Patents and Licensing Session
Full Committee Discussion

DR. TUCKSON: We are officially resumed and back in session, and we turn the gavel back over to Debra.

DR. LEONARD: So, Francis, do you want to give us the update on the Genetic Association Information Network IP policy?

DR. COLLINS: Yes, thanks, and I won't take very long, but I thought this would be something of interest to your task force and to the SACGHS as a whole because it's directly relevant to this discussion about intellectual property policies.

I think everybody is aware that GAIN is this public/private partnership which was announced on February 8, which is an effort to provide resources to enable whole genome association studies of common diseases. This is a partnership between NIH, the Foundation for NIH, Pfizer, Affymetrix, and we hope additional funding from other private sector contributors as well.

Basically, investigators can come forward, and they are being invited to do so right now with a deadline of May 9, if they have 1,000 or thereabouts cases and controls of a common disorder. They can come forward with a fairly simple application indicating their desire to have this kind of genotyping carried out. It will go through a peer review process. The genotypes will be determined, and then all of the data, genotypes and phenotypes, but in a de-identified fashion so there are no personal identifiers left, go into a database that NCBI is constructing. That database will be accessible to anybody who signs a user certification agreement which agrees to various things such as not making an effort to identify the individual participants in the original research study. That means the principal investigators and the rest of the world get access to the genotype and phenotype data at the same moment.

Now, obviously, there is a big question here about how will intellectual property be handled. Just to remind you, a whole genome association study means that you are going to see something like 300,000 or 400,000 single nucleotide polymorphisms genotyped for each of these DNA samples. They are basically serving as proxies for the variation in the entire genome based on what HapMap has told us about how genetic variation is organized into neighborhoods, which is to say you don't have to sample every SNP in the neighborhood to know that you found an interesting neighborhood.

So the initial findings of this kind of study are likely to be, if all goes well, associations where you see a particular SNP is associated with disease at some statistical P value that's pretty convincing. But that SNP itself is probably not the causative variant that is responsible for the risk. It's basically a proxy for others in the neighborhood, and a good deal of follow-up work will be necessary to figure that out.

Based on many conversations in both academia and in the private sector, I think it really has been interesting to see just how much consensus has now developed around this. The strong sense is that this is the kind of data that ought to be considered pre-competitive, ought not to be the subject of intellectual property claims, ought to basically be placed in the public domain. Follow-on discoveries that will be in many steps down the line will ultimately lead, we hope, to diagnostics and therapeutics, some of which might very well have appropriate intellectual property value. But this early stage we don't think should fit that description. Again, "we" in this case is a fairly broad group of interested parties who have weighed in on this.

Notice, however, that this does tread into territory which is a bit closer to what things in the past have been claimed as far as patenting, because if you have found a SNP that is associated with the risk of diabetes, with a P value of 10 to the minus 12, then somebody might decide right then and there that that could be a useful diagnostic. Even if it's not the causative SNP, it still carries that statistical kind of association. Weighing the pros and cons of that kind of patenting versus putting this in the public domain, the strong conclusion of this group has been that this ought to be something that is just put out there.

So what you have in front of you, this one-page document, was arrived at over the course of about nine months by a distinguished group, the steering committee for the GAIN project, which consists of three NIH institute directors, myself, Betsy Nabel and Tom Insel, a variety of distinguished extramural scientists, including people like Eric Lander and Mike Brown -- not the FEMA Mike Brown, the other Mike Brown.

(Laughter.)

DR. COLLINS: And the conclusion was that this is really the kind of policy that we ought to try to inspire.

Now, notice that in this circumstance, the people whose behavior you are trying to in some way influence are the users. The users need not be NIH grantees. Many of them won't be. They may be from the public sector, the private sector, they may be international. All they have to do to become a user is to check a few boxes in this certification agreement, but one of the boxes will be about intellectual property.

Because they are not grantees, we don't really have legal authority over them. We could not, for instance, decide that we're going to do a declaration of exceptional circumstances and legally enforce a no-patent policy. But what we can do is exhort them. So what you see in this document is what you would call very strong hortatory language about what is expected of users of this database and language that they will have to certify that they acknowledge in order to look at this information.

So what this basically says is if you are using this data, you are basically accepting it as a gift here, and that it is best left unencumbered by intellectual property claims. If you go to the third paragraph, the first sentence gives some examples of the kinds of things that we expect this data ought to be available for without requirement for licensing. So it includes such things as use of markers in developing assays and diagnostic tools, utilizing single or multiple technical platforms, the use of combinations or markers in multiplex assays, and the use of markers as guides toward identification of new drug targets, all of which we think ought to be applications that are pre-competitive. So this also references the NIH's best practices and research tools policy.

The other thing that we are doing with this study, which I thought you'd be interested in, is to also, as sort of the suspenders -- I just told you about the belt. So the suspenders is that the associations that come out of this genotype and phenotype data will be pre-computed. They will appear in the database at the same time the data does so that nobody will be able to say, well, I did the chi-square and I found that this SNP has a P value of 10 to the minus 9. That will already be apparent as soon as the database goes live. We will also identify what genes are nearby that associated SNP so nobody can say, well, I figured out that it's gene 229, because it will already be identified as in the neighborhood. We might even, if we can do so in an automated fashion, suggest which genes in the neighborhood might make reasonable candidates based on their

known function and the disease that's currently showing the association. So doing everything possible to try to render as prior art in the public domain the sort of obvious first steps. Meanwhile, of course, not trying to say very much or inhibit anything about what follows after this downstream.

Another thing that has been recommended to us by the intellectual property experts who have weighed in on this -- and again, we've had conference calls with people who are patent experts in the private sector as well as here at NIH and in academia -- is that it would be helpful to have some public statements by distinguished scientific experts about the importance of keeping this kind of information in the public domain and not having it claimed. So there is some interest in having publications of that sort put together and published in visible places.

I guess just to finish this little description, if SACGHS, for instance, were to agree that this is the kind of data which, to benefit science and public health, is best kept in the public domain, your comments in that regard might also have some potential influence on the PTO who, when faced with circumstances of this sort, are always sort of looking around to see what do the experts say, should we consider this as something that ought to be patented or not.

DR. LEONARD: So can I ask -- no. Go ahead, Reed.

DR. TUCKSON: Just a quick question. So in addition to its being high-minded and idealistic, is it, in the opinion of the lawyers, scoundrel-proof?

DR. COLLINS: Nothing is scoundrel-proof, especially not in Washington. So you can't be assured of that, and there is no legal enforceability to these particular statements. One would expect, though, that someone who is an obvious violator of this, and that will come to be apparent, might in the next application to NIH be seen in a slightly different light.

