

Call to Order, Shortening of Agenda, Request for Sponsor 2-Minute Summaries – Day 3

JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE

February 16-18, 2005, Hilton Gaithersburg, 620 Perry Parkway, Gaithersburg, Maryland.

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Highlights

- **AGENDA SHORTENED:** Mr. Levin suggested that the agenda be modified to make sure sufficient time was available for committee discussion, voting and advice to FDA. This was agreed. Dr. Temple and Dr. O’Neill from FDA agreed to give their talks from their seats. With regard to the talk by Dr. Hertz from FDA, Dr. Wood suggested that she remove some of the 45 slides she had planned and commented ‘it is very unusual for the FDA to summarize the meeting for the committee, which is partly what the committee is here to do, I guess’.
- **TWO-MINUTE SUMMARIES BY SPONSORS:** It was also agreed that the sponsors could have 2 minutes each to “make some summary comments”.

Presentation Text

MS. TOPPER: There is one administrative announcement. Would you please make sure that you take your phone calls outside. It is messing up with our audio and we would really appreciate it. Thank you.

DR. WOOD: The other administrative thing that the sound person has asked me to say is, to the committee, try and remember to switch off your microphones when you are not using them. Apparently, it messes it up.

MR. LEVIN: Mr. Chairman?

DR. WOOD: Yes, Arthur?

MR. LEVIN: I wanted to express a concern I have in terms of the agenda for today's meeting. For those of us who have been at advisory committee meetings before, we know that there is often a tendency to sort of squeeze the most important part of these advisory committee meetings which is the discussion and answers to the questions and giving directions to FDA. My

concern is that, given the lengthy discussions we have had over the past two days and, given the fact that this is last day, that we will not have enough time to fully explore all of the questions that have been raised over the last two days and to give some definite direction to the FDA as to how to pursue these issues. So I would like to suggest to the group that we might shorten the presentations, or eliminate them entirely, in order to have adequate time to fully discuss all of our concerns and different points of view around the table. I think it would be really unacceptable to leave here today unable, because of a time constraint, to give direction to the FDA on this issue.

DR. WOOD: Did you have any particular people you wanted to eliminate? Or do you want to pass me a note, privately?

MR. LEVIN: It may be something the committee as a whole should decide.

DR. WOOD: Let me make a suggestion. I think that is a reasonable approach. I am sure the committee will want to hear the data from the ADAPT study and we should hear that in its totality. Milt Packer has come a long way so we should hear from him, I think. Milt is always entertaining, anyway. Do we really need to hear from the two Bobs?

DR. TEMPLE: I don't have any ego involved in this. A fair amount of -- some -- of what I am talking about is about the adverse consequences of blood-pressure elevation which I think I could skip. So I could shorten it considerably. But you guys decide. It is there for you to read if you want.

DR. WOOD: Why don't you do this? Why don't you distribute your talk to us?

DR. TEMPLE: I think it has been.

DR. WOOD: Right; I understand that. I will take that as a given. And both of you make whatever remarks you would like to make from your seats there at the times that you are allotted, but brief and pointed. And let's not revisit all the things we have visited before.

DR. TEMPLE: That's fine.

DR. WOOD: Does that sound fair? Dr. O'Neill?

DR. O'NEILL: Yes; that is fine.

DR. WOOD: That will save us some time. So that is a good thought. In addition, we have got Sharon Hertz's talk which, I notice, has 40-something slides here -- 45 slides -- which is a lot to get through in a few minutes. So I think, while we are sort of working up to that, she may want to look at that and decide what she really needs to say. I mean, after all, it is very unusual for the FDA to summarize the meeting for the committee, which is partly what the committee is here to do, I guess. So let's make sure that she can finish that taking the time she has been allotted for it which is 30 minutes. She would be better to remove some slides rather than rush through it, I think. Having said all that, let's get to the first presentation. Does anyone else have any thoughts on that? Yes, Annette?

DR. STEMHAGEN: I would like to ask whether the manufacturers could have just one or two minutes to make some

summary comments before we start our deliberations after lunch.

DR. WOOD: Do they want to do that now? Is that what you are asking?

DR. STEMHAGEN: No; I think after these presentations.

DR. WOOD: Okay.

DR. STEMHAGEN: Thank you. I appreciate it.

DR. WOOD: Let's have some discussion amongst the committee.

DR. CUSH: What would be the purpose of their having--they have had lots of time already to present their data and had lots of mike time in the back already.

DR. STEMHAGEN: Just in terms of the deliberations that have gone on, there might be some clarifying comments.

DR. CUSH: I think, if we have questions, we can ask for clarifying comments. I think that is what we--I would suggest--and I agree with Arthur Levin in that we should get on to discussion as quickly as possible.

DR. STEMHAGEN: I realize this is sort of in contrast to trying to shorten it. But I

would like to ask that that time be awarded.

DR. WOOD: Any other thoughts on that? Let me get a sense of the committee. What is the committee's pleasure about that? Yes?

DR. BOULWARE: I actually support that recommendation, too, and would suggest you give them a limited time, like you did with the public comment where you will cut them off at two minutes, so we know it will be limited. I would be interested in the direction they plan to take. We heard some startling news yesterday about the possible remarketing of a product that they have withdrawn.

DR. WOOD: Does anyone object to them getting two minutes apart from Dr. Cush? Then, I think, the answer on that is that that is fine. Remind them that, in contrast to most of their experiences in the past for senior managers, the microphone will be cut off.

DR. STEMHAGEN: Thank you very much. I think we saw evidence of that yesterday.

DR. WOOD: Right. So they got the message; right? Okay. Let's move along to the first speaker, Dr. Lyketsos.