCH: No, and they were expressed before. The Task Force has considered them. So most of the folks who have been on the Task Force had an opportunity. What we have here is not a unanimous document but one that best represents the --

DR. EVANS: What was your first clue?

DR. TEUTSCH: Anyway, with that, I'm going to turn the opportunity back to Dr. Evans, who will help walk us through this.

DR. EVANS: Thanks a lot.

DR. TEUTSCH: I don't know, Jim. Did you want to spend a few minutes on the issues?

DR. EVANS: Yes. I think that we have a goal here that by the end of the day we'll get through the recommendations. I do think, given the degree of dissent and given the kind of explosive nature of this issue,

that it's only fair if we spend, say, half an hour so people can vent, and then we'll tackle the recommendations.

I do get some prerogatives as the Task Force chair. So what I'm going to do is just spend a couple of minutes. If you can turn the slides on. I do want to mention the Task Force composition and how we came about things.

Of the people who were really deciding policy and the content of the Task Force, these are the members and the ad hoc experts. The agency experts, consultants were extraordinarily valuable, but they are consultants, basically, and here to lend points of fact and information.

Although Mara was not able to participate extensively in the process, I think Mara is the dissenting voice of the five members within the full members who are on the Task Force.

Of the ad hoc experts, I think it's fair to say that it's basically Brian Stanton who is the dissenting member of the ad hoc experts, as you can see from the document that he wishes to have circulated around.

So I tell you that not to single out any particular individual. It's great to have -- no, it's good to have dissent, and dissent shaped our conclusions in a very good way, but I do want to emphasize that this was not a split decision; this was not a close call, as we went through this.

Maybe it will turn out to be a close call in the Committee, or maybe what the majority of us favored won't carry in the Committee, but I do want you to understand that, that this was not a few people who rammed through a sketchy or minority position.

What I want to do to open up the discussion is I just want to frame briefly, again, the rationale for our recommendations. We have heard a lot about some claims. Those claims include, Number 1, that our original charge had nothing to do with looking at benefits. That is absolutely not the case. We were charged with looking at both harms and benefits of the patent and licensing process on patient access to quality genetic tests. It's not only, I think, illogical to ignore benefits but it would have been contrary to our charge.

I think that, Number 2, we did find harm as opposed to the statement that is selectively quoting, saying that we did not find widespread and pervasive harm. The next sentence states: "However, there was harm found in segments of the population." When I see members of the population who clearly, because of patent-enabled exclusivity, are unable to get genetic tests, that's meaningful to me as a medical provider.

Number 3. The issue that perhaps struck me most forcefully, and I think several on the Task Force most forcefully, was the almost non-existent evidence for the need for patents in the development of genetic diagnostic tests.

Over and over again, in every example you can give, whether it's BRCA testing, whether it's HFE testing for hemochromatosis, whether it's hearing loss, many labs quickly began offering tests, and then the field was shut down or narrowed dramatically when IP was invoked. The combination of harm, along with the very difficult ability to show benefit, I think, is a highly persuasive set of facts.

I want to just mention that we consider our

recommendations to not be dramatic. I think they are narrowly tailored. We should not conflate therapeutics with diagnostics. The scope of our charge was to look at diagnostics. That's what we did.

Our recommendations are attempting to tease out the ability of laboratories to perform diagnostic tests without fear of infringement, and [they] do not alter, do not touch the therapeutic realm. This was for two reasons.

One was that it was not part of our charge. The second is that you can make very strong arguments that patents are doing heavy lifting. They're doing work in the realm of therapeutics with dramatic upfront costs, et cetera, et cetera.

It's extraordinarily difficult to make that claim for diagnostics and thus I would emphasize that these proposed recommendations are narrow in their scope. They look at trying to tease apart diagnostic testing for healthcare-related activities, and I would also just point out that we cannot forget the issue of harm when it comes to quality of testing.

The patent-enabled sole-source provider is a

serious threat to quality, given the infrastructure of quality control for laboratory tests in this country. So I've gotten on my soapbox, and why don't we just turn it over for about a half an hour and then we'll get to the recommendations and I really am going to keep it to a half hour. I'm writing down that it's 2:23.

Muin and Sylvia.

DR. KHOURY: So here is the first question, Jim, for you.

We are opening up Pandora's box on diagnostics versus therapeutics, and I for one have never really believed in genetic exceptionalism, especially in the new era of biomarkers, et cetera.

So using the laws of analogy, as our WARF speaker talked about just before, could you envision the impact of making recommendations on other non-genetic areas of diagnostics? Maybe you can say we don't care, that's not our charge, but I just want us to work through the system.

I mean, I sympathize with a lot of the ideas presented today, but I just want to explore those implications outside the so-called genetic arena.

DR. EVANS: Maybe you can start me off, because I certainly have been focused on genetic diagnostics, so I'm not sure where to go with that.

DR. KHOURY: If those recommendations are read without the genetic lens. Just read them as a biomarker or an assay, or anything, for the purpose of diagnosing, predicting whatever, I mean think about that genetically.

DR. EVANS: Right. I think that, in a way, the reason you can't do that is because it may well be that other diagnostic endeavors are very different in the sense of upfront costs, et cetera. It may be that the development of monoclonal antibodies that are effective for immunohistochemistry is just a whole other animal.

I'm not trying to avoid your question. I guess what I'm trying to do is say that I'm leery that it’s relevant, in the sense that we're focused on genetics here where the landscape is we've got a handle on it.

DR. KHOURY: So maybe I can help you out. Within your three types, you gave different subgroups of patents, et cetera. One is the association types, the other is the assays, et cetera.

Which ones of these are the easiest to deal

with, and which ones are the most difficult? I mean, I'm fast-forwarding to a time where genetic sequences will be cheap. Everyone will have access to them. I can see some of the hiccupping along the road, but if somebody, let's say, comes up with an amazing new technology that would single-handedly do three billion base pair, using an amazing new discovery, plus all the gene expression and epigenetics, in one big swoop, do we want to reward that invention or what?

DR. EVANS: I think that's a very important point, and one of the things I would, again, reiterate is that the narrowness of these recommendations are such that the last thing they would do is interfere with the patenting of a technique, and that's a very important point.

We are not looking to do anything to undermine the patenting of the next PCR, for example. That absolutely should be patentable. We're talking about a very narrow situation which the analysis of a DNA sequence. That's what this basically all boils down to, and I think that what you say about cost is absolutely right.

The cost of DNA sequencing and its decline makes Moore's law look like a piker. It's going to be very cheap, and I think that substantially informs what we're talking about.

With regard to what kind of claims are most difficult to get around, I think it's clear it's association claims, all right because association claims are utterly agnostic to the issue of how you analyze this, et cetera. They simply say that if you have this sequence, we have the patent on thinking about and I'm not using hyperbole there. In fact, Claim 13 of the homocysteine patent with metabolite actually talks about thinking.

Association patents patent associating, thinking about the genotype/phenotype relationship. So they're the hardest to get around and one could see problems in other diagnostic realms for such associations.

Sylvia.

MS. MANN: I'm not going to vent, Jim. I just wanted to talk a little bit about -- to answer Sheila's question.

Most of the Medicaid coverage and reimbursement for genetic testing is done at the state level. Very few national coverage decisions are made on things like that and so having helped state Medicaid make decisions in our region on the West Coast, one of the things that makes it easier is if there is a reference lab that actually does multiple genetic tests for us because we don't want to negotiate 50 contracts. We're not going to negotiate 50 contracts.

So anything that restricts access to testing to sole-source providers or labs that are far away or labs that are inaccessible, there is going to be less and less chance that we're going to actually contract with that lab, unless it's a really bad public health problem in our state. Then we would, because we would have to because so many people have the disease or we had to test for the disease, but otherwise we're going to go with the lab with the biggest bang that we can get the contract for.

MS. WALCOFF: Right. So putting just the general market issues of that aside, if I think this committee thinks that this is such an important issue in

terms of the patient access for genetic tests that are coming from sole-source labs, and not knowing the universe of sole-source labs with exclusive licensing agreements, wouldn't it be a more straightforward fix to carve out an exception or make a requirement for state Medicaid to contract with the sole-source labs in this case of genetic testing, so that there is access for those populations, rather than leaving it up to each individual state, really trying to drive the competitive market between reference labs and the sole-source lab?

I mean, I just think we should not get into that. I am thinking, how can we do this from an HHS perspective. As you know, I'm know the fly in the ointment with this, but I want to challenge the group to really rethink how we structure these recommendations into something that the Secretary can receive and actually take action on, and that's one idea.

I was trying to see if that might be something possible, not knowing how a state Medicaid really works, but I feel that we are not going to be able to get to the solution and answer that we want to through the way these are structured because of the simple limitations of the

Secretary's authority.

MS. MANN: I think that it's going to be talked both ways because if it's going to take legislation reform, either way. I mean whichever one gets through first.

MS. WALCOFF: If it's going to take legislation, couldn't we do it administratively, too?

MS. MANN: I don't know.

MS. WALCOFF: As CMS, can you administratively make requirements like that in terms of state Medicaid policy?

DR. EVANS: No.

MS. WALCOFF: Can Jeff answer?

MR. ROCHE: I'm sorry. The question again was can CMS impose what on state Medicaid?

MS. WALCOFF: What sort of authority does CMS have to make administrative non-statutory -- under your current statutory authority, make administrative requirements on state Medicaid agencies?

MR. ROCHE: Again, I can go back and see if we can find more information that will help explore that question, but I'm not able to answer that now.

DR. EVANS: So I would love it if there was an easy way to ask the Secretary just sign off on this, do such and such and solve the problems.

MS. WALCOFF: I don't know that we can get to that ever, but I think it would be --

DR. EVANS: I don't think that's the case, and I think that even if the answer --

MS. WALCOFF: -- good to give her something that she can take the next step on.

DR. EVANS: -- had been yep, no problem with that, the problem is that it only addresses a small part of the problem. All right. It doesn't address, for example, the quality issues which are real and problematic when you have sole-source labs.

It also doesn't address the future issues which, granted, are future and therefore we don't know for sure, but I guess what I'm getting at is that I don't think there is a simple, easy fix for the problems that we've identified and if we can do it, granted, in a roundabout way, right, because --

MS. WALCOFF: I'm not suggesting simply a simple, easy fix, or even a roundabout way. I mean, if

you want to look at quality, I would look to FDA and CMS in terms of it's their responsibility in managing quality, because they have the authority to do that.

DR. EVANS: That was my initial thought.

Actually, they don't in this sense, not in a practical sense. When I started this process, my view was quality. That's an oversight issue. That's an issue, let's leave it to the FDA, et cetera. The problem is that in practical terms, one cannot ensure quality with laboratory tests unless there are multiple providers in any kind of optimal way.

So the FDA could say, from now until the cows come home, that there should be stringent requirements, but without the ability to do proficiency testing, without the ability of having several labs, you compromise quality, and I think Andrea would confirm that.

DR. BILLINGS: Jim, what is the quality of the evidence for that last statement?

DR. EVANS: I think it is that the entire infrastructure of quality control rests on proficiency testing.

DR. FERREIRA-GONZALEZ: There are many different factors to this issue.

DR. BILLINGS: Just one follow-on and then I'll yield to Andrea. Okay. So I will accept the fact that proficiency testing is important and maybe the most important factor in quality, but then you're also making the claim that sole-source labs don't do proficiency testing as well as multisource labs.

What's the evidence for that?

DR. EVANS: Well, because you simply can't do proficiency testing for sole-source labs.

DR. FERREIRA-GONZALEZ: Well, there are different kinds of proficiency testing that you can do. You can do simple exchange with other laboratories in the testing.

Having done this testing for over 18 years now, what I have learned doing this testing is that when you have more laboratories addressing the same testing, you can learn a lot more faster and you can identify the issues when you're testing, not only by exchanging specimens between laboratories but then you try to address what the different results are you obtain, but

also because you're comparing results from different types of assays that might pick up the answers that you would not be aware of you're testing because you are the only sole provider of that testing.

But if you are the only sole provider of that testing and you're re-running your own specimens, then you wouldn't be picking up some of these issues. So there's more to learning on the process by comparing results with other laboratories and we have actually data from the College of American Pathologists and the Molecular Oncology Proficiency Testing Program that, as we've gone over the years, by comparing results from different methodologies from different laboratories, that we have learned about the disorders and the testing and significantly continued to improve this and that's by collaborating with other institutions, other places that are actually doing the tests.

DR. BILLINGS: I'm sure that that's true, but I would also suggest that it's probably true that for a lab that does, let's say, DNA sequencing tests of a breast cancer gene, that they are constantly looking both at the quality of their results for any number of issues and

looking at methods to improve the throughput, the costs, the kinds of data that they're generating again for their own reasons.

My question was, where are you getting the evidence that there's a big quality difference? I think Andrea's comments are part of that evidence, and is that Type 1 evidence? Is it Type 4 evidence? You're an evidence-based medicine guy. Give me some quality of the basis on which you make this conclusion.

DR. EVANS: Well, for example, you can't do that test when you have a sole-source provider because nobody else can do the test. All right. You can't compare the results which is a necessary factor in trying to figure out the accuracy, the precision, et cetera. So it's simply undoable.

It is basically axiomatic that quality is more easily obtainable when you have several labs that are doing the test. Now, there may be times when there happens to be only one lab and you have to just live with that and you have to rely on those other processes.

I guess my question would be, as an obvious advocate for one position, why should we hog-tie

ourselves into that position when what we can do is have a thriving competition between labs to provide quality testing, innovations, et cetera, with lack of sole source?

MS. WALCOFF: I want to just respond to that, and I'm hoping that we're not suggesting that sole-source labs at this point in time because they can't do that particular type of proficiency testing are somehow providing a test that is of lesser or inadequate quality.

DR. EVANS: The quality is, unfortunately, not as good as you would have in a situation where there was --

DR. WILLIAMS: I'm not sure we can say it's not as good. We certainly don't know, we don't have any independent ability to verify and that is a very different issue. I think it's very dangerous for us to make pronouncements about the fact that the quality is good or not good.

I mean, personally, I think that Paul is mostly right in the sense that it is in their best interests to try and do the highest-quality testing that can be done. However, as someone that has to look -- is on the

outside looking in, I would much rather be able to look at data to say -- and that is something that's addressed within the document. It comes back to the transparency issue.

I'll also just note parenthetically, and then if you'll allow me, I'll go into my other comments, --

MS. WALCOFF: You guys interrupted me. Actually, that wasn't my point. Can I just say one quick thing and then let you go on and on? Not that you go on and on. I'm sorry.

DR. WILLIAMS: I'll accept one on.

MS. WALCOFF: Okay. Just go on. But I was going to get back to my challenge again of sort of relooking at this because as I would receive these, just hearing sort of all of these arguments and assuming that I just accept them, if I am the Secretary and this advisory committee is suggesting to me that I should go to the President because, of course, if we're going to be changing laws at the recommendations of the federal goverment, it doesn't come through one agency or department or another, it comes through the Administration as a whole which is the White House.

So if I go to my boss which is the President and say, Mr. President, we have an issue here, we have an access issue, sometimes the states don't want to contract with these sole-source labs, they find it cumbersome, expensive, whatever the case may be, some people have suggested there are proficiency testing issues related to quality with some of these labs, I would like you to propose that we change the intellectual property laws.

I would have to say, having been in some meetings that are not exactly like that but somewhat like that, there would be a lot of challenges made to that. So you're looking at a huge, huge hurdle changing laws at all, but changing these laws, and I think that some of the challenges you would get back are, so you're telling me our agencies, these amazing agencies, FDA, CMS, can't figure out different ways other than comparison testing to improve quality? You're saying that we can't figure out another way to get these people that cannot afford to pay for these tests?

DR. EVANS: And what I would say to that is that, Number 1, absolutely. We're not asking for things that are easy to do. I wish there were some things that

were easy to do that would fix the problems and take care of these issues.

It was the general feeling of the Task Force, it's my feeling, that targeted changes that are statutory are the best way of dealing with those problems as well as the evidence that is there that we've gone over that we don't really need the patent protection for the development of these genetic tests.

I think the other thing that I would just touch on is that there is considerable feeling in the community and in the country that perhaps we've gone too far with some of the patent protection for genes in general. You heard that today from two of the public commenters.

So I don't think that suggesting statutory change is necessarily a crazy idea just because it's hard.

MS. WALCOFF: No, and I wouldn't say those other suggestions are easy, but I guess my point is to be more realistic because I think that whether we like it or not, it's a nation of lawyers.

DR. EVANS: Right.

MS. WALCOFF: What lawyers will do is exactly

what the gentleman proposed earlier. What are all these unintended consequences? What can we analogize to this? I would suggest that this is not just a hard ask, it is a very, very, very high hurdle, and wouldn't it be more effective, wouldn't we -- rather than causing years of debate which has already been happening over patent and trademark and intellectual property issues, wouldn't we be better served as this committee to find our target again and direct things that are within the immediate authority of the Department of Health and Human Services?

