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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.

1 **Executive Summary Discussion**

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

3
4 Dr. Klaunig explained that he was in the process of addressing Subcommittee comments regarding the
5 executive summary and asked whether any of the Subcommittee members had any additions, deletions, or
6 changes. Dr. Paul Blanc thought it would be difficult to respond to Dr. Klaunig's request until the
7 elliptical comments contained in the executive summary are expanded. Additionally, the comments may
8 change following examination of the face-to-face meeting summary. Dr. George Daston noted that it
9 would be helpful within the report to overtly identify each recommendation with the notation
10 "Recommendation:" and also add a list of the recommendations to the executive summary. He also
11 suggested adding text to explain the context of each recommendation. The comments on the format of the
12 review do not need to be in the executive summary and should be moved to another section, such as the
13 introduction or conclusion; these comments are logistical rather than programmatic. Dr. Klaunig agreed
14 with these comments and noted that because some people may read only the executive summary or just
15 the sections relating to their particular area of interest, it is important to capture the recommendations in
16 both places.

17
18 Dr. Klaunig explained that the Subcommittee needed to assign an overall summary assessment rating for
19 the Program. Three of the Long-Term Goal (LTG) areas met expectations, and one exceeded
20 expectations. He proposed that the overall rating be "Meets Expectations"; the Subcommittee members
21 present on the conference call agreed unanimously.

22 **LTG 1 Discussion**

23 *Dr. George Daston, Procter and Gamble, Workgroup Secondary*

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25
26 Dr. George Daston stated that the discussion regarding LTG 1 needed: (1) substantive editing, (2) a
27 narrative statement that justifies the summary assessment, and (3) explicit recommendations set apart
28 within each section. Dr. Edo Pellizzari noted that he had trouble finding the "meat" in this LTG
29 discussion; it needs additional details to support the statements, and the recommendations should flow
30 from these details. Dr. Klaunig agreed and noted that additional text and details are needed so that this
31 discussion is more consistent with the other LTG discussions.

32 **LTG 2 Discussion**

33 *Dr. Edo Pellizzari, RTI International, Workgroup Lead*

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35
36 Dr. Pellizzari stated that very few edits and additions had been made to this section since the face-to-face
37 meeting, and he noted that it is important to review the meeting summary to ensure that all points from
38 the discussions were included. The issues with the LTG 2 discussion are structural; some material is not
39 in the right location and needs to be moved. The recommendations need to be more explicit. The second-
40 to-last sentence in the fourth paragraph under Program Relevance, which discusses a recommendation
41 regarding definition of goals or guidelines that describe the threshold of acceptable accuracy for models
42 and methods used in making assessments, may need to be modified because ORD has since released a
43 publication that discusses this issue.

44
45 Dr. Blanc noted that many of the recommendations are not specific to each LTG; most specific
46 recommendations are cross-cutting across all LTGs (e.g., the usefulness of the partner survey and
47 bibliometric analysis). There are overarching recommendations that may appear in multiple LTG
48 discussions or appear within an LTG as a reference. Dr. Klaunig agreed that there are several overarching
49 recommendations that ORD will need to address. Dr. Blanc stated that the fundamental question of
50 whether the LTG structure is serving a useful purpose to the Agency is a global issue. This issue is
51 clearer under certain LTGs than others, but it is nonetheless a global issue. Dr. Pellizzari agreed that this
52 is a general issue, but it can be a specific impediment to an LTG being achieved. Dr. Klaunig will capture

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

5
 6 Dr. Pellizzari suggested that the narrative be concise and consistent so that recommendations are easier to
 7 find, and Dr. Blanc agreed. Dr. Pellizzari also suggested that strengths and weaknesses be identified in
 8 addition to recommendations so that ORD scientists can consider those as well.

