

**Continued Discussion and Consensus on Releasing
Public Consultation Draft Report for Public Comment**

DR. TEUTSCH: If not, then we will move back to the primary topic of the day. I think our discussion will be informed by many of these perspectives from our presenters.

Folks, we have about 1.75 hours to get through all of the recommendations.

DR. EVANS: If you want a break.

DR. TEUTSCH: If you want a break. Otherwise we could be here until seven or eight.

Jim and colleagues have done a great job of leading us through a complex area this morning, but we do need to get through the recommendations. We have to get to an approval of a draft for public comment. We don't need it perfect. We need it in such a way that we can at least get it out and solicit opinions. So we will be minimizing the wordsmithing and dealing with the big issues so that we can work our way through this this afternoon.

Jim, having done a masterful job earlier, you are on again.

DR. EVANS: During the break we added a very brief preamble to that policy recommendation that we had discussed earlier saying that HHS should develop a set of principles and guidance in order to facilitate the following. Then we went through those to try to make them more action-oriented.

As we proceed, again, I would emphasize that these are draft proposals to go out. They can be amended later. They can be adjusted later as part of the whole process.

The next one would be having to do with, again, advocacy efforts by these stakeholders. "Professional associations involved in technology transfer policy and practice should embrace and promote the principles reflected in Best Practices, as well as the Nine Points to Consider," that are well known in patent circles.

"They also should 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 forge consensus positions with respect to gene patenting and licensing policy."

So again, although this is in the general nature of an admonition, it does have more granular recommendations in the sense of articulating more specific conditions for exclusive and non-exclusive licensing. Comments?

[No response.]

DR. EVANS: Steve, you must have said something.

DR. TEUTSCH: Lunch was our friend.

[Laughter.]

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DR. EVANS: Everybody has diverted their flood of comments. Regarding transparency, this general issue of opacity, "Holders of patents on genes, genetic tests, and related technologies, including academic institutions and companies, should make their patent licenses or information about their licenses, including such factors as the type of license, field of use, and scope on those patents, publicly available."

Mara.

MS. ASPINALL: Explain what that means? Does that mean that they may have a patent but let the patent information be available to everyone?

DR. EVANS: No, I think it is focusing primarily on the licensing issues. They should make the licenses, including such factors as the type, the field of use, and scope, publicly available. One of the real difficulties in this whole process is figuring out what the parameters are around specific licenses.

MS. ASPINALL: So this means the financial factors?

DR. EVANS: Well, no.

MS. ASPINALL: Just who it goes to and who has the license. So, beyond gene tests.

DR. EVANS: Again, field of use, scope. Yes, the test itself.

MS. ASPINALL: I'm trying to understand the benefit of that.

DR. EVANS: The problem is patents are public records. You can find them. But it is very hard to get information on licenses. That is a problem for several reasons. One is, it is difficult to assess how various agents are acting with regard to exclusivity, non-exclusivity, et cetera.

Number two, it creates problems for developers to know who are they violating license agreements with, et cetera. In that sense, it adds cost. Trying to shed some light on the general licensing landscape would facilitate both being able to assay the field for problems that are occurring for adherence to guidelines, like best practices, but also, presumably, would help in developing tests and commercializing tests because you would know what the landscape was out there that you were dealing with.

That was it, I think. Anybody else on the task force tell me if there is.

MS. ASPINALL: For the patent holder, they would list everyone they have licensed it to, in theory, and then it would be transparent for those who are not licensed. It would also be clear that they are not one of the licensees.

DR. EVANS: Yes. And, field of use, et cetera. Marc.

DR. WILLIAMS: The question that I have from, again, the perspective of what we can advise as a Committee is --

DR. EVANS: Where are the teeth.

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DR. WILLIAMS: Yes. I think it is a desirable thing. I think that there would be a lot of value to that. But what ability does the Secretary have to be able to do this. What legal landscape is there. Are there precedents in other industries.

DR. EVANS: That is what we will get to with these subsequent recommendations. This is more, again, in the nature of general principles, as in that first one.

DR. WILLIAMS: Maybe this would require a fair amount of rewriting, but it seems to me that it would be useful for the discussion to say we are in the "whereases" right now. I think it would be easier in terms of discussing this as a draft going out to almost frame it as such to say here are our principles of belief, whereas, whereas, whereas, and given that here is our recommendations.

If you read these as recommendations, obviously it raises questions just like I asked.

DR. EVANS: That is a point well taken. We were talking about that at lunch. Like in that first one, I think we need to revamp these a bit and say here are some basic principles that we feel are reasonable basic principles, and that, where possible and by mechanisms possible, HHS should facilitate these things.

"As a means to enhance public access to information about the licensing of patents related to gene-based diagnostics, the NIH should amend the Best Practices for the Licensing of Genomic Inventions to encourage licensors and licensees to include in their license contracts a provision that allows each party to disclose information about their licenses, including such factors as type of license, field of use, and scope."

This actually goes beyond the general principle aspect. We can renumber these or restructure these in that sense. This is more of a directive or a recommendation that says the Best Practices, which was presumably released for a reason, should be amended in order to address those specific things which we find are perhaps lacking.

"The Secretary of HHS should seek statutory authority to enable the Food and Drug Administration and the Centers for Medicare and Medicaid Services to require patented DNA-based in vitro diagnostic tests, whether offered as a test kit or a laboratory-developed test, to display on product packaging and/or company/provider websites the issued patent and published patent numbers that the company or provider owns and controls and reasonably believes covers their product or patents licensed by the company/provider in order to market the product."

In other words, labeling. This is designed to shed some light on the general field and ensure that the information about patents and specifically licenses is readily obtainable. Mara.

MS. ASPINALL: I have a question. I don't know where this came from. Is this consistent with how drugs and devices are done today?

DR. EVANS: I believe so.

DR. BILLINGS: Why is this necessary? What is the background and necessity for such a disclosure?

DR. EVANS: The background is that, as evidenced by the case studies, it has proven very difficult to determine, given a specific gene or given a specific test, what the license landscape is surrounding that. Again, for those same purposes of looking for adherence to things like best

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practices as well as for purposes of test development, et cetera, we were attempting to come to mechanisms that shed some light on this and make it approachable and easy for individuals to figure out what licenses, patents, et cetera, apply to a given test.

DR. TEUTSCH: Steve, do you want to answer the question about current labeling practices?

DR. GUTMAN: Yes. Currently, not only is labeling blind to the issue, actually our pre-market review process, at least in devices, is blind to the issue. So we would be happy to clear or approve something that was intensely litigated, as long as it was safe and effective.

[Laughter.]

DR. GUTMAN: I assume that this recommendation is based on an understanding of that, because they are actually not suggesting we do this under existing law. They are actually suggesting statutory authority. If you wanted to make something less onerous, you might suggest that we seek either statutory or regulatory authority.

It is possible that this could be done with a rewrite of the reg rather than with a rewrite of the law. But the deal is, it isn't part of the package we offer right now.

DR. TEUTSCH: That is true of drugs as well?

DR. GUTMAN: I actually don't know. I don't recall ever having seen this information on a drug label.

DR. TEUTSCH: I don't believe so, either. Mara.

MS. ASPINALL: I guess the majority of the Committee thought it was a recommendation to leave in, but I am concerned. As a Committee, we talked about no genetic exceptionalism as part of our last report.

It concerns me that this is diagnostic exceptionalism, which to me is not healthy for the long-term environment of diagnostics or personalized medicine, putting burden on what are today traditionally and have been the lowest-priced interventions in the healthcare arena and the lowest-margin interventions in the healthcare arena, and creating a burden that is not necessary. I am not clear how it corrects access.

DR. EVANS: Two things. I don't think is the forum to decide the pros and cons of this. But I would just say that one could also envision that such transparency would enable test developers to do a more efficacious job of figuring out whether they were in violation of licenses, et cetera. I don't think it is necessarily just a burden.

MS. ASPINALL: Yes, it might be. My concern is in terms of comparability with other parts of the industry, for new start-up companies getting access to capital and public or private access to research dollars, and others. Putting a disproportionate burden on one part of the industry versus others will not help innovation.

DR. EVANS: I think those are things that should come out in the public comments. Marc.

DR. WILLIAMS: I think the other thing to recognize relating to this is we have to be cognizant in the discussion that multiplex testing is going to be a problematic issue. You can imagine in

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terms of the level of burden that if you have a multiplex test you could have a patent and license list that is longer than the labeling.

DR. EVANS: But again, the argument cuts the other way. If you want to develop a multiplex test, you are in big trouble if there isn't transparency in the field and you don't know what is covered by what. The concerns about multiplex testing I think are some of the most powerful in support of this, but again, if people are okay putting this out for comment we can then weigh those various types of arguments.

