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

BOARD OF SCIENTIFIC COUNSELORS EXECUTIVE COMMITTEE MEETING

Washington, DC
June 2-3, 2005

Thursday, June 2, 2005

Welcome

Dr. James H. Johnson, Jr. (Howard University), Chair of the Board of Scientific Counselors (BOSC), called the meeting to order at 8:45 a.m., and welcomed the attendees to the meeting.

Review and Approval of the January 2005 Meeting Minutes

Dr. Johnson stated that he was going to highlight the matters arising from the January meeting minutes that will need to be addressed during this meeting. He asked if there were any comments on the draft meeting minutes. He noted that the word "quickly" should be deleted in the second sentence of the first paragraph on page 1, in the second sentence of the third paragraph on page 14, and in the first sentence of the fourth paragraph on page 21. Dr. Anna Harding (Oregon State University) stated that the word "targeted" was used twice in the fourth sentence of the second paragraph on page 7. She stated that the first use of the word should be deleted.

Dr. Johnson highlighted the following items in the minutes:

- Page 2—A database is being developed for internal use to track information on past and current BOSC Executive Committee members, Subcommittee members, candidates considered for membership, and other information.

- Page 3—Tim Oppelt (ORD/NHSRC) suggested that the BOSC review ORD's Management Multi-Year Plan (MYP). A copy of the plan is in the notebook for discussion as a possible task for BOSC to undertake in the future.

- Page 13—When there are poster sessions at BOSC review meetings, there is a need to record the reviews and discussions regarding the posters so that they become part of the public record of the meeting because the BOSC meetings are governed by Federal Advisory Committee Act (FACA) rules and guidelines. Dr. Rogene Henderson (Lovelace Respiratory Research Institute) asked for clarification of the meaning of the last sentence under the Particulate Matter (PM) Subcommittee Update. Dr. Johnson explained that if there were only two work groups, it would be difficult to have a FACA meeting because you would be communicating with at least 50 percent of the total committee, which would subject the work group meetings to FACA requirements.

- Page 14—The BOSC has 13 members and each one has been involved in some subcommittee activity; therefore, the BOSC Executive Committee is actually a working executive committee. An

updated table of the projects was distributed to the attendees and Dr. Johnson commented that the table shows more progress for some of the projects than was indicated in the January minutes.

- ✧ Page 18—Dr. George Lambert (University of Medicine and Dentistry of New Jersey) is working on a BOSC workshop on international issues and there will be further discussion on it during this meeting.

- ✧ Page 18—EPA has submitted a response to the BOSC Communications Report. A copy of the response was distributed to committee members for review and discussion on June 3.

- ✧ Page 20—Dr. Johnson expressed concern about Dr. Donna Roa's (ORD's Public Affairs and Science Communication Director) use of the word "create" outputs that support ORD's strategic goals. He thought it should be "communicate."

- ✧ Page 24—The next BOSC meeting will be held in Cincinnati, Ohio, and Dr. Johnson suggested a follow up presentation on the National Homeland Security Research Center (NHSRC) and perhaps a poster session on their research.

- ✧ Page 26—There will be an update on the Computational Toxicology Subcommittee during this meeting.

- ✧ Page 27—Dr. George Daston (Proctor & Gamble) was asked to draft a letter to ORD that acknowledges receipt of EPA's response to the Biotechnology Research Letter Report, which has not been done yet.

- ✧ Page 33—Dr. Johnson asked the BOSC members to confirm their availability for the next meeting on September 12-13, 2005. There was a conference call prior to this meeting and the minutes will be provided to the members.

- ✧ Page 36—The last action item concerns the Ad Hoc Communication Subcommittee. A discussion will be held as to whether there was sufficient coverage of communication issues in the program review reports reviewed by the Executive Committee. Dr. Johnson stated that the effectiveness of communication and communication results was included in the charge questions to eliminate the need for a separate subcommittee to address communications.

Dr. Johnson stated that the members were asked to update their biosketches for the BOSC Web Site. He provided copies of the current biosketches and asked that members prepare them in a uniform format and limit the length to one page. The updated biosketches should be given to Ms. Lorelei Kowalski (ORD/OSP), Designated Federal Officer (DFO) for the BOSC.

Seeing that there were no additional comments on the minutes, Dr. Johnson asked for a motion to approve the minutes with the noted corrections/additions. Dr. Herb Windom (Skidaway Institute of Oceanography) made a motion to approve the minutes, which was seconded by Dr. Gary Sayler (University of Tennessee). The minutes were unanimously approved by the BOSC with the noted corrections/additions.

Dr. Johnson reminded the members that the BOSC is an independent group and ORD is seeking independent views on different issues from the Board. One of the reasons that ORD is seeking comments from the BOSC is that ORD wants to improve its processes. Dr. Johnson asked the members to make sure that they provide sound advice and constructive feedback on how to improve ORD programs.

Overview of the Agenda

Dr. Johnson reviewed the agenda, which included comments from Ms. Kowalski and Mr. Tim Oppelt (Acting AA/ORD); updates on the program and MYP reviews; review and approval of the May 5, 2005, Executive Committee conference call minutes; update on the Risk Assessment Workshop; a discussion on open access; an overview of the Science Advisory Board (SAB) activities; a presentation from EPA's Office of International Affairs; and a discussion of future business. An Executive Committee administrative session will be held after the public meeting is adjourned on June 2. Dr. Johnson stated that the article on open access that was provided to members was copyrighted and should not be photocopied because of copyright limitations.

Remarks from the BOSC DFO

Ms. Kowalski reminded the BOSC members that the Board is a federal advisory committee subject to the rules of FACA. As the DFO, she is present at BOSC meetings to ensure compliance with all FACA rules. She commented that the BOSC meetings are advertised in the *Federal Register* and open to the public, and members of the public will be afforded an opportunity to comment on Friday from 10:15 to 10:30 a.m. She established an electronic public docket, which can be accessed at http://www.epa.gov/edocket. This docket provides the public notice, agenda, and public comments for this meeting. The EDOCKET number is ORD-2005-0020. Ms. Kowalski stated that a contractor is present to take notes of the presentations and discussions. Joan Cox (SCG) is substituting for Beverly Campbell as the notetaker for this meeting. The contractor will prepare meeting minutes, which will be posted on the BOSC Web Site once they are approved by the Executive Committee. Members should inform her if they have any potential conflicts of interest with regard to any of the topics to be discussed at the meeting, including if a topic draws in part on their research.

Ms. Kowalski discussed the Gallup Advisory Committee Engagement Survey (ACES) that was completed by 11 BOSC Executive Committee members last year. Several members were new to the BOSC and did not complete the survey. Some members who completed the survey are no longer on the BOSC Executive Committee. The survey was conducted government-wide and its purpose was to provide constructive feedback regarding the way committees are managed to facilitate future improvements. The survey consisted of 22 questions that addressed topics such as the people involved in the committee, the process of the FACA committee, and member opinions on the reports completed by the committee and how the results may have influenced ORD. The 22 questions were rated on a scale of 1 (strongly disagree) to 5 (strongly agree). The survey results were compiled by taking the results of 1 to 5 and averaging them. The top 5 BOSC Executive Committee strengths included: (1) access to senior managers and technical experts; (2) committee meetings are well run; (3) 70 percent strongly agreed they would work with the committee again; (4) the committee fairly considers opinions; and (5) fair operating procedures and guidelines. Dr. Johnson asked about the 30 percent who did not respond that they strongly agree that they would work with the committee again. Did most of them respond with "I agree" or did they rate it much lower. Ms. Kowalski stated that no questions received a rating of 1. She agreed to review the survey results and provide the answer to Dr. Johnson. The bottom 5 areas where improvement is needed included: (1) recommendations used effectively; (2) receives sufficient feedback from the Agency; (3) members well prepared for meetings (this was an assessment of the members and how well they thought they were prepared); (4) Agency more effective due to committee activities; and (5) positive impacts of committee on the public. She stated that the first two areas are related and she was aware of these problems before the survey was completed; ORD has been working to improve these two areas during the past year. Ms. Kowalski stated that she has strived to provide materials to the members prior to the meeting since she has become the DFO and hopefully that is helping everyone be better prepared

for the meetings. She asked members to let her know if there was anything else she could do to help them prepare before or during the meetings. She also has been working over the last year to improve the lowest scoring areas. She encouraged the members to participate in the next survey, which will be conducted in 2006. She also asked the members to let her know if there were other areas that needed improvement so that they could be addressed before the next survey.

