

Next Steps and Concluding Remarks
Reed V. Tuckson, M.D.

DR. TUCKSON: In the spirit that no good deed goes unpunished, each of our three retiring members are drafted back into service and they are now ad hoc members of the subcommittees. So don't let this, the new folks, scare you away but when we get you, we get you for life.

We're now going to go through the process of stocking the committees.

Before we do that, Sarah, while you're there and making sure you've got it up, would you please—there are some of our members who are trying to remember the rules that govern the committee and the subcommittees really about meeting and how many people can meet without having the public announcement and the sunshine-ness of everything that we do. Obviously we take those rules very seriously.

Would you please remind people so that—especially for our new committee members, their questions can be answered about the rules on meeting?

MS. CARR: Yes. We are governed by the Federal Advisory Committee Act. When we meet as a committee we meet in public. Although if we are reviewing confidential information there are processes we can go through to close the meetings but the public has to be informed of that.

We can meet in subgroups and don't have to meet—those subgroups don't have to meet in public but they must report back to the full committee and there must be a report developed for the sake of the public so they know what the discussion in the workgroup was all about.

There's also a process that we go through in terms of evaluating conflicts of interest in the working group level as well. So those kinds of issues are certainly attended to in the working group process.

DR. TUCKSON: Terrific. Now while we get the computer turned back on and the super password that's needed—what does that say? I missed it.

(Laughter.)

What we now want to do is go through the process of creating our subcommittees and making sure that we're squared away. Some of our new colleagues asked how does it work. Like this. We sort of figure it out.

So let's—Sarah, why don't you take us through what we have so far and what we need to do?

MS. CARR: Okay.

DR. TUCKSON: I'll let you drive the train.

MS. CARR: All right. Well, we need to—sorry. We just want to be sure that we reflect on our rosters of task forces the transition of the old members to ad hoc status and the identification of new leadership, and also to incorporate the three new members who have come on board on these task forces.

So we've had some initial discussions but we—

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DR. TUCKSON: Some arms twisted.

MS. CARR: Some arms twisted. And so for the Genetic Discrimination Task Force, which we were thinking might some day go out of business actually but it's still in place and Cynthia Berry has agreed to chair it. Reed will still be on it and Agnes will become an ad hoc member. And you see the rest of the membership here.

DR. TUCKSON: Let me—by the way, before I forget that, let me just make a note real quick about Tim. What did I do with my note? Tim is going to do something fabulous and wonderful.

Tim, where are you at?

MR. LESHAN: I'm going to Brown.

DR. TUCKSON: I know. But come and tell us now that she has put the cat out of the bag that you're going to Brown. By the way, we're happy that you're going to have this big time federal job there with Brown but tell what you're going to do.

MR. LESHAN: Thank you. First of all, it has just been a real pleasure. I have actually come to every one of these meetings.

DR. TUCKSON: Yes, you have.

MR. LESHAN: And participated in them and participated in the subcommittees as you can tell. So, as Reed would say, keep doing. Keep doing.

But I'm going to be going to Brown University to head up their office of government relations and community affairs and doing local, state and federal government relations. So I'll be coming back to Washington and will be able to check up on all of you.

DR. TUCKSON: Hey, man, thank you very much. We really appreciate it.

MR. LESHAN: Thank you.

(Applause.)

DR. TUCKSON: So that means we've got to bump him off the list, right?

MS. CARR: Yes, we do.

Tim, can you—

DR. TUCKSON: Or can he stay?

MS. CARR: --at this juncture—well, not and represent NIH, I guess, but who from NIH will you—

MR. LESHAN: (Not at microphone.)

MS. CARR: Okay.

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DR. TUCKSON: So you're going to do it?

DR. : (Not at microphone.)

(Laughter.)

DR. TUCKSON: Well, terrific. Just so we get it—so has everybody met? Stand up and tell us who you are. Don't be shy.

DR. : (Not at microphone.)

DR. TUCKSON: Well, welcome aboard. If you do a terrific job, we'll applaud you, too, at the end.

(Laughter.)

Thanks. Okay.

So is that a good—that's a good committee, right?

