B·O·S·C
BOARD OF SCIENTIFIC COUNSELORS

HUMAN HEALTH SUBCOMMITTEE
Conference Call Summary
Friday, February 27, 2009
12:30 – 1:30 p.m. Eastern Time

Welcome
Dr. James Klaunig, Indiana University School of Medicine, Subcommittee Chair

Dr. James Klaunig, Chair of the Board of Scientific Counselors (BOSC) Human Health Subcommittee, welcomed the Subcommittee members to the teleconference and took roll. He explained that the purpose of this conference call was to discuss the Subcommittee's draft report. Critiques of the document should be relatively succinct. He expected that at least two more iterations of the report would be needed before it is finalized. Subcommittee members should have received the summary from the face-to-face meeting via e-mail; he asked that they read it to refresh their memories regarding any issues related to writing the report. The summary should be used to identify additional comments that were not included in the draft report and ensure that the issues that were included were addressed completely. Dr. Klaunig stressed the importance of making the recommendations clear for the program so that the Human Health Research Program (HHRP) staff can address them.

BOSC DFO Remarks
Ms. Virginia Houk, U.S. Environmental Protection Agency (EPA)/ Office of Research and Development (ORD), Subcommittee Designated Federal Officer (DFO)

Ms. Virginia Houk, Subcommittee DFO, thanked the Subcommittee members for their attendance and reviewed the Federal Advisory Committee Act (FACA) procedures that are required for all BOSC Subcommittee meetings. All BOSC meetings are public meetings, and as the DFO, Ms. Houk ensures that all FACA requirements are met and that records of board deliberations are made public. The minutes are being recorded by a contractor who will prepare a summary of the meeting; following review of the summary by the Subcommittee members and certification by the Chair, it will be available on the BOSC Web Site. Notices of all public meetings of the Subcommittee must be published in the *Federal Register* at least 15 days prior to the meeting; the notice for this conference call was published on February 3, 2009, and an electronic docket was established. The docket is available at http://www.regulations.gov; the docket number is EPA-HQ-ORD-2008-0649. All meetings and teleconferences involving substantive issues, whether in person, by phone, or by e-mail, that include one-half or more of the Subcommittee members must be open to the public.

This conference call was convened to discuss the draft report in preparation for submitting it to the BOSC Executive Committee. Subcommittee members must inform the DFO if they discover a potential conflict of interest with respect to any of the topics under discussion during this call. Although there were no advance requests for comment from the public, time for public comment was scheduled for 1:25 p.m. Comments must be limited to 3 minutes each.

Executive Summary Discussion

Dr. James Klaunig, Indiana University School of Medicine, Subcommittee Chair

Dr. Klaunig explained that he was in the process of addressing Subcommittee comments regarding the executive summary and asked whether any of the Subcommittee members had any additions, deletions, or changes. Dr. Paul Blanc thought it would be difficult to respond to Dr. Klaunig's request until the elliptical comments contained in the executive summary are expanded. Additionally, the comments may change following examination of the face-to-face meeting summary. Dr. George Daston noted that it would be helpful within the report to overtly identify each recommendation with the notation "Recommendation:" and also add a list of the recommendations to the executive summary. He also suggested adding text to explain the context of each recommendation. The comments on the format of the review do not need to be in the executive summary and should be moved to another section, such as the introduction or conclusion; these comments are logistical rather than programmatic. Dr. Klaunig agreed with these comments and noted that because some people may read only the executive summary or just the sections relating to their particular area of interest, it is important to capture the recommendations in both places.

Dr. Klaunig explained that the Subcommittee needed to assign an overall summary assessment rating for the Program. Three of the Long-Term Goal (LTG) areas met expectations, and one exceeded expectations. He proposed that the overall rating be "Meets Expectations"; the Subcommittee members present on the conference call agreed unanimously.

LTG 1 Discussion

Dr. George Daston, Procter and Gamble, Workgroup Secondary

Dr. George Daston stated that the discussion regarding LTG 1 needed: (1) substantive editing, (2) a narrative statement that justifies the summary assessment, and (3) explicit recommendations set apart within each section. Dr. Edo Pellizzari noted that he had trouble finding the "meat" in this LTG discussion; it needs additional details to support the statements, and the recommendations should flow from these details. Dr. Klaunig agreed and noted that additional text and details are needed so that this discussion is more consistent with the other LTG discussions.

LTG 2 Discussion

Dr. Edo Pellizzari, RTI International, Workgroup Lead

Dr. Pellizzari stated that very few edits and additions had been made to this section since the face-to-face meeting, and he noted that it is important to review the meeting summary to ensure that all points from the discussions were included. The issues with the LTG 2 discussion are structural; some material is not in the right location and needs to be moved. The recommendations need to be more explicit. The second-to-last sentence in the fourth paragraph under Program Relevance, which discusses a recommendation regarding definition of goals or guidelines that describe the threshold of acceptable accuracy for models and methods used in making assessments, may need to be modified because ORD has since released a publication that discusses this issue.

