Session on Gene Patents and Licensing Practices Opening Remarks
James P. Evans, M.D., Ph.D.

DR. TUCKSON: And Jim Evans, who is up next, shouldn't comment because he's got on a periodic table tie.

DR. EVANS: I wear it periodically.

DR. TUCKSON: Which he wears periodically.

(Laughter.)

DR. TUCKSON: And I think it has some outdated symbols.

By the way, thank you to the committee, and again, I do really hope that Andrea is tuning in or will get a copy of the transcript and know that our thoughts are with her as she recovers from her illness and we appreciate her leadership.

We are now going to move to the session on gene patents and licensing practices. We have some very ambitious goals for that. The task force has put together a roundtable on international patent issues, and we'll hear about some pending legislation on patents here in the United States. This information will inform us as we deliberate about the report and recommendations we will make to the Secretary.

Jim Evans will start us off with an overview of the session's goals, and so, Jim, I turn the floor over to you.

By the way, there is a break scheduled at 10:35. We're a little ahead of schedule, but just know that there is a break scheduled somewhere in there and we'll figure out the most convenient way to do it.

DR. EVANS: Great. I'll try to keep us ahead of schedule.

I think that this is a very timely opportunity to address issues relating to patents and licensing practices. I like to think it represents the prescience of the committee. It might just be coincidence.

But be that as it may, in the past year or so since we decided in a formal way to take up this issue as a committee, there's been a confluence of activity in this. There has been a lot of public attention to the issue of gene patents. There has been a variety of proposed legislation relating to gene patents. In fact, this week the Senate will be marking up a patent reform bill, and this has been a very active issue in the courts.

Now, the committee, as you can see, from a membership standpoint is fairly small, and we've relied very heavily on ad hoc members and agency experts. I want to especially note the return of Emily Winn-Deen and Debra Leonard. They've been very important in this task force and just show the adage that with SACGHS, you can run but you can't hide.

The history of us taking up this issue goes back several years. In the spring of 2004, the issue of gene patents and licensing was slated as a priority issue, but at that time, the National Academy

of Sciences was formulating a report that was going to address at least part of this issue. So we deferred effort on our committee until that report came out.

We formed a small group in the fall of '05 to review the NAS report, and what was noticed, when that report was really looked at closely, is it's a great report. It's very important and informative. But it was really heavily focused on issues of research, on how patents will affect the research climate, how they will affect the ability to pursue things. It really did not have much in it that related to patient access and the clinical implications of the current landscape of gene patents and licensing practices. So the fact that that, of course, is the major focus of this committee -- that is, the public's health -- led us to feel that we really needed more information about that.

In June of '06, we held an informational session and decided to move forward with an in-depth study that would focus again on gene patents and -- you'll notice the two are almost always in tandem when we discuss this -- licensing practices because it's felt by many, I think, that it's there in the licensing aspects of how we deal with patents that might give us the greatest leeway to affect changes, if changes are necessary.

We began long, agonizing discussions about the study scope. So you'll see scope throughout here over the next almost year. And we established the Task Force on Gene Patents and Licensing Practices.

In October, we refined the proposed scope for the study, outlined potential approaches for the study, continued to work on the scope. We got the scope approved in November of '06, but then, as you'll see, we refined it some more. We finally finalized our approach for study at that time.

In the spring of '07, we were fortunate enough to elicit the help of the folks at Duke, and as you can see, in the spring of that year, Duke kind of dominated things, unlike in basketball at that time.

(Laughter.)

DR. EVANS: Being from Chapel Hill, I had to get that in.

In March, we heard some wonderful presentations from the Duke folks and discussed next steps. One of the linchpins of the approach is to try to use what could be vaguely classified as experiments of nature. In other words, are there situations where, for example, one clinically important gene has been patented but another has not, and can we learn from the experience through those examples about the impact of patents because one of the things we began to realize, as we looked closely at this on the task force, is that there's a lot of heat but there isn't a lot of light. There is not a lot of hard evidence and data that really inform us about the impacts of patents on what we're interested in, which is the public's access to these things and the impact on their health.