DR. EVANS: That's exactly why what we have done is divide our recommendations into, basically, two levels, two tiers. The first is -- okay, these are hard -- we think that these are best, at least the Task Force as a whole thinks that these are best, but we understand, as we'll get to with the slide when we get to recommendations, that these may not happen. They're very hard.

There are issues that you may not even decide to pursue because of things like unintended consequences, and therefore, here are a set of other recommendations where we think we could at least address, to some extent,

these issues. So we are taking that approach to an extent.

MS. WALCOFF: I obviously have serious problems with that and challenges, but at the very least, if those are the first things I read, I may not get to 2, 3, 4, 5, 6, 7, and 8. I would probably say, oh, well, this is going to be quite a challenge and what's wrong? I would be calling my agency and saying what's going on here?

DR. EVANS: I'm sorry, I think you should read the entire page or two.

MS. WALCOFF: I did, I did. I'm saying the person receiving this report may not.

DR. EVANS: I think we can rely on the Secretary of HHS to do due diligence and look at the recommendations. I think I have a little more faith than you do.

MS. WALCOFF: I'm not suggesting that she would not.

MS. WALCOFF: Number 1, I would start with talking to my agencies and doing that exact due diligence, and finding out exactly what the problem is.

It sounds like there are still some open questions from the agencies. We want their support. We want, when the Secretary goes to do that due diligence on these first primary recommendations that the others support, to get that.

DR. EVANS: I think she will get through the one or two pages.

MS. WALCOFF: But my point is, I hope that in terms of doing her due diligence with the agencies, that those questions we have answers to, and that we know what they're going to say and we know that this is helpful to them.

DR. EVANS: Maybe there are modifications and wording suggestions that you can make that will help ensure that the Secretary gets to those issues if we do decide to keep the general structure intact.

So Marc, and then Mara.

DR. WILLIAMS: I'm going on. So I'm going to move off this area and just highlight a couple things that I reflected on as we heard the public comments in relation to the document.

The first is, I wanted to remind the group that

in the charter of our committee, one of the specific, explicit tasks that we're asked to address relates to disparity. So, in some ways that elevates the potential for harm in the Medicaid population a little bit higher, because I think we are specifically asked to look for where there are potential health disparities within our charter.

The second comment relates to the example that was raised by one of the commenters about Herteneu, which I think is a really interesting example for a couple of different reasons. It illustrates several of the points.

I think it's very clear that this has been hugely important. It is directly related to the appropriate use of a therapeutic. I think it is also fair to say that where we're really going to see expansion in the next couple of years, relating to, if you will, personalized medicine, relates to the use of tumor markers to characterize and direct chemotherapy.

This raises a potential issue relating to some of the points that are made in the document, because if some of these tumor markers end up being sole sourced, there are some pragmatic issues that will have to be

addressed.

One is, is that it's hard to get enough tumor to run the markers that we currently have, and if we have to somehow divvy it up and send it to five different laboratories, that would be, I think, extraordinarily problematic.

I think we also found that within Her-2, it was only through the collaboration of a lot of different laboratories that we identified some of the very significant quality concerns relating to how to do Her-2 testing.

So that obviously falls into the realm of a potential harm, but I think it is an issue, and I know that we're struggling right now in terms of do we have adequate amounts of tissue to do what really is medically appropriate to do using a provider that can provide all the tests.

The third thing is relating to the patent thickets. I do think that this is a real potential problem. I think we do have evidence that laboratorians are now in a position of not being able to report medically-significant results because of the concerns

about infringing on other patents and in the long run that is harmful to patient care, but I think we also have to think about, if we're going to go in this direction and I certainly would favor trying to explore solutions in this area, then we have to understand how we can incent companies that don't have right now any incentive to really participate, I think for good reason, how can we incent that participation so we can really move through this area, and I think I heard that reflected in a couple of the industry representatives, that there has to be that type of incentive put forward.

Lastly, and this just relates to the support for the report, I am not as sanguine about this from the perspective that I think in many ways this is analogous to what we see coming out of committees in the Congress, that you can say what we had overwhelming support, but it was divided on party lines, and if you kind of look at the composition, I think in some ways, and I'm not saying that we should have tried to have equal representation, that's not what we do, but I am concerned that overwhelming support should not be overly-emphasized, given that there may well have been less representation

from people that had more direct interest in patenting.

And the last thing about the composition which I think relates to your question, there were a number of Department of Health and Human Services ex-officios that participated in this which I would hope would have raised some of the issues that you were raising about is this something that we could do, and I would be very interested, at least in some course of the debate, to know where the level of support for the recommendations that would involve some of the very difficult problems.

DR. EVANS: So what I think we ought to do is we can extend it a little beyond half an hour, at 3:00, we are scheduled to have a break anyway. Let's come back from the break after we're done and then tackle the recommendation issues.

Mara.

MS. ASPINALL: Okay. Well, as the not singled-out/singled-out dissenter here in person, I'll take a little bit of prerogative.

DR. EVANS: I figured you'd singled yourself out.

MS. ASPINALL: And I've said a lot to this

committee not just here but to the broader committee but on previous times we've talked about it. So I have several comments, but I will try to get them done before 3:00.

First, I want to say how much I respected the committee and the process we went through and particularly, Jim, your leadership, your commitment and your persistence. We didn't often or always agree on things, but your attempts to ensure that I stayed with it, stayed with the committee, and heard my comments, Brian's, and occasionally others that had dissenting views is very much, I need to say that to the whole committee, acknowledged.

So while you say it wasn't rammed down anyone's throat, and I would have been the throat there, there was not agreement but the process was well done and we took the extra time from two or three meetings ago where I felt very strongly that we needed some more time, as did others, to get public comment, and I would like to publicly acknowledge that and your leadership --

DR. EVANS: Thanks.

MS. ASPINALL: -- in doing that. But now.

DR. EVANS: But.

MS. ASPINALL: That's right. But that was an important process step and it's great actually on a day like this to even twice now agree with Marc.

First, I'm going to start with the charter issue and I wasn't planning on actually going here, but I think the comment that I have to make is on the comments today about quality.

First of all, if we're going to debate the charter, the charter was on access and disparities. It had nothing to do with quality, and you could argue that's a piece of it and I won't go through what the single source labs do which they do on both proficiency and additional time with CAP inspectors because of that exact sensitivity that the labs themselves had, but I have to say that I'm extremely uncomfortable with saying by definition they're less good quality because there are plenty of great labs out there and I'm sure there are plenty of lousy labs out there. But by definition, I can't let that stand. I just have to comment on it.

Secondly, in the charter and you spoke today and in the past because I've spoken about the commentary

between diagnostics and therapeutics, if indeed, as it is in the charter, that it's only about diagnostics, I think one of the issues that you summarized today should not compare the development costs and you called it sufficiently low for diagnostics versus therapeutics.

If what we're talking about is diagnostics, the comparison of what it takes is not relevant and even more relevant, although I would say, as a diagnostic developer, it's not particularly low and it continues to increase, regardless of the patents, just because the burden of proof is and continues to increase, is that we cannot look at it by the amount of dollars that goes in because the reimbursement rates, as we've talked much in this committee, patents or not, unless you have exception pricing, you don't get any premium for patents, as we talked about, is about economic viability. It's not about that it costs $10 to create a test, a thousand dollars or $10,000.

So I think in the summary that is not an accurate depiction of what the issues are, regardless of either because of a comparison or it's not about upfront costs, it's about the full cost of educating, running,

and selling the test. Those are the two comments on charter.

Next, as we look at the summary comments and probably the thing that I'm most disturbed about today and read all the public comments and in detail, I have my 10, as the rest of the committee did, I don't think that we have adequately represented the comments from some of the largest academic institutions in the country who supported the idea of access, supported the idea that we need to deal with disparities, but did comment that the committee's recommendations go too far and solve a problem that, even at the academic centers and some of these were representing technology transfer offices and some of them were representing the university management in the broadest sense, are saying that the committee's recommendations, while there are pieces of it that make sense, go too far.

And I think, again in a summary comment, that needs to be represented and that the comments that you had in here are obviously accurate, but I think more commentary on what the other piece was, not just from industry, is important.

Next, composition of the committee, and as Marc said, the composition of the committee, as I look at it now, I'm wondering why I didn't see that earlier, but, indeed, it's not fair for any one person to represent fully an industry because this is a diverse industry that is not monothematic. So I don't believe that all of industry feels one way and all of academia doesn't, but I think it is important to -- and I actually don't even know where Brian's institution is, but that to be fair, we probably did need more representatives from non-academic laboratories and that's why I acknowledge again that it wasn't just that academic universities and others felt one way. They're not monolithic entities any more than industry is a monolithic entity.

Next, and then just right before my last point, I will go back to the reimbursement point, and Sheila brought up a couple of issues today about it, I think the report needs to also acknowledge the process that needs to be eased, patented or not, but as we're talking about patents and as one of the key findings of the group is that patents create sole access.

Sole access creates access problems which is

the way I saw the three steps here, that one of the things that HHS and other agencies can do more readily than some of these other recommendations is make a process for access when companies and laboratories want to be able to give the test to people who need it and can't afford it, whether they have insurance or not, make it a transparent easy process, so we can, regardless of the bigger issues and changing the world there and that may or may not happen, we can begin to get access to patients which to me is the broader issue that this committee is about.

So, in summary, having those five points, I believe that the purpose of the patent system was done to create innovation in a time-delimited way and having that time-delimination is the piece that provides the checks and balances that both allows innovation and then allows others to come in at the appropriate time.

Thank you.

DR. EVANS: Let's see. I believe that Liz had a comment and then Andrea and then we really have to break. Liz, Rochelle, and Andrea. All right.

DR. MANSFIELD: So I obviously work for HHS.

So I don't have an opinion on whether you're right or wrong, but I just wanted to bring up a couple points that I didn't hear necessarily addressed, although some of them overlap with what Marc and Mara just said.

I didn't see any traditional diagnostic industry input, I mean, on the committee for the report. Did I miss that or was it primarily laboratory-based?

DR. EVANS: I think it was laboratory-based. I would add that with regard to the representation, I think I would echo what Mara said, that to divide it kind of artificially between academic and industry is probably not the best thing.

DR. MANSFIELD: I agree.

DR. EVANS: I think if you look here, we've got people from the public health field, people from the legal profession, people from the laboratory side, clinicians like me, et cetera.

DR. MANSFIELD: I agree, but I just think there may be a distinct feeling among industry about whether it's reasonable to have the sole source or not. I mean, I think it's somewhat regrettable, from the FDA point of view, that a lot of these patented tests, sole source,

that you talk about are laboratory-developed tests.

What I want to actually segue into is, I'm in personalized medicine. That's my job right now, and as Marc brought up, there are going to be tests that go along that to say, this is how you should use this drug, and those tests are going to be required before you use the drug. Probably, a lot of them are going to be genetic tests, and FDA believes that those are tests that do not merit enforcement discretion and will probably require PMA, which is a fairly high bar in the regulatory world.

So I've heard from numerous IVD companies that they don't like the risk involved. If they get in and they put all the work into developing this diagnostic and go through the PMA and the second they're out the door, everyone else can knock them off, they're not going to do it.

So I'm a little -- I think you should take --

DR. FERREIRA-GONZALEZ: Well, then how do you explain KRS testing or treatment?

DR. MANSFIELD: KRS didn't need to go through a PMA process.

DR. FERREIRA-GONZALEZ: But it's going through the process and there are companies, there are commercial laboratories, academic laboratories, and there are IVD manufacturers.

DR. MANSFIELD: I'm not saying it won't happen. I'm saying I've heard from a lot of companies. They don't like the risk.

DR. FERREIRA-GONZALEZ: There's a slew of different laboratories in IVD that actually are going through the process of it and there's no patent for the KRS.

DR. MANSFIELD: Right, right.

DR. FERREIRA-GONZALEZ: I understand that you didn't go through a PMA process, but there is a company going through that. There is a cost associated with that.

DR. MANSFIELD: I'm just relating what I've heard. I'm not advocating one way or the other, but if this actually discourages companies from developing the tests that would get the drug on the market, it may have some unintended consequences. I don't know. You need to analyze that.

And the other thing is the size of the market I think actually drives how many labs will do this. If it's a relatively small market, then there aren't going to be 10 labs doing it because they can't all make money off of it. So it's not just about patentability.

DR. EVANS: Rochelle, and then we'll stop for a break.

MS. DREYFUSS: I just have a couple of little things. One was on the comments that came from the universities. It's important when you think about the university comments to realize that universities are kind of strange. They're not like companies. The technology transfer office does a lot of licensing out but individual researchers do most of the licensing in, if they license in at all. So they're not seeing the entire picture and if they did, then they might have a very different view from the one that we saw and the comments that we made.

On the composition of the committee, the other thing that we didn't have is any antitrust people. So we keep talking about this as though these recommendations are making a huge change in the way that the world worked

before, and I would like to point out that that's very much not true.

If you look at sort of the history of the world, patents are only one component of encouraging innovation. Competition is the other component of encouraging innovation. When you have a lot of competitors, then each competitor has to figure out ways to make the price lower, to make the quality better, to provide more information and so competition has in the past been a huge motivator of innovation, at least as much as the patent system has been.

Now do we have as much competition as we've had before? I would submit that in the last 10 years, 20 years, in fact that's what's changed, is the level of competition and it's changed in a number of ways.

First of all, in the last 10 years we got rid of research exemptions. So when we're talking about asking for research exemption, that's the way the world was until a court decided that there were no research exemptions and they did it on no information. So it's not like there are high burdens that were jumped when the law became the law that it is now. It happened in a

particular case and in that particular case, it looked one way. The court wrote a very broad opinion and the question now is whether that very broad opinion is impacting on healthcare in a way that was completely unforeseen by the court.

So this research exemption is not a new idea. It's returning to an old idea that was part of the law for 200-whatever years. In most cases, we had competition because people could invent around patents. So Jim started off by saying that patents are a limited monopoly. I cringed when he said that, with all due respect, because I think most patent lawyers don't think patents are monopolies. Patents are one way of accomplishing a particular result, solving a particular problem, but there are almost always ways to invent around it.

In this particular space with DNA, when you're trying to do diagnostic tests of people by looking at their DNA, there is no inventing around the DNA patent. That is something that is completely different from anything we have ever seen in history.

Third point, and it's the last one. The

breadth of the patent system. The patent system used to be pretty narrowly directed at technological arts. It has expanded in the last 10 years, I would say, so that it covers business methods, including the methods of being a physician and treating your patients, but that is something new.

So the fact that this committee wants to think about that not through the accretion of common law cases where the court did not have any evidence but by looking at evidence and thinking about how these past decisions are now affecting patient access seems to me to be not the incredibly revolutionary thing that several of the speakers have made it out to be.

So on the burden of proof, I don't understand the burden of proof. I don't understand why it's any higher for us than it is for the courts.

I have one more thing. That's this, that the patent system used to encourage leapfrogging. That is not cherry-picking the next most easy thing to do. It used to encourage people to really push the frontiers of science forward because it was hard to get patents.

In the last bunch of years, it's become easier

to get patents. You don't have to have as inventive a step. The Supreme Court maybe pulled back on that. We have to see how that works out, but until now, it's not been that you could just go out and start sort of cherry-picking the things that are there, getting patent protection for it. Things that were minor leaps, that were simply fairly easy to do, might require some work but fairly easy to do, people did because of competitive reasons, not because of patents.

DR. EVANS: I would just add I was reminded that regarding the composition of the committee, Emily Winn-Deen did represent the industry diagnostics, IVMDI-type perspectives.

So, all right, let's adjourn for 15 minutes and we'll start back at 3:20.

[Recess.]

DR. TEUTSCH: All right, everyone. Time to regroup here, and we've got to get down to brass tacks because we've got to get these recommendations reviewed and moved on. Clearly, we're hearing lots of different perspectives.

As I turn it back to Jim, what I think we'll be

doing is, as we go through them, we're going to limit the discussions to some of the salient issues around the recommendations and then try to get a clear sense and vote on them as to where we stand, how close we are, since I know there's some people who are speaking a great deal and others who are quiet and we need to know sort of are we on track as a group.

So, Jim, all right. Sultamonic Jim.

DR. EVANS: There you go. I'm not going to threaten to cut any babies in half, though, I promise.

All right. So we do need to get through these recommendations. We need to determine whether we are going to adopt them or not. This is certainly -- these are open for wordsmithing. They are open for adjustments, and if any of you have adjustments that make you feel like, okay, I could vote for it with this or that, by all means, bring it up, but we're going to try to move along relatively rapidly here.

The first three are going to be the toughest. All right. They're going to be the ones that evoke the most contentious debate, but we can't debate forever. You guys have read the report. We've been through a lot

of this before.

So let's discuss this first one for a moment. The Secretary of Health and Human Services should support and work with the Secretary of Commerce to promote the following statutory changes:

"(1) The creation of an exemption from liability for infringement of patent claims on genes for anyone making, using, ordering, offering for sale, or selling a test developed under the patent for patient care purposes."