Dr. Blanc noted that many of the recommendations are not specific to each LTG; most specific recommendations are cross-cutting across all LTGs (e.g., the usefulness of the partner survey and bibliometric analysis). There are overarching recommendations that may appear in multiple LTG discussions or appear within an LTG as a reference. Dr. Klaunig agreed that there are several overarching recommendations that ORD will need to address. Dr. Blanc stated that the fundamental question of whether the LTG structure is serving a useful purpose to the Agency is a global issue. This issue is clearer under certain LTGs than others, but it is nonetheless a global issue. Dr. Pellizzari agreed that this is a general issue, but it can be a specific impediment to an LTG being achieved. Dr. Klaunig will capture

these overarching issues and send them to Ms. Houk. Dr. Daston added that an overall assessment needed to be written, and this would be a good place to capture overarching recommendations. Dr. Klaunig will review the meeting summary to ensure that all overarching and specific recommendations have been captured.

Dr. Pellizzari suggested that the narrative be concise and consistent so that recommendations are easier to find, and Dr. Blanc agreed. Dr. Pellizzari also suggested that strengths and weaknesses be identified in addition to recommendations so that ORD scientists can consider those as well.

Dr. Klaunig indicated that the following revisions should be made to the draft: (1) capture strengths, weaknesses, and recommendations explicitly; (2) standardize the format of each LTG discussion; and (3) ensure that the narrative is concise. Dr. Pellizzari suggested that each section be organized so that the strengths and weaknesses are included in the narrative with the recommendations following. Ms. Houk emphasized that the recommendations need to be highlighted so that ORD can easily identify them and prepare a response. Dr. Blanc cautioned that not every section will have a recommendation; perhaps the list of recommendations should be placed at the end of each LTG discussion. Dr. Klaunig agreed with this suggestion and added that it might be helpful to include point-by-point recommendations before the summary assessment. Dr. Pellizzari thought that the recommendations needed to be included within each LTG discussion so that there is context to the recommendations; this context may be lost if all of the recommendations are moved to one section. To address this issue, Dr. Blanc suggested that a parenthetical reference be included for each recommendation. Dr. Klaunig determined that this format would be used for the next draft, but it could be modified if the members did not think that it was optimal.

LTG 3 Discussion

Dr. Paul Blanc, University of California at San Francisco, Workgroup Lead

Dr. Blanc asked which Subcommittee member had added the sentences regarding other conditions of susceptibility (e.g., diabetes and air pollution, lead, genetic risks). Ms. Houk stated that Dr. Joel Schwartz had added these comments. Dr. Henry Falk noted that, from his perspective of not having been present at the face-to-face meeting, he thought this discussion was the most explicit, clear, and direct, especially in terms of identifying missing Program elements. Dr. Blanc asked whether the discussion was overly prescriptive. Dr. Falk responded that he thought the conclusions were very clearly stated and provide the Agency with explicit recommendations to which it can respond.

LTG 4 Discussion

Dr. Donald Mattison, National Institutes of Health, Workgroup Member

Dr. Donald Mattison noted that additional editing within the LTG 4 discussion was needed as well as more explicit discussion of the recommendations. Dr. Klaunig noted that the section on program relevance needed a critique in addition to the explanation. Dr. Blanc commented that this was an area in which the Agency did not have in-house qualitative research resources to systematically review the impact of the Program in a state-of-the-art manner; the Agency's efforts have been very *ad hoc*. There are approaches available to systematically assess impacts.

Dr. Pellizzari asked for clarification regarding the last sentence before the summary assessment that mentioned the *Report on the Environment* and sound scientific leadership. He thought that sentence needed to be reassessed.

Dr. Klaunig noted that narrative is needed in the summary assessment to justify the rating. Dr. Blanc stated that the "Exceeds Expectations" rating was given because given the relatively short timeframe, it was commendable that anything at all had been done, let alone the amount of progress that the Program had made. Dr. Christopher Portier was particularly sensitive to this because of the focus that the National

Institute of Environmental Health Sciences has placed on participatory research, and he had been pleased to see EPA embracing this concept. Dr. Klaunig thought the finding that activities progressed much faster than expected must be included in the summary assessment, especially to provide a context for why this LTG was rated higher than the other LTGs.

Dr. Falk noted that the LTG 4 discussion was not as explicit as the previous discussions in terms of recommendations and there were fewer tie-ins; more detail regarding why this LTG exceeds expectations is needed. Additionally, the Subcommittee must ensure that there is consensus on moving the *Report on the Environment* to the Office of the Administrator. Dr. Pellizzari responded that the *Report on the Environment* was considered to be such a potentially useful piece of descriptive and integrative material that it may benefit the Agency as a whole to show the impact of integrating science and policy to evaluate health consequences and exposure. It is potentially a very powerful communication tool. Dr. Klaunig noted that it is necessary to state that it is a powerful tool that may have broad application within the Agency.

Dr. Falk commented that it would be helpful after the recommendations are collected in a list to determine how they relate to one another in terms of the input to the Program. Examining them as a whole will provide a better sense of what the Subcommittee is advocating; this could be a focus of discussion for the next conference call.