DR. AMOS: If the object is to make it more transparent, then why put the burden on the company to put it on their products? If you have a multiplex of 100,000 gene segments, the packaging would be as big as the table.

You could do it on the website, but at the same time, if the object is to make it more transparent, then maybe we recommend to the HHS Secretary that some sort of central repository of that information should be made available.

DR. EVANS: Right. But somebody is going to have to put it in that central repository.

DR. AMOS: Somebody is going to have to put it in there and maintain it. That is going to be tough, too.

DR. EVANS: Again, those things can come up as we discuss them.

Filling data gaps. "In order to assess the extent to which gene patent or licensing arrangements may be affecting patient access to genetic tests, HHS should develop a voluntary reporting system to encourage researchers and medical practitioners who order, use, or perform genetic tests to report such access problems. Given that patient access problems can occur for a number of reasons, it will be important for the reports to be verified and evaluated to be sure they can be attributed to the gene patent or licensing arrangements. For example, the reports may need to include evidence of patent enforcement actions, such as a cease-and-desist letter.

"It may be prudent to pilot-test and evaluate such a system through a demonstration program before committing to its full development."

Basically, one of the things we have been struggling with in this process is trying to corral what the perceived problems are and trying to figure out whether those perceptions are accurate. By having such a resource, there could be an ongoing forum that is centralized in order to bring to light things that people thought rose to the level of problems.

MS. ASPINALL: I'm not sure I can rephrase it in real time because I like the first sentence. Again, it presumes access problems as opposed to increased access as a result of this. So when it starts out to say "may be affecting patient access," it could be more or less.

DR. EVANS: We could say "In order to assess whether gene patents."

MS. ASPINALL: I think that has to be more neutral.

DR. EVANS: Yes, that's fine.

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COL McLEAN: I would agree. I think if you are going to focus just on finding the problems you are not going to measure the access. You are just going to measure the problems. You may have really good effects or consequences of certain patents that you didn't anticipate, and so you would miss it.

DR. EVANS: I don't envision this as tackling the whole problem. I do see it, though, as a potential part of increased transparency, trying to again fill some of these gaps that exist.

DR. TEUTSCH: If you go up to the benefits of enhanced access, in most of the systems that we are talking about here do people tend to report problems, not successes? I'm trying to figure out what that means in practical terms.

MS. ASPINALL: I guess in terms of doing the report in a broad way I wanted to encourage people to represent enhanced access.

DR. TEUTSCH: No, I think that part is good. Then we have to figure out how does one capture that. I agree; we do want to do that. What concerns me is you are talking about voluntary reporting systems. It is like safety systems. They don't tell you that, I had a great success and there was no safety problem. They only tell you about when there are issues.

I'm just trying to figure out, if we are going to do that, how do you make that operational, which needs to be, usually, a more proactive approach.

DR. PRESSMAN: If the company people who are here would be willing to disclose something about volume, it would be very helpful for an understanding in so many ways: market size, access, how many people are using it. It could be assured in this process that the data would only be presented in aggregate to help preserve confidential company information.

MS. ASPINALL: First of all, it is not all company people. Most of the patents are actually being held by universities. Some go out to the companies, but lots do not. I think we should just describe it as patent holders.

DR. TEUTSCH: Actually, you can get this information from a good claims data system that actually would tell you what tests were being done.

MS. ASPINALL: The problem is, as we found in the other report, you can't get it because of the CPT code system.

DR. TEUTSCH: Correct. That is all part of what needs to be improved. But if you could move to a system that actually captures it, you could actually monitor that.

DR. EVANS: Perhaps that is something we should consider as another, separate policy option.

MS. ASPINALL: I guess, Steve, in answer to your question -- and I'm not sure I have the perfect wording -- the wording should be more neutral to say filling data gaps and evaluating successes. It shouldn't be focused on looking for only the problems, first of all, in terms of the wording. Then part of the challenge with the public comment period is ensuring that people get out to tell both sides of the story.

DR. EVANS: We can work on the wording a little to try to make it a little more neutral and then allow the public comments to refine it. Yes.

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DR. WILLIAMS: I was just going to say, I heard somebody say maybe a new recommendation relating to the coding issues. I would just say don't make a new recommendation. Just reference where that has come up in previous report and say, we support the previous report's recommendation that coding would fix this problem.

DR. EVANS: That is a really good idea.

Again, in the theme of filling data gaps, "Under Bayh-Dole, recipients of federal grants, cooperative agreements, and contracts are required to report to federal agencies about inventions that result from federally funded research. Such reports are submitted through an online information management system called iEdison. The reports are considered proprietary and are not publicly available.

"NIH also requires recipients of NIH funding, upon election of title to an invention, to report utilization data annually for that invention, including whether and how many exclusive and non-exclusive licenses have been granted, if any.

"Research agencies should explore using summary data from their respective federal fund agreements as a tool to help assess the extent to which exclusive licensing practices of identified patents may play a role in inhibiting patient access to diagnostic gene-based inventions.

"NIH also should explore whether iEdison data could be used to assess whether the licensing of genomic inventions has been conducted in accordance with the NIH's best practices." Yes.

MS. ASPINALL: Strike the word "inhibiting." "May play a role in patient access," so we understand positive or negative.

DR. EVANS: We can do that.

DR. WILLIAMS: Do you have any specific research agencies in mind?

DR. EVANS: No, I was hoping you might. I think that that is something that is going to need to be explored. Which are the most applicable and efficacious ones. We didn't want to get too granular at this point. Why; what are your thoughts?

DR. WILLIAMS: Remembering what Reed has said, the more specific we can make the recommendations to the Secretary, the more likely that they are going to go forward. If we can have some feeling about whether this would best reside with AHRQ or something of that nature, we probably should say something like that.

DR. EVANS: There wasn't any consensus on the task force about that. I think that it is something we could add in here and we could specifically ask for comments about that. That might be reasonable to solicit that type of guidance.

DR. FITZGERALD: Just on that note, the easiest thing to do is put in parentheses after "research agencies," "(e.g. AHRQ and others?)" and let people suggest and give reasons for their suggestions.

DR. EVANS: NIH, I think, is what everybody was thinking of here, which might make the most sense. So we might want to put in parentheses "for example, NIH, AHRQ, and others as recommended."

DR. ROHRBAUGH: Jim, I would just note that iEdison is not required. It is not required that people use iEdison. They may submit by iEdison; they may submit by other means.

DR. EVANS: Would you say it is the most commonly used?

DR. ROHRBAUGH: Yes.

DR. EVANS: What we can say is "through online information such as iEdison." We can fix that.

Thank you.

"More data are needed to understand the landscape of gene patenting and the licensing arrangements that are being used to commercialize the inventions. The Secretary of HHS should develop a uniform system for data collection, including database structure and standardized terminology, or enhance the existing iEdison system and encourage HHS funding recipients to submit more data about inventions that, at the time they are patented and licensed, are reasonably anticipated to be associated with clinical genetic tests.

"The data elements that would be most useful," and then this continues on to the next slide. I will back up.

"1) Whether the licensor of the inventor granted the licensee the rights to make and sell a clinical genetic test or provide a clinical service;

"2) The nature of the licensing agreement (for example, exclusive, co-exclusive, non-exclusive) and for licenses with some degree of exclusivity in the grant, information about the grant of license rights (i.e. fields of use, scope) and whether or not the license has non-financial performance incentives (diligence)."

It would be nice to get rid of some parentheses there.

"3) Patent and license timelines (dates of patent filing, publication, issuance, and license effective dates)

"4) The date of first reported sale of the genetic test or service and the periodic notations of whether the test or service remains on the market; and

"5) If possible, some measure of volume of sales and number of tests or kits sold, even if such sales are not royalty bearing.

"Providers of the data should be consulted about the design of the database, the development of its standard terminology, and their perspectives on the burden and implications of reporting such data."

I will go back now to the first part of this rather long one. Marc.

DR. WILLIAMS: Just a clarification. Is iEdison then under HHS?

DR. EVANS: Somebody help me.

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DR. ROHRBAUGH: iEdison was developed by NIH. It is an encrypted Web-based system that is optional. Many parties use it. Many universities use it. It has been adopted by many other agencies. Most of the R&D agencies in the federal government use iEdison for reporting inventions and other annual data.

DR. WILLIAMS: I guess the question I was asking is, administratively, in terms of the actionable item to revise and standardize iEdison, is that something that does reside under the Secretary's purview. I don't know the answer to that question.

DR. EVANS: Yes, Bob. It sounds like it is.

DR. COOK-DEEGAN: That is my understanding of the history.

DR. EVANS: So, with regard to the data elements, do people have other data elements or do these seem like the types of data elements that are most useful?

DR. FITZGERALD: I have a quick question. None of this, I gather, is now put in the iEdison database; is that correct?

DR. EVANS: That is correct, I believe.

DR. COOK-DEEGAN: Some of it is.