DR. TUCKSON: And there's no way, obviously, otherwise you would have done it, for information like this -- the government doesn't have any special opportunity to use its extraordinary influence and clout to say that if you are using -- because this information was developed in significant part by the public taxpayers, there would be the clear enforceable expectation that you are not to gain privately for its use.

DR. COLLINS: If we were to say that, we would be violating the Bayh-Dole Act, although I think that the flavor of what's here very much tries to make that case.

DR. LEONARD: How do you account for existing patents on genes already in this system?

DR. COLLINS: There's not a lot that we can do with this document or this project about patents that have already been issued or others that are about to issue. But the hope would be that this general philosophy, that the discovery of an association with a disease is itself not a discovery that the public benefits from if it is immediately claimed as patented material, might have some influence on what the PTO does in the future. We're powerless to change what's already happened.

DR. LEONARD: I know, but will you have asterisks next to the genes that you name that are the ones that are already patented so people know that they are walking right into a patent thicket if they're going to investigate that P equals 10 to the minus 12 relationship?

DR. COLLINS: Well, I hadn't thought of that asterisk, and you could say that would be sort of up to the person who is going to be doing the next step. I suppose we could do that. I think that's going to happen fairly uncommonly. I mean, again, most of the genes we expect to find here are not going to be ones that people know about. This is for common disease. This is diabetes, heart disease, cancer, schizophrenia. How many genes do you think we really know about that are associated with those common illnesses? I would say maybe 10.

DR. LEONARD: What percentage of the human genome is already patented?

DR. COLLINS: Oh, but not for this application. So if you have a gene that's been patented as a composition of matter because somebody filed an EST on it somewhere down the road, would that in fact prevent somebody from working with that gene for this purpose? If this new data is in the public domain, they are no more or less inhibited than they were before. You could argue they're somewhat less inhibited because the utility of the gene -- that is, its association with the disease -- was not in that original patent and is now publicly accessible. You have to go beyond my level of expertise to be quite sure what the answer to that is, though.

DR. LEONARD: Emily?

DR. WINN-DEEN: So I guess I'm trying to understand if what you're actually asking is to try and move the -- the patent office has already moved back a little bit from we'll just patent something if it's an EST to we'll patent something if it's a gene that's well described to we'll patent something if it's a gene or a polymorphism with some clear utility, as in diagnosis of risk for Disease X. Are you actually hoping that you'll move them back off of that utility claim to a SNP associated with Disease X not being something patentable? And if so, where would you want to move them back to? At what point, then, do you view something -- a test for that? Is that patentable? A drug directed at people carrying that? Where would you sort of like to see that move in the patent office?

DR. COLLINS: I think that's well put. I think NIH has, by a series of guidelines, been attempting to make the case that public benefit, which is our standard for whether something should be patented or not, has not necessarily been well served by claims on genetic variants that are associated with some disease risk, which then lead to exclusive licensed patents on diagnostics. So yes, we are attempting, I think, in a fairly straightforward way here, to move the boundary again a little further, or move the threshold a little higher.

Part of the argument -- again, let's not pass it by too quickly -- is that what you discover in this first pass of a whole genome association will rarely be the thing that is functionally relevant, and in many instances it may not even hold up because, of course, the replication study, if it wasn't a P value of 10 to the minus 12, but maybe it was just 10 to the minus 6, may turn out not to be true, and better not to have the whole place littered up with claims that turn out to be subsequently invalidated.

So again, I think the effort here, with a specific study in mind, is to try to say this sort of stage 1 whole genome pass-through on a number of diseases is going to generate data which is far enough away from public benefit in the way of a product that it ought to be kept in the public domain if that's at all possible. And yes, I think when it comes to diagnostics, the philosophy that this group has very much felt and which is somewhat reflected in this document is that the intellectual property is in the platform. It's not necessarily in the discovery of the association, and if we're ever going to get to the point where multiplex analysis of lots and lots of genetic variants that are associated with prediction of future disease risk is feasible, you don't want those all

tangled up in some thicket of patents that are owned by multiple different individuals, and this is a specific attempt to try to avoid that outcome.

DR. LEONARD: You also end up saving the cost of having every individual investigator do this study which is not cheap to do, a HapMap analysis of all the 300,000 SNPs on a thousand patients and controls -- it's very costly.

DR. COLLINS: And so are the patents. That's another point that I should have made. The other argument to try to discourage this kind of intellectual property claim is that it will be pretty hard to actually have anybody gain much from it, because if you found that SNP in this database and you claim its association, what's to prevent somebody else to claiming another SNP that's right next door that's also associated, because it probably will be? Until you've gotten to the point where you can say, well, that SNP is functionally the cause, which is quite a bit of additional work, are you really going to be able to have broad enough claims to justify the cost of all these patents that all these people will be filing, or is it better to just say let's wait until we get a little further down the road here and really know what we're talking about?

DR. LICINIO: If someone goes to the next step and they just get that finding in one of the adjacent genes that you put there, like in the public domain, and they find a specific variant, that then is part of the (inaudible)? I'm just asking. So let's say there is a haplotype-tagging SNP that's identified with a P of 10 to the minus 12, and you put that adjacent to these, in the vicinity of this particular SNP, there are these genes, A, B, C, that you can either say are relevant to the disease, but you just say what the genes are and the person can put two and two together, and then you go in your own samples and you re-sequence those genes and you find a specific mutation that could be attributable to the disease, is that discovery then patentable? I'm just asking.

DR. COLLINS: I think by PTO's current standards, it probably would be, though raising the question about whether in the long term for public benefit, that's a good thing or not. Now, don't get me wrong. I'm not so naive to think that we're going to have a strong influence on the PTO's decision making about where to set the bar for utility standards. I do think it's useful for the scientific community to say things in this regard. The real reason to bring this forward to you is that what GAIN is trying to do here is to recognize that if the PTO standards stay pretty much the same as they currently are, what steps could we take to try to make sure we don't end up with that thicket of claims on the associations that are going to be coming out of this study and other studies like it in the next two or three years? How can we try to make sure that that information remains as much as possible in the public domain? This is not a foolproof method, as Reed asked the question. It can certainly be got around by scoundrels and legalities. But again, I think this is a way of NIH and FNIH, and Pfizer, who strongly supported this effort, basically putting down the philosophy of why this project is being done and what we hope the outcome will be.