In March, we got a fantastic primer on gene patents and licensing that I think for many of us was instrumental in giving us the sufficient background and the necessary background to really understand the issues at hand.

In May, the task force discussed next steps and developed speaker lists for the session today.

The session today is going to be dominated by international considerations. Now, before we get to that in just a minute, I want to introduce Pauline Newman, but I also want to explain the task

force's rationale for a focus on international patent issues. I want to assure everyone that the task force is not ignorant of the fact that patents are a part of the U.S. Constitution. We don't have leeway to do whatever we want and we can't pick and choose from the world.

On the other hand, again, harkening back to this idea of kind of experiments of nature, I think that we may well learn some important things about the impacts of patents and as long as we see those lessons, in terms of what is doable and what is not doable in the U.S., I think that we maybe able to learn a lot from the international perspective.

I would also just emphasize that we really do try to keep a focus in this task force on practicality. We're not here to tilt at windmills. We're not here to tell the Secretary that we think certain things should be done that are totally ridiculous and not doable. We really would like, at the end of the day, to come up with a set of implementable guidelines that would help the landscape of patents and licensing practices best serve the public's interest.

So here is the scope. It's short. It fits on one slide, but that belies how much work went into getting it. As we mention the scope, I would just point out to people that one of the challenges for this issue with the committee I think in some ways is unique to other things we've brought up. It is very important, like many of the things we've brought up, but it's also very controversial. The issue of genetic discrimination, at its most fundamental level, was not really controversial. We didn't have people getting up and saying we think we should have genetic discrimination.

On the other hand, there are extremely cogent arguments that people on opposite ends of the spectrum, with regard to patents, bring to bear on this subject. It is very complex and it's controversial for a reason. It's because there are legitimate positions on both sides of the issue or on all sides of the issue.

So the scope of the study that we came to is that we want to look at both the positive and the negative effects of current gene patenting and licensing practices on patient access to genetic technologies. Our ultimate arbiter here is patient access. We want to focus on gene patents for health-related tests. That would be diagnostic tests, predictive tests or other clinical purposes. We have purposely not included in the scope in a really explicit way the issue of patents that lead, for example, to drug development. That is a different area. We are focusing primarily on issues of diagnostic testing and predictive testing.

You'll notice throughout our deliberations that we use two terms. We use "clinical access" and "patient access." Ultimately we are interested in the issue of patient access and that's self-explanatory. Clinical access, when we use it, we're really referring to the ability of physicians to order these tests, the ability of physicians to get these tests done in any kind of practical way. Clinical and patient access are, obviously, extremely overlapping but not identical.

Finally, we do feel that it's important to consider the effects of gene patents and licensing practices on translational research, on getting technologies into the clinical arena.

Here's the study plan that we came to, and I would emphasize that these are not done serially but are being pursued and will be pursued in parallel.

Part 1 is data gathering and analysis through literature review, expert consultations, case studies, and perhaps additional research. This is being spearheaded by the Duke group.

Part 2 is to gather public perspectives. As I mentioned and as you all know, this is an issue with a lot of stakeholders, an issue that a lot of people have strong feelings on. It's going to be very important to solicit public perspectives, to compile and summarize those comments for the Secretary, and hold a roundtable that is a public hearing about these things.

Part 3 is what we are in large part going to do today, which is gathering international perspectives, gathering data. Identifying experts was again spearheaded by the Duke group, the roundtable and analysis of these perspectives. We will need to, in a rather daunting task, analyze and synthesize all of this and come up with a draft report that will be released for public comment and ultimately lead to a final report to the Secretary.

So the bulk of today will be focused on international perspectives, but again, given the rapidly shifting landscape, given the dynamic nature of this subject, we felt that we would like to get some kind of background or update on what the current landscape is.

DR. TUCKSON: You're getting ready to introduce somebody.

DR. EVANS: Yes.

DR. TUCKSON: So let me just pause for 10 seconds. So a couple things I think that are key here.

One is our Duke colleagues -- some of them are here. Right?

DR. EVANS: Yes.

DR. TUCKSON: Who is here from Duke? First of all, we want to thank you very much for your effort.