Ms. Kowalski asked that the members submit their travel vouchers by the close of the meeting, particularly those members who are involved with subcommittees. The expenses for the Executive Committee should be kept separate (i.e., submitted on separate forms) from those incurred in support of a subcommittee. She stated that an electronic accounting system is now being used and asked members to let her know if they were not getting paid or experiencing any other problems. Members should receive an e-mail from her stating the hours that were entered into the system and the date to expect their direct deposit. Dr. John Giesy (Michigan State University) asked if the system could provide separate information on reimbursable expenses. Ms. Kowalski will see if it is possible and provide the information to the members.

Ms. Kowalski distributed a handout containing a list of all of the activities that the BOSC has undertaken since last fall. It demonstrates the breadth of activities that have been conducted by the Board in the past 7 months. She thanked the members for the time and effort they have spent working on these activities.

Ms. Kowalski stated that Dr. James Klaunig (Indiana School of Medicine) and Dr. Daston were not able to attend this meeting so they will be providing their presentations by telephone.

Ms. Kowalski indicated that the BOSC has generated a number of reports in the past year and there is no standard format (i.e., header, footer, cover) or anything to distinguish the reports as draft as opposed to final. She suggested that consideration be given to developing a new BOSC logo, including a watermark on every page to indicate drafts, and a standard header and footer. Dr. Johnson stated that this would be a topic discussed in the administrative session and asked members to think of models that they would like to suggest for use by the BOSC. Dr. Johnson will work with Ms. Kowalski to develop a draft model that will be sent to the members for their review. He would like to get the model approved before the next meeting.

Ms. Kowalski reported that a nomination form has been added to the BOSC Web Site as another avenue to solicit candidates for the BOSC Executive Committee and Subcommittees. A notice can be posted in the *Federal Register* announcing that this nomination form is available and can be completed and submitted through the BOSC Web Site. The candidate database has been developed and it will contain information on past and current Executive Committee members, Subcommittee members, candidates considered for membership, and other information. The database will be searchable by specific expertise, which should improve the efficiency of forming BOSC subcommittees.

Ms. Kowalski asked that members provide her with any changes to their mailing addresses. Some members have access to Employee Express, which allows them to electronically update their human resource information. She will try to get access for all BOSC members; members not having access should send any changes in their contact information to her. Ms. Kowalski announced that Ms. Heather Drumm is the official BOSC Alternate DFO and she should be contacted when Ms. Kowalski is not available.

Remarks from the AA/ORD

Dr. Johnson introduced Mr. Tim Oppelt, the Acting AA/ORD, who thanked the Board for its hard work and contributions on the program reviews. He said that ORD is anxious to hear the Board's thoughts on the quality, relevance, and productivity of the work conducted under these programs. He stressed that the Board's comments are very important to ORD, and appropriate changes will be implemented to the programs in response to the Board's comments. ORD also is using this process as a source of independent expert review that is a best practice that many agencies use to help obtain information and input for the Program Assessment Rating Tool (PART) review process implemented by the Office of Management and Budget (OMB). He noted that Steve Johnson, who has a scientific background, has been confirmed as the new EPA Administrator. He is very encouraged by the Administrator's strong support of science. The Administrator consistently mentions the use of sound science and high-quality information in EPA's decision processes as his number one principle for the Agency. Mr. Oppelt stated that the kind of advice the BOSC provides to EPA in terms of the quality and relevance of its science is critical and on point with where the Administrator sees EPA going in the future. Since the last BOSC meeting, Mr. Oppelt has been designated as the Acting Assistant Administrator for ORD. The process is underway to identify a permanent political appointee as the AA/ORD; the individual may be identified by the end of June and appointed by early fall. He noted that many of the senior management positions within ORD are temporarily filled with individuals who are acting in those positions, and he hopes that many of these positions can be filled in the near future.

Mr. Oppelt stated that Congress has changed its appropriations structure. Formerly, EPA was included in Housing and Urban Development (HUD) and independent agencies. EPA now has been moved to Department of the Interior with other natural resource agencies. EPA conducted briefings with the Appropriations Committees in February and March, and the Agency has received a proposed budget markup from the House that provided increased funds for some of ORD's ecological programs that experienced declines in the past few years. There is a possibility that the House may provide a certain amount of funding for line items and the Agency will be able to decide what will be funded. Both the House and the Senate may provide EPA with an authorization to institute a special hiring authority (Title 40) for certain types of scientific positions (e.g., medical professions and biomedical and molecular sciences). It would allow EPA to hire five high-level scientific positions per year at competitive salaries for 5-year term appointments. There also is a provision in the President's Budget for a research funding pilot, which adds $20 million to EPA's budget, to help meet some of the short-term unanticipated needs that arise from the regulatory and regional offices. Mr. Oppelt also reported that ORD has established senior-level Scientific and Professional (ST) National Program Director (NPD) positions to lead the planning and development of cross-cutting ORD research programs.

The annual Science Forum held in May was very successful with approximately 1,200 people attending the event. On May 16-17, 2005, a student design competition for sustainability was held with posters displayed on the National Mall in Washington, DC. It was called the People, Prosperity, and the Planet (P3) Award Competition. A total of 130 teams of college students applied for grants of $10,000; 65 teams competed and 7 teams were awarded the grants, which were presented at a ceremony at the National Academy of Sciences. Six of the teams have the potential to receive up to an additional $75,000 to further develop and commercialize their ideas.

Mr. Oppelt thanked Dr. Johnson for his leadership of the BOSC. Mr. Oppelt concluded his remarks by stating that the advice the Board has provided to ORD has been timely and beneficial. He asked if any of the members had any questions.

Dr. Johnson asked if there has been any thought given to having the agencies collectively approach Congress to ask for the authority to hire high-level scientists. Mr. Oppelt responded that many agencies

have independently requested those authorities. He is going to work hard to utilize these positions if Congress approves them. Mr. Oppelt stated that the only area for which EPA requested new funds was Homeland Security. EPA requested $79 million, but that amount was substantially reduced in the President's proposed budget. The largest portion of the request was for a water surveillance system called Water Sentinel that the Agency proposed because of a Presidential Directive to develop a water surveillance system for unusual contaminants. That portion of the request was reduced from $44 million to $9 million.

Dr. Johnson stated that the next BOSC meeting would be held in Cincinnati, Ohio, and that the Board would be discussing whether another update on the NHSRC would be appropriate and perhaps a poster session on the research being conducted by the Center. Mr. Oppelt suggested that the Executive Committee invest an hour of their time conducting a field trip to visit the test facility.

Dr. Jim Clark (Exxon Mobil) asked when the permanent appointments would be made for the NPD positions. Ms. Kowalski provided the members with a memorandum that announced the appointments. Mr. Oppelt stated that the following NPDs have been approved:

- Dr. Elaine Francis—Pesticides and Toxics Research Program
- Dr. Randy Wentsel—Contaminated Sites/Resource Conservation
- Dr. Joel Scheraga—Global Change Research Program/Mercury Program
- Dr. Dan Costa—Air Program

The following individuals are serving as acting NPDs until final appointments are approved:

- Dr. Rochelle Araujo—Water Quality
- Dr. Kevin Summers—Ecology
- Dr. Hugh Tilson—Human Health
- Dr. Greg Sayles—Drinking Water

Dr. Sayler commented that the P3 award was commendable. He asked whether it would be an ongoing event and how EPA planned to communicate the competition on a national basis. Dr. Bill Farland, Acting Assistant Administrator for Science, responded that for this competition ORD distributed an announcement of the competition to Science To Achieve Results (STAR) grantees, issued press releases, placed notices in the *Federal Register*, and posted a notice on the National Center for Environmental Research Web Site. Mr. Oppelt stated that budget pressures are impacting sustainability research; therefore, ORD is not certain whether there will be adequate funding for an annual P3 competition so a biannual competition is being considered. Ms. Kowalski provided the members a handout containing the 61 abstracts for the P3 competition, the list of award winners, and the honorable mentions. The abstracts for the seven winners were flagged. Ms. Kowalski noted that this information is available on the P3 Web Site. Dr. Windom asked whether the competition could be held on a regional basis through EPA's regional offices. He commented that there was no one entered into the competition from the southeast. He suggested holding a regional competition and then having the regional winners entered into a national competition. Dr. Johnson commented that the list Dr. Windom received included only the finalists for the competition; it did not include everyone who had applied. Dr. Sayler stated that activities such as P3 are tremendously meritorious and anything that can encourage this on an annual basis would be worthwhile. Mr. Oppelt thanked him for his comment and stated that he thought that the P3 competition was a great investment in the future.