DR. FITZGERALD: That is what I'm wondering.

DR. COOK-DEEGAN: None of us have ever seen it. At least I have never seen it. I'm pretty sure licensing data is in there.

DR. EVANS: To this extent?

DR. COOK-DEEGAN: Not to this level of detail. This part, No. 1, would be. Actually, not the genetic test part. Who the licensee is and the conditions of the license.

DR. LEONARD: From your comments, it sounds like this is not a public database.

DR. COOK-DEEGAN: That's right. It is not.

DR. LEONARD: Sarah is shaking her head no. It can't be a public database. If all this information is in there, who uses it? Do we want to make some recommendation about who should have access to this? Is it researchers by IRB approval and getting a grant? Who uses this? You put it all in there; then what?

DR. EVANS: Let's see. Is that addressed up here? The reports are proprietary, not publicly available. So they can't really be publicly available, is my understanding.

DR. LEONARD: So, who are we creating a database for?

DR. EVANS: I think for the NIH.

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DR. COOK-DEEGAN: You are only asking for gathering of information. I presume there is going to be something about doing something with it and telling the world about what you have found out.

DR. EVANS: Right. I think that the idea here would be that these types of data would be collected under the purview of HHS and would be available for as yet undefined individuals or organizations to analyze it for evidence of problems, et cetera.

DR. FERREIRA-GONZALEZ: There is a recommendation that this is created so HHS can have a periodic review of the data and report that to the public in an aggregate form?

DR. TEUTSCH: Go back to 3B, the last paragraph. There it talks about iEdison could be used to access the licensing and being able to do that assessment, which is really what you are asking about.

DR. EVANS: Right. "Should explore whether iEdison data could be used to assess whether the licensing of genomic inventions has been conducted in accordance."

DR. TEUTSCH: We will need to wordsmith it, but it looks like that analysis could be done out of that.

DR. EVANS: No other elements that people [have comments on]?

DR. AMOS: Jim, are you just trying to get to the point where there is somebody that is overseeing this and getting enough data to make it a report to the public where there is an instance of harm being done?

DR. EVANS: To try to coalesce data. To try to gather data in some centralized way by which problems could be enumerated and discovered.

DR. AMOS: In a way that proprietary information is not portrayed to the general public?

DR. EVANS: Right. In other words, there has to be some kind of firewall there. It is proprietary information. It can't just be a public --

DR. AMOS: Can't you put this all under one recommendation and just say that the HHS Secretary should develop a mechanism to do this, and then outline some of the things that you think are critical?

DR. EVANS: Yes, I think we could. It could be, for example, through iEdison, if that is the most facile way.

DR. AMOS: Without getting into exactly what needs to be done, basically the gist of it would be to create a system for reporting back to the public where harm is being done.

DR. TEUTSCH: But as we have heard, it is not just the harms. It is to understand to what extent these uses that should have been done under the various federal granting processes are actually getting acted on and used. It is to see to what extent they are getting out and being used in a way that is consistent with the guidance that is already out there for good or not so that we don't have to have this discussion again if we don't know this information.

DR. EVANS: Especially as we go on to multiplex testing.

DR. AMOS: Basically, you want somebody to keep track of all this.

DR. EVANS: Exactly. Maybe we need to have a preamble that says it that way.

"The Secretary of HHS should establish an advisory board to provide ongoing advice about the public health impact of gene patenting and licensing practices. The board could review new data collected on patient access problems and assess the extent to which they are caused by enforcement of intellectual property rights.

"The advisory board also could provide input on the implementation of any future policy changes, including any that might emerge as a consequence of this report."

Maybe we should somehow make that the start and change the wording so that makes sense. Good, good. We can change the order of that.

"Federal efforts to promote broad licensing and patient access:

"A) Federal agencies, including NIH, should promote wider adoption of the principles reflected in NIH Best Practices for the Licensing of Genomic Inventions and the OECD Guidelines for Licensing of Genetic Inventions, both of which encourage limited use of exclusive licensing for genetic/genomic inventions."

Now, I would anticipate that people are going to say there are no teeth to this, but I think as we go on you will see that there are some emerging potential teeth. Comments? It is teething.

DR. WILLIAMS: I read through these but now I'm not specifically recalling. But when you say there are no teeth, there are actually huge teeth implied there in the sense that federal agencies reimburse a huge fraction of healthcare costs in this country. If there was something tied to reimbursement for tests relating to adherence to best practices --

DR. EVANS: Right. We don't go there yet.

DR. LEONARD: But it is not really the reimbursement agencies here. It is NIH giving future grants based on how they licensed whatever came out of research previously funded by NIH. That would highly motivate academic institutions.

DR. EVANS: Let me go on with this next one.

"Federal agencies, including NIH, should encourage wider use of AUTM's In the Public Interest: Nine Points to Consider in Licensing University Technology. Point Nos. 2 and 9 are particularly relevant for genetic tests. They state in part that exclusive licenses should be structured in a manner that encourages technology development and use and in licensing arrangements institutions should 'consider including provisions that address unmet needs, such as those in neglected patient populations,' giving particular attention to improved diagnostics, among other technologies." Basically, a request to refine the Nine Points.

[No response.]

DR. EVANS: Either it is uncontroversial or everybody is completely confused.

"NIH should explore whether mechanisms such as patent pooling could facilitate the use of rapidly developing technologies for genetic tests that are dependent upon multiple licenses of patents."

This is one that works its way into every type of commission or committee that has ever looked at this. It usually hasn't gone very far, I think for some of the reasons brought up, for example, by Rochelle. But I do think that there is a lot of interest in patent pools and it is worth at least giving a nod to that or throwing that out there.

"Federal agencies should consider providing more detailed guidance for gene-based clinical diagnostic inventions to encourage academic institutions to use terms and licensing agreements, such as due diligence clauses, to foster the availability and quality of clinical diagnostic tests and thereby reduce the likelihood that exclusivity associated with a license would lead to adverse effects on patient access.

"Taking steps likely to increase the number of insurers that reimburse for the test or improving the specificity and sensitivity of the test and enhancing knowledge of its clinical validity are examples of milestones that a licensee could be required to meet to earn or maintain license rights."

Lori might want to expand a little bit on this. The idea is that licenses are a lever which can be used and that the conditions of licenses can be manipulated, presumably, to create more benefit.

MS. ASPINALL: I understand the principle. Why, in the third line of (D) does it say "Encourage academic institutions"?

DR. EVANS: We had a lot of discussion about the fact that it is academic institutions that issue most licenses because they own most of the patents. Now, it doesn't necessarily have to be made to look exclusively as though this is encouraging academic institutions.

MS. ASPINALL: In a way, it is the other way. We have academic institutions that don't license, and there are some that are inventors.

DR. EVANS: That makes sense. It would be silly to just narrow this down to academic institutions.

MS. ASPINALL: In reality, federal agencies may have more power.

DR. EVANS: I can't recall the exact discussion that revolved around this on the task force conference call, but that is what coming back to me. This had to do with the fact that HHS has power over universities through that mechanism.

MS. ASPINALL: I think we should clarify it either way. My key issue, especially as we are talking about transparency, is not to make an assumption that all companies are in one bucket and all academic institutions are in another, or vice versa. We need to keep it broad. If it is meant to be NIH-granted institutions --

DR. EVANS: I think "patent holders" would be a better term.

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DR. PRESSMAN: The origin? I think the origin is just Bayh-Dole and that preamble that talks about protecting the public against the non-use. That is the origin.

DR. EVANS: That is right. Would it still make sense to say "patent holders"?

DR. PRESSMAN: Sure. They are non-academic grantees.

DR. EVANS: Bayh-Dole doesn't affect them if they haven't used federal funds.

MS. ASPINALL: There are grantees that are not academic institutions. We need to keep it broad.

DR. EVANS: "Patent holders" I think would be good. Marc.

DR. WILLIAMS: One minor thing here, which is just for consistency's sake, would be to replace "quality" with "utility" just so we are consistent.

The second thing is, I would be reluctant to articulate the insurance reimbursement here, because that implies that there is actually a rational process that involves evidence for insurance reimbursement.

[Laughter.]

DR. WILLIAMS: I work in the insurance industry. I can say this, all right? The reality is that the decisions that are made are frequently not related to evidence but are related to contracts and decisions by employers in terms of what they want to cover and what they don't want to cover. So I'm not sure that that adds much to the point there.

DR. EVANS: Couldn't that be a point of leverage?

DR. WILLIAMS: For whom?

DR. EVANS: For individuals who are seeking to maintain or obtain a license. Why exclude that from this?

DR. WILLIAMS: I don't understand how it is a lever. Their business interests are to reimburse as many people as possible.

DR. EVANS: Right. But if they are unsuccessful for various reasons, this adds more leverage, more pressure. There must be a reason for this. Why is there not third-party reimbursement.