9
 10 Dr. Klaunig indicated that the following revisions should be made to the draft: (1) capture strengths,
 11 weaknesses, and recommendations explicitly; (2) standardize the format of each LTG discussion; and
 12 (3) ensure that the narrative is concise. Dr. Pellizzari suggested that each section be organized so that the
 13 strengths and weaknesses are included in the narrative with the recommendations following. Ms. Houk
 14 emphasized that the recommendations need to be highlighted so that ORD can easily identify them and
 15 prepare a response. Dr. Blanc cautioned that not every section will have a recommendation; perhaps the
 16 list of recommendations should be placed at the end of each LTG discussion. Dr. Klaunig agreed with
 17 this suggestion and added that it might be helpful to include point-by-point recommendations before the
 18 summary assessment. Dr. Pellizzari thought that the recommendations needed to be included within each
 19 LTG discussion so that there is context to the recommendations; this context may be lost if all of the
 20 recommendations are moved to one section. To address this issue, Dr. Blanc suggested that a
 21 parenthetical reference be included for each recommendation. Dr. Klaunig determined that this format
 22 would be used for the next draft, but it could be modified if the members did not think that it was optimal.

23 24 **LTG 3 Discussion**

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

26
 27 Dr. Blanc asked which Subcommittee member had added the sentences regarding other conditions of
 28 susceptibility (e.g., diabetes and air pollution, lead, genetic risks). Ms. Houk stated that Dr. Joel Schwartz
 29 had added these comments. Dr. Henry Falk noted that, from his perspective of not having been present at
 30 the face-to-face meeting, he thought this discussion was the most explicit, clear, and direct, especially in
 31 terms of identifying missing Program elements. Dr. Blanc asked whether the discussion was overly
 32 prescriptive. Dr. Falk responded that he thought the conclusions were very clearly stated and provide the
 33 Agency with explicit recommendations to which it can respond.

34 35 **LTG 4 Discussion**

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

37
 38 Dr. Donald Mattison noted that additional editing within the LTG 4 discussion was needed as well as
 39 more explicit discussion of the recommendations. Dr. Klaunig noted that the section on program
 40 relevance needed a critique in addition to the explanation. Dr. Blanc commented that this was an area in
 41 which the Agency did not have in-house qualitative research resources to systematically review the
 42 impact of the Program in a state-of-the-art manner; the Agency's efforts have been very *ad hoc*. There
 43 are approaches available to systematically assess impacts.

44
 45 Dr. Pellizzari asked for clarification regarding the last sentence before the summary assessment that
 46 mentioned the *Report on the Environment* and sound scientific leadership. He thought that sentence
 47 needed to be reassessed.

48
 49 Dr. Klaunig noted that narrative is needed in the summary assessment to justify the rating. Dr. Blanc
 50 stated that the "Exceeds Expectations" rating was given because given the relatively short timeframe, it
 51 was commendable that anything at all had been done, let alone the amount of progress that the Program
 52 had made. Dr. Christopher Portier was particularly sensitive to this because of the focus that the National

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

5
6 Dr. Falk noted that the LTG 4 discussion was not as explicit as the previous discussions in terms of
7 recommendations and there were fewer tie-ins; more detail regarding why this LTG exceeds expectations
8 is needed. Additionally, the Subcommittee must ensure that there is consensus on moving the *Report on*
9 *the Environment* to the Office of the Administrator. Dr. Pellizzari responded that the *Report on the*
10 *Environment* was considered to be such a potentially useful piece of descriptive and integrative material
11 that it may benefit the Agency as a whole to show the impact of integrating science and policy to evaluate
12 health consequences and exposure. It is potentially a very powerful communication tool. Dr. Klaunig
13 noted that it is necessary to state that it is a powerful tool that may have broad application within the
14 Agency.

15
16 Dr. Falk commented that it would be helpful after the recommendations are collected in a list to determine
17 how they relate to one another in terms of the input to the Program. Examining them as a whole will
18 provide a better sense of what the Subcommittee is advocating; this could be a focus of discussion for the
19 next conference call.

20 21 **Final Draft Preparations**

22 *Dr. James Klaunig, Subcommittee Chair*

23
24 The Subcommittee members discussed the number of additional drafts likely to be needed. Dr. Blanc
25 thought that if Subcommittee members were proactive in their comments and reviews of sections other
26 than their own, only one more draft would be needed. Dr. Klaunig asked that the next draft be completed
27 by March 13, 2009; the final draft should be completed by April 3, 2009. Another conference call will be
28 scheduled to discuss the draft; each LTG Workgroup Lead will make the adjustments, and the
29 Subcommittee as a whole will discuss the next draft.

