

**U.S. Environmental Protection Agency
Office of Research and Development**

**BOARD OF SCIENTIFIC COUNSELORS
ENDOCRINE-DISRUPTING CHEMICALS SUBCOMMITTEE**

**Conference Call Summary
January 6, 2005
12:00 noon – 2:00 p.m. EST**

Welcome, Overview, Introduction, and Agenda Review

Dr. Anna Harding, (Oregon State University), Chair of the Endocrine Disrupting Chemicals (EDC) Subcommittee of the Environmental Protection Agency's (EPA's) Board of Scientific Counselors (BOSC), welcomed the Subcommittee members to their third conference call and thanked them for their participation. She discussed the purpose of the call, which was to review the Subcommittee's progress on the written report and to evaluate the program review process itself. Dr. Harding informed the Subcommittee that Dr. James Johnson and other EPA program managers are interested in obtaining advice and recommendations from the Subcommittee about their experience with the review process. She hopes to generate a list of bullet points to convey the Subcommittee's ideas about the review process.

Dr. Neil Stiber (EPA/ORD), the Designated Federal Officer (DFO) for the EDC Subcommittee, thanked the Subcommittee for their efforts and commented that he was impressed by the level of detail, expertise, and recommendations put forth by the Subcommittee in the draft report. He informed members of the public that there would be time for public comments at the end of the meeting. Dr. Stiber informed Subcommittee members that he would collect their timesheets after they have completed the report and submit it to the BOSC Executive Committee.

Dr. Harding thanked Dr. Elaine Francis (EPA/ORD) and her group for their excellent work on the program review. She then discussed sending additional budget information to Dr. Juarine Stewart (Morgan State University), who had not received the information because of technical difficulties with her e-mail.

Discussion of Written Report

Dr. Harding opened the discussion on the written report to the BOSC Executive Committee. Dr. George Daston (Procter & Gamble) commented that the report appears to be nearly complete. For all the long-term goals (LTGs), he sees a need to fill in some of the summaries and recommendations; information will be extracted from these sections for the executive summary. He said that the group should focus on drafting the summaries and recommendations and developing abbreviated forms for each of these areas for the executive summary.

Dr. George Lucier (Consulting Toxicologist) addressed LTG2, commenting that the discussion of program design was complete but that the issue of relevance needed comments on specific topics important to Regional offices, state agencies, etc. He said that he would add a few paragraphs to the report detailing this information. Dr. Daston commented that the report might be more useful to its intended audience if relevancy was made clear on a program office-by-program office basis. He suggested a parallel structure for each of the LTGs (LTG3 clearly is designed with one program customer in mind), particularly LTG1 and 2, which describe how research performed under these goals is useful for various EPA program offices and perhaps also for federal partners.

Dr. Lucier asked if Dr. Donald Tillitt (U.S. Geological Survey) or Dr. Glen Boyd (Tulane University) could provide input on relevance for ecological research, which he would incorporate with human studies issues. He said he also needed to write more on program progress, perhaps just a few paragraphs related to the individual annual performance goals relevant to LTG2. Dr. Harding suggested that this could be handled by referencing Agency accomplishments documented in peer review literature and symposium workshops. Dr. Lucier said he would conclude this section of the report with some recommendations, significant accomplishments, and areas where some challenges remain. He asked Subcommittee members to send as soon as possible any particular challenges he may have not covered in the narrative.

Dr. Harding discussed the format of the written report, particularly for outlining strengths and challenges. She asked whether strengths, challenges, and recommendations should be discussed for each of the report's subsections, i.e., program progress, relevance, etc. Another option would be to provide summaries of strengths, challenges, and recommendations at the end of each of the discussions of the LTGs. Dr. Lucier recommended discussing these three issues after each LTG, then using the executive summary to integrate the discussion and provide general statements. Dr. Boyd agreed that he would prefer to see a summary of recommendations along with an outline of strengths and goals at the end of each LTG, since many of the other subissues discussed in the report are considered satisfactory and there may not be any specific recommendations. Dr. Daston agreed with this report format and added that there also may be strengths, challenges and recommendations from the resources and leadership sections that could be synthesized and included in the executive summary.

Dr. Harding reiterated that the report would discuss strengths, challenges, and recommendations in the summaries for each of the LTGs and for the leadership and resources sections. She asked whether Subcommittee members wanted to include recommendations for continuing efforts as well as for challenges. Dr. Daston commented that although strengths of the program include resources and the energy and enthusiasm of the scientists involved, maintaining these in order to carry program goals through to completion will be a challenge. Dr. Harding agreed that the report should include recommendations to continue positive efforts; Dr. Lucier commented that challenges shouldn't always be viewed as weaknesses.