I understand what you are saying, that their business interests are generally aligned.

DR. WILLIAMS: But I'm saying the tying of performance to insurance companies' decisions where those insurance company decisions do not rest solely on the evidence around a given test or product is really not fair.

It is just not fair. If an employer says we are not paying for genetic tests, they are not paying for genetic tests. It doesn't matter if it is a good test, bad test, or indifferent test. They just don't pay for it.

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DR. PRESSMAN: If I could just make a case why it is good to maintain an option. Arguably, perhaps the public is better served this way than they are by an infinite number of non-exclusives, where perhaps no one has an incentive to go up against a recalcitrant insurer. This way, if you got four or five players under co-exclusive, maybe you actually have an incentive. Maybe this would be good for the public.

DR. WILLIAMS: I think we are mixing apples and oranges here. I really think that that is an issue of coverage and reimbursement. It is not an issue relating to patenting.

I think you are trying to get at the fact that we want to accumulate evidence that that is a good thing and making a stronger case for clinical validity and utility is a good thing. There are a lot of people that are going to come along and say, yes, this is something we want to pay for because it is a good thing.

I don't know. I just don't understand the mechanism of this relating to an action item.

DR. EVANS: I have two responses. One is that we could put in there "for example" and then we could let things fall out as people make comments.

My other question would be that many aspects of criteria that licensing might be pegged to are not completely under control of the individuals doing the test. For example, improving specificity and sensitivity. To some extent, that is a simple biological and technological obstacle that might not be able to be improved.

I think that to some extent the devil would be in the details of those particular parameters that the licensing is pegged to. I'm not sure that it is that different from those others.

I think we should have it in there and then have this out at the meeting where we decide. See what the public says. See what people weigh in. If it makes sense to take it out, then do it. But I think that there is at least some feeling around the table that it is worth leaving in for now. Mara.

MS. ASPINALL: I would agree.

DR. EVANS: Why don't we leave it in for now. You can make your case when we meet again.

DR. WILLIAMS: That's fine. What I want at the next meeting when we make our case is, define for me the mechanism of how that would work. I need to understand how measuring insurance reimbursement relates to licensing. Talk about the devil being in the details. I just don't understand it.

DR. EVANS: We will talk about that.

DR. FITZGERALD: Could we just say that we will address in specific the retort from the person in Utah who is going to write in about this?

DR. EVANS: I don't think we should be quite that detailed.

Now, licensing policies governing federally funded research to facilitate access. This is why NIH is focused on this.

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"NIH should explore the feasibility of making compliance with the NIH Best Practices for the Licensing of Genomic Inventions as an important consideration in future grant awards."

This is where you start to get into some explicit teeth. The NIH has promulgated these guidelines or best practices, but they are sitting there. What we would be saying is, let's use them.

"The Secretary of HHS should request an executive order clarifying the authority of HHS under the Bayh-Dole Act to ensure that the goals of the statute are being fulfilled in the context of genetic diagnostic tests in the manner reflected in the NIH Best Practices for Licensing of Genomic Inventions.

"The Secretary of HHS should request an executive order clarifying the authority of HHS under the Bayh-Dole Act to require a grantee or contractor to offer only non-exclusive licensing of DNA-based inventions for diagnostic fields of use, for example, by making the requirement a term and condition of award."

MS. ASPINALL: I don't know where to start.

DR. EVANS: Remember, before you say anything, these are a range of options that are put out there. We are not really debating the merits of implementing these at this point. We are just saying, okay, are these reasonable to go out as a range of options. They are certainly ones that have been discussed.

MS. ASPINALL: But as we get to them, and in my looking at them, I'm not sure it is fair to call them a range of options. We don't have options on the other end that say they should ensure that for most innovation and quickest access that all licenses should be exclusive.

DR. EVANS: We could do that if you want.

I think that we already have a system in which people are free to engage in exclusive licensing. Do you think it is more than just a rhetorical device to put in something saying we should make all licenses exclusive?

MS. ASPINALL: Two pieces. I'm not sure it is fair to say it is a range of options in terms of a full range. It is a range on one end of the spectrum.

DR. EVANS: It is a range. We didn't say a full range.

MS. ASPINALL: It is not the full range, which I respect. I'm not saying it has to be, but I don't think it is a full range of options from A to Z.

DR. EVANS: We didn't say it was.

MS. ASPINALL: You said "a range of options" a few times, implying that.

DR. EVANS: If the public wants to say everything should be exclusively licensed and we get an avalanche of comments like that, then I think we should consider that.

MS. ASPINALL: I'm sure we will consider whatever the public says on either end of that.

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One question I would have is, is there any comparable regulation, executive order or otherwise, where HHS would step in and say how --

DR. EVANS: Under Bayh-Dole you can. It is in Bayh-Dole that there are provisions for march-in.

MS. ASPINALL: Right. But to this extent and requiring only non-exclusive --

DR. EVANS: I think there are more dramatic examples of this. Look at the Ganske-Frist bill. Rochelle.

MS. DREYFUSS: I understood the range of options to be the range of options that flowed out of what the case studies show. What the case studies show is that exclusive licensing is sometimes a problem. The case studies don't show that non-exclusive licensing is a problem. So it seems to me that it makes a lot of sense to say that maybe we should put more teeth into the guidelines.

I think there has also been evidence that hasn't been picked up explicitly in the case studies but implicitly, where universities have a tendency to give exclusive licenses without really thinking hard about it. These guidelines have existed for a while now. These Nine Points have existed for a while now. The better universities, who are licensing non-exclusively, don't seem to be having a problem with that.

Yet there are still some small universities that just don't seem to have the backbone to go up against the companies that want exclusive licenses. If this does nothing else, it will give these universities the option to say, we are going to lose our grants if we give in to this. I think it stiffens their spine in a way that the case studies suggest they need.

MS. ASPINALL: I guess I would say two things. One is, I will go back to not clarifying and generalizing small and large, backbone or not backbone. There are small universities that have had a lot of backbone and won or lost, and there are some very large universities that have said they don't want to go there. I don't think it is the size.

MS. DREYFUSS: No, I agree with that.

MS. ASPINALL: It is a leadership and a discussion within the university for them to make their decisions.

MS. DREYFUSS: I agree with that.

MS. ASPINALL: So I don't want to generalize it. But as you describe what is in there, I take offense to generalizing based on how they do it. HHS can certainly do it for the grantees and contractors, but I think the issue is to provide access, not necessarily on how they provide that access. I was more comfortable one step back on the last one that says access is a key issue, not telling them how to do their business.

DR. EVANS: That's fine. People are going to have different opinions on this, and that is why we are putting these out there.

Just before we move on to the next one, I would agree with what Rochelle said. I think these do flow from the lessons we learned. People are free to submit other ideas.

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Another possibility that we can engage in that is on the table is we do nothing. We may in the end feel that everything is working fine and there are no future problems and we don't have to do anything. That is in the nature of possibility.

MS. ASPINALL: That is what I was going to say. To me, the case studies said there were sometimes problems, sometimes there weren't problems.

DR. EVANS: But again, I would amplify what Rochelle said. I don't think we saw anywhere that, "Boy, exclusive licensing is the way to go." We didn't see any evidence there are lots of problems from non-exclusive licensing and that there are lots of benefits from exclusive licensing.

MS. ASPINALL: I thought in the BRCA versus HNPCC we saw that, did we not?

DR. EVANS: Not at all. Anyway, we need to move on.

MS. DREYFUSS: I think we should change it to put in a presumption of non-exclusive licensing. There might be some places where the costs of developing the tests are really, really high.

DR. EVANS: That is a very good point. I have been trying to figure out how to work that in. Kevin.

DR. FITZGERALD: Sometimes I get the impression what you are saying is that we would like to do No. 1 and No. 2 and No. 3 and No. 4 and No. 5, and other times you are saying we would like to do A or B or C.

DR. EVANS: Right. We experimented with that in the task force. That is why I made that over-the-top admonition at the start to remember that many of these will be mutually exclusive.

DR. FITZGERALD: All I'm doing is clarifying for the public which ones are "or" and which ones are "and."

DR. EVANS: It is not even that simple because there are recommendations in No. 2 that wouldn't be compatible with something in No. 8. It is not a simple or/and in close proximity.

What people have to understand, and we are going to take great pains to illustrate this at the start, is that some of these recommendations are mutually incompatible. We recognize that. But our job, when we meet again after public comment, will be to reconcile and make sure that they are internally consistent. Marc.

DR. WILLIAMS: I just wanted to point out for (B) and (C) here that we have in many of our recommendations asked for clarification of statute in terms of what really falls under the purview of HHS and what doesn't. I think that these are very appropriate. I don't see these as necessarily loaded because I don't think clarification of authority means that there is then a will to exert authority that is defined.

I think we do need to understand where HHS can operate within its scope and where it is really out of scope.