Final Draft Preparations

Dr. James Klaunig, Subcommittee Chair

The Subcommittee members discussed the number of additional drafts likely to be needed. Dr. Blanc thought that if Subcommittee members were proactive in their comments and reviews of sections other than their own, only one more draft would be needed. Dr. Klaunig asked that the next draft be completed by March 13, 2009; the final draft should be completed by April 3, 2009. Another conference call will be scheduled to discuss the draft; each LTG Workgroup Lead will make the adjustments, and the Subcommittee as a whole will discuss the next draft.

Dr. Falk noted that the task of editing the document and highlighting recommendations could be completed via e-mail through the DFO, and the task of discussing the main recommendations and ensuring consensus should be completed during the next conference call. Discussion to ensure that the HHRP is provided with the right message is valuable and necessary. Dr. Klaunig agreed and stated that the report would benefit from adjusting the length and approach of each LTG discussion. To complete the next draft, the Subcommittee members will utilize e-mail to: (1) edit the document, (2) explicitly highlight the recommendations, and (3) use the meeting summary to ensure that all issues are captured. The main recommendations and executive summary will be discussed during the next conference call.

Public Comment

Ms. Houk called for public comment at 1:23 p.m. No comments were offered.

Following the public comment period, Dr. Falk explained that he had made a brief presentation regarding the Subcommittee's review to the BOSC Executive Committee. His presentation focused on the logistics of the review that the Subcommittee members had noted. Dr. Falk mentioned that the Executive Committee currently is discussing standardizing the format of BOSC reviews and reports, so the Subcommittee's comments regarding the poster sessions and partner testimonials were timely.

Ms. Houk stated that she would capture the major comments from the conference call and e-mail them to the Subcommittee members. She will set up a timeline for completion of the report and determine Subcommittee members' availability for a conference call in early April.

Dr. Klaunig thanked everyone for their participation and adjourned the meeting at 1:27 p.m.

Action Items

- ✧ Dr. Klaunig will review the face-to-face meeting summary to ensure that all overarching and specific recommendations have been captured.

- ✧ The Subcommittee members will review the face-to-face meeting summary to ensure that all issues have been captured.

- ✧ Dr. Klaunig will capture overarching issues and send them to Ms. Houk.

- ✧ The Subcommittee will produce another draft report by March 13, 2009, ensuring the following suggestions are captured by each LTG Workgroup Lead:

  - General:
    - Capture strengths, weaknesses, and recommendations explicitly.
    - Standardize the format of each LTG discussion.
    - Provide concise narrative.
    - Write an overall summary assessment that includes overarching recommendations.
    - Point-by-point recommendations with parenthetical references will be collected in one list.
  - Executive Summary:
    - Place recommendations within the executive summary.
    - Move the comments on format of the review to a different section.
  - LTG 1 Discussion:
    - Substantive editing is required.
    - A narrative statement that justifies the rating must be added.
    - Additional text and details to be more consistent with other LTG discussions must be added.
  - LTG 2 Discussion:
    - Structural issues within the discussion should be addressed.
    - The sentence in the fourth paragraph of the Program Relevance section should be updated to reflect ORD's recent publication regarding this issue.
  - LTG 4 Discussion:
    - Critique must be added to the explanation in the section on program relevance.
    - Narrative to justify the rating must be added.
    - State that the *Report on the Environment* has the potential to be a powerful tool with broad applications.
    - The last sentence before the summary assessment regarding the *Report on the Environment* and sound scientific leadership needs to be reassessed.

- ✧ Ms. Houk will capture the major comments from the conference call and e-mail them to the Subcommittee members.

- ✧ Ms. Houk will set up a timeline for the report and determine Subcommittee members' availability for a conference call in early April.

PARTICIPANTS LIST

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AGENDA
February 27, 2009
12:30 – 1:30 p.m. Eastern Time

CONFERENCE CALL
Participation by Teleconference Only
866-299-3188
code: 919-541-7698#

12:30–12:35 p.m.	Welcome - Overview of Agenda	Dr. James Klaunig Subcommittee Chair
	BOSC DFO Remarks	Ms. Virginia Houk, Office of Research and Development
12:35–12:40 p.m.	Executive Summary Discussion	Dr. James Klaunig Subcommittee Chair
12:40–12:50 p.m.	LTG 1 Discussion	Dr. George Daston LTG1 Workgroup Secondary HH Subcommittee
12:50–1:00 p.m.	LTG 2 Discussion	Dr. Edo Pellizzari LTG2 Workgroup Lead HH Subcommittee
1:00–1:10 p.m.	LTG 3 Discussion	Dr. Paul Blanc LTG3 Workgroup Lead HH Subcommittee
1:10–1:20 p.m.	LTG 4 Discussion	Dr. Donald Mattison LTG4 Workgroup HH Subcommittee
1:20–1:25 p.m.	Final Draft Preparations	Dr. James Klaunig Subcommittee Chair
1:25–1:30 p.m.	Public Comment	
1:30 pm	Adjourn	