(Applause.)

DR. TUCKSON: Could you introduce the Duke people? Could you introduce yourselves?

DR. EVANS: Bob, do you want to start?

DR. COOK-DEEGAN: I'm Bob Cook-Deegan, and I can't see where everybody is.

DR. TUCKSON: So Bob Cook-Deegan, and who else?

MR. POWELL: Ashton Powell.

MS. CHANDRASEKHARAN: I'm a postdoc, Subhashini Chandrasekharan, working on some of the case studies.

DR. TUCKSON: Since I can barely do Gurvaneet Randhawa --

DR. EVANS: What do you mean barely?

(Laughter.)

DR. TUCKSON: I can't do that but I'll call you "postdoctoral fellow." That's a good name.

(Laughter.)

DR. TUCKSON: And who else is here?

MS. PARSONS: I'm Deidre Parsons. I'm a graduate student.

DR. TUCKSON: Deidre Parsons. Great.

And somebody way in the back.

MS. HONG: I'm Lee Hong and I'm an undergraduate at Duke University.

DR. TUCKSON: Great.

And who else?

MS. COLAIANNI: I'm Catherine Colaianni. I just graduated from (inaudible).

DR. TUCKSON: Congratulations. It's a great school.

Who else?

MS. RYDHOLM: I'm Carla Rydholm. I'm a second-year law student and (inaudible).

DR. TUCKSON: My God, doubly smart.

And who else?

MS. PADMANABHAN: Swathi Padmanabhan (inaudible).

DR. TUCKSON: I hope you make it through the end of the year.

(Laughter.)

DR. TUCKSON: All right. You should be back studying. What are you doing here?

Who else did we miss?

MS. PRASAD: I'm Shreya Prasad. I'll be a sophomore at Duke.

DR. TUCKSON: Great. So inspiring.

So now we've got who else? Who else is here from Duke?

MS. BERGER: Elana Berger (inaudible).

DR. TUCKSON: Great. Well, listen, thank you all very much.

(Applause.)

DR. TUCKSON: I wanted, as the chairman, just to acknowledge that I am well aware, as is the committee, of how much effort Duke is putting into this, and that needs to be publicly noted. Secondly, go back one more slide, please. Actually one more slide. There.

So I wanted to just ask you. Jim did a terrific job of giving the committee a pretty clear sense of the process that we're undergoing. So, Jim, if either you or Yvette could just give us just a couple of seconds on what was the guidance. If you look at the agenda for the next several hours, we have some of the most incredibly impressive international experts in this field who have traveled to the United States to brief us.

How do you want us again to really -- what should our notes be emphasizing? What are we listening for, other than how articulate and smart they are? But what information are we really focusing in on and what kind of guidance did you give to the speakers just so we're laser-like in terms of how we listen?

DR. EVANS: I'll address that in general terms, but maybe Yvette then wants to make specific comments.

The thing that I would really urge the committee to do is to try to filter everything that is said today through a very practical filter. Again, our ultimate goal is rather simple, deceptively so really, and that is to figure out whether there are issues that we could recommend to the Secretary that would enhance patient care, that would enhance the public's health. Are there barriers now? Are there problems because of current patent law and licensing practices, and are there things that we can learn from other countries that would be implementable? We're not interested again in pie in the sky, unrealistic type things like let's change the Constitution.

This is a subject that evokes -- I'd say second only perhaps to genetic discrimination -- really passionate responses in people, and I think that we have to be careful to be fairly dispassionate and figure out where might we be able to improve things, if improvement is needed, and what lessons can we get from other countries that would be applicable here, and those things that aren't applicable, we just have to kind of skate by.

Yvette?

DR. SEGER: I have to say whoever is staffing is doing a great job.

DR. EVANS: I agree. It's really like a Charlie McCarthy thing. I feel like the ventriloquist's dummy here.

DR. SEGER: It's basically what can we learn from other countries, what can we apply practically, again not changing the Constitution, but what's out there, and eventually we'll pull back as to what we will use in our final report. But it's definitely information-gathering and seeing how other countries have handled these issues.