DR. EVANS: I agree. This has been a nebulous black box.

DR. WILLIAMS: Exactly. These are very important recommendations, from my perspective.

DR. ROHRBAUGH: Jim, I would just point out my concern is that, in (C), the Best Practices don't say "Never exclusive license." It says the exclusive license should be tailored. There may be cases where a very narrow exclusive use, like exclusivity for a proprietary format that the company already has, would not be objectionable.

DR. EVANS: I think that is a really important point. I think Rochelle's issue of presumption might get to that. But I couldn't agree more.

DR. WILLIAMS: And for all the rare diseases.

DR. EVANS: Right. That is the classic example.

"The Secretary of HHS, in collaboration with other departments, should commission a study to evaluate and compare how federal agencies have managed government-owned DNA-based inventions with diagnostic fields of use," again to look at how these things have been used.

"The Secretary of HHS, in collaboration with other departments, should commission a study of how agencies have interpreted and applied the Bayh-Dole Act with respect to the application of the statute's march-in provisions."

This focuses on USPTO policy and trying to clarify some of the issues inherent in that. "The Secretary of HHS should recommend that the Secretary of Commerce."

So we are recommending that one secretary recommend to another, which I will freely admit is a little bit cumbersome. Let us know if you can think of [another way]. It's just that we can't say something to the Secretary of Commerce, and USPTO doesn't report to HHS. Yet this is a very important issue with regard to gene patents and licensing. I don't know if there is a more streamlined way to do that.

"A) 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 and other proceedings;

"B) Gather together in a manner analogous to the Utility Guidelines non-obviousness guidelines to assist USPTO personnel in examining patent applications on nucleic acids and genetic diagnostics, particularly those applications seeking patent protection for human DNA sequences and/or genes for diagnostic purposes analogous to the Utility Guidelines published in 2001."

I'm going to talk about (C) in a second. So, comments on (A) and (B). Yes.

MR. LeGUYADER: I'm going to comment on (B) that we probably would want to wait for Cubin to come out. I'm speaking on behalf of the Patent Office now. We probably don't have enough information to craft guidelines specifically to tell our examiners what is or isn't obviousness until Cubin comes out, which is really a seminal case.

It is about a broad claim to a gene where the Board of Appeals at the Patent Office said that it is not patentable, it is obvious, using KSR and KSR-style language straight from that decision.

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So we would want to wait to see that Cubin really gets affirmed. Then we will have some really clear guidance on how to deal with the obviousness.

DR. EVANS: It might be, you are saying, that after that case is decided we really wouldn't need something like this?

MR. LeGUYADER: No, I think (B) is a very good recommendation. I think that it would be good to say something about Cubin. The Office will want to craft new guidelines based on the guidance developed from Cubin once that is decided.

DR. EVANS: "After the decision has been rendered in Cubin we should gather together."

MR. LeGUYADER: Yes.

MS. ASPINALL: What is the timing?

MR. LeGUYADER: Oral arguments are coming up this month. I don't know what the Federal Circuit has.

DR. EVANS: Is that going to be in Polly Newman's court?

MR. LeGUYADER: I don't really know off the top of my head. Now, you have Klaussen, which is a diagnostic assay that oral arguments were heard in July and we haven't heard anything yet. It has been almost a year since oral arguments have been heard. Sometimes the CFC will sit on things for quite a while.

Then, for (C), there are really three cases. There is the Prometheus case, Arad-AR AID, and then there is also Klaussen. There are three comments in Bilski that talk about whether or not these kind of assays and diagnostics are truly patent-eligible subject matter. They talk about preemption.

There are really three cases that are currently sitting with the Federal Circuit that have not yet been decided, Klaussen being the oldest. They were probably waiting on Bilski. They were probably waiting for the guidance on Bilski. Those are the three you will want to wait for to develop guidelines. You don't want to develop the guidelines on Bilski.

DR. EVANS: Good. I think we should work those in and say after decisions have been rendered in those cases.

Let's discuss (C) for a moment. For everybody here, Bilski was a recently rendered decision that addresses, somewhat obliquely, the issue of association patents.

Remember, for example, the most famous of these for our purposes is probably the Metabolife case, in which there was a request to grant cert to the U.S. Supreme Court to decide on whether an association of a high homocysteine level with Vitamin B12 deficiency could itself be patented. The court did not grant cert, but a dissenting opinion that was written by [Justice] Breyer said they should have because of the implications, at least in part, for medical diagnostics and for medical practice.

Bilski is a case that was just decided. People in this room could speak more eloquently about it than me. Perhaps Rochelle could. It at least begins to suggest that association patents are not going to be looked on real favorably, but there are other cases pending that might influence that.

I think that there is significant feeling about this in the medical community as a whole. We heard, for example, Mike Watson a few minutes ago talk about how association patents could have a chilling effect on the practice of medicine in general.

I'm just going to give you a quick preview. The next recommendation or draft proposed recommendation is to prohibit association patenting. That is just the background on that for people, if that makes sense.

Are people generally okay with having these out there in the draft proposal? Especially the mentions of those pending cases.

MR. LeGUYADER: I just want to mention one thing. Your very last comment and the next slide talking about prohibiting patenting of diagnostic types of assays, that potentially would have a very chilling effect on the biotech industry. That is really a very large part of their patent portfolio, whether or not they are enforced. That needs to be considered if you are going to go out with this as a recommendation.

DR. EVANS: Yes. We are now actually getting into some of the ones that will prove most controversial and where people will have the most ardently held opinions.

But before we go on with that, it sounds like Mike and Marc.

DR. AMOS: I just think that we need to make sure that the language that we use is something that the Secretary can actually do something with. I don't think he has the authority to change patent law or even recommend necessarily to the USPTO or to the Department of Commerce that they do that. That is a legal matter.

DR. EVANS: I think there are a couple mechanisms by which to do that. One would be a statutory remedy for that. One would be a statute that addresses association patents.

DR. AMOS: When you say "prohibiting association patents," I don't think --

DR. EVANS: We are getting there with the next one. I think developing guidelines is something that can be done. Guidelines can be developed on patentable subject matter in the wake of these cases.

MR. LeGUYADER: Absolutely. We could do everything in this slide. In fact, we are going to. We have our eyes very keenly on the Federal Circuit to see what the decisions are. We are obligated to follow the law based on those decisions. Therefore, we will have to develop guidelines and train our examiners once that law comes out.

DR. EVANS: Now we get into ones that are, again, a little more controversial, I'm sure.

"The Secretary of HHS should work within the administration to encourage support for legislative change." Here is where we are talking about seeking statutory changes. "The following are potential options to consider.

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"A) Prohibit patenting of an association of a particular genotype with a disease or disorder."
Again, I'm not asking whether you think that should be done or not. What we are talking about here is putting that out there for public comment as a possible option. It is certainly one that is out there in the ether. Yes.

DR. WILLIAMS: This just is an operational question for the next time we get together after we receive public comments. I think we can fairly well predict the public comments that we are going to get. We are going to get a lot on one side and a lot on the other side, which means that we are going to be in the position of having to adjudicate those.

So we really don't have a sense about whether this is a good thing or a bad thing going into it.

DR. EVANS: Oh, I think some of us have a sense.

DR. WILLIAMS: Yes, I know that. But I suspect if we went around the table, we would have a bunch of people on one side and a bunch of people on the other side.

DR. EVANS: That's why, from the start this topic, I see as maybe the most difficult and contentious that the Secretary's Committee has addressed. When you think about some of our big topics like genetic discrimination, that was pretty much "mom and apple pie." It was pretty hard for people to get up there and say in no uncertain terms that we should engage in genetic discrimination.

I think that this is difficult. This is very difficult. Very reasonable people have different views on these things. It is going to be hard. I'm not sure how to make it easier, but we are going to have to sit down and figure out what to do.

DR. WILLIAMS: My point is that if we know ahead of time where things sit, which is there is going to be polarization and we know that the public comments are going to be polarized, would it make more sense to pull this out until we can have --

DR. EVANS: Not at all. I think we need the public's comments.

DR. WILLIAMS: No, I don't think the public comment is going to solve anything for us. Are we going to weigh the comments for one side or the other? I think we are just going to see a bunch on both sides. I don't see how that helps us in terms of operationalizing this.

DR. EVANS: Just because we think we know what the public is going to say doesn't mean we know. I think it would be presumptuous of us to come out with a recommendation when we have not asked the public. In fact, it is not the way we can operate.

DR. WILLIAMS: I'm not saying we make a recommendation without it. I'm saying that putting something out there that says our default position is we are going to prohibit all --

DR. EVANS: But I don't know if that is our default position. We haven't had that discussion.

DR. WILLIAMS: It looks like it. That is the issue. You say that "The following potential options are," and the options that you give there are very punitive options. They are not balanced options.