Now, let me remind you of the Task Force's rationale. This is meant to address patient access problems and quality concerns, and to enable laboratories and test kit makers to offer multiplex tests and other innovations.

So let's have 10 minutes or so of discussion about this, and then let's put it to a vote. Who wants to talk?

DR. RODRIGUEZ: Laura Rodriguez from NIH, and I just wanted to ask -- well, I guess first going back to Marc's comment earlier about the technical members and contributions that were made during the Task Force

committee, we were very much present and I was not speaking during the earlier discussion because we had shared our thoughts in that process and I thought that was the forum for the committee to have that and also to thank Jim, as well, for the process, as Mara said, that was there so that different opinions could be heard in there and say that we do share many of the comments that came up before about actionability and some of the other scope questions.

But for this particular issue, coming back to the recommendation, I will apologize because I came on to the Task Force later in the development, but I did have a question about why the Task Force put forward this language that really was so open in terms of this exemption being available to anyone versus being more restrictive around the patient care issue.

DR. EVANS: Right. First off, it all funnels into patient care purposes, so that's meant to be the overarching issue. The reason that we had it say, for example, not just applicable to a physician ordering the test or doing the test was primarily, correct me if I'm wrong, other members of the Task Force, driven by Emily

Winn-Deen, who, as an industry representative, who develops kits, et cetera, felt that it was unfairly privileging the academic university laboratory over others by allowing them the exemption.

So we were trying to broaden it to be inclusive of industry, as well, and it was really her advocacy that got us to add the making. Otherwise using or ordering, right, or maybe offering for sale in the service lab would have been sufficient. All right.

Who's next? David.

DR. DALE: Well, I speak in favor of this statement or recommendation. I think the simplest way I could phrase it is I don't see why anyone could prevent me as an individual from asking a reliable source or laboratory to sequence my whole genome and tell me what they found. I think that's my personal right, and I can't see how the University of California could have sold that right to a company to deny me that access to information.

Thinking about it as an access issue, I would say the same thing to my patient, that I think they should have access to that information without obstacles

as a part of general access to care.

So I would say this is the high ground in terms of what we're doing in terms of principles and that sets aside the issues surrounding the use of patented materials for product development or therapeutics, but it does improve access, and I think it's a modern thing to do because when we started down this pathway of patenting and licensing of specific genes, it was in an era when it was a very unique thing to do and now we're certainly in a different era and to look ahead, I think to continue on the path we're on will be cumbersome and impair the health of the country.

DR. EVANS: Other comments? Mara.

MS. ASPINALL: This is a process issue both on Number 1. Have we ever heard from the PTO? Don't we have a representative from the PTO? Because one of the issues --

DR. EVANS: PTO joined us on every conference call.

MS. ASPINALL: But are they here today to talk about some of the issues that we've brought up and discussed as to feasibility?

DR. EVANS: I mean, again, the PTO was represented at every single conference call that we went through.

MS. ASPINALL: And their comments on some of the questions? I don't remember anything.

DR. EVANS: They informed us all along the way about the recommendations, et cetera.

MS. ASPINALL: But on the specific questions about feasibility and viability, as we got close to the end of the recommendations?

DR. EVANS: I don't think that this, for example, recommendation, I don't think that PTO is particularly relevant to this particular recommendation. This would kind of take the PTO out of it. It would say --

MS. ASPINALL: Well, I mean, I would think that by definition of taking them out of it, they would have a strong opinion about it.

DR. EVANS: Again, they were there in every conference call.

MS. DREYFUSS: The PTO only decides whether there should be a patent. They have nothing to do with

infringement or exemptions from liability. That just is not something that PTO does.

MS. ASPINALL: They have come out in various statements over the years and talking about what they believe on how infringements and how they structure patents and one of the things you talked about is the patentability of new claims and why --

MS. DREYFUSS: Yes. But this doesn't affect patentability.

MS. ASPINALL: -- this is something -- as I said, this is both Number 1 and then more broadly. So I wanted to know if their representative was here and we could talk to them today.

DR. EVANS: Certainly, I mean, it doesn't look like at the table we have one now, but again I would assure that PTO has been intimately involved.

MS. DREYFUSS: When we added the last bit that Jim just described, we spent a lot of time talking about whether these patents would even be infringed by the kinds of things that are being sold. We spent a lot of time talking to them about it, but that was just because they're patent lawyers, not because they're the PTO.

MS. ASPINALL: On this comment in particular, was this the one -- and I don't remember -- Deb Leonard had some issues on?

DR. EVANS: Deb Leonard signed off on this. She was in support of it.

MS. CARR: I just wanted to clarify, I think. This may not be what you're getting at, Mara, but the agency experts were part of the Task Force to provide technical information and it's important that we don't, I think, read anything one way or another into their participation in the Task Force. They're technical experts and providing information and technical corrections.

MS. ASPINALL: Speak for the agency with an opinion.

MS. CARR: Right. And whether they support one thing or another, if you were getting at the feasibility, the question of feasibility, John Legeider may have -- I don't know that we actually probed that with him, but he, as Jim said, was very much involved in the Task Force meetings.

MS. ASPINALL: I was moving it to the broader

issue as opposed to on the committee, on the technical expertise that he and others gave us.

DR. EVANS: All right. I think Paul is next.

DR. BILLINGS: I just have a question, a point of clarification about this.

So does this have implications then for the next generation of patents on tests in the sense that a patent without an infringement capability or component is a different kind of patent than before?

DR. EVANS: Yes. I think that what this does is it tries to dissect out specific claims, right, and the claims that would be operative here would be claims that have to do with diagnosis. So this wouldn't affect claims on therapeutics, et cetera, but it would certainly -- yes, it would have an impact on diagnostic analysis of nucleic acids in the future.

DR. BILLINGS: Rochelle, do you not agree with that?

MS. DREYFUSS: This is just an exemption from liability for infringement of the patent claim on the genes. So if there were patent claims --

DR. BILLINGS: No, that's not what it says. It

says tests. It's all tests.

MS. DREYFUSS: The patent claims on the genes that are involved in the test. So if you had invented some fabulous new test, you could get a patent on the test.

DR. BILLINGS: That's not what it says.

DR. EVANS: A test developed under the patent --

MS. DREYFUSS: On genes.

DR. EVANS: -- for patient under the patent. Okay.

DR. BILLINGS: What patent?

DR. EVANS: The exemption from liability for infringement of patent claims on genes.

MS. DREYFUSS: On genes.

DR. EVANS: Patent claims on genes. So let's say you invented some fabulous new test for something. So you could get a patent on the test, somebody else might have a patent on the gene. So, first of all, that's one of the problems this is trying to treat, is that somebody who wants to develop a brand new test should be allowed to develop the test. That's the second

part.

This part says that if somebody does develop the test, they would -- somebody would still have to pay them royalties for the test, but they wouldn't have to pay royalties to the person who owns the patent on the genes for doing the tests.

DR. EVANS: Are you -- this might be a good point. Does there need to be a modifier test that says diagnostic test? I mean, is that necessary? Is that what you're advocating?

DR. BILLINGS: Well, I want to understand the implications for patents on genes, patents on tests.

DR. EVANS: This says patent claims on genes.

DR. FERREIRA-GONZALEZ: You can develop a test and you can patent the actual process of the test. That's no different than we did in the whole report. So you can come out with a new PCR methodology to detect this gene and you can patent that methodology, but you wouldn't be infringing on the patent of the gene.

DR. EVANS: Gwen, I think you were next.

MS. DARIEN: So perhaps this is a naive comment, but if the entire reason to develop these

diagnostic tests is to improve patient care, how could there be an objection to this recommendation?

DR. EVANS: Well, you're probably asking the wrong guy.

MS. DARIEN: It's a general comment, but the fact is, is that the entire basis of what we're looking at here is improving patient care and if you improve diagnostics, then you improve the treatment, then that flows into therapeutics and then that flows into --

DR. EVANS: And that's what I think the fear is. Here's the fear. You're going to harm patient care by doing this. That's the fear. I don't think that's justified. I've enumerated those reasons over and over. The fear, though, by the people who object to it is that you're going to harm patient care. I'm dismissing those people who are worried simply about profits, et cetera, but that would be the legitimate response.

MS. ASPINALL: No, and I think the fear is not necessarily today because you'd say the gene tests are already out there. So you're saying anyone can infringe on the patents that we have. We have a patent system for a reason. We might improve patient care if all

healthcare was free and we're debating that in a pretty broad way as to lowering the costs so there's more access for everybody all the time.

We have a process and what this says is the process of gene patents was nice, but we don't respect it and anyone can use the genes. I understand the issue about the test. Anyone can use the genes anyway and what I would say is does it -- for diagnostic purposes. I think it has broader implications than that, but I understand that's what it says and that what happens in the next generation when you need to be able to create something that has some economic viability as the rest of the healthcare system looks at.

DR. EVANS: So what I would propose is that -- let me ask a very, very specific question. Does anybody have wording changes, specific wording changes that they feel would make this substantially better? I'm not talking about, yes, erase it all, right. I mean if that's the case, you'll just vote against it, right.

Yes, David.

DR. DALE: I just would insert the word "diagnostic" before "test." I think it adds clarity.

DR. MANSFIELD: I would just put the clarifying for infringement of patent claims on genes but not methods or whatever it is that you mean to exclude because I'm not sure I would have read this exactly that way about the health.

DR. FERREIRA-GONZALEZ: This was an issue that was brought in our conference call, that we needed to be really clear --

DR. EVANS: Oh, that's a good point, Andrea.

DR. FERREIRA-GONZALEZ: -- in the methodology.

DR. TEUTSCH: In the additional information.

DR. FERREIRA-GONZALEZ: Somebody brought it up during our discussions.

DR. EVANS: Okay. Is this what people suggest here? Andrea, is this a problem, given the issue of -- okay. So here's a potential monkey-wrench by inserting diagnostic. Many of these tests will be used to determine predisposition. That's not a diagnostic issue. So it makes me wonder whether diagnostic is --

DR. FERREIRA-GONZALEZ: Saying predisposition is not a diagnostic?

DR. EVANS: Well, I think a lot of people would

construe it that way.

DR. TEUTSCH: I think diagnostic usually means for people who have a condition --

DR. EVANS: I'm not exactly -- when we do BRCA testing, that's not considered a diagnostic test. It's considered a predisposition test.

DR. FERREIRA-GONZALEZ: Actually, --

DR. DALE: I withdraw my suggestion.

DR. FERREIRA-GONZALEZ: -- I disagree with that, but I don't think that's the big issue here.

DR. TEUTSCH: You do what?

DR. DALE: I agree to take it back out.

DR. TEUTSCH: Okay.

DR. MANSFIELD: Under FDA's regulations, diagnostic doesn't just mean diagnosis. So we can look at the IVD definition.

DR. FERREIRA-GONZALEZ: So, for example, pharmacogenetic testing for 2D6 for metabolism is --

DR. MANSFIELD: Right.

DR. FERREIRA-GONZALEZ: -- screening and monitoring.

DR. MANSFIELD: Anything.

DR. FERREIRA-GONZALEZ: So we need to cover all.

DR. EVANS: And we need to cover it all.

DR. TEUTSCH: For some of these issues, like the genes and not methods, what we mean by diagnostic, there needs to be a paragraph or so that provides a little elaboration of those kind of details so people know what we mean.

DR. FERREIRA-GONZALEZ: But I don't think we can have a comprehensive list to all this, so some examples.

DR. EVANS: At this point, I think we should vote, and the Committee members vote.

Darren brings up an important issue. Here is what I would propose. I think we can wait and ask that question, so I would propose at this point that we vote on this and then proceed. Any last-minute comments before we vote?

[No response.]

DR. EVANS: All right. So all in favor of this recommendation, raise your hands.

[Show of hands.]

DR. TEUTSCH: Eleven.

DR. EVANS: All opposed?

[Show of hands.]

DR. TEUTSCH: Three.

DR. EVANS: All right. Oh, abstentions, good point. Abstentions or recusals, any abstentions or recusals?

DR. TEUTSCH: I think we're good.

DR. EVANS: Okay, Number 2. Let me go to the wording on the next point. The second statutory change is research exemption. It would enable test developers to conduct research to design new tests, and it reads as follows:

> "The creation of an exemption from patent infringement liability for those who use patent-protected genes in the pursuit of research. Related healthcare and research entities also should be covered by this exemption."

So are there general comments and are there specific comments about how this could be improved, if you in general favor it?

DR. RODRIGUEZ: I just have a question on there because the term "research" isn't defined. So I thought it would be helpful, to better understand what the goals here are, to have a definition of that.

DR. WILLIAMS: I would add to that “related healthcare and research entities.” I mean, this one, for me, is problematic because it's not adequately explicit about what we're really talking about.

DR. EVANS: Okay. So the reason that we initially cast a wide net with regard to research was that we wanted to not again privilege clinical research, basic research, transitional research, not only because we didn't want to privilege them, but it is often difficult to parse those definitions.

I would certainly be in favor of any clarifying language that people want to suggest that we can discuss.

Marc, did you have any ideas about how we might be able to gain more specificity without undercutting a research exemption?

DR. WILLIAMS: Well, I'm not sure I can come up with the solution to it, but I do think that we could create the same sort of a situation where we allow people

to self-define what they're doing, much the same way that we'll be talking about with DTC, where they said, well, we're not doing health-related tests.

If there are existing definitions of “research” or what a healthcare entity is that we're really talking about here, I think we're obligated to use those definitions and to try and be as clean-cut about it as we possibly can. I just would be uncomfortable that it's just way too nebulous.

DR. EVANS: So one of the things we discussed in the Task Force was whether we could gain tremendous specificity by saying, "in the pursuit of NIH-funded research." That would be one option. I'm just throwing that out there. You're shaking your head. There are problems with that, as well.

The other issue is “healthcare and research entities.” There actually are very specific definitions for those.

Darren, do you remember? We talked about this in the Task Force call. I believe [it is] actually defined in Ganski-Frist, who a healthcare entity is.

There are specific recommendations or

definitions of that, but let's tackle the research issue first. Do people feel that we should try to get more granular about what research is? I think Marc's point is a good one.

Andrea, you had some thoughts, I think, about, for example, if we were to say "NIH-funded research," is that problematic or health-related.

DR. FERREIRA-GONZALEZ: There is more to NIH-funded research.

DR. MANSFIELD: I mean, HMI, yes. What about "health-related research"? Gwen?

MS. DARIEN: I don't even know which one to use. I think "health-related research" is better, but just for an example, which is from our organization, we're the scientific partner for a major, major funding initiative on cancer. Five teams were funded on this, and it's not NIH-funded.

The whole point of this project is that they are only funding team science. They are only funding people that are crossing institutions. So IP issues are huge to this. If the IP issues aren't solved, they aren't going to be able to work with each other.

So I think that it has to be "health research." Just to the second point, I would like Rochelle to comment on the history of research exemptions, because you started saying something about that earlier.

MS. DREYFUSS: Like in 1819 or something, Justice Story wrote this case in which he said that there is an exemption for people who are doing research for their own curiosity, and that has always been understood as meaning non-profit research, basically. There are very few cases on it, because it was generally understood that that was an exemption. Everybody in universities, for example, assumed that they had that exemption.

Then in 1998, I think, there was this case called Media v. Duke in which a professor sued Duke University for using what had been his patented laser-something or other, and he won. The court said, well, anybody that is doing research in the ordinary course of whatever their business is isn't entitled to the research exemption. So then they said, well, what is the university's business? The university's business is doing research, and high-falutin' researchers, and encouraging fancy students to come to their school. So

they decided that Duke didn't get the research exemption, and by extension nobody would.

Now, it's a strange case, because first of all, the facts are really weird. People don't usually sue their own universities.

PARTICIPANT: They should.

MS. DREYFUSS: Don't tell my dean. It was a kind of research tool. I can't remember what you did with it, but it was a tool and various judges of the Federal Circuit have since said, we really only meant that for research tools; we really didn't mean it for run-of-the-mill things, but they've never changed it at all.

The Supreme Court got a chance to look at it, but they didn't argue that issue. They argued, instead, the statutory research defense, which is only for doing research for FDA approval. So we have been living, in the last 10 years, with people thinking that probably the research exemption does continue, but not really knowing, because we haven't had another case.

So in a way, this just clarifies what the law is, and clarifies it in a way that I think quite a few of

the various judges on the Federal Circuit, informally, would agree with. Certainly, the dicta in the Supreme Court case, which looked at the statutory exemption, indicated the Supreme Court was kind of on the side of thinking that we should read patent law as having a research exemption. Now, that research exemption would be for non-profit research, so it would extend to universities, not to industry.

In Europe, they've had an exemption like that always, and it's a statutory exemption. It is clear what it is. They have actually had the kind of problem that you're talking about, of joint research projects, and also projects being done by for-profit companies but very, very far upstream. They say, if we're doing upstream research, why are we any different from a university doing upstream research?