Dr. Harding informed Dr. Stewart that she soon would receive additional information detailing funds enacted for FY 2003 and 2004 and funds requested for FY 2005. Dr. Stewart will use this information to revise her section of the report on program resources.

Dr. Harding discussed deadlines for receiving drafts from subgroups in order to finish the final draft of the report and present it to the BOSC Executive Committee. She asked if Subcommittee members wanted to review any of the other LTGs or if the report was at a point where only minor editing and refinement was needed. Dr. Lucier commented that there were still several issues to address for LTG2, but agreed with what has been written for LTG1 and 3 and for leadership and resource issues. With no further comments from the Subcommittee, Dr. Harding proposed a deadline of January 13, 2005 for submission of final drafts for each section to herself and Dr. Daston. Dr. Lucier asked that comments and changes for the section on LTG2 be sent to him by January 10, 2005. Dr. Harding instructed Subcommittee members to send changes to their subgroup leaders, and then she and Dr. Daston will assemble the final report. Dr. Stewart should send her section directly to Drs. Harding, Daston, and Stiber.

Discussion of Program Review Process

Dr. Harding next opened discussion on the program review process. Dr. Johnson has asked that the Subcommittee submit to him comments concerning their opinion of the review process. Dr. Harding instructed committee members to discuss positive aspects of the review process as well as parts that should have been done differently.

Dr. Lucier commented that the posters were well done and very helpful, and addressed many of the concerns and questions he had after reading the written material; the combination of written material and posters was very useful. He thought the oral presentations also were very good and provided necessary information, but could have been shorter. Concerning changes, he felt that there was a lot of “dead time” the first day of the meeting, especially for people writing about LTG1 and 2, which had not been presented yet. It would have been more efficient to have LTG1 and 2 presentations, poster sessions, and poster discussion sessions earlier in the meeting, then provide more time toward the end of the meeting for working sessions, discussion sessions, and writing. Dr. Stewart commented that she found the discussions sessions, written information, and posters to be helpful, but felt that less time could have been devoted to the poster discussion sessions, which also would have allowed some of the presentations to be moved to earlier in the meeting.

Dr. Glen Van Der Kraak (University of Guelph) agreed with Dr. Lucier’s comments, and added that a positive aspect of the review was the involvement of both the intramural and the extramural scientists. These scientists conveyed to Subcommittee members their active engagement in the science, which was critical to the success of the program. Some adjustments to timelines and the order of events are warranted, to allow the Subcommittee access to as much information as possible early in the meeting, with time at the end of the meeting saved for writing duties.

Dr. Harding asked whether Subcommittee members felt that the 2.5-day meeting provided enough time to accomplish their specific tasks. Dr. Lucier answered that he thought it would be difficult to perform the review in a shorter time period especially if the reviewers have to develop a report to be presented at the end of the meeting. Time is needed to write a substantive report.

Dr. Harding next asked Subcommittee members to comment on the review materials they were given. At the meeting, the Subcommittee had discussed asking the EPA program managers to provide a different kind of report, similar to a self-study, rather than a compilation of information. Dr. Daston commented that he thought the review material they had received, while voluminous, was well organized and indexed, and provided needed information. Dr. Lucier agreed and added that it may have been helpful to have the materials sooner, but overall he was happy with the materials themselves and with the timeframe allotted for the review. He commented that he was unsure whether a self-study would be better than receiving a compilation of review materials. It is the Subcommittee's job to perform the evaluation; Subcommittee members are selected to perform the reviews, whether on endocrine disruptors or some other topic, according to their area of expertise. Some self-evaluation is evident in the oral presentations, and perhaps the Subcommittee could recommend encouraging those giving the oral presentations to include more self-evaluation.

Dr. Boyd commented that he found all the information to be useful, but still favors a self-assessment prepared beforehand, and perhaps also cutting back on some of the specific material. The one-on-one time with the individual investigators and program managers to discuss specific issues about a particular program area was very useful, but he thought some critical self-assessments would contribute to these discussions. Dr. Stewart commented that for the laboratory reviews, self-assessments were performed, and reviewers received the same amount and kind of information, but it was more analytical, rather than just a presentation of information. She felt that the format for this meeting provided all the information necessary to perform the evaluation. Dr. Harding said that the Subcommittee could suggest that some measure of self-assessment might be helpful, and the program directors could decide whether or not they wanted to choose that format and respond to the charge questions. This also could be an alternative way to conduct the program review. She added that the organization of the materials was very helpful, and the review process probably would have been more difficult if the materials had not been so well organized.