DR. EVANS: How would you remedy that?

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DR. WILLIAMS: That is what I'm saying. We need to decide that before we send that out. We as a group need to decide.

DR. FITZGERALD: One possible remedy would be, like we have done in the past when we have hit these gridlock issues, is to step back and then say, "The Secretary should form a group to look into the issue," providing therefore the variety of options.

DR. EVANS: That is just punting it. We are not going to make a decision.

DR. FITZGERALD: No, we can't. We don't have the stuff to make the decision. Or, just stand up and say that there is gridlock on this. I don't know.

DR. EVANS: I think part of this is trying to get across to the public that this is an option. It has certainly been an option. We are not the first to raise this option, by any means. As you will see in the next slide or two, there are options that are even more inflammatory. But I think that they need to be out there as options. Yes.

DR. KECKLER: Why is this section distinct. It is distinct I think not necessarily because it is controversial. The concern would be what has been raised before about these policy options, which is that they flow from the case studies as potential remedies to that.

Can the same be said of all of the options that are proposed in this section? I certainly don't feel that about the most severe ones. They might be right or wrong, but in either case they don't flow from what the task force has developed in the case studies. I think that that is what raises the concern about some elements at least of this section.

DR. EVANS: I would agree with you that the one that probably flows the least is 7A. Let's come back to that. Rochelle.

MS. DREYFUSS: I think this one does flow very directly from what we have seen. I think one of the things that the case studies show is that patents are not the biggest motivator of doing these genetic tests. The case studies also show that whether there are patents on the basic association or not on the basic association, it is still possible to get patents on the end product, which is the thing that costs the most.

I actually do think that this possibility is raised very much by the case studies. I think it would be odd to put in all these other policy options and not give the public an opportunity to comment on this particular one. This is the one obvious answer if you think that there is any impediment to access to genetic testing.

DR. EVANS: We talked a lot in the task force conference calls about, gosh, should we have this in, should we have that in. One of the things we felt is that if there are things floating around out there that indeed -- as we will see in the next slide or two -- have actually been introduced into legislation, it would be rather remiss of us to not include these in possible recommendations. We are supposed to look at this whole landscape. Joseph.

DR. TELFAIR: Actually, I would agree with the last statement and also with the admonishment that we really need to consider in advance if we can. We already have a device that we have used here, which is a preamble.

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It seems to me that this section begs for a preamble, if for no other reason than as a clarification and a reference back. I think we have a clear understanding where this directly flows from, but by the time you get to this in the review and in public comment, you may not necessarily have that level of recollection and consideration.

For just very practical reasons, I think it is really important to just have this here. You should have options that are going to create some division, but you also want to make it a utilitarian document in the sense that you just don't want people to react to this. You want them to give you a very thoughtful set of recommendations that we could consider.

DR. EVANS: I like the idea of perhaps a preamble that couches this. Debra, I think you are next.

DR. LEONARD: Marc, I think it is wrong to presuppose what responses the SACGHS will be getting back from people. I know in my opinion this (A) would be throwing the baby out with the bath water because we are thinking only about genetic testing. This would really screw up PhRMA, and I don't think we want to do this. There are ways that you can do that without messing up PhRMA.

So you may be surprised at the responses you get back to this 8A even from people who are pro-availability of gene patents for diagnostic testing.

DR. WILLIAMS: I guess the point I'm trying to make is, the position that we are articulating here I think is clearly at one extreme. So, is the intent of this to be deliberately provocative.

DR. LEONARD: No.

DR. WILLIAMS: Let me finish. You obviously have an emotional investment in this. I'm just reflecting as someone that is reading this.

I think I would very clearly look at that and say this is no different than when the Republican National Committee sends me a survey about what I think. It is all in how the questions are asked. If the question is, here is a possible option prohibiting that, I think you at least have to say that we are putting these out as intentionally extreme positions to solicit comment. If we were to do that, then I could perhaps live with this.

DR. EVANS: As I said at the start like six times, this is a range of options. I would ardently tell you that we are not trying to be provocative. Nobody is trying to be provocative. You may find this provocative. Others may find that an exceptionally reasonable policy option.

Again, I don't think that we can ignore policy options that have been discussed that many people perceive as problems. If you look at the association patent issue, these types of things have been discussed a lot.

I would take exception to the idea that we are trying to be provocative. We are not. We are trying to put out a range of options. I completely agree with you that we have to make it very clear to people that this is a range of options, we are not wedded to any of these, and we want to get people's comments.

DR. FERREIRA-GONZALEZ: I think that maybe we can put a preamble, as recommended earlier, that can address some of these issues. But I think we need to offer the range of options and, again, give the public the opportunity to comment on this.

DR. EVANS: Right. Mara.

MS. ASPINALL: Two comments, one on Andrea's comment and going back to the range of options. I still have a problem with that. If we wanted to truly have a broad range of options, one of them should be reinforcing the current patent system and ensuring that exclusive licenses are easily granted and can be used on a regular basis.

DR. EVANS: I think that would be reasonable.

MS. ASPINALL: Then, to me, it is a range of options. To Marc's point -- and naturally, I agree with Marc -- the way it sounds it tacitly implies that this is the straw man that SACGHS is throwing out. I think the survey example is a good one. I actually happen to think it is provocative, but even if you didn't, it implies this is the straw man that we are starting with and this is the base that we are only putting in sand now, not concrete. I'm not ready or comfortable to do that.

DR. EVANS: Would people be okay with putting in an option just like what she said, that we should maintain the status quo in which exclusive licenses are frequently sought?

MS. ASPINALL: That is the middle of the range. The further end of the range is saying to reinforce the system as the best way to get innovative tests.

DR. EVANS: I think that is nuts, but if you really want that in there. I think that would be seen as a straw man. There are very few people who advocate that we should have nothing but exclusive licenses.

MS. ASPINALL: That gets, then, to Marc's other point, made three times today, that I agree with. Are we here to reflect the public view and hear the public view in a way that we have 60/40 or 70/30, or are we here to listen to it and then vote with our own opinions on doing this.

DR. EVANS: Well, I would hope that we are listening to the public for a reason.

MS. ASPINALL: Right. We are listening to the public, but ultimately, if 90 percent of the public comes in with one viewpoint, are we here to represent that we heard 90 percent of the views on one side and say, I feel the 10 percent side but 90 percent of the people came to tell us they disagreed?

DR. TEUTSCH: I don't think we are here at any point to do vote counting of the public or the comments that we get. We are here to find out what we think in our collective judgment is the best way to ensure that effective technologies are available to patients. We should be looking at the range of options and listening to them. It is not a straw poll. If one person has an extraordinarily compelling point of view, we need to listen to it.

But it seems to me that is what we are here to do. Although we represent a broad range of disciplines, I hope nobody in the room feels that they are representing the company they work for or the academic institution they work for. We are here as a group of collective individuals trying to provide our best advice on a thorny set of issues.

We should make sure that the recommendations that we lay out here as potential options are the kind of things that we think are potentially viable and that we should seek comment on. Then, after we have gone through the process, we will have another rich discussion and vote. We just

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need to decide today what are the kinds of things that we want to lay on the table because we think that they are within the reasonable realm of possibility that we are going to solicit comments on.

DR. EVANS: I'm fine if people want to do this. I'm fine having something in here, if that is the consensus, that is more ardent about maintaining the status quo. That is great. I don't want to be seen as provocative. I want to be seen as, we are considering all options.

DR. TEUTSCH: Kevin.

DR. FITZGERALD: In light of what you just said, Steve, and what Rochelle was saying, I think the preamble that we were talking should say, "Looking at the results gleaned from the case studies with the goal," as you just mentioned, "of making these technologies available to patients." Then you just say, "The best option for statutory change is," and then you list your possibilities.

That takes away the idea that you are putting forward something from this Committee as the best option. What you are saying is, here is our list. I don't know if this is the whole list that you would want. But one of them obviously would be to prohibit patenting of association to particular genes. There I think you would have to be clear it is an "or." You would have that preamble.

MS. ASPINALL: You would still have the status quo or something on there.

DR. FITZGERALD: That's right. Yes.

MS. ASPINALL: I'm happy with that compromise.

DR. FERREIRA-GONZALEZ: I agree with that, too.

DR. EVANS: Mike is next.

DR. AMOS: I just want to say, I think there are profound economic implications in all this that have not been taken into consideration. Our colleague said there would be a chilling effect on the biotech industry.

I want to get back to Kevin's comment that maybe we should recommend that a more expert group look at this. With all due respect to everyone's expertise around the table, we are not economists. Perhaps that should be part of the recommendation. What are the really global aspects. To Debra's point, how will our recommendations on diagnostics affect other aspects of the healthcare industry.

I think you have done a great job of taking a look at this from a patient advocacy and laboratory perspective. But I think there are a lot of other things that need to be taken into consideration. For us to really put a stake in the ground and say that these are the only options I think would be a mistake.