DR. LICINIO: And just going one step further, if you put in the NIH site that people would have access to, if you put the haplotype-tagging SNP and say this variation or a variation in the following genes, and then you put the genes there that could be related to the disease, could someone make a claim if they actually find the specific variation, if you make the site even more explicit and say it's highly probable that a variation in one of these genes here would be associated with a disease?

DR. COLLINS: I think that would depend on the breadth of the claims of the original patent application and the degree to which the patent office allowed those whether then, when you got to the point of having the specific variant, that would be considered an infringement and whether you would have to cross-license or not.

DR. LEONARD: David?

DR. KORN: I think this is a very exciting step forward, and I was just curious. I mean, it may not be proper to answer this in public, but I'm going to ask it anyway. Were other, let's say, large pharmaceutical companies or large biotech companies invited to the party and to date declined to play?

DR. COLLINS: In this public/private partnership?

DR. KORN: Yes.

DR. COLLINS: They're in the process of being invited right now, actually. So that's underway through the auspices of the Foundation for NIH, who are empowered to do that sort of thing, whereas NIH, as you could imagine, is somewhat inhibited in raising such conversations when money is involved.

DR. LEONARD: Francis, thanks very much. This is very exciting, a step in the right direction.

Reed, should we have a discussion as to whether we want to take action in supporting this, or if the committee feels this is a good thing?

DR. TUCKSON: Always concerned about things that have deadlines, and I don't know what the timing is again. As I ask for that, what's the timing again?

DR. COLLINS: I don't think this one is under any great pressure. This is already issued. This information is on the website that you see there.

DR. TUCKSON: First of all, let the record state that this is the first time that Francis has ever brought anything to our attention that does not have a deadline of tomorrow, which is nice.

(Laughter.)

DR. TUCKSON: I would suggest that the committee put this into its deliberative package and then report back out a package of things that work together.

DR. LEONARD: Great.

So I have rearranged the order of the discussion a slight bit, and you can see that the first question to be deliberated by the committee is whether or not you feel that the NAS report addresses the research questions that we had. If so, good. If not, what's missing? Then we'll move on to discussing the second point.

Jim?

DR. EVANS: I think the answer to the first question is no. I think the NAS report is great, but I do think, as you pointed out, there's a paucity of consideration of the clinical implications.

DR. LEONARD: Right, but at this point let's talk about whether it addresses the research questions, and I think that's mostly what the letter that we're recommending to the Secretary addresses, the NAS report itself and the research questions.

So are there other issues? As I stated before, the task force felt that the NAS committee had done a very thorough job of investigating the different options, the types of recommendations that could be made, the research impact, not only for genetics and genomics but also proteomics, and the task force felt that we couldn't add a whole lot more to the work that had already been done.

Do we just go for a vote since there doesn't seem to be much discussion? I mean, is there consensus that the NAS report is addressing most of the research questions raised? Yes, I'm seeing shaking heads. Okay.

So then given that, and given that the NAS report really did focus predominantly on research, do we want to send a letter to the Secretary making some statements about this NAS report?

Emily?

DR. WINN-DEEN: I think if we send some kind of letter it's going to have to be sort of yes, but. So it addresses some things, but here are all the things that we're still concerned about. I think it would be better for us to wait on what letter to send the Secretary until we've discussed all the other stuff as well, and then come back to that.

DR. LEONARD: Okay.

DR. EVANS: I agree with that. I think that we should talk about the other issues and send a two-part letter at one time, instead of sending two halves.

DR. LEONARD: Great. Can you advance the slide one? So the task force reached the conclusion that there were areas that were not addressed in the NAS report. Can everybody shake heads if you agree? Okay. So the question is should we move this gene patents and access or DNA-based patents and access issue from a monitoring standpoint, which is we had this as an issue that was high priority for the committee but we basically left it as monitoring until the NAS report was issued. Do we now want to move it from a monitoring to a working issue?

DR. TUCKSON: If I understand the thesis of the question, it is that given that we think that the NAS report did what it should do and that it has its own cycle of activity, if we were happy with just that agenda, we would monitor. I think what you're asking is given that there is an additional part that was not covered by them, basically the clinical and the economic access, do we then feel, I think is your question, that that's important enough that we want to tackle that on our own?

DR. LEONARD: Right.

DR. TUCKSON: Got it. Now I understand the question.

DR. LEONARD: Can you go one more slide forward? We have identified a number of steps that this committee could take. So it's not like it's sort of theoretical. We have some fairly concrete things that over the next meetings this committee could do, and just so everybody is on the same page, that's following the NIH committee's follow-up to the NAS report, looking at whatever research data has been generated since SACGT basically raised this same question, because there has been research, and we could have those investigators come as panelists, do descriptions of the work. The NAS committee in its own work did identify areas of concern related to clinical practice. So we could either go on their website or talk to them, find out who they spoke with and have those people come and talk with us in the same way. We could also look at the other ways that patents are handled in relationship to clinical practice and economic issues in Europe and in

Canada and Japan since even David said that these countries do have a different system for handling these, and then whether we follow the Supreme Court case or not, it's going to happen.

DR. TUCKSON: As one member of the committee, and I'm going to be listening carefully to my colleagues, I think for me on this, first of all, I'm very happy that we have this whole other area being addressed and that it's got its own train, and we'll monitor.

Where I'm concerned is as we think about the protection of the public. Can we find out the answer to the question does the issue of patenting increase the cost of these technologies, thereby decreasing access to care for people. I keep getting stuck on the notion that as it is, health care costs continue to be costing more and more and more and more and more, and people can't afford this stuff. We went through a lot on the coverage and reimbursement report that really tried to talk about the notion that the context for all of these issues is that genetic technologies and genetic interventions are part of an overall challenge in health care today.

So if it is true, and I don't know if it is, but if it is true that the patenting issue does directly result in unnecessary or preventably high costs for tests, then that becomes an issue that I think I would hope that we would attend to. I think it's unavoidable given what we've already talked about in terms of the coverage and reimbursement issues. But what I'm not sure of, to conclude, is that that is in fact proven yet, because the National Academy committee didn't look at it. So I would sort of start with trying to determine whether or not that is, in fact, a fact and a legitimate concern.

DR. LEONARD: But Reed, I would just point out that cost isn't the only thing that prevents access.

DR. TUCKSON: Right.

DR. LEONARD: If you have a sole provider of a service, that may be more limiting to access than anything that cost would do since when you talk about cost inhibiting access, that's the 43 million or whatever uninsured. That's a different perspective, and it also combines with the fact that from the data we heard this morning, there's evidence that people may not have genetic tests anyway.