MS. CARR: Yes. Peter Gray from EEOC, Robinson Frohboese from HHS Office for Civil Rights. And just among the new members or even the old, anybody else want to come aboard this task force, and if you don't you can—I mean if you don't today, you can think about it and let us know if you'd like to join. We don't—I don't think we made any next steps for this task force today.

DR. TUCKSON: Right.

MS. CARR: Except to continue as full committee members—in full committee to monitor the situation.

DR. TUCKSON: I think you're right.

MS. CARR: Okay.

DR. TUCKSON: So I think we've probably got a good group there. Cindy is not shy about reaching out.

When we went to CMS to talk to Dr. McClellan, it's really fun to walk the halls of HHS with Cindy Berry because you're stopped every three seconds like you're with Sting or some rock person, and everybody wants to shake her hand and she knows every single person in the building. It was just really terrific. So Cindy is very connected so she'll be fine.

(Laughter.)

MS. CARR: And then the Pharmacogenomics Task Force is we have transitioned from Emily as chair to Kevin Fitzgerald has agreed to lead our efforts.

(Laughter.)

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DR. FITZGERALD: (Not at microphone.)

MS. CARR: Kevin, did I forget to talk to you about that? Sorry.

(Laughter.)

DR. TUCKSON: It's Kevin. It's Kevin. Kevin is the chair of that.

MS. CARR: Yes.

DR. TUCKSON: And we appreciate it.

MS. CARR: The existing members are Jim Evans, Julio Licinio, Hunt Willard, Andrea Ferreira-Gonzalez will be joining, as well as Steve—our new member, Steve Teutsch, and the ex officio or the—from the ex officio agencies we have Francis Chesley from AHRQ; Guvarneet Randhawa from AHRQ; and Muin Khoury from CDC; Steve Gutman, FDA; and Joe Hackett, FDA; Allen Rudman, FDA; and Alan Gutmacher from NIH; and Rochelle Long from NIH.

And then our—so any of the other new members? Barbara has—well, I know what Barbara is going to do so we'll get to her next.

DR. TUCKSON: So Emily is key in terms of--first of all, we're thankful you're willing to stay on. We really are and so you'll learn Kevin up on all that. We're going to go in a minute and review what we think the next steps are from—just to try to get a quick synopsis of that. I think that's going to be an important conversation which we'll rush through in just a minute.

Let's move to the next committee.

MS. CARR: Yes. The next task force is the Large Population Studies Task Force, which has been developing the draft report and organizing and managing the public consultation process. That's chaired by Hunt Willard; Sylvia Au; Chira Chen; Julio Licinio; Kevin Fitzgerald. Barbara has joined that task force and Joseph Telfair are the members. Muin Khoury from CDC; Francis Collins from NIH; as well as Alan Gutmacher from NIH; and Alan Fox and Sherrie Hans from the Veterans Affairs Department are members of that task force.

We'll be hearing—they'll be working over the summer reviewing the public comments and helping incorporate them into the draft report and you'll be seeing that in November.

Then the Patents Task Force is now going to be chaired by Jim Evans.

DR. TUCKSON: Great.

MS. CARR: Sylvia Au; Andrea Ferreira-Gonzalez has joined; and Debra will become ad hoc.

DR. TUCKSON: Thank you, Debra.

MS. CARR: And other members can join if you would like.

DR. TUCKSON: Is that enough?

MS. CARR: Yes. That's a good question.

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DR. : We need ex officios.

DR. TUCKSON: That's what it is. Okay.

MS. CARR: Yes. Actually Tim Leshan had been helping in that task force's initial efforts.

DR. TUCKSON: She starts smiling like oh god.

(Simultaneous discussion.)

DR. TUCKSON: Joe, you have a hand up?

DR. TELFAIR: (Not at microphone.)

MS. CARR: Well, that is sort of the way we've been referring to the task force but it's access in relation—the effects of gene patents on patient access. So it's—this is the gene patent task force really.

DR. TUCKSON: Yes, James?

DR. ROLLINS: Just put me down on the—as ex officio on this committee.

DR. TUCKSON: Terrific. That's what we're looking for, volunteers. Who else has their hand up? Scott?

