

Perspectives of the Task Force on the NAS Report and Proposed Recommendations
Debra Leonard, M.D., Ph.D.

DR. LEONARD: Given the time, I think we'll move on to the task force's recommendations and what they did, and then break for lunch, leave you pending, and then come back from lunch to discuss what our next steps should be, what the task force recommendations are, discuss those, and what next steps would be.

DR. TUCKSON: Debra, can I just say one thing while you do that? Is there any presumed timetable for this NIH review of the 13 recommendations?

DR. COLLINS: I was warned not to get boxed into a corner on this, so I will try not to give a really precise answer. I think I can assure you there is great energy and hard work going into this, but it's not one of those things where you can just necessarily pinpoint exactly what steps are necessary to get to the closure. So as soon as we can.

DR. TUCKSON: Debra, obviously, I was just trying to see what the timeline was for that effort, and as you guide us through your analysis what, if any, relationship, sequential versus concentric paths, that activity at NIH is having and what that means for us, which things are sequential and which things happen at the same time.

DR. LEONARD: Right.

DR. TUCKSON: Does that make any sense?

DR. LEONARD: Maybe.

(Laughter.)

DR. TUCKSON: I await your guidance.

DR. LEONARD: So the task force did look at the NAS report, and at this point I want to make a disclaimer in that I am chair of this, and when Reed asked me to chair this I immediately asked him is that like the fox guarding the henhouse? Because I do have very strong opinions about gene patents and the impact that those are having, and I think everyone in this room probably knows that. I am trying to be measured and take a balanced viewpoint, and thus when this task force was being formed I specifically asked Emily, who has an industry perspective, to be on this as well, and Jim Evans volunteered, and I'm grateful for their working on this project together. My disclaimer is that when I was at the University of Pennsylvania I was stopped from doing a number of tests because of gene patent enforcement. I'm no longer at the University of Pennsylvania. I'm vice chair at Cornell, so a little more removed from the actual enforcements.

So our charge was first to review the NAS report and assess whether issues and questions raised by SACGHS were addressed in the report and then determine whether there are areas that warrant further exploration and/or attention by SACGHS. So as background, Sarah and staff, as they are wont to do, brought to our attention that the gene patenting and licensing issue was also raised by SACGT, and there's a quote from SACGT that "Gene patenting and licensing practices may be having adverse effects on accessibility to and the cost and quality of genetic tests," and that was from a November 17, 2000 meeting.

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So SACGT sent recommendations to HHS, and in that recommendation they raised concerns and questions about possible adverse effects on access and that this should be assessed more fully by HHS, and that this may warrant further study by appropriate experts, and they urged HHS to initiate this further study. So the response that SACGT got back from HHS is that they agreed that patents raised important issues that need further exploration. The NHGRI ELSI program was initiating a study to gather further data on DNA-based patents, and the NIH Office of Technology Transfer planned to work with HHS to determine whether further steps needed to be taken. As you are well aware, SACGT was reformulated as us, SACGHS.

In the meantime, there has been NHGRI-funded research on gene patents. There's a Pressman article that was just published in January 2006 that focused on DNA-based patents and licensing practices at research institutions. So again, this article focuses, like the NAS report, very much on the research impact of patents. There are other studies of DNA-based patents that are more related to the clinical aspects or impacts of these gene patents. So one of the things that the committee may want to consider is that there is additional research out there since SACGT has looked at this issue that SACGHS may want to look at and investigate and see what this has to do with health care.

So the first part of the charge was to review the NAS report and assess whether the issues and questions raised by SACGHS are addressed by the NAS report. Basically, the task force is generally supportive of the first 12 NAS recommendations that relate to research issues and focus on ensuring that the public investment in genomics and proteomics is optimally benefiting society. If I can paraphrase the task force's discussions, basically we felt that the NAS committee had very thoroughly investigated the research issues, research and innovation issues, and felt that they had done a very good job of coming to recommendations that really addressed many of the issues, and I think the task force at this point felt like NIH needed a chance to look at those recommendations, respond, and not really interrupt this process.

So recommendations 1 through 11 basically address the concerns related to research, as David outlined for us. Recommendation 12 addresses extraordinary circumstances where the public health is threatened and suggests remedies through the courts.

Recommendation 13 is the only recommendation that relates specifically to clinical practice if you say that 12 is related to public health. We spent a lot of time discussing this recommendation and basically felt that it was untenable as written because if you look at laboratory practice, what this recommendation states is that there should be other laboratories that can validate the test results of a sole provider of a laboratory test. Those other laboratories will not go through the hardship, expense, work of validating a CLIA-certified test that could be used to check the results of a sole provider laboratory when a second opinion is requested. So basically, we felt like this was nice in theory, but when you get down to the implementation of this, it's untenable that laboratories would set themselves up just to give second opinions or to validate results of a sole provider laboratory.

So in reviewing the NAS report, basically none of the recommendations address questions related to the economic impact questions or issues that the SACGHS had raised in its priority-setting process. So research issues we felt were thoroughly investigated, and the recommendations address most of the research concerns that SACGHS had raised. The clinical practice and economic impact issues of concern to SACGHS were not addressed by the NAS recommendations.

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So this is where I was supposed to turn to Francis Collins and he was to tell you that they formed a committee. So since we've done that, I think we will want to also follow up with NIH on what they are doing with this.

