Patents and Licensing Session Overview and Framing the Topic
Debra Leonard, M.D., Ph.D.

DR. TUCKSON: We're going to get started again. I am very pleased that Debra Leonard came to me, in very somber tones, and said we need to get started. So this time it's not me being the bad guy, which is great. We are really, actually, though, excited to get into this next agenda, and we're going to start to talk now about the patent issues.

I just will say, since Debra is going to lead us through it, that I am just personally pleased by the way one of my mentors in health care, David Korn, is actually with us, and I just want to take the privilege of personally welcoming David to the committee again, and I'm always pleased when he is in our presence.

With that, Debra, please take it away.

DR. LEONARD: Thank you. It's my pleasure to head up this session on patents and access. The goals today for this session are to first be briefed about the NAS Report on Intellectual Property Rights in Genomics and Protein Research and Innovation by Dr. Korn, review the report and recommendations of the SACGHS Patent and Access Task Force, and then open up the discussion to the committee as to whether there are next steps that SACGHS would like to take.

So a little background before David walks us through the report. In March 2004, during our priority-setting process, we did rank DNA-based patents and licenses and the impact those are having on research and clinical practice as a high-priority issue. But at that same time, NIH let us know that they had just commissioned the NAS to review the patenting and licensing of human genetic material and proteins and the impact that this was having on research and clinical practice. So we deferred consideration of this topic until the NAS work was completed.

So that report was available in November 2005, and in anticipation of this in October SACGHS charged a small working group, the Patents and Access Task Force, to review the NAS report and correlate the NAS report with the questions that we had raised during our priority-setting process and determine whether there are still areas that warrant further exploration or attention or whether the report really addresses all of our concerns.

I just want to review for you the areas of concern that SACGHS did identify in its priority-setting process so you keep those in mind when Dr. Korn is going through his presentation. We had raised issues specific to patents and then the licensing practices used for licensing those patents, and the impacts that the patents and licensing practices were having on research, clinical practice, and economic issues.

So in the area of patent issues specifically, we raised the following questions. Do DNA-based patents blur the distinction between information or natural phenomena and products or things that are created or invented? Are DNA-based patents too broad or obvious to a person practiced in the art? Which means someone who knows genetics and molecular biology. Have the changes in the PTO's utility guidelines, basically raising the bar that you have to show the usefulness of the thing that is being patented, been effective in reducing DNA-based patent submissions whose utility is questionable?

Regarding licensing practice issues, which licensing terms are creating the majority of problems for genetic/genomic test providers? There are a number of issues that the committee became aware of, high royalty fees, the field of use being constrained by the patent, sub-licensing issues,

reach-through rights in which a patent holder or licensee would have the ability to gain control of future knowledge, and exclusivity clauses. Do exclusive licenses raise particular concerns for genetic/genomic test providers, and how prevalent are exclusive licenses? Patents are exclusive by definition.

Then SACGHS raised questions on the impact on research. To what extent do gene patents and licensing practices inhibit research progress? To what extent do delays in publication due to patent submissions affect the progress of science? Does patent stacking inhibit scientific discovery and technology development by making it difficult for a researcher to obtain all of the licenses necessary to carry out specific research projects?

Further, on the impacts on research, in 2000 technology transfer laws were amended to prohibit federally funded researchers from imposing undue restrictions on future research and discovery. Is the impact of this amendment being monitored and analyzed, and has it had an effect?

In the area of clinical practice, there were a number of questions that were raised. Do patents facilitate or inhibit the translation of scientific information into medical practice? Are patent incentives needed for the translation of genetic/genomic discoveries in the area of genetic or genomic testing? How do patent and licensing policies affect the availability of and equitable access to genetic test services in the practice of medicine? Does the current system of patents and licensing genetic technologies affect the training of laboratory clinicians?

A final slide on clinical practice. DNA-based patent holders can license their inventions to a single provider of a genetic test or be that single provider in themselves. Is there being a sole provider of a medical test in the best interest of the public health given the difficulty of sending samples to multiple labs, lack of competition for the way the testing is done or the accuracy of the testing, and absence of independent test validation? Do DNA-based patents and licenses reduce access by either increasing costs due to licensing fees, reduced availability, or other reasons? Is there a mechanism for balancing the protection of an inventor's intellectual property with the broad utilization of gene discoveries for health care purposes? Do DNA-based patents require special consideration due to their potential ability to improve public health?

In the area of economic impacts of patents and licenses, there were a number of questions as well. Do patent and licensing policies increase the cost of medical products, including genetic tests and gene technology-based treatments? Are current patenting policies and practices critical to the success of the biotechnology and pharmaceutical industries? Could any changes in current law undermine innovation, thus doing more harm than good?

So with that as background as questions that SACGHS had raised, I would like to introduce David Korn to give us an overview of the NAS report, which you all have received at your place, the nice hard-bound copy for your keeping and reference, which is the NAS report.

David?