Dr. Harding asked if the Endocrine Disrupting Chemicals (EDC) Program was part of the Pesticides and Toxics Research Program. Mr. Oppelt replied that it was.

Human Health Subcommittee Update

Dr. Johnson introduced Dr. James Klaunig from the Indiana University School of Medicine, who joined the meeting via telephone, as the Chair of the Human Health Subcommittee. He thanked Dr. Klaunig for chairing this Subcommittee. Dr. Kaunig stated that it was a pleasure to chair the Subcommittee because it was a very hard working group. He commented that the Subcommittee members should be applauded for their excellent team work. He also thanked Virginia Houk (DFO for the Subcommittee) for her excellent job of keeping the review on track.

Dr. Johnson noted that one of the BOSC Executive Committee members, Dr. Anna Harding, and the SAB Liaison to the BOSC, Dr. George Lambert, have conflicts of interest pertaining to the activities of the Human Health Subcommittee. Although they were allowed to remain for the presentation, they could not provide any comments.

Dr. Klaunig stated that the Subcommittee was charged with evaluating ORD's Human Health Research Program with respect to four criteria: (1) relevance, (2) quality, (3) performance, and (4) scientific leadership. The Subcommittee chose to organize its response according to the four long-term goals (LTGs) outlined in the Human Health MYP:

- LTG 1: Use of Mechanistic Research in Risk Assessment
- LTG 2: Aggregate/Cumulative Risk
- LTG 3: Susceptible Subpopulations
- LTG 4: Evaluation of Public Health Outcomes

The program review included a 2 ½ day face-to-face meeting held February 28-March 2, 2005, in Research Triangle Park (RTP), North Carolina. At this meeting, the Subcommittee members heard a series of presentations organized around the program's four LTGs. For each LTG, an overview of the key issues and the research approaches used to address these issues were presented by the ORD Lead for the LTG. The information was augmented by a poster session where intramural researchers presented their studies and results, which included the impact and outcomes of their research. The poster sessions provided the Subcommittee members with the opportunity for one-on-one discussions with the principal investigators. Prior to the face-to-face meeting, two public conference calls were held to define the charge to the Subcommittee, make individual writing assignments, and discuss the expectations of the panel's report. A third conference call was held after the meeting in North Carolina to discuss the draft report. Minutes of these conference calls are available on the BOSC Web Site.

Dr. Klaunig stated that the Subcommittee recognized and appreciated the amount of work ORD put into the preparatory materials. There is evidence that ORD has responded to previous reviews by the Human Health Research Strategy Committee, the Drinking Water Research Committee, the BOSC, and the National Research Council (NRC). The panel expressed disappointment that the information provided to the Subcommittee was not presented in a format that specifically addressed the review criteria. Future BOSC reviews would be facilitated by EPA organizing the presentations around the review criteria. This process can be enhanced by providing the reports/critiques from previous reviews and asking EPA staff to tailor their presentations to the review criteria and critiques from previous reviews.

Dr. Klaunig provided an overview of the conclusions and recommendations resulting from the Human Health Research Program Review. The Subcommittee identified many strengths of the program. The

research was found to be of high quality and appropriately focused. It was multidisciplinary, displayed good stakeholder participation, informed risk assessments, and achieved the goal of reducing uncertainty. The hallmarks of the program are that the research is multidisciplinary and yet coherent and coordinated. The scientists display an overall high level of enthusiasm and commitment, and development of new data is encouraged at the same time that extant data are fully explored and utilized to inform the risk assessment decisions of stakeholders. Managerial excellence across the program appears to be another hallmark of the overall program. The excellent management support is reflected in the high level of excitement, commitment, and passion displayed by the scientists when describing their work. It was suggested by one Subcommittee member that this strong positive aspect of the program be explicitly recognized, continually rewarded, and carefully guarded.

Dr. Klaunig stated that as part of its conclusions and recommendations, the Subcommittee identified overall opportunities for the future. To some extent, the direction, choice, and focus of the research topics are areas where national politics interact and shape the development of the specific scientific programs. The program should monitor, engage in, and advise research efforts of other international groups such as the European Union (EU). The creation of the new National Center for Computational Toxicology may produce challenges with regard to teamwork for this program. There is a concern that the most quantitatively oriented individuals in the National Health and Environmental Effects Research Laboratory (NHEERL) and the most biologically oriented individuals in the National Exposure Research Laboratory (NERL) will become part of the new center. Although this reorganization does not involve a change in location, there is a potential that the staff of the new center will become focused on the mission of the new organization and to some extent lose contact with the scientists in their former organization. A greater level of interaction between the externally funded University Centers and inhouse research could result in more significant research progress (e.g., role of GST polymorphisms in autism, childhood asthma). A listing of inter-government agency collaborations between ORD's Human Health Research Program and its sister governmental agencies was missing from the review documents, so the full extent of this partnering could not be judged accurately and given appropriate credit.

On the issue of program quality, Dr. Klaunig stated that the Human Health Research Program is of high quality and appropriately focused. There is an overall high level of excitement and commitment displayed by the scientists in describing their work. Peer review is recognized as a critical component of this program. In regard to program performance, a remarkably positive and valuable aspect of this program is a decisive propensity within the program to encourage the mining of available data and science to inform the risk assessment decisions of stakeholders. The materials presented, however, lacked sufficient detail regarding the specific program elements to be able to reasonably conclude that the focus is consistent with the stated goals. The majority of the Subcommittee members thought that the scientific leadership of the program was excellent. Members of the program contribute and frequently take on leadership roles in environmental science, toxicology, carcinogenesis, risk assessment, exposure assessment, and public health. Most of the researchers participating in the program have made significant contributions to the peer-reviewed scientific literature. The Subcommittee noted an area of opportunity for further participation and suggested that involvement and potential collaboration with similar programs in the EU and Health Canada be explored. Another area of opportunity relates to leadership transition. There is evidence of a gap in the program between the number of senior, established scientists currently holding leadership positions and younger, less experienced researchers.

Dr. Klaunig discussed the following major points expressed by the Subcommittee regarding the LTGs:

- ✧ LTG 1: Use of Mechanistic Research in Risk Assessment. The Subcommittee found that within this LTG, there is an effective mixture of multidisciplinary research. ORD scientists have been and continue to be leaders in developing research to support EPA risk assessments. Mechanistic research

by ORD scientists has positively and significantly affected risk assessments, and will benefit future assessments of other chemicals. The Agency has successfully utilized its extramural grants program to advance its research agenda. The program, however, needs to be better advertised and perhaps even better financed and expanded to attract the widest possible competitive applicant pool. New, broad strategies should be developed by the program to manage the risks from the thousands of new chemicals that are being synthesized and released into the environment.

- ✧ LTG 2: Aggregate/Cumulative Risk. The research efforts are highly relevant to the problems of the Agency in assessing the risks faced by the public. The research described in the area of cumulative risk assessment is particularly creative, effective, and well conducted. The work shows a propensity to develop new data and to mine available data to inform risk assessment decisions. Assessments should be more comprehensive, however, and include a wider array of chemicals important to human exposure. The overall criteria and framework for decisions regarding why specific elements are vital and have been included in the research program could be further enhanced in the written material. A more transparent explanation of these aspects would be most valuable. This program plays a leadership role in advancing the realm of scientific development in the areas that currently are addressed. The scientific staff is excellent, as are the facilities, and the funding appears to be adequate. Within this realm, the managers and researchers are overseeing and participating in a program that is leading the state-of-the-science.