So there has been a move in Europe to change it to something more broad. This broadens what we thought we had, because it doesn't only apply to non-profit research but it broadens it in a way that it looks like other countries are moving.

DR. EVANS: I would also bring up another thing

that is kind of interesting, and it gets to Marc's point and Rochelle's point, Gwen.

I am skeptical, to some extent, of claims by some of these new companies that we are going to be doing research in a new way, but they might be. They really might come up with new models that I don't think we should dismiss.

I think that also would drive me to advocate for the broad term and not put limitations on research. I think all of those reasons, to me, dissuade one from limiting it.

DR. WILLIAMS: Yes. I understand what you're saying. I'm more comfortable with, we can really be more definitional about the related healthcare and research entities, and if we do have some definitions that we can take from statute that seem to be applicable here, I think it would be appropriate to reference those.

I would just say, philosophically, I think this is really critically important, because to assume that a patent holder is going to have all of the novel ideas around a certain entity, I think that has not been the case in history.

So I could see this really impeding important science, particularly given the areas that we really, at the present time, have no clue around, like regulation of genes and this type of thing, where if you can't really look at the gene but you're interested in the regulation, how can you really answer those questions.

So I am philosophically predisposed to being in favor of this, but I also recognize the fact that there is potential for harm if we're not tight.

DR. EVANS: Mara, one more comment and then let's take a vote.

MS. ASPINALL: I think it is part of what Marc said, but I believe there is another Merck case around universities and the ability to do research. So, to me, this seems like a non-issue, because when people have rights, they have rights to commercial --

DR. EVANS: It's very much an issue. For example, BRCA1 and 2 research, clinical research funded by the NIH was shut down.

MS. ASPINALL: I know I've heard that, and there have been some negotiations around that one in particular, but if you look at a number of the issues

[the benefits] that you get are only on commercial rights, not on research rights.

MS. DREYFUSS: No. The statutory research exemption, which is the one that was at issue in the Merck case, applies if you're doing research in order to generate data that is going to be submitted to the FDA, to federal agencies.

So if you're doing research that is going to be submitted to state agencies, or that is not going to be submitted to any agency at all, you don't get the benefit of that.

It is a very narrow research exemption. It's written a little bit broader, but it was basically done so that generic drug companies could do research to prove bioequivalence. It is pretty narrow, and the Supreme Court broadened it a little bit, but you still have to have data. You still have to be generating data.

DR. FERREIRA-GONZALEZ: I think if you look at any of the diagnostic licenses that I've ever seen, it is not relevant in the current diagnostic licenses you get from universities today.

DR. EVANS: Let me just say that I think it's

well established that those doing research do not have any kind of established exemption, except in narrow circumstances, like if they're going to submit.

MS. DREYFUSS: Some universities are following the nine points, and the nine points suggest that they reserve research rights either for themselves.

DR. EVANS: Some are and some are not.

MS. DREYFUSS: So most universities do that, or for other universities, but they're not reserving research rights in the kind of situation where there is a joint venture between the university and a for-profit company.

In Europe, you're seeing these cases being brought by for-profit companies who say they think they should have the same rights to do upstream research as anybody else.

DR. EVANS: With the understanding that we will explicitly define a healthcare and research entity using established nomenclature, how many are in favor of this recommendation?

[Show of hands.]

DR. EVANS: Okay. And opposed?

[Show of hands.]

DR. EVANS: Okay, you're abstaining. Okay.

Now, the third issue is connected. We might have to have two votes on the third issue. There was some question in the Task Force as to whether, in those first recommendations, association patents should be folded in, reading something like liability for infringement of patent claims, including association patents.

The reason I did not address that at the time is that we have a separate recommendation that could stand on its own, all right, and this recommendation specifically addresses association patent claims. The rationale behind this was not that there was some discrete statutory function that the Secretary could advocate, not that there was some executive action she could carry out, but the reason the Task Force felt that association patents should be addressed is that they are an extraordinarily active area of debate and interest now in the field.

There are pending court cases that hinge, that revolve around association patents, and the courts pay

attention to what bodies, such as ours, say. So we felt we should weigh in on it and what this would do is say the Secretary should use her powers to discourage the seeking, the granting, and the invoking of simple association patent claims. It is the committee's position that these claims represent basic laws of nature that cannot be invented around, and I would make two comments about this.

One is that again, as you can see, it's quite a general thing. It doesn't advocate some specific action. The word "simple" was one that we spent a lot of time on and the reason for the insertion of "simple" there is that there is, my understanding and Rochelle can speak, I'm sure, in a more knowledgeable way to this, there is question as to whether, once complex enough, would, say, an algorithm that associates two things rise to the level of an invention. That will ultimately be something that the courts will have to work out.

What we are trying to advocate for here is that we did not feel, most of us on the Task Force, that simple associations, say GWAS results that are now flooding the medical literature, where we say this locus

is related to a relative risk of 1.3 for this disease, it's a simple association, and we didn't feel that that association should be patentable.

We did not want to imply that there couldn't be such labryinthic and complex algorithm that took tremendous inventiveness that we would want to preclude all options for patenting.

So I'll be quiet now. Any comments on this? I think we should have basically a discussion about whether this should, if we want, stand on its own or should we fold it into the first rec.

Marc.

DR. WILLIAMS: So I would have two comments. First of all, simple is just not adequately explicit. No one would know what simple means and everybody would define it differently.

DR. EVANS: Well, we do address it in the report.

DR. WILLIAMS: I know you address it, but it's not defined in an explicit way so that somebody reasonable could look at it and say this is simple, this is not, and so in some ways that's going to be

problematic.

I think the more problematic thing here relates to the fact that in fact, as opposed to the first two instances where I think we do have a lot of challenge, a lot of unclarity, the fact is that there are cases that are going to provide clarity to this issue that are under adjudication.

I'm not sure that what you said, which is the courts pay attention to what bodies like this say, I'm not sure that that realistically is true in the sense of how the court would know that this is what we're saying, but it seems to me that if the court is actively considering this, that this may be premature.

DR. EVANS: Other comments? Rochelle?

MS. DREYFUSS: I don't think it is premature. The federal circuit is certainly struggling with that same question of whether all associations are patentable or not. They just handed down an opinion a couple of weeks ago struggling with exactly that question. That was one where you injected the patient with something and then you saw how it was metabolized. They said, well, that is not a law of nature, although somebody might say

it is a law of nature. How you metabolize that thing is a law of nature.

DR. EVANS: That was Prometheus.

MS. DREYFUSS: Yes. That was Prometheus, but maybe we could do something like a direct association between a genotype and a phenotype, because that would narrow it to genes.

DR. EVANS: That's interesting.

MS. DREYFUSS: So we would be out of the rest of the Prometheus world.

DR. EVANS: That would be invoking direct association product claims between a genotype and a phenotype.

DR. FERREIRA-GONZALEZ: Yes. Because when you use the direct association between the phenotype and genotype, when you have to use multiple genes to do a calculation that you invented that form of the calculation, then that goes into the invention part. So I think that will actually help to motivate this.

DR. EVANS: That's interesting.

MS. DREYFUSS: Then you get out of using the words "association patent claims."

DR. EVANS: Yes. So, okay.

DR. WILLIAMS: Again, I want to make sure we all understand what we mean by "direct."

DR. EVANS: Again, I think your points are well taken, and we talked a lot about this in the Task Force. At some level, you read the U.S. Constitution, there are all kinds of things that require interpretation. It's not completely clear, but you can't be so specific that you gut the intent. You have to let the process kind of define what those are.

DR. WILLIAMS: Well, the process will ultimately define what they are, but I'm saying that I think that we have -- this is not something like life, liberty, and the pursuit of happiness, which I think are very difficult to define in any reasonable sense of the term, but when we talk about a genotype and a phenotype, I think we can take a crack at that. I think we could have a reasonable definition of what we consider to be direct.

DR. EVANS: So give me some possible wording here: "Discourage seeking, granting, and invoking of association patent claims"? I mean how would you

rephrase this to get that desired level?

MS. DREYFUSS: Would it be enough to define "direct" in the comments?

DR. WILLIAMS: That's fine, but we need to do that if we're going to vote on this. I mean, this gets at the point that was made, I think, in the previous one, which is, we can vote on it, but if we don't really understand or don't agree with what the definition of the comments are going to be, then it's problematic.

DR. MANSFIELD: Sheila.

MS. WALCOFF: I was just going to say I have -- well, you finish your thought because it wasn't totally done.

DR. EVANS: I was going to say, we could go so far as to say the association between a single gene's allele, a single allele and a phenotype. The problem I get to is that, okay, look at the prostate cancer situation. There are now really four well-established loci that result in an increased risk if you have the risk allele of prostate cancer. It doesn't take a rocket scientist or geneticist to figure out that, okay, I can just use all four loci. I mean to me, that's still a

direct association.

So I tend to not want to get so granular that we start to name the number of loci, et cetera. I understand that "direct" has some nebulousness associated with it, but I'm not sure we can do better.

Anybody?

MS. WALCOFF: I'm just going to make my comment and then my recommendation, and just back to the original point on the courts and what is happening, and what this committee's role is.

I mean, we get right back to it again. Our recommendation is for the Secretary. We're not making recommendations to a court, various courts, on any particular case. At the end of the day, when she receives these recommendations, she is going to have to reconcile those with whatever the current case law is and whatever the future rulings are from those pending cases. She will have to get advice from OGC on doing that.

And so, I was actually going to recommend, in terms of the recommendations, that some of these things be more couched as examples, which might get us past this definitional question, because I think it is going to be

one that is somewhat going to depend on where the law is at that point.

We have, under Recommendation No. 7, "Licensing policies governing federally-funded research to facilitate access." At the end of the day, Numbers 2, 4, and I think 6 -- I have listed out a number of them -- really could be tucked under this, because the Secretary's authority and power really rests, in these cases, with what she can and cannot do with federal funds.

And so, if we are going to be recommending that there be a more thorough legal review -- and that's some of the sticking points I have in this report, is I don't feel like I have enough information on exactly where the law is with respect to some of the claims we're making -- perhaps we tuck those in as examples, under the part about legal review.

DR. EVANS: So, again, I don't think you were here when we went over how we were going to approach this particular session. I think that I am in favor of going through these recommendations and deciding whether we want them or not.

I think that I would like to see us decide whether we want to say something about association patent claims. If we don't, then we can talk about, do we want to tuck it in as an example. I'm not sure exactly where that would go.

In response to what the Secretary can do with this, I think we, on the Task Force, were very cognizant of the fact that this is a nebulous recommendation, but I think that is important for the following reason.

There is some attention paid to what we say, and as a body that has spent five years looking at this, I think it is not unreasonable to take a stand on certain things that may be for purposes that go beyond, simply, the Secretary should absolutely do this.

It's not unreasonable to say, well, we've spent five years, this is what we think, and we would like the Secretary to use her powers to discourage the seekings. See what I'm saying?

So what I think we need to do is, we need to decide whether we want to say this. If there are discrete changes to the wording that could make it better, I think we should do that. At this point, I have

trouble finding a better modifier than "direct".

Any other ideas?

DR. DALE: Jim, if I could help. At least I would suggest deleting the second phrase "the committee's position," and moving that phrase "if necessary" into the discussion. So then we are left with [choosing] the position [of] whether we should encourage her to use her powers, discourage her from using her powers, or say nothing.

I would favor leaving the phrase as it is, but simply better defining "association patent claims"; that is, have a modifier just to say what that is.

DR. EVANS: What kind of modifier do you think?

DR. DALE: I would say that is and put it into plain English.

DR. EVANS: I just heard Rochelle say a direct correlation between that. So what about something like this: "The Secretary should use her powers to discourage the seeking, the granting, and the invoking of direct association patent claims on a direct correlation."

DR. DALE: You need another word than "association". So the simple word is "link".

DR. EVANS: Muin.

DR. KHOURY: I don't know what the word "direct" means as opposed to "indirect". I mean, what we're talking about are genotype/phenotype associations or genotype/phenotype correlations or linkages, whatever you want to use. I mean, if it's indirect, does it make it more patentable? I don't know what it means. Just genotype/phenotype correlation, why complicate it?

DR. TEUTSCH: Sometimes you have multiple polygenic things that really will be discoveries.

DR. KHOURY: But there are still genotype/phenotype correlations at multiple loci. I mean, if you put five prostate cancer SNPs together, it is still a genotype/phenotype association.

DR. FERREIRA-GONZALEZ: We're making a distinction between a genotype/phenotype, for example, of single genes versus expression of 21 different genes, where you have to run an algorithm that you have come up with, and where, through that algorithm --

DR. EVANS: That's what we're trying to parse.

DR. FERREIRA-GONZALEZ: So that is patentable, and we don't want it to be in here. So it's just the law

of nature that you have these two findings, that you didn't have to come up with any mathematical computation for all the different --

DR. WILLIAMS: So maybe what we're talking about as a difference here, or maybe I'm completely missing the point, is patenting an observation of an association as opposed to taking that observation and doing something with it.

DR. EVANS: It requires little in the way of sophisticated inference.

MS. ASPINALL: But don't you want to put single gene in, then, as Andrea just described?

DR. EVANS: Well, no. I definitely don't want to put single genes in.

DR. FERREIRA-GONZALEZ: It could be more than this. You might find 15 different genes.

DR. EVANS: For example, diabetes. It doesn't, again, take a great intellectual leap to say, there are 19 Type II diabetes loci that have been documented, and we're going to combine those. I mean, any first-year statistics class student can do that. I think that we certainly don't want to say "single gene".

Again, what we originally had here is invoking of association patent claims. We had "simple" in there, and, again, my initial view was, can I define precisely what simple is? No, okay. I think like Potter Stuart said, I know it when I see it. In other words, the courts will --

DR. BILLINGS: That's not our role. We're here as experts to be clear.

DR. EVANS: Well, as clear as we can, as clear as we can.

DR. BILLINGS: We can be clearer than this.

DR. EVANS: Okay, how can we be clearer?

DR. BILLINGS: Well, we've just had a suggestion of cutting out the second half of this thing, which I think actually makes it clearer.

DR. EVANS: So we could put this in the report.

DR. BILLINGS: Of course. I mean, we're talking about clarity of language here.

DR. EVANS: So just for the moment, we can always back up on this, I'm going to delete that. Now it reads: "The Secretary should use her powers to discourage the seeking, the granting, and the invoking of direct

association patent claims between a genotype and a phenotype."

DR. KHOURY: Jim, this can apply to multiple genes.

DR. EVANS: It can.

DR. KHOURY: It could apply to one gene. It could apply to whatever. Where things become a bit more complicated is when people put genes together, make an inference, develop algorithms.

DR. BILLINGS: But that's why people patent that. There are going to be access issues to that, too. I mean, the whole point, the whole argument you've just made about patenting, we're going to have the problem with algorithms put onto those things. There may be an access issue.

MS. DREYFUSS: Our argument is a two-fold argument. One is, you don't really need patents on these things; second, there is an access issue.

The problem with complicated algorithms is, you might actually need a patent on it because figuring it out isn't going to be very easy to do; verifying it is going to be very hard.

I mean, I do think maybe we have enough data to say some of the things that we're saying, but I don't think we have data to support that you get rid of patents entirely.

DR. BILLINGS: As I said before, the report is silent as to the quality of the data. That seems to be glaring.

DR. EVANS: So again, bringing it back to this, the Task Force felt that we did not want to preclude the possibility that an association claim that relied on a sophisticated algorithm, that took tremendous inventiveness, would be disallowed. We did want to take the stand that simple association patents or direct associations were not legitimate.

I think at some point very soon, in the next few minutes, we need to just vote on this. To me, the remaining sticking point is the modifier: should we have "direct" there; should we have "simple" there; or should we have no modifier?

Marc.

DR. WILLIAMS: This is going to raise another sticking point, which is, the other part of this that is

problematic is, how can the Secretary use her powers to discourage? Does the Secretary in fact have any ability to influence this at the present time?

If the answer is no, then we should get rid of this.

DR. EVANS: Well, there is another option here that that raises, and that is to not have this as a formal recommendation but to put in the report that the Task Force feels that association patents are illegitimate. That's okay with me.

DR. RODRIGUEZ: You should do something with "NIH-funded research".

DR. WILLIAMS: That is another recommendation. I agree. I think I understand what simple is. I'm not sure anybody else would agree with what I think simple is.

I think that this is a problematic recommendation. I think it would be good to highlight this in the report and say we're very concerned about this. There are some ongoing cases. We need to be aware, and as appropriate, for the Department of Health and Human Services to respond as this landscape begins to

change.

DR. EVANS: I think that gets to the issue, too, the very legitimate issue, [that] none of us are quite sure exactly what the Secretary is supposed to do with this.

So I would move, then, that we make a statement in the report that the committee feels, basically, this. We could elaborate a little bit on what "simple" means. I mean, we don't have to have the necessity for brevity there that we would with the recommendation. So I think that would be a very reasonable option.