DR. TUCKSON: Let me take that as a friendly amendment. I would see both. So I'm saying cost in the sense that if I have the patent on it and therefore I'm going to allow you to build your test, but you've got to pay me double the price of what I normally would have charged, now that's got to be passed off to the poor consumer, paying for the patent, license fee, and da-da-da. That's what I'm worried about. I'm equally worried about the issue that you described. So I would sort of put the ability to control access through limited distribution portals -- you phrased it better than I did. I was saying it's both, worthy of at least exploration, and I'm not making a point that I know that it exists. I'm just raising the concern.

DR. WINN-DEEN: I think we have to face the reality that any time there's a patent, it's going to increase the cost because anyone who is going to use that patented technology, except the patent holder, has to pay a royalty. So even if it's non-exclusively licensed and broadly available, there is a cost. There's also a pretty significant royalty stacking issue in genetic testing. Probably two-thirds of it right now is associated with the platform technology of choice, and the rest is associated with gene patents and polymorphism patents and other things that you need to run the assay, like dyes or whatever.

So the royalty stacking issue is there, and until all these things expire, it's going to be there. So the question, I think, is really just going forward how do we want to manage this? There is the NIH approach of trying to find things first and put them in the public domain, which was the goal with the Genome Project and the SNP Consortium, and now this GAIN Project. That puts a certain amount of things in the public domain, but there are lots of things that are not in the public domain, whether they're genetic tests or infectious disease tests. There's a lot of infectious organisms whose entire sequence is patented. If you want to make a test to any part of that genome, you have to pay a royalty. So it's not something that's unique to genetics, but it is something that is a focus of molecular diagnostic testing.

So I think really what we have to try to get a handle on is do we want to model best practices? Do we want to recommend to the Secretary that, for example, although the Bayh-Dole Act allows NIH-funded researchers to license things, the reality is that the tech transfer offices have absolutely no incentive to do non-exclusive licensing? It's a pain in the butt for them. They have to deal with multiple licensees. It's much easier to do an exclusive license with just one party than to have a non-exclusive licensing program.

So in order to change that practice, because they're going to do the practice that's easiest for them, and they are not the recipient of the grant, they're in some different office, how do we try and change behavior if we're going to allow -- well, we do under current circumstances. Patenting is allowed, and the U.S. Patent Office has certain things that they've said they will accept as patents. So we can work to change what the U.S. Patent Office does, but we also I think have a better chance to change licensing practices within NIH-funded programs and to really try to take up what the NAS study did, which was to use that very slight wording emphasis really to try to force a licensing practice which, to my knowledge, is really out there as a guideline that nobody follows.

So that's just my view as someone who has to do licensing.

DR. LEONARD: Francis, are you responding to Emily?

DR. COLLINS: I completely endorse what you're saying, and that was the motivation for the NIH Best Practices for the Licensing of Genomic Inventions, which has only been out now for about a year. If you look at the article in Nature Biotechnology that came out of the ELSI research grant, Pressman et al., which is focused specifically on licensing practices, it does provide some glimmer of optimism there that, in fact, such practices may be improving a bit, moving a bit more away from the exclusive license for diagnostics, which we all agree has been the biggest problem. But we certainly have a way to go.

I think NIH is prepared, with that document out there, and they ought to bring it to the attention of grantees, and basically while we can't, short of doing a declaration of exceptional circumstances, which in many instances we can't do, we certainly can exhort people to pay attention to this and tell them we're watching.

DR. WINN-DEEN: I can just tell you that I have, on more than one occasion, sent a PDF of that document to a tech transfer office and said you should be following these guidelines, here's what the NIH is recommending, and basically had them totally blow me off.

DR. COLLINS: I want their names.

(Laughter.)

DR. WINN-DEEN: Well, we'll talk about that privately. But I think there needs to be some stronger carrot because there's a disconnect between the research who you interact with as the grantee and their institution's tech transfer office, which has a different set of goals and objectives and workload issues to deal with. Unless we figure out how to deal with that disconnect between what you're asking the grantees to do -- maybe their institutions have to sign on as well as the individual grantees when they get the money and make sure that the tech transfer office is re-trained. But there needs to be something else. There's a disconnect in that system.

DR. LEONARD: So is that something that is not addressed in the NAS report that is a hole? I don't know whether the tech transfer -

DR. KORN: No, we did not address that specifically, I think. But just to clarify, a grant is awarded by the NIH to an institution, not an individual. The institution is the legal recipient and the responsible agent for that grant. So presumably if the institution knows that all of its faculty applicants are making some kind of commitment in their grant application, like the data sharing requirement right now, presumably the institution is aware that it has to enforce that.

I think there is a disconnect in institutions, and I think it's between the academic leadership of the institutions and the tech transfer offices, which in too many places are separated by a yawning chasm. Not all, and you can see that in their practices. The ones where academic values are informing tech transfer, you can see that in some of the institutions, and then you can see others where the practices are problematic and less informed. I'm not sure what this committee can do about that, though.

DR. LEONARD: Jim?

DR. EVANS: I just wanted to point out a couple of things that I think are relatively unique to the genetics field that make the potential public health problems and the access for patients to be magnified in the future, and I think it could get a lot worse. I think it boils down to the fact that right now genetic testing, a major barrier to it is its cost and the fact that there are oftentimes a number of genes that would need to be assayed and sequenced if you're looking at a monogenic disorder, and certainly when it comes to common disorders there will be many genes.

But that barrier is falling really rapidly, and I think that unless we re-think the issue of broad patents with exclusive licenses, we could be locking in a situation where the actual cost of genetic testing is going to be falling, and therefore one could see great access and great utility to this kind of information for patients, and yet there will be this huge barrier because of patents and exclusive licenses.

I think that genetics is one of those rare areas where things actually get cheaper, right? It's like computers. The cost per base pair of sequencing has plummeted largely because of the Human Genome Project, and the thing that really worries me about the current patent atmosphere is that we could lock in a situation of very expensive testing that's artificial that could have an incredible chilling effect on the access to care, and the public health impact, the deleterious public health impact of this could really be magnified.

So I think this is a very important issue for this committee, one that requires more work, and I think that we have to look at the issue of licensing as part of this and not just the patent segment.

DR. LEONARD: Cynthia?

MS. BERRY: I have a somewhat ignorant question but fundamental nonetheless, so I'll ask it. Are we focused solely on patent issues as they relate to genetic tests, or is there any application at all to the development of biologics and other therapies? In other words, gene patents. Are we venturing into that?

DR. LEONARD: Do you mean gene therapies?

MS. BERRY: Yes.