- ✧ LTG 3: Susceptible Subpopulations. The susceptible subpopulations program is well grounded within the ORD strategic plan. There is evidence of good coordination with other programs in the Human Health Research Program, as well as with outside research organizations (nationally and internationally), and there is leveraging of effort across federal agencies. Agency scientists involved in the research on children's susceptibility are internationally recognized experts in children's environmental health and play a strong role in fostering a continuing emphasis on this research area. While appropriately directed, the justification of the research should be expanded. This can be accomplished through a description of the scientific basis supporting the decision to focus on children's health (e.g., why this subpopulation and not the elderly?). The current level of involvement of program offices, regional offices, and other stakeholders provides strength to the program; it should be sustained and possibly upgraded. There is a need to expand EPA expertise to include community-based participatory research. The single dimensional model presented in this program did not fully represent what is a dynamic multidimensional research program. The justification to focus on children should be strengthened.

- ✧ LTG 4: Evaluation of Public Health Outcomes. This program is relatively new to ORD and the Human Health Research Program. It is consistent with the overall mission of EPA in the protection of human health. The program on public health outcomes is being built upon the exposure-dose-effect continuum. The public health outcomes program is highly relevant to the mission of the Agency and has the potential to serve as the nucleus for integrating and evaluating ORD research. The goals of this program could be further focused to guide future activities and a process needs to be articulated for making decisions about which actions to evaluate, which endpoints to study, and which environmental indicators to apply. It is recommended that a mechanism be put into place with formal and informal components to promote dialogue among the LTGs and to provide a process for assessing research outputs. The program will require additional monies and personnel to broaden expertise in the areas of public health, especially in biostatistics and environmental epidemiology.

Dr. Klaunig explained that the draft report is more detailed than his presentation. He asked if there were any questions or comments. Dr. Clark praised the efforts of Dr. Klaunig in chairing this Subcommittee. There were some very strong opinions among the Subcommittee members and all of them were

accommodated in this presentation and in the report. The members' opinions ranged from very complimentary and enthusiastic to very critical and judgmental. Dr. Klaunig found a way to reflect all of the points of view of the Subcommittee members. He thanked Dr. Klaunig for his assistance and work on this report.

Dr. Henderson stated that when she thinks of human health research and EPA, the first thing she thinks of is epidemiology. She believes that the Agency decided long ago that it could not afford to focus its health research on epidemiology. Dr. Klaunig responded that epidemiology is part of the process and there is an effort to include epidemiology under LTG 4. It is underlying everything as part of the driver for the research. Dr. Farland thanked Dr. Klaunig for the good work on the report. He commented that, over the years, EPA has looked at trying to build an epidemiology program, but that Agency has chosen a multidisciplinary, team approach and elected not to conduct long-term, large epidemiology studies. EPA relies on large national institutes to carry out those kinds of studies. There is an epidemiology group that is associated with EPA's Human Studies Division in the health laboratory in RTP, which is affiliated with the University of North Carolina. That group provides an underlying epidemiology expertise, but epidemiology is not a major part of EPA's health program. Dr. Henderson agreed with EPA's decision not to do large epidemiology studies, as these studies are extremely expensive and others are doing them well. She asked whether the chemical exposure studies conducted by EPA on clinical exposures of people to defined atmospheres or to hazardous air pollutants (HAPs) are part of the air research program. Dr. Johnson confirmed that those studies are part of the air program. Dr. Henderson complimented Dr. Klaunig and the Subcommittee members on this report. She thought EPA's health research was on target—directed toward national priorities as is appropriate for a government organization.

Dr. Henderson stated that on page 2 of the report LTG 1 of the *Human Health Research Strategy* is harmonizing cancer and noncancer risk assessments; however, further down on that page, LTG 1 is listed as use of mechanistic information in risk assessment. Apparently, the goal has been changed to mechanistic research. She suggested that the report reflect this change. Dr. Farland stated that harmonizing cancer and noncancer was the first of the goals that was described in the research strategy. When the MYP was prepared, that goal was broadened to include more mechanistic work. Dr. Klaunig agreed to clarify this section.

Dr. Henderson suggested that the summary of strengths and opportunities that Dr. Klaunig provided in his presentation should be included in bullet form in the executive summary. It would be much clearer to the reader than the prose that currently is in the report. She noted several places in the report where there are redundancies; the same sentences are used twice, even within the same section (e.g., on page 34, lines 1-4 and on page 35, lines 24-26). On page 4, line 10, she questioned the wording "Interaction is occurring among the LTGs...", and suggested inserting "leaders of the LTGs." The same situation occurs on page 11, line 7 ("to promote dialogue among the LTGs"). She commented on the sentence "This analysis should differentiate the intramural from the extramural programs" (page 7, lines 6-7) and asked why the programs needed to be differentiated. Dr. Klaunig responded that he would clarify that sentence. Dr. Henderson stated that, although she had provided a few suggestions to improve the report, she thought it was an excellent report. Dr. Klaunig asked if she could provide a copy of the report with her comments. Dr. Clark volunteered to obtain Dr. Henderson's comments, and Ms. Houk agreed to send the marked up copy to Dr. Klaunig.

Dr. Johnson commented that the BOSC Executive Committee must be careful to eliminate any contradictions within and between the various reports. He noted that there are potential contradictions between the Human Health Program Review Report and the Computational Toxicology Report. On Friday, the BOSC will be discussing the Computational Toxicology Report, which identifies the staff as modelers and not as biologists and epidemiologists. The Human Health Program Review Report

mentions that staff of the human health research program may be lost to the new Computational Toxicology Center. That may not happen, however, because it may be more modelers transferring to the new Center rather than content experts. Dr. Johnson commented that on slide 14 of Dr. Klaunig's presentation, there is mention of a need to further international participation; however, on slide 18, the program is complimented for its national and international collaborations. Dr. Klaunig stated that international participation was reflected in LTG 2, but it was not apparent to the Subcommittee that the overall program leadership participated in national and international collaborations. Dr. Johnson suggested using the verbage "overall, except as noted within."

Dr. Johnson stated that the issue of transparency as it relates to funding priorities and projects is something that is turning up as a common theme in other reports and will be discussed later. On slide 17 of the presentation, the issue of transparency refers to how projects are selected and the selection of intramural research versus extramural projects (i.e., STAR grants), mentioning that the rationale for project selection is clearer for extramural projects. Dr. Klaunig stated that he would clarify that section as it really referred to the intramural work.

Dr. Sayler stated that slide 10 mentions the concern that people will be transferred from the human health program to the Computational Toxicology Center. He asked if this concern arose from the Subcommittee or from the human health program staff. Dr. Klaunig responded that it was a concern of the Subcommittee, but he cautioned the program leadership to guard against this possibility. There is some concern that there will be a gap in program leadership as some of the leaders may move to the new Computational Toxicology Center and no mechanisms were identified to fill that void. ORD senior leadership thinks that there will not be a void as there will be a lot of continued interaction between the two programs, and there was nothing presented to suggest that this interaction would not occur.

Dr. Sayler commented that slide 15 of the presentation indicated that stakeholders were using the mechanistic research and it had significantly affected risk assessments. He asked if there was any evidence to support this and how good was the evidence. Dr. Klaunig responded that there were several examples under LTG 1 in the draft report. In addition, the lead reviewer for LTG 1 thought that in talking to the ORD presenters and reviewing the materials provided, there were examples where stakeholders were using the information. These additional examples could be included in the report if necessary. Dr. Clark stated that the evidence came from the discussions of how the risk assessors are using benchmark dose and how the models are being used to set up exposure pathways and assessment pathways. Most of the examples came from testimonials from the regional offices. Dr. Johnson commented that the examples are on pages 19 and 20 of the report.

Dr. Johnson asked for a motion to accept the report with the noted editorial corrections and format changes. Dr. Henderson made a motion to accept the report, which was seconded by Dr. Clark. The report was approved by the BOSC with two exceptions—Drs. Harding and Lambert recused themselves from participation in this discussion. Dr. Clark will collect comments on the report and send them to Dr. Klaunig who will make the final corrections.