DR. EVANS: I think that is in keeping with having a range. I think that ultimately, after we receive public comment, we are going to have to face some hard decisions about whether we come out with specific recommendations or not. That will weigh into it. Did we have sufficient expertise; did we take into account sufficient breadth to make these recommendations.

DR. TEUTSCH: We need to move along.

DR. WILLIAMS: No, I understand. I must admit, though, that I feel much more like Charles feels. This really is a non sequitur because none of the case studies specifically address association patents, even though, as Rochelle says, there are aspects of associations that are within the intellectual property issues in all the case studies.

I think in some ways it just does stick out this way in the sense that if you read all of the preliminary material you wouldn't necessarily come to say this is where we should be.

DR. EVANS: Right. We can talk about this all day. I think your point is well taken. I do think that it does relate to patentable subject matter.

DR. WILLIAMS: I think what we need to do, though, is we need to clarify, again, perhaps within the preamble or perhaps within the text of the report that goes out, why we are picking this out and how that relates to where the associations reside within the case studies.

DR. EVANS: In my mind, what legitimacy it has with residence there has to do with what is patentable subject matter, an issue which, in general, is of great interest to this Committee.

DR. WILLIAMS: I agree. It is just that, for those of us that weren't intimately involved and not living with it, you look at that and you say, where did that come from?

DR. TELFAIR: A quick comment. I would say, in respect to the preamble that is being recommended, we would like very specific comments with specific recommendations from the public so that whatever we get back is very targeted and very clear, independent of what side it goes on.

I would just add that part of the recommendation up to this point is that an appropriate committee be formed to review these. I'm just trying to address the issue related to the breadth of the persons who are going to look at this.

DR. EVANS: In the vein of not trying to be provocative, "Modify the Patent Act as necessary to expressly withhold the right of injunctive relief from patent holders or their licensees who are impeding patient access to a genetic diagnostic test." I think this is probably best seen in the context of the subsequent ones. Then we can go back.

"The Secretary of HHS should work within the administration to encourage support for legislative change. The following are potential options:

"Create an exemption from patent infringement liability for medical practitioners who order, use, or perform diagnostic genetic tests in clinical care. Related healthcare entities should also be covered by this exemption." This is essentially expanding the Ganske-Frist Act to include diagnostics.

The issue of research is one that comes up time and time again as one looks at the patent and licensing landscape. That is what C2 is addressing. "Create an exemption from patent infringement liability for those who order, use, or perform diagnostic genetic tests in the pursuit of research." The only reason those are underlined is to make clear their differences.

"Related healthcare and research entities should also be covered by this exemption."

Again, we are still talking about 7B and these. I think it is very important to craft a preamble that states that this is a range. We are not wedded to this. We want people's specific comments.

In the spirit of trying to adopt what Mara and Marc have said, do you feel that there are other recommendations? Are these unbalanced in your minds? Could they be balanced with other recommendations that are on a different end of a spectrum? What are people's thoughts about these?

DR. WILLIAMS: Since it was addressed to me, I will just say that these are much less problematic from my perspective. That just may reflect ignorance on my part.

But it seems that this is not something where we are looking at necessarily opening up the competitive landscape. That would damage industry relating to things in terms of a clinical provision of a test as opposed to a test that is being used for research purposes that might gain knowledge.

I'm not even sure about C1. It makes me worry as a practitioner about what I'm actually liable for as I write that test order form. Am I actually incurring some liability? I don't know. But these are less problematic for me than the previous two.

MS. ASPINALL: I hate to go back to disagreeing with Marc, but first of all, my understanding is that C2 is the current state of events in terms of the use of patents.

DR. EVANS: No. That is a total presumption. It is not explicit by any means.

MS. ASPINALL: But if it is in the pursuit of research, at least until the patent is granted there is no ability to enforce patents.

DR. EVANS: Once a patent is granted, many of those patent holders could, if they chose, eliminate research.

MS. ASPINALL: If it is granted. Not all the patents are granted. So for me, this goes into the same category.

I will go back. I don't mind being provocative, but I think the only way we can be provocative in throwing a straw man out there is if there is a unanimous opinion in the group that that is true to what we would like to throw out there. In and of itself, I don't mind being provocative, but I think this is an inappropriate time to do it.

DR. EVANS: I think these entirely flow from our case studies.

MS. ASPINALL: For me, that is probably the fundamental gap that I see. C1, and actually C2, really just undercuts the whole. Regardless of how you phrase it with association studies, it essentially undercuts the patent system entirely.

DR. EVANS: No more than Ganske-Frist did.

MS. ASPINALL: Except for the separation of diagnostics in a way that says that you cannot --

DR. EVANS: In a way, Ganske-Frist could be seen as being incomplete in the sense that there is an exemption for this type of thing.

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MS. ASPINALL: Yes. But we talked about chilling effect and the ability to not have any reason to be innovative if we create this exemption. Clinical care is basically all patient use.

DR. EVANS: Rochelle.

MS. DREYFUSS: I think there is some confusion in the room. Every single one of these options so far has its place in the law as we now know of it. None of these things are entirely impossible under current law. For example, the association test. Justice Breyer said, I don't think that ought to be patentable, and several of the judges in the Bilski case said, I don't think under current law that is patentable.

It is not like we are throwing out something that doesn't already exist. These two certainly exist. People used to think that there was a research exemption. It is only very recently that the Federal Circuit has hinted that maybe there isn't.

The Supreme Court has already indicated they think the Federal Circuit should rethink that, and the Federal Circuit has itself already said, not in a case but in speeches by the judges, that maybe that case where they said there was no research exemption was special and dealt only with specific things. That is not a general, run-of-the-mill case. As has been pointed out, the clinical care one is just an extension of Ganske-Frist.

So it is not like any of these things are totally new to what people have been thinking. This is all a natural progression from where various justices or judges have staked out their position on what the law is. The question is whether or not we ought to either create a statute about this.

It is also a little bit of a push to the judges to say, look at the studies that we did when you are thinking about what you want to do as a matter of common law. We have some data for you, which I think is very helpful to judges.

MS. ASPINALL: I would agree with that. I don't see these completely coming out of the blue. We can argue as to whether they came directly or indirectly from the case studies. For me, that is not the point. I would agree with Rochelle that these come out of what is there. These are extensions.

DR. EVANS: Right. But that is not what we are discussing here.

MS. ASPINALL: A few minutes ago I was going to make the decision as to whether it would even make sense to go through these in such detail. You could take the philosophy that if we add what Kevin had suggested that these are straw men and meant to be straw men, we are putting them out for comment and SACGHS is not ready to say this is our opinion now. I'm okay with that.

DR. EVANS: We are doing two things. There are possible recommendations in here that, for example, don't make sense. They just don't make sense from a legislative or rules standpoint. The other is, to think of are there things we have missed. We are a small task force. In this process of these conference calls we tried to grapple with these things, but we certainly recognize there may be ones we have missed.

So, in the vein again of being provocative, "The Secretary of HHS should work within the administration to encourage support for legislative change. The following are potential options." Again, we will recraft the preamble to try to make this a little more clear.

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Let me just read these as a unit. "Require the patents on DNA sequences be limited to the utilities specified in the patent, or prohibit patents on DNA sequences for diagnostic purposes, or prohibit patents on DNA sequences."

Now, we had a lot of discussion on the conference calls about whether, for example, D3 should be in here. Our final analysis was not only is it something people have thought of, it has been introduced as legislation in the House. This is not something we can duck. We have to at least discuss this.

I think that there are, again, differences about whether that is too blunt of an instrument or not, but I think that it would be a glaring omission were we not to have that in there because it is already on the table.

DR. FITZGERALD: A quick question. When you say DNA sequences, is that supposed to be limited to human or opened up?

DR. EVANS: Great question. We talked a lot about that.

DR. FITZGERALD: That is why you pay me the money that you do.

DR. EVANS: That's right. That is why you get the big bucks for driving the big rigs.

[Laughter.]

DR. EVANS: Somewhere in the draft -- and we discussed this and I must admit now it eludes me where -- we were going to address that. As I was looking through the draft, I realized that perhaps we did not get that in there.

The task force's general conclusion was that we are talking about DNA and RNA nucleic acid sequences that are related to human health. I don't know what to think about this. This has been kind of a messy issue lurking in the corner and we have about 32 minutes to resolve it.

DR. TEUTSCH: Actually, 18.

DR. EVANS: Eighteen minutes. I don't know. What do you think? Should it include SARS? Should it include human pathogens?

MS. DREYFUSS: It seems to me that what makes this different from other areas of patenting is the inability to invent around. It really, I think, has to do with natural DNA and not with man-made DNA.

DR. EVANS: I think what Kevin is getting to is, does it include non-human DNA like pathogens.