MR. BOWEN: I'd be glad to add my name as well.

DR. TUCKSON: My man. I mean good.

(Laughter.)

Denise? Denise is putting her hand up as well.

DR. : (Not at microphone.)

DR. : Who from the NIH?

DR. TUCKSON: Are you willing? Are you the right person?

DR. : Yes.

(Laughter.)

DR. TUCKSON: Francis, you wanted to comment?

DR. COLLINS: No, I think MK would be terrific for this but we were just powwowing that we really ought to have somebody from OTT on this particular group and that may as well be Mark Rohrbaugh who is the head of OTT. Now he may figure he can't do it.

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DR. TUCKSON: So we're going to reach out to Mark and putting MK on—we've got Denise on—Cindy Berry wants on. Cindy, oh, yes.

DR. : (Not at microphone.)

DR. TUCKSON: Oh, good. All right. So wait a minute now. Hold on. Let me see. This is terrific. Wait a minute now. So we've got a lot of people here so let me just make sure. Do you want other ones?

(Simultaneous discussion.)

DR. TUCKSON: Let's put Chira on there, too. And then we have—put Chira on there.

MS. CARR: Chira.

DR. TUCKSON: Martin is willing to be ex officio.

MS. CARR: So the ex officios are Scott Bowen, James Rollins, MK from NIH, Mark Rohrbaugh from the OTT, NIH, and Denise. And was there another?

DR. TUCKSON: Martin?

MS. CARR: Martin.

DR. TUCKSON: This is going to be a pretty intense committee. All right. Very good.

That's all the committees. Okay.

DR. TELFAIR: (Not at microphone.)

DR. TUCKSON: We don't know. It's sort of in quiescence for the moment although we're going to have the committee chair pay a lot of attention to what's going on and she will give us the—because she's so connected. She will raise the alarm bell.

(Simultaneous discussion.)

DR. TUCKSON: Yes, I think you might hold off. We're going to use you—we're going to put you into some other things when crises come up. Okay.

First of all, let me thank everybody for their willingness to be on these subcommittees. This is tough, tough work.

I want to let you know that what I'm going to probably do is to have a session with the committee chairs sort of almost like as a little—I just want to talk some ideas out and then bring them back to the full group around greater public visibility about the work we're doing, the way in which we use the reports that we write, and to try to find a way to have them a little bit more noted.

I also want to talk a little bit about some issues regarding briefing the media about what we're doing and we're going to get some guidance from the communications office about what we can and cannot do.

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I'd like to find a way to see if we can't have some of the media at least be briefed about the issues that we are concerned about and why we're concerned and get those more into the public discourse. I think that's something that we need to be thinking about doing.

As I started this meeting off, I want to sort of—as we start to get into closure and reviewing the next steps and end right on time, I want to sort of get at this idea of getting—the theme from the very beginning was getting stuff done. I think we had a lot of evidence at this meeting that there is a logical place we begin and something happens as a result of what we're doing. I think we need to keep at that and keep going forward. So I want to find ways in which we can enhance the visibility of the work that we're doing and so I probably will have a little meeting of the subcommittee—use a subcommittee of the committee—a committee of the subcommittee chairs, something like that, and then work it out a little bit and then present it back to the full group at the next meeting.

All right.

Sarah, can we go through what we sort of see as the high level summary today?

MS. CARR: This is the—what was agreed yesterday and today on the issues of the work that the committee wants to do on oversight.

DR. TUCKSON: Just one second, Sarah. By the way, we've got like 15 or so minutes to do this. Please if you—as she goes through this, if there's something that you see as a glaring error of omission, shout it out so that we can get it captured now.

MS. CARR: After the presentation about the plans to augment the CLIA regulations, it was decided that we develop a document that describes the current regulations and outlines the gaps that the planned augmentation would address and review components to be addressed in the notice of proposed rule making.

I think we're going to bring that back to the full committee or did the committee want to share that with—distribute it among the members and get some better sense of where we want to go with the oversight issue?

I'm not sure apart from this that we came to a clear next step on this issue. There was discussion later in the day about the home brew issue or the—rather—

(Simultaneous discussion.)