Particulate Matter (PM) Subcommittee Update

Dr. Henderson commented that the PM Subcommittee members were very talented and worked very hard on the review. Lawrence Martin, the DFO for the PM Subcommittee, was excellent and provided much needed assistance to the Subcommittee. Dr. Henderson served as the Subcommittee Chair, and Dr. Juarine Stewart (Morgan State University) served as the Vice-Chair. The Subcommittee originally decided to organize the review along the LTGs; however, EPA was in the process of integrating the PM

and ozone programs and there were separate LTGs in the MYPs for each of these programs. Therefore, the decision was made to organize the review around the charge questions.

The Subcommittee was formed by mid-February and an initial conference call was held on February 25, 2005, to discuss the logistics. A second conference call was held March 3 to discuss the charge questions and writing assignments. Review materials were received from EPA on March 10. The poster review session assignments were made on March 28. The face-to-face meeting was held March 30-April 1, 2005, in RTP. The first draft of the report was completed on April 1 and a conference call was held April 12 to discuss that draft. Dr. Dan Costa was sent a preliminary draft report on April 14 so that he could submit it to OMB along with other materials for the program's PART review. The final draft report was completed on April 21, 2005.

Dr. Henderson stated that the topics of the four charge questions were: (1) program design and demonstrated leadership, (2) science quality, (3) relevance, and (4) demonstrated outcomes. She noted that there was some problem with demonstrated outcomes in the previous PART review because the scientists were concerned with outputs, but not so much with outcomes.

In the face-to-face meeting, three major areas were presented: exposure health outcomes, air quality, and source to outcomes (an atmospheric approach intended for use in the future when they begin to look at mixtures of pollutants rather than at one pollutant at a time). The meeting included both oral presentations and a poster session, which covered both intramural and extramural research. The presentations were very well done. One Subcommittee member thought that the work should be separated into the work conducted within EPA and the work conducted by contractors, but the majority of the Subcommittee members held strong opinions that the intramural and extramural research should be integrated.

Dr. Henderson then reviewed the charge questions, organized under the four topics. They included:

Program Design and Demonstrated Leadership

- ✧ Does the new draft PM/Ozone MYP structure reflect the identified science needs of the program and show integration leveraging of human and fiscal resources?

- ✧ Is ORD sufficiently coordinating research across categories of the risk assessment paradigm (source, exposure, health assessment, and management)?

- ✧ Is ORD providing evident and appropriate science leadership and program management?

- ✧ Are there important interagency or extramural collaborations that should and can be improved to advance the Agency's research agenda?

Science Quality

- ✧ Is the science being conducted by EPA ORD research laboratories and centers of recognized high quality and appropriate to the perceived needs?

- ✧ Is program integration across laboratories, centers, and science discipline making full advantage of research opportunities?

- ✧ Does the program ensure high quality research through competitive, merit-based funding? If funds are not competitively awarded, what process does the program use to allocate funds? Does this process ensure that quality is maintained?

Relevance

- ✧ Does the PM/Ozone structure and research program clearly reflect its focus and the rationale behind its research direction and out-year emphasis?

- ✧ Are the potential public benefits in terms of public health protection and pollution abatement clearly articulated?

- ✧ Has the PM/Ozone program effectively engaged stakeholders in its assessment processes, and provided useful information and tools in a timely manner?

- ✧ Has the program begun to establish a process for using the results of assessments, along with stakeholder feedback, to identify key research gaps and to update the program's research agenda?

Demonstrated Outcomes

- ✧ Does the program have a limited number of specific long-term performance measures that focus on outcomes and meaningfully reflect the purpose of the program?

- ✧ Has the program made significant progress in the conduct of the planned research and in answering the key science questions related to public health and pollution abatement?

- ✧ Does the program have ambitious targets and time-frames for LTGs?

- ✧ Do independent evaluations of sufficient scope and quality indicate that the program is effective and is achieving results?

- ✧ Do EPA ORD and program leadership make adjustments in the program's science and emphasis to meet the evolving science and research needs?

Dr. Henderson stated that the demonstrated outcomes questions were the most important for the program because of ORD's need to measure the outcomes. Dr. Dan Costa, the newly appointed NPD for the air program, needs some type of quantitative measure of the outcomes. Dr. Henderson noted that outcomes are different from outputs. Scientists do their experiments and they generate an output. How that output affects outcome, which is some measure of improving the protection of public health, is difficult to determine. Dr. Costa related to her that OMB was pleased with quantitative measures, such as the percentage of EPA documents cited in the criteria document for setting the PM standards.

Dr. Henderson presented the major conclusions from the program review. The Subcommittee found that the PM/Ozone program directly addresses NRC (and OMB) concerns in terms of its new proposed LTGs, the plans to meet these goals, and the ways to measure progress toward these goals. The ORD PM research program has resulted in significant reductions in scientific uncertainty in critical areas, especially the distribution and dosimetry of inhaled ultrafine particles, the relationship of ambient, fixed-site PM monitoring to real-world human exposures, the identification of susceptible subpopulations, the identification of biologically plausible mechanisms of PM toxicity (including cardiovascular effects), and the validity of PM epidemiological studies, including confounding and misclassification of exposure, as

well as improved emissions monitoring and air quality modeling. Dr. Farland asked if it should be inhaled ultrafine or fine particles. Dr. Stewart responded that it was both, but the emphasis was on ultrafine particles. Many of the posters focused on ultrafine and there appeared to be some shifting of emphasis toward ultrafine. Dr. Henderson said that they could change the report to read fine/ultrafine. Dr. Henderson stated that the outputs produced by research to support these reductions in uncertainty have provided a sound basis for subsequent improvements in public health (outcomes). The current ORD PM program provides a balanced blend of research outputs targeted at uncertainty reduction and outcome-directed research to assist EPA's Office of Air and Radiation (OAR) in protecting public health. The Subcommittee considers that this blend of output- and outcome-directed research is critical to the long-term success and relevance of the program.

The Subcommittee finds the overall science being conducted by the ORD PM/Ozone program in both the intramural and extramural research laboratories to be of high quality as indicated by: (1) scholarship and scientific publications, (2) credentials of participating investigators, (3) integrative and outcome-oriented program design, and (4) building of a knowledge and information database. There is a high degree of integration in the conduct of intramural and extramural research across the various laboratories, centers, and scientific disciplines. ORD has been responsive to the needs of its primary client, OAR, and to its other stakeholders, particularly the EPA regions and the states. The stakeholders have multiple opportunities for involvement in ORD's assessment and prioritization of research needs.

Dr. Henderson stated that the funding for extramural research is based on a highly competitive, merit-based process. The process for intramural funding is not as transparent, but is based on the recommendations of the Air Research Coordination Team (RCT), which includes the NPD for the Air Program, high-level representatives of ORD's laboratories and the extramural research program, a regional representative, senior scientists from OAR, and others.

The strategic decision to terminate ozone-related health research undercuts part of ORD's first LTG (i.e., "In 2012, reduced uncertainties in the air pollution sciences will lead to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment"). Dr. Henderson stated that the recent appointment of a permanent NPD for the Air Program is a step forward to improve the overall management of the program.

The Subcommittee recommended that the wording of the two LTGs be revised to read:

- ✧ LTG 1: In 2012, enhance understanding in the air pollution sciences and reduce associated uncertainties leading to more effective and efficient PM and ozone standard setting and air quality management during each regulatory cycle to minimize adverse risks to human health and the environment.

- ✧ LTG 2: In 2015, demonstrate the integrated linkages of pollutant sources to health outcomes and reduce their associated uncertainties to ensure that ORD clients target air pollutant strategies more effectively and efficiently to best protect human health and the environment.

Only slight word changes were made to these LTGs to try to improve the link between research and outcomes. Dr. Johnson commented that the original wording of the two LTGs should be included in the report so that the changes suggested by the BOSC are evident.

Dr. Henderson stated that the Subcommittee recommended structuring the performance of LTG 2 around two to three hypothesis-driven pilot studies that would demonstrate the source-to-health outcome concept

and should provide a reasonable metric to measure the success of the program, both from a science and policy perspective. It also was recommended that an expert panel or workshop be used to review the pilot studies and to follow their progress on a regular basis. The Subcommittee recommended that the MYP, which was not finalized at the time of the program review, include a discussion indicating how the 10-12 goals set out by the NRC flow into the cross-cutting research issues and how they are embodied under the two LTGs. The Subcommittee reinforces the NRC recommendation that includes the establishment of multi-agency goals and measures of success in meeting national goals, preparation of an MYP for PM/Ozone that incorporates other federal agencies as well as states and private organizations, defines the roles of individual agencies, provides for input from nonfederal organizations into the federal planning process, and expands communication of the planning process to the public. These remain worthwhile recommendations and areas where ORD can assume a leadership role.