MS. DREYFUSS: That has the same problem. You can't invent around it. If you are going to deal with the pathogen you have to use its DNA. So I would include it. That would be the line I would use.

DR. EVANS: Other comments? John.

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MR. LeGUYADER: First off, personally, I don't like this recommendation for the same reasons that I didn't like the previous one. It will have a chilling effect on the industry.

But if you are going to do this, I think you should probably include pathogens or other DNAs that are associated with disease. But I think you would want to be careful also to craft this so you exclude industrially useful DNA that are used, for example, in micro-organisms to make amino acids or to make a particular protein because it is useful in detergents and so forth.

DR. EVANS: Steve's suggestion is to define it as health-related nucleic acids.

DR. FITZGERALD: A clarification on that, because I know one of the things that is going to come up again. Does that include nutrition and nutritious capacity or content of plants?

DR. EVANS: Maybe "medically relevant."

DR. FITZGERALD: That is why I say it. Try to be as precise as you can.

MR. LeGUYADER: That is a good point because plants are being used to genetically grow and make antibodies. You can use that straight as a vaccine.

MS. DREYFUSS: I guess you can create your own pathogens, but we are not trying to find ways to treat those. It is the things that are naturally occurring that we care about as a clinical matter, things that are used the laboratory to make insulin or to do lots of other clinical activities.

DR. FITZGERALD: I guess my only concern with that is this whole area now of synthetic biology. A group of undergraduates from Slovenia just create a vaccine to *Helicobacter pylori*. That is not a naturally occurring sequence, but it would be a vaccine.

MS. DREYFUSS: Right. I would think that that should be patentable. Making the dividing line medical I think is a bad idea. You do want to be able to create medically relevant products through DNA genetic manipulation, and you certainly want to have patents on those things.

DR. EVANS: That just reminded me of something on the conference call that did address this. By having diagnostic purposes in there, in many ways that solves much of this problem. Diagnostic purposes then would include SARS and the genome of *Helicobacter pylori*.

MS. ASPINALL: But I think if you are going to put this in, you have to put in the third one because the idea of what is diagnostic and what is therapeutic is --

DR. EVANS: The third one would be which?

MS. ASPINALL: "Prohibit patents on DNA sequencing," as opposed to just diagnostic.

DR. EVANS: I think that is the most extreme.

MS. ASPINALL: I much prefer D3 to D2. You separate one part of the industry.

DR. EVANS: That is your opinion.

MS. ASPINALL: Yes, personally. But the idea of looking at it broadly, I think having a line between a therapeutic vaccine and what is a diagnostic and what is a therapeutic [is an issue].

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Somebody made the point before that we are going to be thinking forward to the future. Those lines are going to continue to blur as to how we use a drug as a tracer.

DR. EVANS: Again, those are discussions for later.

DR. AMOS: I think that once you make these rules for DNA and RNA, there is not a big leap to go to proteins and metabolites and all these other things, too.

DR. EVANS: But we are not --

DR. AMOS: I'm just bringing it up.

MS. ASPINALL: I assumed this would include that.

DR. EVANS: Yes. It says DNA.

MS. ASPINALL: But if we use Rochelle's definition, do we assume it is the broader definition of naturally occurring substances?

DR. EVANS: It is DNA sequences.

MS. ASPINALL: So, not protein.

DR. EVANS: Not protein.

MS. ASPINALL: RNA, protein enzymes?

DR. EVANS: I think one could certainly put in nucleic acid. But I certainly think it is beyond the purview of this Committee to now start talking about proteins.

MS. ASPINALL: But, how would it philosophically be different if the next wave of technology is proteins?

DR. EVANS: It is totally different. Look at our initial definitions at the start. We are talking about diagnostic tests that are predicated upon the analysis of nucleic acids.

DR. AMOS: For this report.

DR. EVANS: I actually do think you bring up a point. This should be "nucleic acid sequences" and not DNA because RNA is a major player in this.

DR. AMOS: Jim, I think it might be good to get some sort of legal opinion on how difficult it would be to take the legislation and language that is written on a naturally occurring DNA substance and translate that into other things.

DR. EVANS: But what is the point?

DR. AMOS: Well, everybody might get upset that protein patents are getting in the way of diagnostics.

DR. EVANS: They might, but that is not in our scope. It is not in the purview of this

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Committee.

DR. AMOS: I'm just saying that somebody needs to take a look at how big of a leap it would be to go from one to the other.

DR. EVANS: I think that could be something that we could talk about whether the Committee should discuss. But I don't think it is in the purview of the scope of this task force.

DR. AMOS: Except in the Oversight of Genetic Testing report. We defined a genetic test in that document --

DR. EVANS: That is different. But for very good reasons, I think.

Discussion questions. We have been hammering all this out. Here is the big question. Do you think there should be anything that should be added that is not here?

MS. ASPINALL: We talked about the preamble and showing a broader range of options.

DR. EVANS: Absolutely. Yes. That assumes that we are going to include the broader range, including status quo. I don't think we came to a definitive decision on whether there should be an option that we should encourage exclusive licenses. That seems nuts to me. Is there strong feeling we should encourage that?

[No response.]

DR. EVANS: I think status quo would be appropriate.

So, with the changes we have discussed, should we release this for public comment, with the understanding that it is a draft? We will make that clear. We will get the public comment. It is going to be quite a conversation.

DR. TEUTSCH: Just to be clear, though, we will take the comments we got today, make the revisions, and then, as you say, the task force actually will look at it once more.

DR. EVANS: Yes.

DR. TEUTSCH: Not the whole Committee but the task force will look at it before it goes out.

DR. EVANS: In December, if approved, we will send it out. February through April will be the comment period. April and May will be analysis. Clear your calendars for those delightful calls. June 11th and 12th we all meet again. At that point we will discuss preliminary findings, but it is during the summer of 2009 that we will be revising the draft report. It will be at the October 2009 meeting that we hope to have final recommendations. That will also give some time for some of these decisions.

DR. TEUTSCH: I think it is fair to say that if we get crystalline recommendations that we can agree to in June, that would be great. But we didn't want to tie our hands too much, so we wanted to leave it open until October.

DR. EVANS: Yes, Debra.

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DR. LEONARD: With the public comment invitation, how is that going to be worded? You could say, just comment on what we have written, or is it open to bring other ideas?

DR. EVANS: Yes.

DR. LEONARD: Can people say what their own experiences are?

DR. EVANS: Absolutely.

DR. LEONARD: I think that request for public comment is really critical.

DR. EVANS: Right. Yvette is pulling that out. It is not just "Confine your comments to these particular points."

DR. FERREIRA-GONZALEZ: I think we should encourage people to provide proposals. Be very specific.

DR. TEUTSCH: Page V in the report in your briefing book in the beginning is the note that goes along with it to the public.

DR. EVANS: Right. Tab 3, page V.

MR. LeGUYADER: I can say, having been through the rulemaking process from the Patent Office point of view, I can guarantee you they will comment and they will not be afraid to let you know what they think.

DR. FITZGERALD: Actually, on that note, just building onto past experience -- you can ask Andrea about this, too -- I think you are going to get a huge amount of public comments.

DR. EVANS: I completely agree. I'm sure we will.

DR. FITZGERALD: Going through that is going to take you [time].

DR. EVANS: Thank you. It will be very interesting.

MS. ASPINALL: Can I just ask a question? In the vein of the large questions that we are talking about, are there any other organizations that we want to ask this group that need to be notified?

DR. EVANS: I think that you have basically a long list of whom to target with regard to soliciting comments.

MS. ASPINALL: Maybe just to suggest that this Committee, given that this is a more legal view and a broader healthcare view than some of our other perspectives, could give recommendations on other people to ensure are on the list.

DR. EVANS: Absolutely. We want this widely disseminated for comment. Any ideas that anyone has, public or at the table, please let us know so we can target them.

MS. ASPINALL: That would be great. After the Committee reviews it, when would this go out and start the 60-day time frame?

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DR. EVANS: If you want to go back to those slides. Again, February through April will be the comment period; April and May will be analysis. At the next meeting, we will discuss preliminary findings, except Yvette is telling me we won't be done by that point.

DR. SEGER: We will be mid course.

DR. EVANS: With emphasis on the word "preliminary." Then, a revision of the draft report will be taking place in the summer, and then we hope to have final approval in October.

MS. ASPINALL: Well done. Amidst the controversy, well done.

DR. EVANS: Thank you.

DR. TEUTSCH: Jim and colleagues, a yeoman's job to get us through this. Tremendous.

[Applause.]

DR. TEUTSCH: Many thanks to all of you. I thought that was a very rich discussion and an appropriate one.

We will take a break. Since I think most of the folks are here for the next session, why don't we begin at 25 past. Then we will hear comments from NIST and other agencies about standards.

Thank you all very much.