DR. RODRIGUEZ: I don't have a vote, so I just wanted to express my support for going in that direction because of the outstanding questions and the court cases.

DR. EVANS: All right. Other input before we take a vote as to that effect?

MS. WALCOFF: I might have a ridiculously basic question, but in terms of the position that these claims, which we're having a very hard time exactly defining, represent basic laws of nature that cannot be invented around, what is the basis of that, if we can't really define what we're talking about?

DR. EVANS: Well, if you look, for example, at Breyer's dissent to the rejection of their initial granting of certiorari in the Metabolite case, that, if I'm not mistaken, basically went to what he said, these are laws of nature; they should not be subject to patents.

We've taken that out, anyway. So that's the issue.

MS. WALCOFF: Okay. So we're taking the whole thing out?

DR. EVANS: Well, that is what we're advocating.

MS. WALCOFF: That's my point. Where are we putting it in the report?

DR. EVANS: We're going to put it in the report.

MS. WALCOFF: That's my point. If it's in the report, it's still part of the report.

DR. EVANS: It's a finding. It's something that the committee, and that's what we're going to vote on, I feel we've spent five years dealing with this. It is not out of bounds for us to express some conclusions.

MS. WALCOFF: That's not my concern. I don't understand the basis for it. Where did we talk about it? I mean, it's just Breyer's dissent, that's what we're relying on?

DR. EVANS: No. It's the question of whether simple associations are patentable material because, as we went through this morning in great detail, association patents between genotype and phenotype present tremendous potential obstacles to the use of multiplex tests, whole-genome sequencing, et cetera. So they're very germane.

MS. WALCOFF: Are we certain that you cannot invent around these associations that we are defining that are not defined?

MS. ASPINALL: Let me just say something. I mean technology fundamentally changes. The things that we're calling simple associations now were not.

DR. EVANS: It's technology independent.

DR. FERREIRA-GONZALEZ: You cannot invent around them.

DR. EVANS: Absolutely. It is an association between saying, in the classic case, homocysteine levels are tied to B-12 levels. It has nothing to do with

technology.

MS. ASPINALL: You go back 50 years, and these are supposed to last over generations. Things that are simple now and that we described are a direct influence.

DR. EVANS: No, no, Mara. Did you listen to what I said? It is an association between two things.

Okay, I'm going to make a proposal. We need to vote on it so we can move on. I'm going to propose that we eliminate this recommendation, and that we put in the report that the committee feels something basically along these lines. I know everybody doesn't agree, but that's why we're going to have a vote.

MS. WALCOFF: Two separate votes?

DR. EVANS: I think it's clear to me that there is a consensus it should not be a recommendation.

MS. WALCOFF: So the question is, should it be in the report?

DR. EVANS: Does anybody want to have a vote on that? We can have a vote on that. Who wants to keep --

MS. WALCOFF: I thought it's whether it's in the report.

DR. EVANS: Okay. So we're going to put it in

the report. What are you asking me?

MS. WALCOFF: I thought I heard you say we're going to have a vote about -- I guess we're not having a vote about it being a recommendation.

DR. EVANS: Let's have a vote. Let's have a vote. Who wants this as a recommendation? Who's in favor of having this as a recommendation? Who's against it? Okay. So who abstains? All right.

So what we've decided then is that it's not going to be a recommendation. What I would move is that we at least address this in the report with wording that is substantially similar to this.

Now, I would say we should have a vote on that. Who would vote for that option?

[Show of hands.]

DR. EVANS: Okay. Who's against?

[Show of hands.]

DR. EVANS: Okay. So we initially had removed the issue of law of nature, all right, from the recommendation which isn't a recommendation anymore.

My view is that in the report, we can be more expansive and I don't think there's an imperative to

remove that language at this point.

DR. WILLIAMS: My recollection from reading the full report was that in the description about why this is a potential problem, we do have adequate detail there that does go into the issues relating to the law of nature. So my recollection of this discussion was that it actually was fairly broad. It was not just Breyer. There were a number of other examples that were presented, and I think that that stands on its own reasonably well and that people can take from it what they will.

DR. EVANS: Right. Okay. All right. I think we've done most of the heavy lifting, but I might be surprised. The remainder of the recommendations are meant to -- there's going to be wording that says, and I think that was in the original wording this morning in the presentation, that says, okay, we recognize that evoking statutory changes is a complex, hard process, and you may not even choose, as the Secretary, to do this.

Because of the difficulties with that, we have come up with a number of other recommendations that we feel could address the issues that have been raised

during the report and that's what most of these really focus on. So this one is concerning promoting adherence to norms designed to ensure access. It's kind of long.

The Secretary should develop mechanisms to promote voluntary adherence to the principles reflected in NIH's Best Practices for the Licensing of Genomic Inventions, the OECD Guidelines for Licensing of Genetic Inventions, the NIH Policy for Sharing of Data Obtained in NIH-Supported or Conducted Genome-Wide Association Studies, and in the public interest. Nine points.

The Secretary of Health and Human Services should also advocate that professional organizations involved in intellectual property policy and practice in this area work together to build on those norms and practices as they relate to gene-based diagnostics by articulating more specific conditions under which exclusive licensing and non-exclusive licensing of uses relevant to genetic testing are appropriate. Professional societies should work cooperatively to forego consensus positions with respect to gene patenting and licensing policies.

B. The Secretary should encourage

stakeholders, for example industry, academic institutions, researchers, patients, to continue their work of developing a code of conduct that will enable broad access to such technologies.

Now, as we discussed, one of the things that inevitably came up with was the question should these recommendations somehow have teeth. We're certainly all familiar with this litany of recommendations that say plain ice and should there be more in the way of teeth to this and, if so, how would we do that? So why don't we discuss those issues?

DR. TEUTSCH: I think the issue there, just to be clear, these were already out there as voluntary guidelines. So the question is what are we saying, besides --

DR. EVANS: Besides these are good guidelines.

DR. TEUTSCH: If we think they're issues and the report provides some evidence, then we probably need to take out words, like "promote voluntary adherence" and say "promote adherence," and give them some more clout. I mean that's the question. Where do we want to go with this?

DR. EVANS: Right.

DR. TEUTSCH: But it worries me, frankly, to simply reiterate what's already out there as a recommendation.

DR. EVANS: I know. I share that.

DR. TEUTSCH: I mean, if we think that they're important.

DR. BILLINGS: I have a question and maybe we don't have the -- this has to do with payment and the Secretary's control of the purse strings.

But if the Secretary were to say something like laboratories that don't license broadly and thus cause all the problems that the report suggests that they might in terms of access and quality, the laboratories will not have access or entities doing business with them will not have access to federal dollars that are administered by HHS.

Wouldn't that have a rather strong impact on the situation?

DR. EVANS: So, actually, in a subsequent recommendation, we discussed that. There's also the issue of, for example, whether Bayh-Dole allows the

Secretary, whether the law is such that that can be done, say, with funding dollars, et cetera.

So one way of trying to put more teeth in this, if we chose to do so, would be to, for example, get rid of voluntary and that simple change does, I think, do a little bit of work in communicating the frustration that Steve articulates.

B is pretty much kind of milktoast, and I don't know whether it makes sense to even have it. I mean, it does seem --

MS. WALCOFF: Maybe you can make it more direct in the way that Steve had suggested and instead of encourage stakeholders to continue their work of developing the code of conduct, I mean, you could make it a little less milktoast by saying develop a code of conduct by X or something, for review by something.

Then to the other point, there are also purse strings without a doubt in terms of restrictions and limitations on federal funding of grants and whatnot, so long as it's not precluded by other statutory restrictions which I think is what we're getting to in terms of the evaluation of that.

DR. EVANS: So I guess we could -- okay. So let me -- we can always go back. I don't mean to ram anything through here.

DR. TEUTSCH: That's a pulse point. There's a variety of things you can use. You talked about several. One could be a contingent --

DR. EVANS: The whole recommendation went away.

DR. TEUTSCH: That they adhere to these things, if they're going to seek --

DR. BILLINGS: It would be very interesting for someone to tell us, this committee, what options for influencing this kind of phenomenon we have, yes, so we can make recommendations that then would be relevant.

DR. EVANS: What if we were to say that the committee supports these following things, the nine points, OECD, et cetera? Somebody help write this down, if it makes sense. That the Secretary should investigate ways of promoting adherence that might include or that would include the use of funding as a deterrent or incentive. Something like that?

DR. TEUTSCH: More than investigate is the point.

DR. WILLIAMS: I don't know. I don't know that I would -- I think again, within the recommendation that goes to the Secretary, I was thinking along the same lines that Jim was saying, that we think that these are good guidelines for how things should go. They are voluntary.

We, as a committee, do not know what avenues would be available to promote adherence, if you want to use those words. So we would recommend that the Secretary investigate or explore what are the options to promote adherence to these guidelines. I mean, I think that that's a reasonable thing to do.

DR. EVANS: Again, I'm just thinking out loud here. The committee supports guidelines and then we could insert in there such as OECD, nine points, et cetera, that encourage broad licensing and access to diagnostic and genetic tests.

Okay. Help me out here. We would request that the Secretary --

DR. WILLIAMS: I think technically we recommend. We're advisory.

DR. EVANS: We recommend. Okay. We recommend

that the Secretary.

DR. WILLIAMS: Explore options that would promote adherence beyond voluntary.

DR. TEUTSCH: I would go further and say because you've got to explore them, you've got to identify them and implement them.

DR. WILLIAMS: Explore, identify and implement is what Steve just said.

DR. MANSFIELD: And implement such recommendations in ways that go beyond simply --

DR. TEUTSCH: Adherence, that promote adherence to those recommendations.

DR. MANSFIELD: Such recommendations. Oh, well, we recommend the Secretary explore, identify and implement such recommendations. Give me -- okay. What were you saying?

DR. WILLIAMS: So that the Secretary explore, identify and implement processes --

DR. MANSFIELD: And implement mechanisms.

DR. WILLIAMS: Mechanisms that --

DR. TEUTSCH: That promote adherence to those guidelines.

DR. WILLIAMS: -- promote adherence, right.
DR. MANSFIELD: That promote --
DR. WILLIAMS: Promote adherence beyond voluntary --
DR. EVANS: To these guidelines that go beyond voluntary adherence.
DR. WILLIAMS: And then the second part of that would be, I think, whoever suggested that we recommend that the Secretary convene the group as opposed to just continue, that we change the verb to convene, so that there's an intentionality about bringing the people to the table to figure it out.
DR. EVANS: Should convene.
DR. WILLIAMS: Whatever the second part that you previously said.
DR. EVANS: The Secretary should convene stakeholders.
DR. WILLIAMS: Yes.
DR. EVANS: Yes, okay.
MS. ASPINALL: That's consistent with what we've done on previous reports. We've asked the Secretary to convene people.

DR. EVANS: It is, yes. The Secretary should convene stakeholders. We can worry about formatting later. Okay. Stakeholders, for example industry, academic institutions, researchers, to continue their work of developing a code of conduct -- yes, yes. To develop -- we'll have to wordsmith. To develop a code of conduct that will enable broad access to such technology. Okay.

Yes?

DR. RODRIGUEZ: I have a comment. So some of the comments that I had have changed now that the language has been altered a little bit and we're exploring things and looking further at these issues, but some of the power that the guidelines have had is the fact that they are guidelines and they're voluntary and they promote flexibility and by shifting to adherence, I think again that, as written, things would have to be looked at differently.

They weren't originally developed with the intent of being regulations or anything that was mandatory and so that could change how some of it works and actually take away some of their power because the

flexibility to look at the individual situation is helpful in moving some things forward, but as written and in terms of convening, I think that is something that's well within the scope of the Secretary to do and to bring stakeholders together and to have them go through these issues again and put something forward.

I think that could be very constructive, but another question that I had again is that all of this would only affect HHS-funded research.

DR. EVANS: Right. Absolutely.

DR. RODRIGUEZ: And so there's a question of impact overall.

DR. EVANS: Right. That's an acknowledged limitation of all these types of things. That's one of the reasons for Recommendations 1 and 2.

MS. DREYFUSS: First of all, I think the guidelines internally have some flexibility in them. So taking and making them more -- making it more required that you follow the guidelines doesn't remove all flexibility.

But I thought Paul had some ideas of ways to broaden the teeth by saying the Secretary -- maybe I

misunderstood you -- could also do things with funding of organizations that deal with these organizations.

DR. BILLINGS: Exactly. I mean, she has both direct and indirect influence on the environment in which these laboratories and the patent holders exist in nature and so --

DR. EVANS: So can you think -- so it sounds to me like a possibility to include that would be to have a sub-bullet that says something about the types of mechanisms, right?

DR. BILLINGS: She has authorities and influences. We don't happen to know all of them, but she does and we want her to -- the point here is that we want her to marshal them for this end.

DR. EVANS: And implement mechanisms using her authority and resources?

DR. BILLINGS: Yes.

DR. EVANS: Mechanisms, using her authority, and what was the other thing? Resources. Thank you. Resources, in order to promote adherence to these guidelines in a way that goes beyond voluntary adherence. Okay?

All right. Other suggestions? Which point? I mean, the one point is you can't get around it, right? It's only going to impact NIH-funded research.

DR. RODRIGUEZ: Right. And may actually in some ways be a disincentive to interact with HHS-funded research if this is a problem and so that companies may just not --

DR. EVANS: For most people it's the only game in town.

DR. RODRIGUEZ: I don't know. I don't know that really most -- again, talking about all of the research that goes on in the private sector.

MS. ASPINALL: For lots of private sector companies and the research and early developmental stage, NIH funding is a very big piece of it.

DR. EVANS: So that actually is a good thing for the potency of this.

All right. So we'll do some wordsmithing and find some time tomorrow or something to circulate things.

DR. TEUTSCH: I think from a process point of view, if we can get a sense that these are now directionally correct, we should wordsmith them tonight

and bring them back to the whole committee, not the ones that we've already voted with, but the ones that we're still extensively rewriting, and get some final approval on those tomorrow. We'll find some time.

DR. EVANS: Okay. That's right, and I'm going to now move this one.

DR. TEUTSCH: So I think what you should probably take a vote on those two that were basically correct.

DR. EVANS: Yes, okay, right. Okay. I'm just putting that at the end, so we'll still have it as a model.

All right. So let me just go over it again. This is for promoting adherence to norms designed to ensure access.

The committee supports guidelines, and we'll fill in the litany, that encourage broad licensing and broad, I think we should probably have broad, modifying those, as well, access to diagnostic genetic tests. We recommend that the Secretary explore, identify and implement mechanisms, using her authority and resources, in order to promote or that will, I guess that would be,

that will promote adherence to these guidelines in a way that goes beyond voluntary adherence.

The Secretary should convene stakeholders, for example, to develop a code of conduct that will enable broad access to such technologies.

So all those in favor.

[Show of hands.]

DR. TEUTSCH: 14, one abstention.

DR. EVANS: All right.

DR. TEUTSCH: Any opposed?

DR. EVANS: All right. Let me get rid of that. Okay. Enhancing transparency in licensing, and the reason for this was, okay, there was some dissent here. Gee, imagine that.

The Secretary should encourage holders of patents associated with genetic tests and their licensees to make information about patent licenses readily available, either by making the signed licenses publicly available or by disseminating information about their technology and licensing conditions, including any terms that pertain to the type of license, field of use, and scope of the technologies that are still available.

And B. As a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary should direct NIH to amend its Best Practices to the Licensing of Genomic Inventions to encourage licensers and licensees to include in their license contracts a provision that allows each party to disclose information about its licenses, including such factors as type of license, field of use, and scope, in order to encourage next generation innovation.

Comments?

DR. WILLIAMS: So I guess I would like to understand if there was dissent about this, what the nature of the --

DR. EVANS: That's what I'm trying to remember.

DR. WILLIAMS: -- dissent was and probably better for someone that --

MS. ASPINALL: I think that several of the universities also dissented to this in the letters and just saying they did not want their financial information on good, bad, or indifferent business practices public information.

DR. WILLIAMS: So this is -- I don't want to make this a pejorative sense of the term, but the issue is then less about the fact that there could be challenges relating to discovery of IP or things. It's more related to public perception of what it is we're actually doing with --

MS. ASPINALL: Disclosure on financial terms in the effort to not say you negotiated a good deal or a bad deal with this type of company or other university and they did not want that information public.

DR. WILLIAMS: Do we say anything about financial terms here? I mean, my reading of this, and maybe again I completely missed the boat, but my reading of this was really the idea was to know who was involved so that people that are looking to actually be engaged would at least know what the landscape looks like, that it's not necessarily disclosing all financial information or anything else like that, right? It's just who --

DR. FERREIRA-GONZALEZ: It's who has been licensed to whom for what application and what it covers, not what money or how. I mean just to know there's already a license out there, so I don't have to try to do

this because there's already a license.

MS. ASPINALL: I think you have to make that clear because terms and fields of use to many who had read it said that's the term sheet, that's all the conditions for which we're licensing.