30
31 Dr. Falk noted that the task of editing the document and highlighting recommendations could be
32 completed via e-mail through the DFO, and the task of discussing the main recommendations and
33 ensuring consensus should be completed during the next conference call. Discussion to ensure that the
34 HHRP is provided with the right message is valuable and necessary. Dr. Klaunig agreed and stated that
35 the report would benefit from adjusting the length and approach of each LTG discussion. To complete
36 the next draft, the Subcommittee members will utilize e-mail to: (1) edit the document, (2) explicitly
37 highlight the recommendations, and (3) use the meeting summary to ensure that all issues are captured.
38 The main recommendations and executive summary will be discussed during the next conference call.

39 40 **Public Comment**

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

42
43 Following the public comment period, Dr. Falk explained that he had made a brief presentation regarding
44 the Subcommittee's review to the BOSC Executive Committee. His presentation focused on the logistics
45 of the review that the Subcommittee members had noted. Dr. Falk mentioned that the Executive
46 Committee currently is discussing standardizing the format of BOSC reviews and reports, so the
47 Subcommittee's comments regarding the poster sessions and partner testimonials were timely.

48
49 Ms. Houk stated that she would capture the major comments from the conference call and e-mail them to
50 the Subcommittee members. She will set up a timeline for completion of the report and determine
51 Subcommittee members' availability for a conference call in early April.

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

2 **Action Items**

- 3
- 4 ✧ Dr. Klaunig will review the face-to-face meeting summary to ensure that all overarching and specific
5 recommendations have been captured.
- 6
- 7 ✧ The Subcommittee members will review the face-to-face meeting summary to ensure that all issues
8 have been captured.
- 9
- 10 ✧ Dr. Klaunig will capture overarching issues and send them to Ms. Houk.
- 11
- 12 ✧ The Subcommittee will produce another draft report by March 13, 2009, ensuring the following
13 suggestions are captured by each LTG Workgroup Lead:
- 14
- 15 • General:
 - 16 ○ Capture strengths, weaknesses, and recommendations explicitly.
 - 17 ○ Standardize the format of each LTG discussion.
 - 18 ○ Provide concise narrative.
 - 19 ○ Write an overall summary assessment that includes overarching recommendations.
 - 20 ○ Point-by-point recommendations with parenthetical references will be collected in one list.
 - 21 • Executive Summary:
 - 22 ○ Place recommendations within the executive summary.
 - 23 ○ Move the comments on format of the review to a different section.
 - 24 • LTG 1 Discussion:
 - 25 ○ Substantive editing is required.
 - 26 ○ A narrative statement that justifies the rating must be added.
 - 27 ○ Additional text and details to be more consistent with other LTG discussions must be added.
 - 28 • LTG 2 Discussion:
 - 29 ○ Structural issues within the discussion should be addressed.
 - 30 ○ The sentence in the fourth paragraph of the Program Relevance section should be updated to
31 reflect ORD's recent publication regarding this issue.
 - 32 • LTG 4 Discussion:
 - 33 ○ Critique must be added to the explanation in the section on program relevance.
 - 34 ○ Narrative to justify the rating must be added.
 - 35 ○ State that the *Report on the Environment* has the potential to be a powerful tool with broad
36 applications.
 - 37 ○ The last sentence before the summary assessment regarding the *Report on the Environment*
38 and sound scientific leadership needs to be reassessed.
- 39
- 40 ✧ Ms. Houk will capture the major comments from the conference call and e-mail them to the
41 Subcommittee members.
- 42
- 43 ✧ Ms. Houk will set up a timeline for the report and determine Subcommittee members' availability for
44 a conference call in early April.

PARTICIPANTS LIST

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HUMAN HEALTH SUBCOMMITTEE

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 BOSC DFO Remarks	Dr. James Klaunig Subcommittee Chair 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	