So what do we recommend based on this initial analysis? We recommend to the full committee that we convey in a letter to the Secretary of HHS support for the first 12 NAS recommendations, emphasizing those recommendations over which the Secretary has authority to have some effect, specifically Recommendations 1, 2, 3, 4 and 11. In particular, the task force felt that it was important to emphasize or encourage the need to implement Recommendation 4, which is the requirement, this emphasis that David stated of enforcing and monitoring that funded investigators share published materials. And consider recommending that the Secretary use HHS' resources to educate researchers and clinicians on their rights and responsibilities with regard to intellectual property, especially on the lack of a true research exemption as evidenced by the Madey case for use of patented information and materials.

I don't know. At this point we're not going to stop and have discussion about this, but we'll go back to these three recommendations as the initial discussion after lunch. So be thinking about these three recommendations, whether you want to tweak them, change them, throw them out, support them, whatever.

Then the second part of the charge to the task force was to determine whether there are areas that warrant further exploration and/or attention by this committee. The task force basically made three official recommendations, that SACGHS may want to consider exploring issues related to licensing of genomic inventions and its impact on clinical practice, the economic impact of patenting and licensing of genomic inventions, and even get into the issue of the patent thicket or patent pooling, and there's current legislation regarding this that this committee may want to follow that was mentioned in the NAS report.

I want to bring to your attention on page 148 of the NAS report that in this NAS committee's work, they did identify concerns related to clinical practice, and some of these overlap with the concerns that SACGHS had raised, specifically whether or not patents and licensing practices are affecting patient access to genetic and genomic technologies; whether the current patent system allows competition in doing a better test in a better way of identifying genetic mutations that are either more accurate, more cost effective, shorter turn-around time, whatever; IRB-approved clinical research in academic medical centers regardless of funding sources.

I think, and maybe, David, you can comment, that this implies that when you do clinical testing, you also are making new discoveries, particularly in the area of genetics and genomics. There may be additional mutations identified, and can this be inhibited? Professional education and training could be inhibited, independent validation of test results, which is the one that Recommendation 13 tries to address, and then regulatory compliance issues.

So the goals for the discussion after lunch are to discuss and come to consensus on whether to forward a letter to the Secretary related to the NAS report, and whether to include the task force recommendations basically supporting the first 12 recommendations, highlighting Recommendation 4, and suggesting educational efforts for researchers and clinicians on intellectual property issues. Then secondly the discussion would turn to determining also whether the SACGHS research questions are sufficiently addressed by the NAS report.

Then given that the NAS report -- we may want to reach agreement that the NAS report doesn't address SACGHS' concerns related to clinical practice and economic impacts. So we can decide

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whether everyone agrees with that statement. But if so, should SACGHS move this issue from monitoring, where it currently is on our list, to a working issue that SACGHS now wants to do work on, and to facilitate the answering of this question, in doing the work of the task force we basically came up with proposed ways to move forward if the full committee would decide that this was something they wanted to do.

One was to follow the progress of the NIH committee in looking at what they will do with this report and the recommendations; to review data from the research supported by ELSI programs as a result of SACGT concerns, basically looking at the published research that may address some of the either research concerns or clinical practice concerns raised by patents and licensing practices. Since NAS did identify areas of concern, we could potentially hear from the same people that NAS heard from to understand where the concerns came from on the clinical practice issues.

We could also explore the experiences and patent policies of other countries and see if those can enlighten the committee on how to address concerns. Then also, finally, monitor the outcome of the Supreme Court patent case that David was mentioning. Basically, this Supreme Court case is *LabCorp v. Metabolite Laboratories*, and the question before the court is can a monopoly be validly claimed over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result? This does not directly bear on the gene patent issue, but some of the gene patents basically are claiming a mutation/disease relationship, and so there may be a relationship of the outcome of this court decision to the gene patent discussion, and we could follow that and see if it does.

So at this point, unless there are specific questions about our path forward, I think that we'll break for lunch on time and then start the discussion after lunch.

DR. TUCKSON: Dr. Korn has one comment.

DR. KORN: I appreciated listening to Debra's recount of the committee's task force. The only concern I would raise is on the third recommendation, I think, to the Secretary about reminding awardees of the current lack of a robust research exemption. Sometimes it's better to let sleeping dogs lie. I'm not sure that getting the Secretary involved in this issue would be very helpful to the research enterprise. But that's a personal opinion only.

DR. LEONARD: Well, David, I hope that you will remain at the table. I hope you can stay for the discussions after lunch. I don't know if you can.

DR. KORN: I can stay for a while, yes.

DR. TUCKSON: It's a free lunch, David.

(Laughter.)

DR. KORN: There is no free lunch in this building.

(Laughter.)

DR. TUCKSON: I'll pay for it for you.

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DR. LEONARD: So if you are available to remain here for the discussions, at least a portion of them, then you can feel free to chime in on our discussions of the recommendations from the task force.

DR. TUCKSON: By the way, we are breaking for lunch on time, for which I am assuming credit.

(Laughter.)

DR. LEONARD: So noted.

DR. TUCKSON: Return at exactly what it says on the program.

(Whereupon, at 12:30 p.m., the meeting was recessed for lunch, to reconvene at 1:15 p.m.)