DR. LEONARD: I don't think it has to be. I mean, our mandate is broad enough. Correct me if I'm wrong, Sarah and Reed, but our mandate is broad enough that anything that's controlled by patents could be relevant to this discussion.

DR. EVANS: And it's my understanding that many of the patents that are issued are broad enough so that if the entity that patents it chose to, they could exert tremendous pressure on almost any use of that gene. That's my understanding.

DR. LEONARD: Some of them.

MS. BERRY: On a separate note, while not much can be done with regard to patents that have already been issued, since genetic technologies are new and the human genome was just relatively recently mapped out, we haven't faced this yet, but I know in the drug realm, after the life of a patent or when it's about to expire, there are often legislative efforts to extend those patents. It would seem to me that if the data support the theory that these things are having a detrimental effect on clinical access, outcomes, clinical practice and what-not, then collecting that information would be useful when we get to the point where some of these patents are about to expire, because undoubtedly I would imagine there will be legislative efforts to extend them. If we don't have that information, there won't be much ammunition to prevent that from happening on the legislative front. But if the data don't support that, then carry on. There's not much we could do or should do, I would suspect.

DR. LEONARD: Jim?

DR. EVANS: I have a question, and I don't know the answer to this. That's why I'm asking the question. What data do we have or how could we get data that address the question of cost impact of an exclusively licensed patent? I'm thinking, for example, about the BRCA1 and 2, which I deal with on a regular basis. How would one go about trying to acquire the data to figure out what is the real cost, what is the effect of the patent?

DR. LEONARD: I've given many grand rounds talks on gene patents, and in my talk is some data that relates to this in which we were performing a test and charging $100.50, and we were required then to send that to an exclusively licensed laboratory for $195 per test. So I can't say that therefore it's increasing the health care costs, but that's some data. I know that the BRCA1 testing was thought to be relatively expensive. Did the NIH negotiate -- that was on research pricing for BRCA testing for research purposes. But I think if you did a cost comparison of labs that had previously been doing that test, then the pricing would be less than the Myriad price.

So if this is the kind of data that you're talking about, then that can be gathered.

DR. TUCKSON: I think what I like about the question is, and I keep coming back to it, you have so much more experience than the rest of us do on this. Maybe one of the utilities that we will

have is not only to explore whether this is a concern -- I keep coming back to questioning my own thesis, which is this a concern. But secondly, how would one rationally approach the analysis of it? It could be within the public interest just trying to figure out whether you can, in fact, do that. So I think those are questions that would be contributions that we might make, and it may turn out at the end of the day that it can't be done, which is an important finding, or it's so confused and chaotic that you can't get anything substantive out of it, and number three, you may discover that, in fact, it doesn't lead to problems with access. So I don't want to presuppose the work, but this is a long way to say that I think I'm supporting the thesis that I hear you saying, which is ultimately maybe that's something that we might try to figure out, or figure out what the state of the art is on how do you figure it out.

DR. LEONARD: Right.

Any other comments, questions, concerns?

(No response.)

DR. LEONARD: So can we go back to my original question, which was is this an issue which SACGHS wants to do work on, looking at the impact of patents on access and cost? We may just collect information. There may not be solutions that we could suggest that are under the purview of the Secretary of Health and Human Services, but at least we could get information that might be useful to the Secretary, or to the public, or to other organizations.

DR. KORN: I have to leave and I'm very grateful to the committee for letting me be here for as long as I have today.

I would just like to offer you some unsolicited observation on this. I think trying to change the patent law in the United States is an extraordinarily difficult, low-odds effort.

(Laughter.)

DR. KORN: No, I mean that. It is exceedingly hard to get agreement in the Congress on any changes in patent law, and right now two efforts, one in the House and one in the Senate, to reform the patent statute and the battling over the most technical language is fierce, and I mean really, really fierce. So I think going after patenting is not a profitable enterprise right now.

I do think there are two things you could do or think about. One of them is to focus on licensing practices, as several of your members have said, because if something if patented and widely licensed, then a lot of the access problem goes away, I think. I mean, if you were able to practice the test -

DR. LEONARD: But broadly and reasonably.

DR. KORN: And reasonably, sure, broadly and reasonably, because you can punitively price the royalty to prevent the broad license from having any meaning.

The other opening that you could explore, although it isn't easy, is the amendment to the statute that allows physicians and surgeons to practice medicine without fear of infringement. That is, you can patent a surgical incision, but a surgeon cannot be prevented from using that incision in violation of your patent. There's a protection for doctors, for physicians practicing medicine. That exemption does not include -- in fact, it explicitly excludes laboratory diagnostics.

DR. LEONARD: And biotechnology patents.

DR. KORN: And biotechnology patents. This was done by the biotech industry, obviously, when that law was being written in 1996, I think. You could go back to that and argue that the exclusion of the practices of laboratory diagnostics from that protection was ill considered, and you'd have to be very cautious in doing that because you certainly don't want to violate people's legitimate patent rights. That's a second potential route over this mountain. But a frontal assault on the patent system I really think is not going to be a good use of your time. That's really just some advice.

DR. TUCKSON: Debra, I just want to make sure. I think David does a good job of making sure that we're being precise in our thinking, and I absolutely agree and hope that nothing that I suggested is -- because first of all, it makes my hair hurt as it is on this. So I'm not interested in going after the patent law. It is a matter of, as you said, looking at those kinds of issues, and also shining light on this issue of how does it work, what is the effect. I mean, if you think about it, there is no area in health care today in terms of this not being looked at in terms of medical technologies and those sort of things that people aren't trying to look at. But I don't think anybody is looking, and no one has gotten ahead of the curve on a whole new field of clinical interventions like in this field.

So the idea that we would bring some light to bear on that early -- it's probably arguably already too late, but to bring light at least at this stage I think is an important thing, but definitely not to try to go after the entire patent law.

DR. LEONARD: Right, and in fact there was a bill introduced by Lynn Rivers back in I don't know when, several years back that was targeted at amending the Ganske-Frist law. So there is wording of a bill that's actually available.

So I agree with David completely. I don't think we're going to change the U.S. PTO laws or practices. So where do we go from here?

DR. WINN-DEEN: I think what we should do is probably go back to what you were talking about earlier. To what extent do we want to write a letter to the Secretary? Do we want to just write a letter that says we endorse this report but we think it still falls short and we intend to work on the following areas which we feel were important to our committee but this report really didn't deal with? I think we first should decide if we want to work on this, if we want to put it out of monitoring and into active, and if we do then we can get to some specific action items. If the team doesn't feel like it's the right time to move it from monitor to active, then we should deal with that in a different way.