The Subcommittee recommends that funding decisions for any active intramural project undergo review by the Air RCT. The Subcommittee members thought that this was being done, but it was not apparent to them. Recognizing that EPA faces serious resource constraints, the Subcommittee nevertheless recommends that ORD reconsider the decision to completely disinvest in ozone health research.

Another recommendation is that ORD consider establishing a periodic formalized process for assessing its primary stakeholders' perceptions of and satisfaction with its efforts. To facilitate the evaluation of progress, expert panels or workshops should be asked to define a baseline of the current uncertainties for each component of the program. Then, the expert panels can assess the reduction of or alterations in uncertainties at regular intervals.

The Subcommittee suggests that EPA develop a methodology to clarify how the cost effectiveness of its regulations can be quantified. There should be a timely transfer of basic research products into practical tools (e.g., the development of more detailed and complete emissions inventories for biogenic VOCs using all available information). Finally, the Subcommittee recommends that funding be set aside for anticipatory research needs, and that steps be taken by ORD to identify and highlight key anticipatory research needs to inform longer term research, and to assure that current and out-year funded levels of research will be consistent with potential long-term regulatory needs.

Dr. Henderson reported that the Subcommittee members did not review detailed resource allocations by research program area because the information was not provided to them. The Subcommittee concluded that while such information might have provided useful insights in selected areas, the members were not required to address this issue under the charge questions posed by EPA.

Dr. Harding asked why resources were not part of their charge questions, adding that the subject of resources was part of the EDC Program review. She noticed that adequacy of resources was not included in the charge questions for the last two programs that were reviewed. Dr. Johnson responded that he was not sure why that happened; they may have been dropped erroneously. Dr. Farland commented that it was probably better that resource questions were dropped from the Human Health Research Program Review as the program is so big and broad that it would have been difficult to try to answer the questions. Dr. Henderson added that they would have had the same problem with answering those questions for the Air Program.

Dr. Stewart stated that Dr. Henderson did an excellent job as the Subcommittee Chair, commending her leadership of the group. Dr. Stewart commented that the Subcommittee observed excellent communication between the intramural and extramural scientists. The efforts were well integrated and workshops were conducted that provided opportunities to identify any research gaps and ensure they were filled by one of the research groups. Adequacy of resources was an issue in the review because

there was no information provided about resources, so there was no way to determine how the research was prioritized. This is an important issue for PM and ozone; if the budget is being cut by one-third, then how will EPA determine what research should continue? She emphasized the need to include the adequacy of resources question in future reviews. Dr. Stewart stated that the reports should explicitly discuss communication, including intramural and extramural, interagency, and key stakeholders (e.g., OAR) communication. There also is a need to address communication with the public, to assess how well the research results are being disseminated and how they contribute to the betterment of health.

Dr. Giesy stated that the report was well organized and well written. He commented on two broad areas that apply to all of the program review reports being prepared by the BOSC. It has become apparent that the various divisions within ORD need help with the OMB PART process. The ORD scientists are very capable technically, but the rules have changed. The old metrics that they used to determine the quality of the work they were doing and its impact are no longer being used. If at all possible, the BOSC needs to try to give them more specific help in trying to establish the outcomes relative to human health or make statements that indicate the difficulty in developing the outcomes. The reports need to be specific in telling ORD scientists what we think they can do to make something better or give them statements that are helpful to them by saying it is practically impossible to do that. The second broad area is the need to clarify who (e.g., NIH, EPA) is responsible for each activity. This input would help ORD better communicate how it has coordinated its activities and it would demonstrate to OMB that EPA has a critical role to play. The reviews to date have concluded that ORD has excellent scientists and they are doing great research, but the review reports are not being packaged in a way that the administration can understand the value of the research and that will translate into resource reductions. Dr. Henderson commented that in the face-to-face meeting there was a discussion of why EPA should be doing this type of research rather than NIH, universities, or other organizations. EPA needs to do the type of research that helps the Agency set standards. Dr. Giesy responded that some of that is discussed in the text of the report, but is not included in the bullets at the front of the report. Some of the conclusions and recommendations should have more focused statements that everyone (including non-scientists) can understand. Dr. Giesy agreed, however, that it was an excellent report.

Dr. Johnson commented that Recommendation 2 on page 5, was an attempt to provide an approach to measure outcomes. He expressed concern that the communication issue was not addressed in the executive summary. Dr. Johnson suggested that the communication issue be included in the executive summary of all program review reports. He also recommended that the original wording for the LTGs be included in the report. The comment about terminating the ozone program does not appear until late in the report; it should be included earlier in the report, possibly on page 13. On page 17, lines 29-30 , there is a reference to 12 areas of emphasis proposed by the NRC; on page 29, line 40, there is a reference to 10 questions raised by the NRC, which makes it appear as if there is an inconsistency in the report. He agreed to provide these and additional editorial comments on the report to Dr. Henderson.

Dr. Giesy commented that all of the program review reports should include more discussion of the extramural programs and how they are integrated with the intramural research. As funding gets tighter in ORD, the extramural programs are being significantly reduced to the detriment of ORD. One of the hallmarks of ORD is the interaction through extramural funding and cooperative agreements that benefits both parties, not only enhancing the quality of the work that is done but also the innovation. In addition, such interaction offers opportunities to recruit the best of the next generation of young scientists into the Agency. Dr. Henderson stated that the PM program has a very strong extramural component. One reason the Subcommittee wanted to see the resource allocation information was to identify the split between intramural and extramural.

Dr. Farland referred to Recommendation 3 (the Subcommittee recommended that the MYP include a discussion indicating how the 10-12 goals set out by the NRC flow into the cross-cutting issues), page 6, and stated that the discussion was in the strategy that was behind the MYP. He was not sure if the Subcommittee was suggesting that it was missing completely or whether it should be included in the MYP. He commented that in September 2004, a 5-year synopsis of the PM research was developed and EPA made a point of communicating it to the public; this, however, was not reflected in the report. Dr. Stewart said that the report should more explicitly identify the communication efforts for the program. Dr. Farland suggested that Recommendation 8 be clarified as he was not sure of its meaning. He read it as an increase in social science research that basically moves scientific data into conclusions about cost effectiveness. That would be a directional change in ORD's research program.

Dr. Giesy questioned Recommendation 9; he was not sure what the problem was or what the Subcommittee was trying to correct. Dr. Henderson stated that the first sentence was poorly worded. This recommendation resulted from one Subcommittee member's concern for biogenic materials. The report may overemphasize this one comment and she would be willing to delete the recommendation. Dr. Johnson suggested that, before the recommendation is deleted, it should be reviewed to ensure that there is not a general message that should be retained but just needs to be reworded with a better example.

Dr. Harding asked whether the outcomes (e.g., page 27, line 37) in the report were developed by the Subcommittee or provided to them by EPA. Dr. Henderson replied that the outcomes were provided by EPA. That specific example was provided by Dr. Costa who informed the Subcommittee that it met with OMB's approval. Dr. Harding questioned whether the italicized outcomes in the report were really outputs. Dr. Stewart stated that there is a bureaucratic difference between what scientists and OMB view as outcomes and outputs. OMB prefers numbers that result in something that can be measured. Dr. Henderson stated that she was told that OMB preferred quantitative outcomes. The program scientists generate outputs that are provided to OAR, which then sets standards. Outcomes are measured after the standards are set; therefore, the outcomes are attributed to OAR and not ORD. Dr. Farland stated that there are near-term outcomes and long-term outcomes, the latter of which are related to public health. This is an example where ORD can be quantitative about the research that is being produced and used to support regulatory activity. It is quantitative, but it also suggests that there is an increased use of the information to support a regulatory decision and that is a near-term outcome. Dr. Harding suggested that the italicized outcomes in the report be clarifed by stating that they were being used for regulatory decisions.