DR. WILLIAMS: I would certainly favor clarifying that because I don't think that that information needs to be made public. I think then if that's the case, if people are concerned that that's what we're saying, then we need to modify the language to make it clear that we're just trying to identify who's actually involved and if licenses are out there.

MS. DREYFUSS: I thought that was the only information we were requiring, but my impression was that some people considered that trade secrets. What deals they had, not the nature of the deal, the simple fact that they had deals, they wish to regard as trade secrets.

MS. ASPINALL: That was the second level that was absolutely voiced by industry as well as research and academia.

DR. EVANS: Brian Stanton was a dissenter on

this. I think he was the major dissenter and what he says here is that he doesn't believe the evidence supports the need for this.

First, patent information is readily available from USPTO, the European Patent Office, the Japan Patent, private sources, such as Google, and others.

So I think that, for example, the individuals who pursued the case studies would argue that actually this information is very hard to come by and I think most of us would agree with that latter point.

So how could we change this then to address the points that Mara and Marc, Rochelle were talking about?

MS. DREYFUSS: I think Brian was thinking of finding out whether there were patents you could Google, first of all, but that isn't so easy either, but what Bob Keegan said was that it was very hard to find out who you'd go to to even get a license and that just seems to me to be the kind of information that ought not be regarded as a trade secret.

I agree about the financial information. That seems like really important information that people might want to withhold. So I would try to change it so it's

clear it's not financial information but that people would be able to find out who they need to get licenses from if they want licenses because that's an important part of getting access.

DR. WILLIAMS: The other point I would make, as I read through both of those, is that the operative verb for the Secretary in both of those cases is encourage which implies voluntary and so that would also then raise the question that we brought up previously which is are we really looking just to enhance voluntary reporting or do we really want to --

DR. EVANS: Should we use her authority? Again, we could use the same wording here, that the Secretary explore, identify and implement mechanisms using her authority and resources, so that holders of patents associated with genetic tests, blah-blah-blah, and then have a clause that, for example, excludes the financial aspects. Does that make sense? Well, in a way this does it, right?

Here, let me go back to the full screen. I mean what this is is about technology and licensing conditions, including any terms that pertain to the type

of license, field of use, and scope. So that isn't financial, right?

MS. WALCOFF: Are we trying to identify -- you say we're trying to identify where licenses are. Does that necessarily follow that because a company that holds a patent has licensed it to another entity, that they would naturally license it further? I mean, aren't we trying to figure out who the patent holders are?

DR. EVANS: Well, what we're really trying to do with this, I think, is find out who it's been licensed to for what fields of use, right, because that proves to be very hard and it's going to be a big deal as multiplex testing becomes the norm.

DR. FERREIRA-GONZALEZ: For example, I want to set up a new test and I want to, first of all, you try to figure out if the finding of the gene, there's a gene patent. You normally go to the first original publication and you try to contact the authors there or the university there or whoever is the entity and sometimes you can't find them and you don't know where to go and then from there, they might already have licensing or they might not be willing to tell or not. So it's

very hard to find that information.

MS. WALCOFF: If you identify the licensee, just that, I mean that's --

DR. FERREIRA-GONZALEZ: Also what they have been licensed for.

DR. EVANS: Right. The terms of use, the field.

MS. WALCOFF: I was trying to think of a way to get around the fact that people would be sensitive to however we define the use.

DR. FERREIRA-GONZALEZ: Just finding the licensee might be compromised.

MS. WALCOFF: Right. That's what I'm suggesting because then you could easily identify just their contact information and then that entity could seek to clarify the terms under which they could use --

DR. FERREIRA-GONZALEZ: They might decide not to do that and then I try to set up a test and then they contact me to send cease and desist letter.

MS. WALCOFF: Right. So you'd avoid a cease and desist because you actually have a clear contact beyond the original patent, but if it doesn't make people

nervous about all these other things, they may be required to disclose beyond this is the licensee.

MS. ASPINALL: Well, I don't agree with it, but I think that's closer because when you put in any terms that pertain to the type of license, then it says you need to be able to do this much research at this time and keep it exclusive. I mean, there are all sorts of terms that relate to licenses and I did not believe it was the -- well, actually, I wasn't sure what the full intention was, but I think when you have the way it's phrased initially as any terms that go to scope of technologies in the broad second sentence, I think it's very easy to say I've got to make public all the information regarding this license and I did not think that was the committee's intention.

DR. EVANS: Okay. I'm trying to make this bigger so that we can --

DR. FERREIRA-GONZALEZ: Is there a way to dissect all these different terms? I'm doing research for this amount of time or do this data support? That part is not -- but do you still know what you're using the test for, why you're licensing it for? For

diagnostic, prognostic and clinical scenario and so forth.

DR. EVANS: Okay. So what the heck happened? All right. So trying to work our way towards this, trying to put a little more teeth into it. One way of achieving that would be to use the same wording we did in the last one.

We recommend the Secretary explore, identify and implement mechanisms, using her authority and resources, that will make information about patent licenses readily available either by making the signed licenses publicly available or by, and here's where we have to do some wordsmithing, disseminating information about their technology and licensing conditions, including, and you felt like any terms was too broad.

What if we said including the type of license or just get rid of any?

DR. WILLIAMS: What I would probably do with this is to not be as -- I mean, the first part of it is we're asking her to explore and then we're telling her exactly how to do it in some ways.

I would almost say, and it's just at the bare

edge of my readability here, so that will make information about patent licenses readily available, period, and then say the information that is necessary because of the concerns referenced in the report are around the field but would not constitute financial.

So, in other words, you wouldn't have to articulate everything in the recommendation. You could basically say we're interested in this. We're not interested in that and then expound on it in the report.

DR. TEUTSCH: Or just indicate that she should develop the elements of the following type.

DR. WILLIAMS: Right.

DR. EVANS: So something like information needed for greater transparency due to concerns articulated in the report include information about their technology and licensing conditions, licensing conditions, terms that pertain to the type of license, field of use, and the scope of technologies. What about that?

DR. DALE: Jim, that phrase at the end, though, "that are still available," doesn't make sense.

DR. EVANS: Yes. I just took it out because it

didn't make sense with the change there.

Now in B, as a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the Secretary should direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to encourage licensers and -- encourage again, to include in their license contracts a provision that allows each party to disclose information about its licenses.

So should we say here the Secretary should direct NIH to amend its Best Practices for the Licensing of Genomic Inventions to require?

DR. WILLIAMS: Would it be appropriate just to ask the Secretary for the NIH to revisit its recommendations to specifically address this point and then bring those forward, I mean, as opposed to saying this is exactly what should be done? Are we absolutely certain that that's exactly what should be done or should we give NIH -- let them use their expertise.

DR. EVANS: Or we could say the Secretary should consider directing the NIH to require blah-blah-blah.

DR. RODRIGUEZ: I was just wondering, actually, since, in the first part of this, it's been changed to explore all of the authorities, then I would think that this becomes a little bit moot in terms of that would be done in the course of doing the first part and so again I think that it needs to be explored and there would be a lot of questions that the NIH would have about doing that.

So certainly changing it to a consider, if it's going to go beyond encourage, I think there are definitely --

DR. WILLIAMS: So B would move to the report as part of the explication about the different opportunities that could potentially be looked at and, yes, I agree, I think it is redundant. I would just take B out and move it to the report.

DR. EVANS: So, okay, we're talking about then moving this sentence maybe with exactly or close to that wording to the report in the context or in the discussion of this recommendation, right?

DR. RODRIGUEZ: Right. Because I don't know that there is existing authority to do this.

DR. EVANS: Right. And that you have to explore that which we kind of say. Okay. All right.

So other comments about this? All right.

DR. WILLIAMS: So B is out then?

DR. EVANS: B moves to the report. So the vote then would be, unless somebody -- here, let me get it up here.

We recommend that the Secretary explore, identify and implement mechanisms, using her authority and resources, that will make information about patent licenses readily available. The information needed for greater transparency due to concerns articulated in the report include information about technology and licensing conditions, terms that pertain to the type of license, field of use, and the scope of technologies.

Okay. So all those in favor.

[Show of hands.]

DR. EVANS: Okay. All right. Moving on, we can get rid of that. All right.

Advisory board. All right. To assess the impact of gene patenting and licensing practices. The Secretary should establish an advisory board which would

be available to provide ongoing advice about the public health impact of gene patenting and licensing practices.

This advisory board would also be available to receive any reports of problems in patient access to genetic tests from the public and medical community. The board then could review new data collected on patient access and assess the extent to which access problems are occurring.

One of the board's missions would also be to recommend what information should be systematically collected through iEdison so that iEdison can be used to research questions about licensing, including whether the licensing of genomic inventions has been conducted in accordance with NIH's Best Practices for the Licensing of Genomic Inventions.

The advisory board also could provide input on the implementation of any future policy changes, including the other proposed recommendations in the report.

Basically what this is saying is -- this arose because there seemed to be frustration that there was kind of a vacuum there, that if people perceived

problems, they didn't know where to go. There wasn't any mechanism and this would take care of that.

Barbara.

MS. McGRATH: I think, just to make it simple, I would keep the first sentence and then cut out everything and then go down to the last sentence, the advisory board also should provide, and then just have that be the recommendation and then in the text, since there's a lot of discussion about who should be at the table on this committee and other places, maybe specify a list of potential stakeholders that would be part of that advisory board.

DR. EVANS: I'm all for simplifying because my eyes glaze over when I see a recommendation like this. So tell me again your specific --

MS. McGRATH: I just end up with two sentences, the first and the last.

DR. EVANS: So the Secretary should establish an advisory board which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices. The advisory board also could provide input. Is that what you're saying?

MS. McGRATH: Exactly.

DR. EVANS: And then what we could do, if this makes sense, is we could try to incorporate in the report these other things.

MS. McGRATH: As well as making explicit that the composition of the advisory board would be reflective of all the groups that we've sort of mentioned.

DR. EVANS: Okay. So in the report, then insert a discussion along the following lines which also includes suggestions about the composition of such a board and then put --

MS. WALCOFF: So would this be an advisory committee, in addition to SACGHS, or also --

DR. EVANS: Yes. I don't think this would be SACGHS.

DR. WILLIAMS: I was going to -- I think I'm going where you are, which is advisory has a very specific meaning, I think, in the context of the Secretary. So I had that question which was would that in fact be us.

The second question is whether there would be expertise from -- would it somehow be an

interdepartmental board because we've already acknowledged that there are different people that hold different pieces of this puzzle.

And the third point is that in our recommendation, I think it was Number 3 maybe, we do establish or recommend establishing another group to explore best practices. So in some sense, could we look at folding this into that? Would that be a potential -- because again, I don't think we should necessarily have recommendations for 15 new committees or boards, et cetera.

DR. EVANS: Right. So that makes sense.

MS. WALCOFF: And also, I like your idea of the interdepartmental workgroup to continue to look at these issues.

DR. EVANS: So what we could do -- so this now is something --

MS. WALCOFF: Your five-year tenure will end.

DR. EVANS: That's right, that's right. Exactly, exactly. So what we could -- in this wording, which we'll figure out, that will go in the report that won't be in the recommendation, help me out here.

You're saying we could discuss the need for interdepartmental membership. We could also --

MS. WALCOFF: I think it would be an advisory board then. I think it would be more of like an interdepartmental workgroup or committee. I mean, there are technical terms for those.

DR. EVANS: Okay.

MS. WALCOFF: Maybe we could just find those out.

MS. CARR: Are you suggesting feds only? An internal working group?

MS. WALCOFF: Are we suggesting feds only? That's what I was thinking, but I don't know.

MS. CARR: This was outside, I think, outside advisors.

MS. WALCOFF: Okay. I guess when you mentioned the point about needing advice from the other implicated departments, my mind went to feds only, but maybe so.

I mean, is there something between a departmental working group and an advisory board because the chartering of an advisory board just kind of looks like we're duplicating ourselves.

DR. EVANS: Yes.

MS. DARIEN: Can't you just call it an advisory body and then allow it to be constituted the way that it should be constituted?

DR. EVANS: As long as we discuss like whether it should be interdepartmental advisory body, which would be more intentionally vague, and let her --

MS. CARR: It could be inside or outside. You're not going to specify your wishes in that regard.

DR. TEUTSCH: You need to talk about who it's advisory to. This one was advisory to the Secretary.

MS. CARR: But if it's interdepartmental, then it may have more than one advisor.

DR. TEUTSCH: Right. Well, here because Number 8 refers to a group that's advisory to the Patent Office.

DR. EVANS: Yes. I mean, my assumption with this would be that it was an advisory body that would report to her. Do we need to say that?

MS. CARR: I think you're focused on the public health impact here, so perhaps you could have interdepartmental but still reporting to the Secretary of Health.

DR. EVANS: Do we need to say that? That's the question. Should such an advisory board or body be reportable to her or do we need to get there? At this point, I'm going to leave that off for a moment.

I was going to mention, I was going to put down here -- I'm sensitive to the idea that, oh, go ahead and create another board, another advisory body, when think about what our committee does, right. It's supposed to address issues of genetics, health, and society. We're talking about gene patents here.

It does seem to me that it might not be illogical to suggest that there could be a role for this committee as this. I mean, we've got interdepartmental input, et cetera. Does that make sense?

MS. WALCOFF: Sadly, it does.

DR. EVANS: Sadly, it does, yes.

MS. WALCOFF: Maybe we're just thinking of ways --

PARTICIPANT: Still not fully representative.

DR. EVANS: Right. So we could discuss interdepartmental membership. We could even say that others could be brought into it. We could also suggest

it might be a role.

MS. WALCOFF: Is it an advisory group that really would be advising the SACGHS?

DR. EVANS: No. I mean, my reason for bringing it up is the idea that it seems a rather natural function of this committee, not a group that would advise this committee, but kind of a function of this committee.

MS. WALCOFF: Are you still trying to get into the broad -- some way to enable broader membership in terms of views that we might --

DR. TEUTSCH: Is this where public/private partnership can look at these issues and bringing recommendations on technologies and changes to the appropriate public or private bodies?

MS. WALCOFF: Right. Because then we could vet it.

DR. TEUTSCH: We've done that in some of the other things when we've talked about --

DR. WILLIAMS: In the oversight report, we recommended constituting that.

I mean, I didn't want to necessarily substitute one buzz word for another, but I think I'm envisioning

that it needs to have representation from within the federal goverment and then it needs to have outside representation, as well, and again I'm going to reflect back just to try and simplify things, that if we're recommending we create whatever this body is, that we task it to do several things.

This. We task it to look at the best practices, which was represented, I think, in Recommendation 3, that that should be pulled into this, and if there's any subsequent recommendations that talk about forming a group, that they be given charge over all of this.

DR. TEUTSCH: And 8, the one that deals with the PTO.

DR. EVANS: Right. So, okay, now this is -- just bear with me because I'm trying to piece together these various ideas. So again, the recommendation, as we've got it now, is just this very first part, per Barbara's recommendation or suggestion.

In the report, we would then discuss those issues, like iEdison and all, and then to try to get to what we're talking about here, we could discuss the need

for interdepartmental membership, representation from a broad array of experts and stakeholders, and the nature of membership. We could also suggest it might be a role for SACGHS.

Does that get what we're talking about?

DR. DALE: Jim, another structural way would be that there become over time, as this field evolves, standing subcommittees of this committee.

DR. EVANS: That's a good point, and we could discuss that in the report.

DR. DALE: And then we wouldn't spend quite as much time around this table talking about details but rather receive reports.

DR. EVANS: Right. And we can include in that verbiage, we'll figure out in the report, and there might be a role for standing subcommittees of the SACGHS.

DR. WILLIAMS: Chaired in perpetuity by Dr. James Evans.

DR. EVANS: No, thanks. I think I have some kind of conflict of interest or financial impropriety or something.

All right. So let me read the actual

recommendation.

The Secretary should establish an advisory body which would be available to provide ongoing advice about the public health impact of gene patenting and licensing practices. The advisory board also could provide input on the implementation of any future policy changes, including the other proposed recommendations in this report, and then within the report, we would talk about the composition, the need for interdepartmental membership and a broad array of experts. We could suggest the possibility that it's an appropriate role for SACGHS perhaps with the standing subcommittee.

Oh, okay. Gotta change the boards to bodies. All right. This is body. All right.

All in favor of this recommendation and the attendant insertions into the report.

[Show of hands.]

DR. TEUTSCH: 13, one abstention, one no.

DR. EVANS: Okay. Federal efforts to promote broad licensing and patient access.

"The Secretary shall encourage federal agencies within the Department of Health and Human Services to

undertake the following actions: (a) federal agencies should promote wider adoption of the principles reflected in the best practices and OECD guidelines, both of which encourage limited use" -- is this redundant? -- "and (b) federal agencies should encourage wider use of the nine points to consider in licensing university technology."