I personally think that this is the right time to start thinking about where the gaps are in this report and dealing with them, but we do have a couple of other big things ongoing right now, so I don't know how much either staff bandwidth or meeting time bandwidth we have to take on something additional.

DR. LEONARD: Sarah, do you want to comment on that, or not?

MS. CARR: Well, we've always known that it was a possibility that you would take this on, and I think that the pharmacogenomics and the large population studies projects will be hopefully in good shape by June to maybe put those to bed.

DR. LEONARD: And we're done with coverage and reimbursement.

MS. CARR: We're done with coverage. So there is, I think, room for another big project. Now, I think Reed is going to talk about a revisiting of our priorities in June, and that may add some other things to our plate.

DR. TUCKSON: Let me make this proposal.

DR. LEONARD: Do Jim and Cynthia have comments? Are they related to this? Good.

DR. TUCKSON: Okay.

DR. EVANS: In reference to what Emily was saying, I think that there is no huge time pressure as far as getting a letter to the Secretary. I think we could, therefore, certainly tackle this general issue, and I think we could wait to issue a letter, part of which would be that we endorse the specific issues in the NAS report, but here are some other things.

DR. LEONARD: Cynthia?

MS. BERRY: I just pose this question because I don't have a strong feeling one way or the other, but are we the best group to assess and review the data, take in new data, hear from people and make an evaluation of the potential effect of this issue on clinical practice? Is it us? If it's not us, is there somebody better positioned or better qualified to do this type of analysis? I just pose that as sort of a threshold question, because if there's somebody else better suited to this, then perhaps we should continue to monitor and then see if things are being addressed. But if there is no one else out there and it falls to us, then that would advocate for a more active role.

DR. TUCKSON: Maybe one way to do this, and maybe I could propose it this way to give you something to shoot at, is that we would say that this is an issue, this issue of access is an issue of interest to the committee, that we charge our subcommittee to go back and ask the Cindy Berry question, is this something that we should be interested in, how to help us to think about whether or not we are an organization that could look at it, ask our subcommittee -

DR. LEONARD: Reed, could I just interrupt here? It is in our charge to look at this. I believe that that's true, isn't it Sarah? Yes.

DR. TUCKSON: I'm sorry. Yes. So more the sense that is it something that with our expertise, our resource availability, is this something that makes sense for us to try to take on?

DR. LEONARD: I don't think you have to send that back to the task force because I don't think we've had the expertise for pharmacogenomics, we haven't had the expertise for coverage and reimbursement, we haven't had the expertise for large population studies, but we are a deliberative body that can bring experts to provide us with information. Sorry.

DR. TUCKSON: No, no, you're doing good. But I'm going to try to march down a road -- but you're terrific. I think you're right, by the way.

DR. LEONARD: Okay. Sorry.

DR. TUCKSON: So first, though, is this something that we can do? You've already answered it, but we're asking anyway if this is something we can do.

Secondly was what you said. Jim said something -- timing. It was something else. So anyway, secondly is, then, starting to ask the subcommittee how might we approach analyzing these issues.

DR. EVANS: Probably you mean collecting information about what is the impact.

DR. TUCKSON: Exactly. So what would be a battle plan for trying to get our arms around this? What would be the mechanism in asking our committee to start thinking about who might be invited to come, are there places that we might go for information, who would be the kind of people we'd bring forward.

Third would be a sense of what, if anything, just helping us to look at what does the Secretary have available in his armamentarium that would be relevant to this. I mean, what part of the domain of HHS would be important, and then getting those ex officios sort of involved as a part of that.

So really sort of saying to the subcommittee, just to make this more contained, is we are expressing that we are interested, we are expressing that we would like to look at it. We would like to get a battle plan from our subcommittee as to how they might think about us proceeding and then bring that back to us at the next meeting, whereupon we can then start to work it.

DR. LEONARD: We did, and that's the list that's on the board. So that was our proposal for an approach. Now, we could get down to more specifically the names of the people to invite, but that would be planning the session for the next meeting, and the task force certainly can take that on if this is something that the full committee decides they want to do, and I think also asking for ex officio input is extremely important and a valuable comment to see where everyone who sits around this table is.

DR. TUCKSON: I think what I'm looking at, and maybe it's buried in the part about the ELSI program, I think if we could sort of take it down to another level of granularity then, is that what we're sort of saying is we want to know whether or not it is possible to determine whether the licensure of tests based on patents causes there to be a delay or a lack of access for care that's meaningful to people. We want to know whether or not the process of patenting and the stacking, the royalty stacking that Emily talks about, causes there to be -- what is the relationship between that and the costs of this technology, and what is the effect that it has? Is it significant or is it not? What we're asking the committee is give us those kinds of granularity of questions, and then sort of say -- and I'm trying to see if it's up here. You're saying the way you would explore that, the way you would try to get at the answer to that question would require certain inputs. Are those there yet?

DR. LEONARD: We would certainly get input by looking at the data that's been generated since SACGT in research studies that have been done. I think also the NAS committee heard from certain individuals that made them concerned about patient access. So who did they hear from, and can we hear from those people? In fact, those six bullets -- I hate to keep referring to them, but it's one of the most valuable things in the clinical practice area that these were concerns that the NAS committee identified somehow by people that they heard from, presenters or studies that they did or whatever, and that's access to testing for patients, allowing competitive perfection of the tests, facilitating professional education and training, the other research that goes on when

you're doing this clinical testing, independent validation of test results. So they heard from someone, some groups.

DR. TUCKSON: I don't want to monopolize this, and I'm going to try to stop my comments and let the rest of the committee decide how they want to proceed with this because I think I'm getting to be too pushy from my end. I like what you said a little while ago when you said you have experience where you do a test for this amount of money, but you have to send it on to the patent folk and it costs you this amount of money. I mean, that level of specificity is pretty interesting. So it's like how do you capture more of what you are experiencing? Who are the other people who know that? And maybe you're saying that's what they must have heard from to cause them to write those six bullets.

DR. LEONARD: One of the people they heard from was me, and John Meers.

DR. EVANS: One of the other things -- and again, we don't need to get into the nitty-gritty details of it now, but one of the things that makes this so difficult is it's a rapidly moving target. These platforms are changing, the costs are changing, that is going down, more genes are being discovered and attempts at patents. So it's a very difficult -

DR. LEONARD: It would also be interesting to hear from biotech companies who are trying to develop tests who have the patent stacking -- I mean, they are faced, face on, with the patent stacking issue. If you want to create a Jewish panel, you've got to get cystic fibrosis and Canavan and Tay-Sachs, and how much does each one of those cost? I don't know, because most academic institutions will try to fly under the radar screen of the patent enforcers until they're caught. But biotech can't do that because they have to be up front. So that may be where you get at the cost, because more and more companies are putting together tests for FDA approval.