Dr. Lambert commented that on page 2, line 28, there was a statement that OMB has estimated an annual savings of $101 to $119 billion attributed to air pollution regulations resulting in decreased PM. He suggested that this statement be included as an outcome in a conclusion in the report. Dr. Cliff Duke (Ecological Society of America) commented that on page 9, line 4, the word "reviewed" should be added after the words "Subcommittee has." He asked whether the BOSC is considering preparing a synthesis document of the common threads that are starting to appear in the program review reports that have been prepared. Dr. Johnson responded that the intention is to prepare a document of the common threads found throughout the program reviews once a few more reports have been completed. He already has identified transparency of the intramural funding and communications as two possible common threads. Dr. Farland stated that there will be an internal EPA meeting in July at which the staff will be looking at the issue of common threads, issues relating to the information provided to the subcommittees, the kinds of responses the subcommittees provided, and the structure of the reports. The meeting will be attended by the NPDs and the DFOs who have worked with the BOSC subcommittees. Dr. Farland said that he would appreciate the BOSC's input on the program review process to improve the effectiveness of future reviews.

Dr. Johnson suggested that Recommendation 5 be split into two recommendations—one on funding for the intramural program and one on the termination of ozone health research. He asked Dr. Henderson and Dr. Stewart to incorporate the comments into the report and send it to the BOSC members to review. An Executive Committee conference call will be scheduled to discuss the revised report. Ms. Kowalski stated that the Executive Committee members may send their comments to Dr. Henderson, but they should not copy the entire BOSC. The revised draft report will need to be discussed in a public forum. Dr. Johnson stated that many of the issues discussed for this report apply to all of the reports. He asked the members to be aware of these issues and ensure they are addressed when future reports are prepared.

Dr. Farland announced that the President intends to nominate Marcus Peacock to be EPA's Deputy Administrator. He currently serves as the Associate Director for Natural Resource Programs at OMB.

Dr. Lambert reported that some of the Children's Centers already have met with Dr. Farland to firm up the interactions between these Centers and EPA. Their annual meeting will be held July 11-12, 2005, in Research Triangle Park, North Carolina. There will be breakout sessions with specific intramural programs to enhance intramural and extramural relationships.

Drinking Water Subcommittee Update

Dr. Sayler, Chair of the Drinking Water Subcommittee, reported that this program review should have been completed by April 2005; however, the DFO informed the Subcommittee that the face-to-face meeting scheduled to be held in Cincinnati, Ohio, in late March 2005 had to be postponed. The meeting has been rescheduled for June 21-23, 2005. A conference call will be held on June 6. One Subcommittee member has been replaced by Mary Ward from the National Cancer Institute, who is an environmental epidemiologist. Dr. Johnson asked if the BOSC table of projects has been updated to reflect these changes. Ms. Kowalski responded that the table was updated and it is anticipated that the BOSC Executive Committee will review the draft report at its September meeting. The report should be finalized by October.

Global Change Subcommittee Update

Dr. Duke, Vice-Chair of the Global Change Subcommittee, reported that a Subcommittee nomination package was sent to the Administrator's office on May 11, 2005. He is planning to schedule several conference calls during the summer. The face-to-face meeting will be held September 26-28, 2005, in Washington, DC. It is anticipated that the draft report will be ready for review at the January 2006 BOSC Executive Committee meeting. Dr. Johnson commented that the Chair of the Global Change Subcommittee will not be a member of the Executive Committee, and the name will be announced as soon at the nomination package is approved. He suggested that Dr. Duke speak with Dr. Clark regarding his experiences in assisting an external Chair in understanding the BOSC and what is expected for a program review.

Mercury MYP Subcommittee Letter Report

Dr. Windom, Chair of the Mercury MYP Subcommittee, reported that it has taken almost 2 years to form this Subcommittee. He attributed the delays to a variety of reasons—a change in the DFO, obtaining approval of the Subcommittee members, and recruiting a member with expertise in combustion technology. The Subcommittee consists of three BOSC Executive Committee members—Drs. Windom, Henderson, and Johnson, and four additional members—Drs. George Lambert, Rui Afonso, Cynthia Gilmour, and Michael Waalkes. Dr. Windom reported the Subcommittee held a public conference call on January 19, 2005, and the public face-to-face meeting was held February 23-24, 2005, in Washington,

DC. A first draft of the letter report was prepared and comments were sent to Dr. Windom in accordance with FACA rules. There was a final conference call on March 29, 2005, to discuss the revised letter report.

Dr. Windom explained that this review differs from the program reviews in that it is based on a process of developing the MYP, not the research program itself. The MYP covers a number of different programs and requires collaboration from each of the programs to develop and implement the plan. The Subcommittee reviewed the most recent Mercury MYP, which was dated May 2003. The charge questions to the Subcommittee were:

- ✧ What changes should be made to ensure that the proposed scope of the work is consistent with: (a) ORD's subject area Research Strategy, (b) current state-of-the-science, and (c) research by others?

- ✧ What changes should be made to ensure that the science questions address the most important scientific gaps and uncertainties in the subject area?

- ✧ What changes should be made to ensure that the LTGs are relevant to the science needs of the Agency, and the MYP situates the annual research products (Annual Performance Goals [APGs], Annual Performance Measures [APMs]) on a clear path to accomplishing each of the LTGs (and APMs contribute to APGs)?

- ✧ What changes should be made to ensure that the research products and emphases over the next 5 to 7 years are sequenced appropriately to accomplish goals and meet program and regional needs?

- ✧ What changes should be made to ensure that the MYP is flexible enough to adapt to future science and policy changes?

- ✧ What changes should be made to ensure that the MYP articulates a strategy that facilitates effective communication and utilization of research products (with domestic and international parties)?

- ✧ What changes should be made to ensure that there is a clear path for assessing/evaluating the MYP and progress toward its goals?

Dr. Windom stated that all of the charge questions were addressed, comments were generated for each of the questions, and recommendations were developed for most of the questions. Page 2 of the report presents the five overriding recommendations resulting from the review.

The first recommendation is that the MYP planning process would benefit from an interagency council to institutionalize and harmonize collaboration across federal agencies and to provide for proactive leveraging of resources. Such coordination is necessary to assure that all aspects of the mercury problem are being addressed and is particularly important in assessing the adequacy of ORD's funding for research on its part of the problem as compared with the parts addressed by other agencies. The Subcommittee considers the present level of ORD funding for mercury research to be limited considering the regulatory needs of the Agency to address the effects of mercury on human condition and ecosystems.

The second recommendation addresses prioritizing and sequencing the APMs, which need to be discussed more fully in the Mercury MYP. Some APMs must be completed before others can be accomplished, but some are probably more flexible with regard to when they are accomplished. Prioritization often is a "moving target." For example, a program need may require that resources be

shifted from research aimed at one APM to another one. Flexibility is required to accommodate such shifts, but for the purpose of communicating the Mercury MYP, the criteria for sequencing and for shifting priorities should be stated and reflected in an annual update of the plan as recommended in the response to Charge Question 4. The Mercury MYP is only 22 pages and is meant to be a communication document.

The third recommendation is that the value of the Mercury MYP as a "living" document would be enhanced if it were updated annually instead of every 3 years. A rewrite of the text would not be required; rather, the appendices could be used to provide an indication of progress on the APMs. For example, if an APM was proposed to be completed during a given year and for some reason it was not, the explanation for why the APM was not completed could be annotated in a footnote that might relate to the criteria for prioritizing/sequencing as discussed in the second recommendation.

The fourth recommendation addressed the Mercury MYP as a communication document as well as a planning document. Communication should be made a major part of the plan if the program is to successful. The Subcommittee strongly recommends that the MYP articulate a detailed plan for communications with domestic and international parties. These parties include EPA outside of ORD, other federal agencies, states, tribes, the general public, industry, extramural research groups, and governments of other countries. The plan should recognize that communication is a two-way process and feedback from partners is crucial to success.

The fifth recommendation addressed the issue of measuring outcomes. It would be helpful if the Mercury MYP provided an assessment of outcomes related to the various APGs and APMs since the previous plan. This would help to track progress and to translate just how the results are being used.