Points 2 and 9, including their explanatory text, are particularly relevant. For example, the explanatory test under Point 2 recognizes that "licenses should not hinder clinical research, professional education and training used by public health authorities, independent validation of test results for quality verification and/or control."

So the question would be, as I read these again, are these redundant?

DR. WILLIAMS: Yes. Fold it into the previous one.

DR. EVANS: All right. So the motion is to fold this into the recommendations, or to fold it into the discussion that refers to the recommendation?

DR. WILLIAMS: Into the discussions first.

DR. EVANS: That's what I would think, too.

Okay, good. So the consensus, if people agree, is fold this verbiage into the report's discussion of Rec 3.

Yes, okay. Are people okay with that? I don't think we need an actual vote on that.

Federal efforts. This is continued, and I think it's going to be the same thing: "Federal agencies should explore whether approaches to addressing patent thickets" -- okay, this is a little different. This might be a separate recommendation -- "to explore patent pools, clearinghouses and cross-licensing agreements to facilitate the development of multiplex tests for whole-genome sequencing."

DR. WILLIAMS: So to me, this would fall under the purview of Recommendation 5, where we create this group that is exploring it. This is a really important issue, I think, that we need to explore in much greater detail. This would be one more thing I would task that group to explicitly explore.

DR. EVANS: So the suggestion, then, is to fold this into the report where we discuss the advisory body, right? Are people okay with that? I mean, I like the fact that we're making this simpler.

Licensing policies governing federally-funded research to facilitate access. So this is now a shift and a totally different issue. Because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Secretary should seek clarification about this legal question.

"If it is determined that such authority exists, the Secretary should promulgate regulations that enable the Department's agencies to limit the ability of grantees to exclusively license inventions resulting from government funding when they are licensed for the genetic diagnostic field of use."

Exceptions should also be allowed if a grantee can show that an exclusive license is more appropriate in a particular case. For example, because of high costs of developing the test.

The Secretary should also direct NIH to make compliance with NIH's Best Practices for the Licensing of Genomic Inventions an important consideration in future grant awards, and let me see. There was something -- okay.

And the question was should the below sentence from this recommendation be deleted, modified, or left the same, and that is that last sentence.

DR. WILLIAMS: The last sentence really relates to what we were talking about in terms of exploring different options. So that should go into the report relevant to, I think, Recommendation 3.

DR. EVANS: I agree. So I think what Marc is saying is that this should be inserted into the report where we discuss Recommendation 3, okay, and this stands on its own as a recommendation that basically calls for a clarification of legal question. Does that make sense to people?

MS. WALCOFF: I just want to make sure I'm clear. So in terms of the clarification of the legal question, but then we had discussed earlier, and this is what you just said, Marc, folding the rest of that into the earlier -- or are you still saying --

DR. WILLIAMS: Actually just referring to the last sentence be folded, but I think that, as I was listening to this again, we're sort of presuming in the recommendation that we think we know what they're going

to find and here's some things that you could do.

I would basically limit the recommendation to just say seek clarification on this and then you could put again in the text of the report here are some of the specific issues that are coming up that we need clarification about. So I don't think we need to clutter the recommendation per se with all the rest of it.

DR. EVANS: So you're saying --

MS. WALCOFF: It's really just the first sentence?

DR. WILLIAMS: Yes

DR. EVANS: Yes. So you're saying take this and fold it into the report, as well.

DR. RODRIGUEZ: I would just agree with that because I think otherwise that language is premature before we have --

DR. EVANS: That makes sense. Okay. All right.

DR. RODRIGUEZ: I also just a question on the last sentence that was suggested to be moved under the discussion for Recommendation 3 because again that's directive in the sense that the committee's stating that

this should happen with regard to making the best practices a condition related to grant award, and we're saying, as it goes into under 3, it will be something that's explored.

DR. EVANS: I'm sorry. I was preoccupied. Say that again.

DR. RODRIGUEZ: The sentence that Marc suggested be moved under Recommendation 3 about where the committee states that they should direct NIH to make compliance with the best practices related to consideration for future grant awards, that would now be more conditional under Recommendation 3 where there's -- the actual recommendation is to explore the authorities that are possible.

DR. EVANS: Right.

DR. RODRIGUEZ: So this response statement would not be there.

DR. EVANS: As a condition of that discussion of Recommendation 3. Is that what you're saying?

DR. RODRIGUEZ: Right. So that I think there's a question to be asked and answered with whether or not that authority exists.

MS. CARR: May I just ask you, though, could you not also put it under -- as part of what's left of this recommendation because isn't one of the issues here whether NIH or the Secretary has authority to --

DR. RODRIGUEZ: Right. I think it's related to clarifying.

MS. CARR: It is. So it would stay here with this recommendation.

DR. WILLIAMS: I'm not sure, Sarah, because this is really -- as I understand it, this is relating to that we're suggesting that we explore whether this should be an element that would be part of the grant review and scoring process in terms of -- that's how I read this and if that's the case, that's not Bayh-Dole, is it?

DR. EVANS: Well, yes, I think that the question is does Bayh-Dole allow her to use that information, right, and, if so, what we're saying is then she should direct the NIH to make compliance with it a condition of granting.

So I actually do think this probably belongs in the discussion of this recommendation.

DR. WILLIAMS: Okay. All right.

DR. RODRIGUEZ: It's relevant to both recommendations because it will depend on the answers in exploring her authorities under Recommendation 3 and the analysis of Bayh-Dole.

MS. CARR: Actually, isn't this, the first part of this, of Number 7, like the most overarching thing for what's now Number 3?

DR. WILLIAMS: That was the question that I was wondering now, too.

DR. EVANS: Yes.

DR. WILLIAMS: In some sense, as we look at the ordering of the recommendations, that this may proceed because that may well define what is within purview and what isn't.

DR. EVANS: Yes. So maybe we need to --

MS. CARR: I think this falls after 3, I think, because 3 has the possibility of affecting people that interact with fundees. So 3 might affect more people than --

DR. EVANS: So we can discuss this. Okay. I'm pointing on the computer. You guys probably can't see that. Okay. So we could discuss this in relation to

this, but we could also emphasize its relevance to 3 and put them together, yes, yes, and so put 3 and current 7 adjacent. I don't want to make a mistake and think we're fusing them. Right? Okay.

All right. So are people okay with this? This then would be the recommendation.

Because it is unclear whether the Bayh-Dole Act gives agencies authority to influence how grantees license patented inventions, the Secretary should seek clarification about this legal question.

Then in the report, we would discuss this issue of using that authority to influence funding decisions as we discuss this recommendation and then we would take this information where we discuss Recommendation 3 about promulgating regulations that enable the department's agencies to limit ability of grantees to exclusively license.

All right. All in favor.

[Show of hands.]

DR. EVANS: Okay. All right. I know. We have 6D, right. I'm aware of that. All right. Let's just keep going and then we'll go back. Okay. So you think

we're on the last slide but we're really now. We have to go back to one more.

8. Providing needed expertise to USPTO. This is something we asked the USPTO representative about. As I recall, the comment was we'll take all the advice we can get. I don't want to put words in their mouth, but I don't want to overstep bounds either.

I don't want to say -- I don't want to force an advisory kind of board on USPTO if they don't want it or don't need it, but that was not my sense from the Task Force, just to get that out there.

So this says that the Secretary should recommend that the Secretary of Commerce advise the USPTO to establish an advisory committee to provide advice about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications in the realm of human genes.

The committee believes experts in the field should help USPTO in its development of guidelines on determinations of non-obviousness and subject matter eligibility in this field once pending court decisions,

such as Bilski v. Kappos, are decided.

DR. WILLIAMS: So again, it seems to me that this would be a role that could be defined under that previous group.

DR. EVANS: Yes.

MS. DREYFUSS: I thought that this group is really about scientists, that it's the scientific advice that we're wanting to give the PTO rather than the stakeholder kind of advice.

DR. EVANS: That's a good point.

MS. DREYFUSS: I mean maybe we want to do that other thing, but --

DR. EVANS: Because we are talking about scientific and technological development.

MS. DREYFUSS: I thought it was that, but maybe a bigger role would make some sense.

MS. WALCOFF: Does OSTP advise USPTO, at the risk of using a billion letters there?

DR. EVANS: I'm confused.

MS. WALCOFF: The White House Office of Science, Technology, and Policy advise the USPTO.

DR. EVANS: I don't know.

MS. WALCOFF: The Patent and Technology Office. I mean, I'm wondering if that already exists and maybe there just needs to --

MS. DREYFUSS: I was at a National Academy's committee once and we explored this question of who gives advice to the PTO and the PTO at that time was saying that they really would like more advice than they actually get, that they're left sort of on their own quite a bit, but that was about avenues for finding out more scientific information rather than information about sort of the economic value of patents and things like that.

I mean, if you think about a broader committee, it would be about the economic place of patents in the overall system of promoting innovation, but that's not what I know the PTO wants. What the PTO has said it wants is more actual science, scientists who actually understand where the technology is right now, how much this new advance really is different from something that a person of ordinary skill in the art could have done, how broad is the technology, how broad are the claims, and really science-type questions.

MS. WALCOFF: Right. It seems like, I mean, they can certainly ask the White House for that kind of information and that kind of focus, I know, for OSTP. So I'm wondering in terms of recommending to another Secretary to do something, I'm just thinking is there a possible way to alert to existing resources and suggest that those be drawn upon or that they expand what OSTP is currently looking at.

MS. DREYFUSS: OSTP is more science policy. It's more science policy role than what's the actual science of this widget technology.

DR. EVANS: My initial reaction, as we were discussing this in the Task Force, was kind of, I thought, well, you know, this probably exists and do they really want the advice, but as we queried the USPTO, that didn't seem to be the case. So this did seem, kind of to my surprise, as something that would be welcomed.

DR. BILLINGS: But do we want them to establish an advisory committee or do we want them to take heed of these issues that we've raised and change patenting policy?

DR. EVANS: Well, we're trying to help them do

that. I mean, this, I think, actually is not designed to change patenting policy. This one. I mean, we certainly have ones in there that are, but this one, I think, is saying, look, it's a rapidly-moving field, both technologically and legally. It would behoove the Secretary or it would behoove everybody if the Patent Office had some technical experts that were on call to --

DR. BILLINGS: But we're not the only field that has this issue, right?

DR. EVANS: That's what I said. That's what I said when we were discussing this and to my surprise, and it sounds like Rochelle got the same reaction, the USPTO is like, yes, we'll take that. So this surprised me and I don't want to put words in their mouth, but I understand your reaction, I had the same reaction, but it sounds like -- and what we could say, we could use Gwen's recommendation. We could leave it looser and say an advisory body.

DR. BILLINGS: How about advisors?

MS. WALCOFF: Making it so siloed, I mean maybe this should be something where USPTO and the science advisors are all with this interdepartmental, whatever we

decided to call that earlier, group and then everyone's talking to everyone, instead of creating a lot of independent bodies that do exactly what we do.

DR. EVANS: Yes. Again, that's interesting. The only issue with that is that, as Rochelle points out, the intent of this was to try to really hone down on the technical issues in this rapidly-changing field in light of -- things like non-obviousness are a very technical issue. Is it obvious to a person versed in the art?

So the only problem with kind of folding this into that previous body is that that has all this membership of policy people and we're talking here about science.

MS. DREYFUSS: Part of the problem the PTO has is that for each new science, they really need new advisors. So you can't have like a standing committee that's going to help them because the next science, the next new thing, we have no nano technologists here, even though who knows what nano technology could do for genetics. So they really need the kind of people that will help point them to the right people to ask about new things because if they just chose somebody, they could

choose the right person, they could choose the wrong person. If a stakeholder tells them to choose somebody, you always wonder whether that's a biased person. So sort of a neutral advisory committee to help them kind of ferret out who the right people to talk to is more along the lines of what I was thinking about, the way I understood what they wanted.

MS. WALCOFF: You want to identify experts?

DR. EVANS: No. Advisory committee to provide advice. So I think what we would want to say is perhaps establish a body of scientists or technical experts to provide advice about scientific and technological developments.

MS. WALCOFF: Rochelle said we don't want a standing committee.

DR. DALE: I was going to suggest something a little short of that and that is, that the Secretary explore a liaison relationship with this committee, with the Patent Office, on issues related to genetic technologies and then see where that goes.

DR. EVANS: Yes. I like explore because I think there's enough uncertainty around the table here

that we're not sure we want to say you gotta do this. So help me out. Something like this.

Advise USPTO to explore the establishment of a -- and now you're going to see my horrible spelling.

MS. CARR: We actually already have a representative. Michael Amos is from the Department of Commerce. He sits on this committee. He's from NIST.

DR. EVANS: Between this committee and USPTO.

MS. CARR: Were we thinking of something more than that?

DR. DALE: It could be more specific. We could leave that to the Secretary and the Patent Office.

DR. EVANS: What if we say the Secretary and the Secretary of Commerce should explore? Can we say that?

DR. FERREIRA-GONZALEZ: Do we have an idea how often they would need this advice? I mean, is it something that we need? So that's what I mean. Do we need a different kind of advisory group?

MS. DREYFUSS: Think about this. The USPTO's granting these patents on gene sequences long after sequencing was really easy to do and they were still

granting them up to, what, last year when the federal circuit finally said wait, maybe not. That's a kind of a problem and at the same time as our committee's doing this, there's also a committee exploring how much the PTO should be owed deference by the federal circuit so that when the PTO says something is obvious, the federal circuit would then pretty much have to say, unless there's some clear reason to think it's wrong, we're going with the PTO's decision.

So that kind of thing happens fairly often. Technology is patenting, patenting, patenting. Nobody's saying wait a minute, everything in this field has changed. There's now 10,000 machines that do all of this automatically. You don't need patenting anymore. So that's the advantage of a continuing relationship. So I like the liaison idea.

DR. EVANS: Look. I spelled liaison right.

MS. DREYFUSS: The second time around.

DR. EVANS: With Spell Check. Okay. So what about this? Again, just throwing this out there, I don't know if I've captured what people want. Let me get it here.

The Secretary should explore with the Secretary of Commerce, because that's necessary because of the USPTO, a liaison relationship between this committee and the USPTO which would provide advice about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications in the realm of human genes.

The committee believes experts in the field could help USPTO in its development of guidelines on determinations of non-obviousness and subject matter eligibility in this field, once pending court decisions are --

MS. DREYFUSS: How about provide advice or that would recommend advisors?

DR. EVANS: Okay. So you're saying that this committee would recommend advisors?

MS. DREYFUSS: If the PTO is having trouble identifying people.

DR. EVANS: Forget the liaisons?

MS. DREYFUSS: "Provide advice and identify advisors."

DR. EVANS: "Would provide advice" --

MS. DREYFUSS: "And recommend."

DR. EVANS: -- "and recommend technical advisors" -- I'm losing it here -- "and recommend technical advisors who would provide" -- say what? -- "would provide input about scientific and technological developments related to genetics." Okay.

DR. BILLINGS: You could take the second sentence out.

DR. EVANS: This might go in the report. Okay, so in the report's discussion of this rec.

So what we've got, at this point, is: "The Secretary should explore, with the Secretary of Commerce, a liaison relationship between this committee and the USPTO, which would provide advice and recommend technical advisors who would provide input about scientific and technological developments related to genetic tests and technologies that may inform its examination of patent applications."

It could use a little tweaking, which, we can tweak this so it doesn't sound like William Faulkner on drugs. One bestial sentence, then in the report we would discuss those things.

Do we have approval for this? Approved? Okay. So 6D is the last one. We really are about there. Somehow I spaced this out. Are we done with that?

[Recommendation] 6D, all right. "Federal agencies should provide more detailed guidance regarding the licensing of patents associated with genetic tests. In particular, this guidance should encourage the use of terms in licensing agreements, particularly those with exclusivity, increasing the number of insurers that reimburse for the test or improving the specificity and sensitivity, or examples of milestones that a license could be required to meet, or to earn or to maintain license rights."

So what this is saying is that there should be more guidance about the kinds of milestones that need to be adhered to in terms. Does this rise to the level of a recommendation? Is this something that should be in the report?

MS. DREYFUSS: A different question. What about the recommendations that Sheila started with, about more ways of getting funding for sole-source tests or for poor people?

MS. WALCOFF: I'm reading this differently, as increasing the number of insurers that reimburse for the test; whose responsibility would that be.

DR. EVANS: Yes.

MS. WALCOFF: That's a milestone for the company.

DR. EVANS: Well, that came up with discussions. Again, look what Myriad's done. They've been able to steadily increase the number of payers that --

MS. WALCOFF: I think everybody would like to have more payers.

DR. EVANS: Right, right.

MS. WALCOFF: But all those individual contract negotiations, and I am not sure that we're not reaching, a little bit, into that with something like this.

DR. EVANS: Yes.

MS. WALCOFF: I think what you were thinking of, Rochelle, was related but different on the other side. We don't have a reimbursement recommendation, and that seems to be, to me, the biggest crux of this report.