DR. TUCKSON: By the way, Tim, does NIH have any plans to look at this?

MR. LESHAN: To look at the clinical issues you're saying?

DR. TUCKSON: Yes, the things we're talking about.

MR. LESHAN: Not specifically, but I think in the deliberation following up on the IP study, it will be considered. But it's not a major focus. It's the research focus we're going to be looking at.

DR. TUCKSON: Since I've blocked everything up here pretty good, I want to try to see how can we then give the subcommittee a little more focus. The only other focusing comment I want to make is based on what Debra just said, which I thought was pretty good. I keep coming back to the notion that I know I'm not smart enough to know whether this is a problem, and I'm also not smart enough to know whether or not people are behaving inappropriately. I mean, you've got folks who are trying to develop these tests, and they have some business issues that causes them to need some of this protection. So I'm not saying that it's all wrong. I'm just trying to figure out at the end of the day does the result of this system as it exists today cause a problem for people to be able to afford life-saving diagnostic technology. Is this a problem or not? I just simply wanted -- I can't phrase it any more specifically. I want us to determine whether or not this is a problem.

DR. LEONARD: Well, we could also hear from genetic counselors and patients, like we did on the genetic non-discrimination process that we went through, to know whether genetic counselors have -- I mean, one-third of patients won't have the test just because they're afraid of the

information getting to the insurance company or employer. But the genetic counselors must be on the forefront of knowing whether or not they don't have it because they can't afford it or it's not covered by their insurance.

DR. TELFAIR: I actually, like Ms. Berry, have a basic question because this is not an area that I understand. But I'm just wondering, in terms of just gathering information to be able to make decisions, to what degree do you need to go through that process? It seems to me that one of the things is to have enough information to make a decision to influence recommendations. That's sort of the path that we need to go to, and I'm wondering, for those who know this well, is there some idea, at least from the task force, how much information we should be gathering? Because I've heard a lot of discussion and sort of the list of who you can speak to, but it seems to me that even some of the persons at different levels, there are different ways this influences them. You just mentioned genetic counselors, which is on the supply side of things, the clinical side, the practice side. But then there's the question about researchers and other things.

It would help me to make a decision in terms of whether or not we should, to answer your first question. If I had some idea of what you all as a task force were thinking, what level of information do you need to make that decision that you do not already have? I mean, I know this is a tough question. It's just that if you look at the amount of information that you have, the way you can make a decision, is it enough to make decisions where you can come up with some very solid recommendations that this committee can then go over, or do you need additional information?

DR. LEONARD: I think that it is possible to identify problems that patents are creating. The NAS committee, when they did their deliberations and identified fairly and investigated fairly thoroughly the research problems that patents create, they identified some concerns on the clinical side. They really didn't look at the economic side, which, in a sense, what we're talking about on the economic side is really the clinical economics of this.

So there is information out there that can be brought to this committee to inform them about what the basic patent issues are. I mean, I think we'd have to start with a primer of what are patents, what are they supposed to do, who is patenting what in genetics and genomics, what's being restricted, and then go from there about enforcement. So there are patent holders. They have enforced against clinical laboratories and prevented doing testing. There is data out there that's been done by researchers demonstrating the extent of that enforcement issue.

When you get down to costs, I think individual laboratories may have that information. I don't know that it's been compiled in any one area. When you get down to the impact on patients, I don't know how you get to that except through genetic counselors who may be seeing the face of that impact. Certainly biotech companies -- clinical laboratories want biotech companies to do FDA-approved tests. But if they're being prevented and their test kits are so much more expensive than what we can do by in-house-developed testing, then is that an issue that needs to be addressed? Because indirectly it has a cost effect on the clinical testing that can be done. I don't know if there are other areas in medical practice -- I don't know in medical genetics, Jim, if there are issues that are related to patents. I think in genetic counseling there are genetic counselors who can speak to those issues.

DR. EVANS: I think there are huge issues in medical genetics related to patents. I think that the hard part is quantifying it, and I think that will be a difficult task for the subcommittee and for the committee, but I think it's something that we need to tackle, in my opinion.

DR. LEONARD: Agnes?

MS. MASNY: Just as you asked about the clinical impact, I think that sometimes the insurers themselves are people who we might get information from as to actually what is paid for or covered just in view of the cost of some of the testing. I know in the oncology field, the nurses would have information specifically with regard to some of the newer genomic tests, like this oncotype testing that's doing tumor expression profiles. So not just for single-gene things but more broadly genomic types of tests. So I think there would be other health professionals that could respond to that question as well.

DR. LEONARD: I think that's a good point, because genetics is broader than just medical genetics and genetic counselors as it moves more and more into clinical practice.

Chira?

MS. CHEN: I was thinking that we kind of just talked about one side of the issue. There's also the other side. There is a reason why a company sets this price, and we should also know why they set that price before we can tackle the patent issues. I actually had heard about how come Herceptin is being charged the way it's charged, because the amount of time it took for doing the research, going through the Phase I trial, Phase II and Phase III and all that. So they use that to kind of do a calculation estimation of how much is sort of spent around that time, and that's how they charge the price for Herceptin.

Then for the second drug that they came out with, this is about how much we charged for Herceptin and this has even more impact, so that's why they charge X amount more or whatever. So we need to know why companies choose that information before we can decide, in addition to the patent.

DR. TUCKSON: I think that's very important. I would just sort of say that part of the challenge to the committee would be how far to take this to an overall understanding of how they set the charge versus how much to emphasize within that how much does a patent issue or a license issue then affect it. Because let's say at the end of the day the Herceptin price was -- just the normal process of developing it was a million dollars, but they couldn't do it unless they got a license for something that one person controlled because of something they did at the university of who knows where -- and, by the way, that was half a million. That's what I'm trying to discover, is that half a million of the million was because of a patent or license issue. I'm just trying to figure out how it works.

DR. LEONARD: Well, I also don't know whether biotech companies are going to be willing to share or able to share their licensing fees.

DR. WINN-DEEN: I think you could go through the basics. There's the cost to develop the test, there's the cost of physically making it in your manufacturing, there's the cost of getting regulatory approval, and then there's the profit that you need to make to pay back all your investment. I'd be happy to go through that with the committee in general terms, what companies look for when they are trying to make a decision to even start, and I can tell you that if at the end it's not a positive number, that you don't even start.

