

Opening Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: All right. It is exactly 8:30 and I appreciate everybody being on time. We have a pretty ambitious agenda again and we thank everybody. I know we're ready for a great meeting and we're just full of energy, and we're going to just be terrific, aren't we? Of course, we are. Yes, thank you. Of course, thank you.

DR. : But the game hasn't started yet.

(Laughter.)

DR. TUCKSON: And when you hear somebody go yea, we've got to know who is rooting for who so you'll know whether you should feel good or bad. So I don't know where Julio is but—

DR. : He's on the phone.

DR. TUCKSON: Julio is on his phone getting the last bet in, I think, with the bookie.

(Laughter.)

DR. : He's the one taking the bet.

DR. TUCKSON: He's taking the bet. Apparently, according to Julio, there is no issue. It is already over. It's just a matter of somebody writing down the score.

Let me do one quick housekeeping thing super fast. In terms of the—where is—oh, good. Abbe? In terms of the meeting and the logistics one thing, before Abbe makes me forget, you've got to sign up, of course, if you want to transfer—that you need transportation. So you need to do that or else you'll be in trouble. You can't do it now but in a few minutes.

The second thing is you have to be in this room by 1:28 this afternoon from the lunch break. If you're not, you're going to get caught up in the fire drill. You don't want that to happen. So woe befalls any of you who aren't in here at 1:28. We're going to work through the fire drill. We've got special dispensation or it was determined that we're not that important.

(Laughter.)

So we were just in—we were just in a—so it's fine but—so be—you've got to be back here or else you're going to have to walk.

The last thing real quick is in terms of the meeting logistics for the next meeting, some of you have expressed to me that it probably makes more sense to just be at a hotel and just stay there and you don't have to go through all the back and forth with the dogs and the police, and the thing, and this is hard. So I thought this was good and it was exciting to be at the mother ship but maybe that's not so good for you so the next time we're going to be out in College Park.

Abbe is trying to always find us good places.

Somebody was telling me in the lobby that they had—like they have a study section meeting at the Watergate and another one has got a meeting at Mayflower. But I think the issue is that you

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all are small meetings without the public part and I think where the challenge for Abbe and the team is, it's the public part.

So I just wanted to make the committee—I mean, I'm sensitive as your representative that we're supposed to try to make this as easy and painless as possible. So apparently this isn't easy or painless so we heard that.

College Park is a little further out but I think that will be okay but it's not that bad and so we'll do that. But I just—Abbe is trying to get us to the Mayflower and the Watergate, and we'll keep trying to do that.

So I just wanted—Abbe, thank you, by the way, for all the effort that you—we really do appreciate it so thank you.

(Applause.)

Okay. All right. The other thing is I think we're going to try on the first night of the next meeting—we are going to have a dinner where we all go out together. We used to do that and this curmudgeon chairman, who is not socially adept, forgot to request that or whatever. So Barbara and—it's really Barbara and Steven's fault that we're going to go to dinner because they think it's a good idea. They wanted to go to a bar and I thought—so now I knew it was time for dinner so we're going to have dinner. So anyway we'll build that into the schedule and those that can make it that will be terrific and give us a chance to bond a little bit and get to know each other.

All right. Well, welcome to the second day of the tenth meeting.

God, this is like theologian, Kevin. I mean it's like—

(Laughter.)

--the second day of the tenth meeting with the rain.

(Laughter.)

Build the ark.

We're going to be joined later, we think, by Dr. Christine Beato, which is terrific because she's pretty important as principal deputy assistant for the Secretary of Health, and she's ex officio for the HHS Office on Public Health and Science. So we'll—hopefully, she'll be here and I'll make special note when she comes.

Our first session today is on patents and access. You'll recall that in March of '03 SACGHS identified concerns about the impact of gene patents and licensing patents on access to genetic technologies as one of our high priority issues. At that time we decided to table the work until the National Academies, and this is to keep our new folks up to speed here, until they completed their work on the issue. At our March meeting we heard from David Korn on the findings and conclusions of the NAS Committee on Intellectual Property Rights in Genomic and Protein Research and Innovation. After a careful review of their report by our task force, we concluded that while the NAS committee thoroughly explored the research issues surrounding gene patents and licensing, the clinical aspects could benefit from further exploration. Before deciding

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whether and how to proceed with this issue, we wanted to learn more about, and hear the various perspectives on this topic so we have several experts with us today to provide us with the necessary background and to share their perspectives on this issue.

I will turn the floor over to our very capable and able Dr. Debra Leonard, Chair of the Patents Task Force, who will also be giving the first presentation on fundamentals of patents of licensing and their implications on access to clinical genetic tests.

Take it away, Debra.