MS. CARR: Yes, I know. Sorry, Debra. The question about whether FDA—getting clarification from FDA about the status of their authority to regulate laboratory developed tests.

DR. TUCKSON: Right. So your question—I mean I think your question is—I think everybody—I think we agreed that those are high priority issues that we want attended to and so that we are expecting that you would put together this analysis, this document, that describes the current state of the art. We're going to give the people, the committee members, as part of the preparatory background for this the work done from the previous committee. We're going to ask you to succinctly in the introduction to your document define the problem and we want you to also take the opportunity in this to draw the bridge between this issue and the pharmacogenomics—I mean the patent issue, I think, which is also all related. So I think it's important that all those things get defined.

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At the end of the day I think that what we really want is to have it presented to us in a way that tell us that—that defines the oversight hole, the hole in the oversight process, that we are concerned about and then, therefore, analyzes the situation for us and so that it becomes very clear as to whether or not we feel that this is an important enough issue that deserves further activity or not. So you really are presenting for us a definition of the problem—a sense of what the—defining where the controls are and by inference where the controls are insufficient, and then we decide whether or not we want to do anything about that or to make suggestions.

I see—does anybody else have a different view on how they heard that discussion?

All right. So that's really what we're looking for. I think that will be important. This, again, as you continue to keep in your mind our grid of our priority issues, oversight is one of those major issues that we have to be attentive to. As we said, this is a problem that has been hanging around a long time so we're going to decide one way or the other whether we're going to deal with it or not any further.

All right. Next?

MS. CARR: Yes. On pharmacogenomics we had the long discussion yesterday afternoon and I think the committee, as a whole, agreed that we—the task force needs to continue to work on the transformation of the literature review, the review of the Lewin effort to transform that into the draft report of the committee, and to identify the gaps from that report and work on the refinement of recommendations and the consolidation of some of the recommendations that were presented yesterday.

A number of the committee decided to take off the table and so the goal—the work of the task force will focus over the summer on really narrowing down and refining what recommendations to bring back to you and to again bring the draft report to you in November. After the—after you have a chance to consider it in November it will then go—if you're comfortable with it at that point—out for public comment.

DR. TUCKSON: All right. So most of this work again, as I recall, will take place in the task force itself. However, each of you were encouraged to take a look at the yellow pages of the literature review that was done and to see whether you believe that there are any glaring gaps or omissions in their analysis that you think are important.

Secondly, I think that the task force would appreciate any thoughts that you all may have around the prioritization of that menu of issues that we've sort of discussed.

I think the real challenge here for that committee is lumping and splitting of those things, lumping and splitting and then prioritizing. So which things go together and then what the priorities are? And again we—and I think, Kevin, it's good that you're the chair of this. I think we—because you, I think, expressed it, in fact--but the notion of remembering what can we do within the scope of this committee's bounds and authority, I think, are important.

However, having said that, I am beginning to realize from that discussion, and I'm not prepared to present it to the committee today, but this idea of what I meant by press briefing and other things—I am beginning to get interested in the idea that as we discuss these big issues and discover things that it's almost sort of being able to, in an intelligent way, sort of being able to describe and capture our reasoning. So we think this is important because of these things. These

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are the things that we're choosing to do but here are some things that we can't do because they're outside of our priority but they are thing that others may want to take up.

I think that's an important clarion call in some ways and so it's just an idea to think about. I've always sort of, during my tenure as chair, I've been very vigilant at restricting us to only thinking about things that we could recommend to the Secretary. I think that's probably appropriate for focus but I would say that there may be some things in each of these reports now that may beyond our ability to respond to ask the Secretary to do but that you think are important enough to at least raise to the public discourse. I want you all to be thinking about ways in which you get those things into the public conversation.

I see a hand. Is that you, Jim? No.

So anyway just a thought. I don't want to take it anywhere but just that.

So, Kevin, I think that is really the challenge, though, is what's there.

Is that a shared understanding of what we did?

Again, I think one of the great things about the conversation yesterday that Emily led us through was at least we got a chance to all sort of talk about the issues so at least we are familiar with the lexicon and the concepts, the ideas, and the beginning of a shared vision.