DR. LEONARD: Cynthia, did you have a comment, or did I get you? No, okay.

Julio, did you have a comment or a question?

DR. LICINIO: I think the issue of the cost is crucial and can affect access and all of that, but I think that the issue that was discussed briefly but I think is even, in my view, more alarming is the issue of validation, because if a designated laboratory has a license for that gene or gene product, and therefore a test, and others cannot validate it, then irrespective of cost -- and it could be that the test is for free. But if there is a lot of error, there is going to be a huge impact on public health.

So you tell somebody that they have or don't have the risk for a disease, which could reach surgery in BRCA, et cetera, and there is an error, it's a huge problem. There is an error rate in laboratory tests, and if you're not constantly doing quality control and optimizing and checking, the error rate begins to creep up. If you had a test that you just had running in your lab and it hadn't been optimized and compared to others, validated and tested, really validated for a long time, there will be errors creeping in over time, even if it was very good to begin with. So how do you address that if the laboratory has a patent and others cannot validate it?

DR. LEONARD: Sylvia?

MS. AU: I just wanted to mention that besides the one-on-one patients that the clinical geneticists, genetic counselors, nurses and other clinical people see, this issue can also have a chilling effect on public health programs, because personally we were going to start a breast cancer counseling program for our low-income women, but because of the patent issue and the cost we could not ethically do that because we could not cover the cost of testing for the women that would accept the testing. So there could be some chilling effects to public health programs, too.

DR. LEONARD: And there was no other way to have the testing done other than through the sole provider.

MS. AU: We did try to negotiate with the company, but they said that there was no provision for us to get a discount for the purpose that we were using it for, for these low-income women, that they could go through some kind of -- there's an application you can go through for hardship, and then it's a gamble whether or not they would get that hardship lower cost testing or not, and we just couldn't ethically do that with our population.

DR. LEONARD: Linda, do you see other kinds of public health impacts of gene patents or DNA-based genomics patents?

DR. BRADLEY: Yes. I mean, I think the one that we struggle with a bit is the ability to collect data, because the data is proprietary and the company has issues about sharing it, some of which are good reasons, and that really frustrates data collection efforts. So that's the one that we've talked about quite a bit.

DR. LEONARD: Jim?

DR. EVANS: One that I hadn't really thought of until just now but I think is the case is that translational research can be thought of in some ways as having a public health benefit, and translational research can definitely be inhibited by this situation because of exactly what Sylvia brings up. You can negotiate a bit lower price for a project, say sequencing BRCA1 and 2, but it takes it from $3,000 per individual to, say, $2,700. It's still very difficult.

DR. WINN-DEEN: I think you have to also recognize that a fair amount of that cost is real cost. You're sequencing 27 exons in both directions.

DR. EVANS: Right, and that's why I completely agree that we have to figure out what is the real cost and all, because people have to make a profit too. It's just that we also would like to keep it from being usury.

DR. LEONARD: I think if the committee wants to take on this as an issue, you have to understand that it's very complex. There are many aspects to it. It's not going to be simple and straightforward. As complex as the large population cohort project has been, this has many, many different aspects to it, and I don't know also whether we want to confine it to a narrower field or whether we want to look at the full impact of DNA-based patents.

DR. LICINIO: Could I suggest that before we even make a decision, do you think that a good way to look at this is would there be a cost benefit? In other words, if we have the best possible outcome of a task force, what kind of impact would that have? If we think that the impact would be something of value, then I think we have something to discuss and to pursue. If we think that even if we put our best effort forward it's really not going to result in very much change in policy or in outcome, then we should think more cautiously.

DR. LEONARD: For people who have thought about this over the years, I think David's statement right before he exited is exactly what people who have spent a tremendous amount of time thinking about this is, to try and achieve broad licensing practices at a reasonable royalty rate, and I don't know if that's something we can influence from this committee, and then the second is to try to amend the Ganske-Frist law to extend that to genetic testing services, which there was some effort in that direction, except Lynn Rivers wasn't reelected. So that has to do with the political system.

So I think there are very concrete things that we may or may not conclude are appropriate actions that may be taken to help remedy problems if we find that there are problems. I mean, I don't want to pre-determine what the committee does because I'm one of those people who have thought about this long and hard and I don't want to drag you all kicking and screaming into something that is not worthwhile to do.

DR. TUCKSON: Well, given that you're trying to moderate this and be the chairperson of the committee, I think that the committee has given you an awful lot of input. I think we're starting to say the same things over and over again, so I think that what we would like to do is to trust in our committee and trust in you as the leader of that committee to take the input that you've received and bring back something to the committee in terms of your next steps. I think you've made some recommendations already in a slide there. I think we're asking you to probably revisit those recommendations and all the input that you've had and can come back and let us know if and how you would like to proceed and give us something to react to, because I think we've given you a lot of thoughts and input. But I don't think right now we're able to formulate for you -- and I'm more than willing, by the way, in terms of the time. We have enough time. If the committee senses that you want to drill a little deeper and give a specific guidance to the subcommittee at any more levels of specificity, I'm more than willing to take the time to do it. It's really the will of the committee. Or would you rather like them to take back what they've got and then reformulate it and come back to you with something? What is the will of the committee?

DR. LEONARD: As Fay is whispering in my ear, and it's very accurate, I think part of the concern here is that many of the members currently on SACGHS weren't part of the

priority-setting process, may not know a lot about gene patents and the issues. So maybe what needs to be done in June is some level of informational session to inform the committee about what gene patents are, some of the issues that you've raised here that you'd like to know about so that the whole committee could have a better background to be able to choose whether or not to go forward on this or not, and the task force could put together an informational session for the committee.

DR. TUCKSON: Just to remind the committee that this has been a difficult discussion, and we like to always have discussions that have an A plus B equals C, leading to a logical D by timeline Z. This is not going to happen in this case. This is complicated and it's difficult. I do want to remind you so that you're not frustrated that the function of the committee, among many things listed, is to examine current patent policy and licensing practices for their impact on access to genetic technologies. So it's right there. It's right in front of us. It's what our charge is, and so we know it's there, and now the question is how to get at it. So if you would come back, that would be great.

So you will have time on the next agenda. You have time to make a presentation, and we can negotiate how much time you want and whether you want to bring speakers, the whole thing that you want to do. I think that's going to be important. So we thank you for taking what is complex stuff and agreeing to come back and make it simple and crystal clear.

DR. LEONARD: Jim and Emily, you're okay with this? Okay.

DR. TUCKSON: Right. Thank you very much for a very good discussion. We really appreciate it.