DR. WILLIAMS: I would say two things. One is,

this specific recommendation isn't specific enough to what the Secretary can and can't do and includes some things that I think the Secretary really does not have. I mean, federal agencies. The only federal agencies would be the ones that are actually under Department of Health and Human Services.

MS. WALCOFF: Which would mean CMS.

DR. WILLIAMS: The other issue is that the report that we have issued on reimbursement, there is no reason why we couldn't include language, as we have done in other instances, that says we have addressed a number of issues relating to reimbursement of genetic tests. The patenting issues that are outlined in this report are another impediment to this, but an overall solution to reimbursement reflecting these previous recommendations is still needed.

MS. WALCOFF: Isn't it direct to the whole patient access issue? I mean, it seems like a lot of this report talked about reimbursement and the resulting challenges in reimbursement on patient access.

DR. WILLIAMS: I'll speak for Sam since he can't speak. He is not fully vetted. I think I'm

vaccinated against what he's not vetted for, but I'm not sure.

The issue from the payer perspective is that they would not equate reimbursement with access. They would say that patients always have the ability to access services if they're willing to pay out of pocket. So then it refers to issues of health and equity, and then you say, well, yes, we understand the healthcare system is inequitable in the way it's currently configured.

Is it our job to solve all the problems of the healthcare system, or are there specific issues here that are very narrow that do in fact impact access and reimbursement?

MS. WALCOFF: It sounded like Medicaid was that issue.

DR. WILLIAMS: I didn't bring this up because I really didn't want to muddy the waters, but the reality with Medicaid is that each state defines its benefits. In the State of Utah, the benefit package says, we do not cover genetic tests. It's not a contracting issue.

DR. EVANS: In many, many states, it is.

DR. WILLIAMS: But in other states it is. I'm

just saying that we shouldn't delude ourselves into thinking that somehow the Secretary can do something in the Medicaid system that is going to fix it.

The other point I would make is that, while Myriad has in some ways solved the Medicare problem, the way they solved it was in a very unique way. They are located in Utah. They went to the Medicare carrier for the State of Utah, and that carrier issued a local medical decision that covered that testing. What they have told every other Medicare carrier is that, because we're located in Utah, this is covered by all Medicare.

DR. EVANS: Well, and I think also what was on their side was that it became more and more clinically useful.

DR. WILLIAMS: Well, I'm not disagreeing with that, but I'm saying that the mechanism by which that reimbursement was accomplished was basically by playing some of the little funny issues about how Medicare's actually administered at the state level. So again to presume that somehow this happened because of a national fiat is delusional.

DR. EVANS: So we've got to get back to 6D.

The question is is there a role for a recommendation, that there is a need for more detailed guidance regarding licensing of patents, about terms in licensing agreements, et cetera, and, if so, does that rise to the level of a recommendation or should this be basically a part of the report?

DR. WILLIAMS: I mean, it seems to me that this is one more part of exploration of what can we do around this and is there guidance needed? So in some ways, doesn't this reflect a general exploration of this that we referenced under Recommendation 3 or whatever? I mean, I'm not seeing anything necessarily unique or new here.

DR. EVANS: That's kind of my feeling. I mean, my feeling is that this is not too different from the previous recommendation, that it could be folded into the discussion of that recommendation.

MS. DREYFUSS: And also, actually, the Recommendation 7 where you're asking for clarification around Bayh-Dole of what licensing terms you can do, so we don't even know yet whether or not we can put forward or we can take forward guidance in this regard.

DR. EVANS: Right. In fact, what that leads me to feel like is that perhaps this should be folded into the report where we discuss Recommendation 7.

How do people feel about that? All right. Sam?

DR. NUSSBAUM: First, I will speak. Marc did a beautiful job in representing a viewpoint of the health insurers, but there is a fundamental issue here that I think needs to be addressed, and that is that if these tests, sole-source or others, become very expensive and they're not covered as benefits, then I think it's important for us to recognize that we have an access issue.

While coverage decisions are generally based on science and on clinical results, I think it would be important, somewhere, to write in a review of whether these tests are being offered to communities, to citizens. I think you can do that without trying to mandate what insurers or what Medicaid or Medicare --

DR. EVANS: Within the report?

DR. NUSSBAUM: I think so.

DR. EVANS: Give me some wording. What would

you say?

DR. NUSSBAUM: I think one would want to look into these. When genetic tests are proven of clinical merit, we would want to be sure that they're provided broadly in insurance policies and in Medicaid/Medicare as payers.

I think one of the debates can be that people can write out preventive services. They can write them out, just as we talked about, and I think you would want to be sure that that is not occurring in a drive for affordability.

DR. EVANS: Yes. So as genetic tests are incorporated into medical care, it will be important to ensure that they are included in --

DR. NUSSBAUM: Benefit structures and coverages by governmental and non-governmental payers and this could be reviewed in a responsible --

DR. EVANS: Governmental and non-governmental payers.

DR. WILLIAMS: And the other thing we could reference in there is in our letter to the Secretary regarding the reimbursement issues, to kind of update

that report and highlight new issues.

One of the things that we did specifically talk about was the opening of the Medicare National Coverage Decision and the Medicare Advisory Committee to evidence-based assessment and so some reference to saying that we've mentioned genetics in this context before and this would be another place where this could be -- again, just reinforcing what we've said in numerous other situations.

DR. EVANS: Okay.

MS. ASPINALL: Can we add a piece here that I had mentioned earlier which is streamlining the process for diagnostics to be able to -- for diagnostic providers to be able to provide -- I don't know if we call it free testing, but testing available to -- well, free testing, for lack of a better word right now, and simplify and streamline that process because right now, as I've heard from physicians at all sorts of institutions, it is considered a kickback. You can't do it and as you described earlier, it's a very cumbersome process today that needs to be streamlined so companies would have the ability to do it.

DR. TEUTSCH: Help us focus. What would the

Secretary -- what are you advising that the Secretary should do? What would our recommendation be? I think the issues --

MS. ASPINALL: The recommendation in the same context of this and reimbursement is to consider -- to explore, understand, and streamline the process for indigent testing.

DR. EVANS: I'm not sure if it rises to the level of a formal rec, but what if, in this discussion, in the report, we put as genetic tests are incorporated in medical care, the importance of ensuring they're included in benefit structures covered by governmental and when -- I guess when not covered, that the mechanisms for providing --

MS. ASPINALL: Well, you can include in there review the relevant mechanisms for --

DR. WILLIAMS: Examine the barriers is what I'm hearing, right?

MS. ASPINALL: Yes. To approval, because it's not only one issue and it's, quite frankly, bigger than genetic tests, patented or not, but this is something that has become more of an issue, particularly -- and

this was two of the letters that came in to say there's been perceived criticism directly here, saying they're too expensive.

One of the ways to deal with access is to allow this to happen.

DR. TEUTSCH: Can you write some language?

DR. EVANS: That would be great. Could you write something that could go in the report, because I'm not sure how to do that right now.

MS. ASPINALL: Yes.

DR. WILLIAMS: It fits within the exploration piece, because there are a number of different pieces that roll into this. It has to do with STARK and STARK II.

MS. ASPINALL: That's exactly the issue.

DR. WILLIAMS: It has to do with the statutory things. I know it's statutory for its rules within Medicaid, that to say, here is what you can or you can't do in terms of discounting.

DR. EVANS: I mean, this sounds like a laudable goal. The thing I wonder about is, is it at all unique to genetic testing? It sounds like a very overarching

thing.

MS. ASPINALL: Well, several of our recommendations are not unique. We talked about genetic exceptionalism, I think, three days ago when we got into this room.

DR. EVANS: Come up with something.

MS. ASPINALL: Not specific, but it's relevant to the reimbursement piece.

DR. TEUTSCH: It's related to the sole sourcing issue, right?

MS. ASPINALL: I used it as a sole sourcing issue because it's often used as an example of why sole sources can't do it, but, quite frankly, it's relevant more broadly when you have an indigent patient and you have a test you want to get done.

DR. TEUTSCH: So help me here.

DR. EVANS: Are we talking about charity care?

MS. ASPINALL: I would describe it more broadly and I know patient advocates would not call it charity care. It's for people for whom, for whatever reason, whether they're insured or not, do not have access to the test and for the companies and laboratories, academic,

university and otherwise, to have a streamlined process to do it, and to make people aware of what that process is, because unanimously they all complain about that.

Sole-source test is one area, but if the test if $500 at everyone's lab and they can't afford it, it doesn't have to be sole sourced.

DR. EVANS: Okay. So Mara will address streamlining the mechanisms by which labs/companies can provide testing when not covered. Is that right?

MS. ASPINALL: We can work on the language. I think it's just laboratories. It doesn't matter where they are.

DR. EVANS: Got you. Okay.

DR. TEUTSCH: Paul.

DR. WISE: Paul Wise from Stanford. The last two issues relate to more generic equity issues, and I've kept my mouth shut pretty much all day because, as somebody who focuses on disparity reduction, I was content with the conversation focusing specifically on patent issues.

The fact that we're bringing in more generic issues diminishes the equity arguments because it makes

it a peripheral clause within a subcategory on one of the less exciting recommendations.

If we're going to include this, which I think would be fine, then I would suggest in the recommendation a preamble that says this is merely one component of this committee's concern, or set of recommendations for ensuring equity in the provision of genetic-related tests and services and therapies, period.

We would remind the Secretary that earlier reports, like the reimbursement report and other components of equity issues, that have come up in prior things that have not been acted upon are also relevant to this conversation. Then, in an appendix or someplace, list the recommendations that came through the relatively recent reports that address the issue of inequitable provision. Otherwise, my concern is that we're really peripheralizing this issue merely by putting it in in this small way.

So my general suggestion would be to have an intro or a preamble.

DR. EVANS: So we need to go back and rework the wording of the recommendation here?

DR. WISE: Not the recommendation but the set-up of the recommendations, to ensure that the context for this report and its recommendations is really part of a much larger commitment from this committee to equitable provision of relevant tests and services, and reference, if you will, the other relevant recommendations from prior reports that speak to this issue.

Closing Remarks

Steven Teutsch, M.D., M.P.H.

DR. TEUTSCH: I think the hour is late. It seems to me there are a few things.

One is that Jim is probably going to have a busy evening.

Sam, did you want to say something first?

DR. NUSSBAUM: Just again it's because of my newness to the committee and clearly this has been a five-year journey, Jim, that you have led so many of our colleagues on and congratulations, and I would have been voting largely with you, but having said that, at the very beginning there were some really substantive issues, and it seems to me that a minority of the committee and what we heard from public comments are strong views and

they're not nuanced views. They're 180-degree viewpoints that are different.

I guess the question that I have, since these are complex legal issues that are going to be determined in many ways, perhaps in courts, is there room, in past deliberations by this group, in the body of succinct minority representation, to say, here are some concerns that did exist?

Because I think that, while voices have been heard -- we've heard a little bit about balance, we've heard a bit about the evidence -- these are case studies, but the evidence, perhaps, isn't as strong as we would all like, and I just wonder if that's something that would happen or not.

DR. EVANS: I guess this is probably a very long discussion. My feeling is this, we don't issue minority reports in this committee, we hash things out. We try to produce as balanced a report as possible that includes various issues.

I am not in favor of some kind of minority report that then dilutes what we have had a hard-fought battle to achieve consensus on, and I would say have done

so with a relatively decent proportion of the committee that endorses these things. So, no, I'm not in favor.

DR. BILLINGS: Is there a precedent?

DR. TEUTSCH: I mean, the report can talk about some of the challenges and some of the --

DR. EVANS: I think we do. I have been told on numerous occasions that this especially has brought balance, et cetera, et cetera. So I think the place for trying to discuss the controversies is the report.

MS. WALCOFF: Has there been a report before, where you have not had unanimous agreement?

DR. EVANS: Oh, yes.

MS. WALCOFF: Which one? I don't remember one.

DR. WILLIAMS: Oversight was clearly not a unanimous report.

MS. ASPINALL: I thought, in the end, there were no 'no' votes.

DR. NUSSBAUM: I certainly understand that. Perhaps, then it's just writing the final document to include some of those issues in a more direct way.

DR. EVANS: I'm very sensitive to that, and we will do that.

DR. WILLIAMS: Of course, all of the comments and all of the written public comments, the oral public, they are all available in the public record, and they are all associated with the report.

Now, we all recognize that not everybody will read those.

DR. EVANS: But, look, that's the way it goes. I mean, I think we have accommodated diverse viewpoints. We have had an extraordinarily open deliberation process. We have had abundant public comments and we've had time for discussion. I think that you can't make everybody happy, and I think you dilute the purpose of the report if you now start issuing alternate minority reports.

MS. ASPINALL: Jim, I have to disagree with that. I mean, at least what I heard Sam say is not alternate minority reports in any way, shape or form, because the vast majority of the information and the discussion is there. I was parts of much of it, and part of the team was much of it.

I think that there are a couple things. One is, to acknowledge the dissenting views.

DR. EVANS: I think we do that in the report.

MS. ASPINALL: It was not just one, and I think that that's important. I don't see that in the report today. I didn't see it in the summary slides today.

I made a comment earlier that I didn't see the summary slides today truly represent the breadth of view from the public comments, in addition to some factual changes which are relatively small on the piece of it.

I think we need to acknowledge that to ensure that that is represented because, while all of this is public, it's not going to get out and people are not going to read the 101st letter, or even the first letter in there.

DR. EVANS: I certainly think that we can look at the report to try to make sure again, as we've done the whole process through, to make sure that minority opinions are represented. All right? But they are minority opinions and I do not think that we should delay approval of this entire report --

DR. TEUTSCH: Jim, I'm going to step in here because I'm not hearing people say that we should delay approval of the report or the recommendations.

What I'm hearing is that some people do not feel that some of these perspectives are represented as well as they might be, not that they need to carry the day -- we've had the discussions -- but as we go through and finalize the report, that we make sure that some of these perspectives are clear and incorporated.

I would ask those of you who hold those minority reports to provide us the specific places where you think they don't come out clearly enough --

DR. EVANS: With specific wording.

DR. TEUTSCH: -- so we can do that, because at the end of the day, we do want people to feel like their voices have been heard and are recognized.

And so, I would ask you to please help us with that because I know Jim, to the best of his ability, has listened to this committee, the Task Force, to try and do that. If it is not coming through clearly, please help us do that in specific ways so that we can move it forward.

MS. ASPINALL: I appreciate that, because I think Jim has listened, but it was written as the majority, which is the intention.

DR. EVANS: This also gets very convoluted because the insertion of certain statements can then change the entire thrust of the report, which then makes the recommendations paradoxical. We have to be very careful.

DR. TEUTSCH: No, no, no, no.

MS. ASPINALL: Let's issue a majority opinion. That's what holds is a majority opinion, but you see what is the logic that says there's a different way to think about it. We're not saying changing the sense of the report. It is pages and pages and pages.

DR. EVANS: As long as we can do it without making the report a disjointed and self-contradictory entity, that's fine.

DR. TEUTSCH: No. I think we can do that and I hope we can.

MS. ASPINALL: I think therefore having it almost separate is actually a better way to do that, but we can do it as an integrated one.

DR. TEUTSCH: There may be notes at the bottom. The committee took note of other opinions. There are ways that we can do that.

DR. EVANS: Right. And these were discussions we had at Task Force meetings over and over.

MS. ASPINALL: I recognize there was much discussion about it. I acknowledged at the beginning it wasn't that there wasn't much discussion. It's just that the final report, if anything, as one of the public comments made, had hardened in a position that had fewer broader issues discussed.

DR. NUSSBAUM: It strikes me that critics and criticism will be muted if in fact the issues are shared.

DR. EVANS: I completely agree. I would maintain, and I've had a lot of feedback, that it is balanced. Now, if we can achieve greater balance, that's great. I'm all for it, but I just don't want to gut the report or, essentially, start over.

DR. NUSSBAUM: Jim, let me be straight. Again, I read this with a fresh set of eyes, not the five years of intense -- I think it's extremely well done. As I said, there's clarity. Look at the way the vote has come down on the recommendations.

I think from what I've heard from the public comment, and as I read it, I thought there could be,

particularly since it was case study method, not pure science, there could be a reflection of other viewpoints in it, not mitigating at all the impact of the final discussion.

DR. TEUTSCH: All right. We are being told we must leave because they're using this room for another function tonight. So those who are going to the dinner tonight, it's at 6:30. Let’s meet in the lobby at 6:15.

Jim, if we can get a revision of things we can look at tomorrow. Yes, we're going to come back and review the draft that we had.

Finally, take everything with you.

[Whereupon, at 6:02 p.m., the meeting was recessed to reconvene the following day.]

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CERTIFICATION

This is to certify that the attached proceedings

BEFORE THE: **20th Meeting of the Secretary's Advisory Committee on Genetics, Health, and Society (SACGHS)**

HELD: **October 8-9, 2009**

were convened as herein appears, and that this is the official transcript thereof for the file of the Department or Commission.

SONIA GONZALEZ, Court Reporter