Next?

MS. CARR: The Patents and Access Task Force will be picking up from the decisions made today and I think, Reed, you weren't here but Debra did get a consensus of the group that the committee is concerned about the effects of gene patents on clinical practice, including but not limited to patient access, the use of genetic/genomic services, the economic impact and the quality of those services.

The group decided—the committee decided that we will investigate the effects of patents on clinical practice and that as we do that we'll consider—the scope will include single and complex gene diseases. We'll consider legal and legislative issues, industry perspectives, economic considerations, and the processes of granting and licensing medically relevant patents.

DR. TUCKSON: I really applaud that summary there and I really like the use of the word "balanced." I think that that's very important and I think that—again, the way in which—just to give the—again I hope the new members—this is the last time I'm going to refer to the new members but I do want to try to keep you—to underscore some of the nuances and things. One of the things that just happened with this genetics discrimination deal is that we could have come out really hard ball and tough on some of the folks that were constituencies that were considered to be not helpful in the legislation.

I think what we did was to create an opportunity for win-win scenarios by a balanced approach by inviting people to the table and creating a friendly environment for different points of view to get expressed and to be worked on behind the scenes.

I think that's important and so as we look at this issue of the patents and access issue, being able to bring the industry folk to the table and have them feel comfortable about participating in the process, even as we work through our issues, I think is important. So I would commend the

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leadership of Debra as reflected there by the balanced approach and getting everybody at the table and finding a way to get multiple folks working together to solve a problem. I think that's terrific.

DR. LEONARD: And we did generate a complete list of all the things that—we didn't include each—every last item but we kind of lumped to be able to describe but there is a complete list that will be handed to Jim that can be used for thinking about different sessions and what needs to be done.

DR. TUCKSON: Terrific. A good job.

MS. CARR: And then I think the only other thing—action item was that the committee wants to write another letter to the Secretary and I guess to the FTC to commend the agency efforts and the collaboration among them.

DR. TUCKSON: Outstanding. All right.

DR. : (Not at microphone.)

DR. TUCKSON: I think that we—I'll tell you what. That's a great question. Let's just quickly—what would you like?

MR. DAYNARD: I think wisdom would dictate that you wait until we publish it.

DR. TUCKSON: And then say it's a good job.

MR. DAYNARD: Yes.

DR. TUCKSON: Or beat you up if it's a lousy job.

MR. DAYNARD: Yes.

DR. TUCKSON: So would the committee—would the sense of the committee be to wait until it's done and then we'll send it out? All right. I see a consensus.

Let me ask, as we close out a little ahead of time, are there any other issues, process, substantive, topic that you would like to raise that are important to you?

Barbara?

DR. McGRATH: I think this is the last time I get to claim being a new member so I thought I'd use the last few minutes to say that and maybe it's coming from a position of naiveté that I'm allowed this one meeting but I really applaud what you were just saying about balanced reports and doing things we can make a point—I think the three members joined us hoping that this could be a body that actually makes a change, and balance is important with that.

But I also heard yesterday somebody talking about this is a great bully pulpit and this room is filled with incredible people. So I would also hope that the committee addresses issues that maybe we can't have an influence on but we bring to the public discourse and not just go after the sort of low lying fruit of things that have a solution right in front of us but really get at some of the thornier issues. There may be other multidisciplinary—I mean this is such a multidisciplinary

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group here that it's a pretty rich room and I hope we get to approach those things as well. So I applaud what you were just saying about that.

DR. TUCKSON: Well, that is important. Thank you. One of the things, I guess, that we need to consider—I don't think we can perhaps debate it today but, as you know, again, we start every meeting off—it's almost semi-theologic with me that we put that vision document up there in terms of our priorities. We have not visited that since 2004 and we're working our way through.

(Slide.)

There it is. And so we deliberately for this meeting developed check marks and circles about—circles—what was my—give me my code again?

DR. : (Not at microphone.)

DR. TUCKSON: Right. So I mean I knew. I just wanted her to say that because she did the slide.

(Laughter.)