Dr. Harding asked whether the timelines for the review were acceptable to the Subcommittee members. Dr. Tillitt previously had commented that he approved of the rather short timeline because it forced Subcommittee members to complete the work within a very defined time period. Dr. Daston agreed that the timelines were acceptable adding that while the holidays may have cut into the time somewhat, there is the danger of forgetting issues and information if there is too much time between the meeting and the deadline for the final report. Dr. Lucier commented that he would reserve judgment on the timelines, because this Subcommittee is the first to perform a review of this sort. He suggested the Subcommittee should wait for feedback on the report from the BOSC

Executive Committee to determine whether the level of detail and depth of information was appropriate for the report's intended audience (the rest of the BOSC, EPA, and Office of Management and Budget). If the report is acceptable, the timeframe obviously was sufficient.

Dr. Lucier added that this Subcommittee may not be the best test case for determining whether the information and timelines were appropriate for a review of this sort. Most of the Subcommittee members, with the possible exception of Dr. Boyd, are known experts in the field of endocrine disruptors, understand the area very well, and have already reviewed some aspects of the program in the past. This group may not have benefited from more time but he would be concerned about future reviews if there was a group of reviewers who were not as familiar or comfortable with the field or who did not already have established interpersonal relationships with other members of the review committee. Dr. Boyd agreed, saying that he had to spend a great deal of time familiarizing himself with aspects of the program because he is not as experienced in this field as other Subcommittee members. He agreed that if less experienced people are reviewing a program, they might need more time to perform a thorough and accurate review. Dr. Harding agreed that for a review at this level to be completed in a relatively short time, the Subcommittee needs to be composed of people with significant experience in the field.

Budgetary and Human Resource Authority

Dr. Van Der Kraak returned to the discussion of the final report. The Subcommittee members strongly commented on budget issues and Dr. Francis's responsibility overseeing the entire program with respect to the division directors and the allocation of human resources to Endocrine Disruptors Research Program projects. The Subcommittee members agreed that Dr. Francis should have more control over both human and monetary resources, but potential downsides to this suggestion should be discussed. Dr. Lucier commented that budget issues within the federal government are very complicated, and, given this, Subcommittee members probably had not performed an adequate review to make conferring more control to Dr. Francis a firm conclusion in the report.

Dr. Van Der Kraak commented that many of the scientists involved with the EDC program have multiple duties. Someone needs to be in a position of oversight to assign and balance tasks for the scientists so adequate time is allotted for their duties. A laboratory director may have this broad oversight, as does Dr. Francis, but another program director may not. According to Dr. Van Der Kraak, the Subcommittee should be able to explain their decision while realizing that there needs to be somebody with a broad perspective involved in allocating human and monetary resources. Dr. Harding added that another issue of concern for the current model was lack of budgetary authorization by the program manager, a point raised by Dr. Stewart during discussions on resources. The Subcommittee may want to make a qualified recommendation, based on the information they currently have, that the program director position should be

elevated and given budgetary authority. Dr. Stewart offered to rewrite her section of the report to include this discussion.

Dr. Lucier added that budgetary control by the program director is needed, but care needs to be taken not to place the laboratory group leader scientists in a position where they are being pulled in too many directions. The Subcommittee does not want to undermine the ability of branch chiefs or division directors to bring together scientists in their groups on other projects of interest to EPA. At the same time, there needs to be some budgetary control by the program director, given the visibility and responsibility they have for projects like the endocrine disruptors effort. Dr. Van Der Kraak commented that the way in which Dr. Francis has been able to work with the various division directors has been admirable; the interactions clearly have been very positive and constructive. Difficulties could arise, however, if she has no power and the laboratory directors do not want to participate, or conversely, if somebody in Dr. Francis's position was too strong and was taking all of the resources in one direction, potentially leaving serious gaps in other directions. Dr. Harding said that she could add to the report a statement of limitations regarding recommendations in the resources area and perhaps the leadership area as well.

Dr. Harding asked about the next step after the report is finished to the Subcommittee's satisfaction. Drs. Stewart and Stiber explained that the report will be presented at the January meeting of the BOSC Executive Committee as a draft for discussion. The Committee will provide comments and edits to be included in the report. Dr. Harding informed Subcommittee members that she and Dr. Daston would submit the report to all of them once it was ready for distribution to the BOSC. She added that edits and changes still can be made at this point.

Dr. Harding called for public comments. No public comments were made during this call.

Dr. Harding adjourned the meeting at 1:00 p.m.

List of Action Items

- Subgroups are to submit edits to subgroup leaders by 1/13/05.
- Drs. Harding and Daston will work together on the executive summary and any other issues that arise.
- Comments on LTG2 should be sent to Dr. Lucier by 1/10/05 (Drs. Safe and Tillitt will be informed of this deadline by e-mail).
- Dr. Stewart will send her section on resources to Drs. Harding and Daston by 1/13/05.

List of Participants

Subcommittee Members:

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