But I think the idea is that that is it there and so we are moving forward on some of those things. So maybe with the sense that genetic discrimination may not—although it's going to always be important and we're always going to be on our list, since this may not be something that we're going to be rolling up our sleeves on, maybe it's time to think about adding something.

So, Barbara, what I would sort of suggest is that each of us think about it between now and the next meeting, whether there is some urgent issue that you think ought to be added to that list—Joe?

DR. TELFAIR: (Not at microphone.)

DR. TUCKSON: Put your thing on so they'll know what you're saying. Your mike.

DR. TELFAIR: Okay. Put the microphone on. That's my thing. Thank you.

(Laughter.)

I have to get as many in before you leave. Okay.

The thing that I—I think it is important. I mean there are a couple of liaisons that this committee serves to other groups and I just want to bring up something because you were closing out is that the group on heritable disorders that I sit on actually was extremely appreciative—the staff, of course, helped me put together a slide presentation on what we do. They really had no clue as to what this committee does when I started out. So I actually took advantage of just providing from start to finish, even though I was only supposed to report on the meeting itself, and they were very impressed on many things.

It struck me at that discussion that there are issues that come up on these committees that we serve—that we serve as liaisons that are relevant to this group that maybe we can just take the opportunity to ask them because I know that one of the big issues they brought up was direct to consumer testing and we talked about that.

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Also they were very impressed with the fact that this committee is very active in getting letters written and also that we have been doing that, and that's not something that it does yet but it's working towards that.

So I think that maybe one of the things to do or us who are liaisons can just ask other committees we serve on or the groups we work with about issues that are relevant and we can do that but that's just a suggestion.

DR. TUCKSON: Do you want to tell them where you got this?

DR. LEONARD: It's the evaluation of genomic application in prevention—

(Simultaneous discussion.)

DR. LEONARD: Yes, thank you. Steve Teutsch is a member of EGAP.

DR. TUCKSON: Well, why can't Steve do both?

DR. LEONARD: Right. So I think Steve is the logical person to take over for me.

DR. TUCKSON: Bing!

(Laughter.)

All right. Good job.

Yes?

DR. FROHBOESE: On the issue of looking at our priorities, I just—I'd feel remiss if I didn't mention that Secretary Leavitt in his senior leadership retreat last week where he brought together the heads of all of the operating divisions and staff divisions within HHS focused again on his top nine priorities which he describes with a sense of urgency because he's doing the count down of number of days left in this administration. We're now at about 930.

Interestingly enough, the work of this committee, I think, fits into a number of these objectives but for the first time genetics/genomics is specifically mentioned in one of the priorities and that is a priority of personalized health care. In that area I think all of the work that we're doing on pharmacogenomics and really focusing in on individualized personalized care is something to consider in terms of the Secretary's major areas of focus.

DR. TUCKSON: Terrific.

DR. FROHBOESE: And just looking at that window of opportunity.

DR. TUCKSON: So let's use that for what it is. This is important.

Thank you, Robinsue. That's great.

As we communicate with the Secretary, we will have the best opportunity to get him to pay attention to what we are doing if we can show that his involvement or the administration's involvement in our issue is something that can fit within the 913 day window.

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So to the extent that they can—because he's really focused in on that and that was important to hear. So it's like, okay, what can we get done in the time we have left?

So as we write our letters to the Secretary, Sarah, or do any communication, it has got to sort of be saying, hey, look, you can achieve this in a reasonable period of time, therefore you ought to focus. That's part one.

Part two is the personalized agenda.

Now one of the things that the committee has asked us to do is to get our work more in front of the Secretary.

Greg Downing from the Secretary's office has been at these meetings in the last two days. He is going to be key at getting us in front of the Secretary and/or the Secretary in front of us.

So I think this--and where he was most interested in his conversations with me off to the side has been on the pharmacogenomics because of its connection to personalized medicine.

So I think you really said some tactically important things there and I thank you for it so keep that in mind.

Great. Any last thing with one minute left? Not to chill the comment.

I want to thank you all for a terrific meeting. Feel good about what you accomplished.

And all of our ex officios and committee, thank you all very much.

Staff, you're terrific.

(Whereupon, at 3:00 p.m., the proceedings were adjourned.)