Dr. Windom completed his presentation and asked if there were any questions. Dr. Sayler said he found the two levels of recommendations in the report to be confusing—there are overriding recommendations and recommendations in response to the charge questions. Also, there are no recommendations for some charge questions; however, he thought there were recommendations for all of the questions in the text. He encouraged the Subcommittee to develop parallelism in the underlying recommendations relative to each charge question and differentiate those recommendations from the overriding recommendations. He also asked about the Agency needs. The report points out that the fate and transport research is probably the best work within the Agency; however, there is no discussion about other needs such as modeling, monitoring, and issues of human health, ecosystems, and communications. It would be better if the report could identify the critical needs of the Agency with respect to this primary goal of reducing scientific uncertainties that limit the ability of the Agency to assess and manage mercury. Are fate and transport issues the most significant or are there other needs? Dr. Windom responded that the review was limited to the process of the plan and did not focus on the program. The review was to determine if the process involved communicating with other ORD programs to ensure that the plan was integrated with other research and addressing the Agency's needs. It was unclear where the Agency's needs ended and those of other agencies (such as the National Institutes of Health [NIH]) began. The Mercury Strategic Plan identifies six questions that need to be addressed. ORD's mercury program does not address all of those questions because it has limited resources; the program only addresses those questions that the scientists are best qualified to address. The program's leadership believes that fate and transport research will yield the greatest return for the limited resources available. With regard to the recommendations, some of the responses to the charge questions were so positive that the Subcommittee had no recommendations for improvement. In some cases, recommendations applied to more than one charge question, which is why the overriding recommendations were developed and included at the front of the report.

Dr. Clark liked the overriding recommendations at the front of the report as well as the explanation as to how the overriding recommendations were developed in the responses to the charge questions. The BOSC should probably go no farther than stating that there are other priorities that should be considered; however, the report also should have recognized the funding constraints and stated that EPA is tackling the areas for which they are best qualified at present. Additional needs could be identified. It then is up to ORD to sort out what is to be done and when. He believes that the report strikes the right balance in terms of the funding constraints and identifying areas that ought to be considered. Regarding the timing for updating the MYP, the report presents a rational argument for why more frequent updates are necessary and how the information would be used. It would result in the MYP achieving a balance between a planning and communication tool. Although this recommendation carries an administrative burden, the utility of it outweighs the burden. Dr. Clark also appreciated that the Subcommittee provided specifics about what was needed and how that information should be used. Dr. Windom commented that the Subcommittee was concerned about the increased administrative burden on ORD; however, the members were assured by ORD staff that they more or less do it already and it would just be a matter of formalizing the process. Dr. Clark stated that on page 5, line 18, there is a statement that MMAPS assumes a linear response. Is that attributed to the Agency or the Subcommittee? On page 8, lines 5-8, there is a recommendation that the MYP include a detailed plan on how the research products will be marketed. Dr. Clark suggested that a few examples be added. Dr. Windom commented that under the mercury plan, EPA is testing new technologies and proposing better technologies such as emissions control technologies. The Subcommittee was not clear how EPA markets these technologies to encourage their use, or how the Agency assesses who used them, which is an outcome.

Dr. Johnson questioned the use of outputs and outcomes on page 8, lines 7-10. This needs to be clarified. Dr. Windom responded that those lines refer to research outputs; how they are used determines the outcome and there needs to be a process in place to assess the outcomes. Dr. Johnson suggested that the report state that outputs lead to outcomes, and include some descriptions of outcomes and how they impacted regulations. The letter report should contain an opening paragraph that identifies the Subcommittee members and a concluding sentence, similar to that in the Computational Toxicology Letter Report. The format of the all of the letter reports should be consistent.

Dr. Johnson commented that it should be clearly stated in the report when there is no recommendation for a charge question. There was a recommendation in the text for charge question 3 on page 5, line 36, but it is not included in the list. Dr. Sayler suggested that a recommendation also could be developed for charge question 5, page 7, lines 14-15—the plan should prioritize future research directions in case this increase is not fully realized. Dr. Johnson asked Dr. Windom to develop these recommendations for the specific charge questions so that they can be discussed on Friday. Dr. Windom responded that he would meet with Ms. Drumm, revise the report, and provide it to the BOSC Executive Committee for review.

Dr. Harding asked about EPA's role and stature in global mercury research. It might be helpful to state that EPA is a leader and doing state-of-the-science mercury research. Dr. Windom responded that the program has a small budget spread over a large number of projects; the Agency is doing a very good job with its limited resources. He was not sure the Subcommittee could state that EPA is a leader because of the number of other national and international research efforts underway, but EPA has supported some of the most important research in terms of fate and transport. EPA's real contribution and expertise is in this area. Dr. Harding suggested that the report clearly identify what distinguishes EPA's niche from those of other organizations. Dr. Johnson cautioned that such a statement must be justified by facts. Dr. Farland agreed that it would be worthwhile to make that connection if it was a general understanding in the scientific community; however, the 2003 MYP does not contain this information. Last spring, EPA provided the United Nations Environmental Programme (UNEP) with recommendations for a global mercury action plan. EPA led the discussion on mercury control technologies that could be applied in

various countries and the importance of gaining a better understanding of fate and transport of mercury in the environment. Dr. Windom responded that on page 1, lines 39-43 of the report, the Subcommittee acknowledges that ORD has accomplished much with its limited resources and is poised to contribute significantly more to the better understanding of the global mercury problem. The Subcommittee members did not think that they had the facts needed to support any other type of statement. Dr. Johnson commented that ORD's response to the letter report could provide more examples of the type of leadership roles that EPA is assuming in this area. Dr. Duke said that on page 7, line 43, the words "to believe" should be changed to "that their beliefs."

Because there was extra time on the agenda, Dr. Johnson asked the members to take an hour to update their biosketches. He also asked Dr. Windom to use this time to update the letter report.

Computational Toxicology Subcommittee Letter Report

Dr. Johnson announced that Dr. Giesy had a conflict of interest on this topic. He was allowed to attend the session, but could not provide comments.

Because Dr. Daston, Chair of the Computational Toxicology Subcommittee, was unable to join the meeting by telephone, Dr. Clark was asked to update the BOSC on the Computational Toxicology Subcommittee's activities. The Subcommittee consists of Drs. George Daston, James Clark, Richard DiGiulio, Michael Clegg, and Ken Ramos. The intent was that this Subcommittee would be a standing committee once the National Center for Computational Toxicology (NCCT) was established and operating. Dr. Ramos recused himself from the April site visit and Subcommittee activities for now due to a potential conflict of interest, which will not be resolved until the fall. Dr. Clegg was unable to participate in the site visit because of a scheduling conflict. Therefore, Drs. Ramos and Clegg did not participate in the review of the newly organized Center.

The charge questions for the Center review were:

- ✧ Success of the NCCT will depend upon establishing effective collaborations with the other ORD laboratories and centers. What advice can you provide to ensure that operations remain integrated with the other laboratories and centers within ORD?

- ✧ In terms of anticipated staffing, are there particular areas that should receive greater or less attention?

- ✧ As we find ourselves in the post-genome era, science is progressing at a rapid pace. This makes it difficult to stay abreast with the current state-of-the-science. Clearly, being cognizant of and understanding the technologies and advanced methods in the areas of the omics, modeling, and statistics is a considerable vested interest to NCCT for several reasons, such as being able to make decisions about which technologies are best for the Center to pursue and most beneficial to the Agency. Can the BOSC provide any suggestions on how best to keep apace with new technologies and methodologies?

- ✧ Has the Center articulated a clear rationale for each topic area, and has it provided evidence that the contemplated approaches will be able to address the major goals stated in *A Framework for a Computational Toxicology Research Program*?

- ✧ To be successful in addressing the Concept Topics, can the BOSC help identify potentially fruitful partnerships with others outside the Agency?

Dr. Clark reported that the NCCT was set up to be a small center with limited staff that builds on collaborations. NCCT's mission is to serve as a focal point for EPA in the application of mathematical computational tools to all facets of the risk assessment process. The Center has a steering committee with representatives from the ORD laboratories, program offices, and regions. A number of the people who were leaders in various fields of computational toxicology were recruited for the Center. It appears that EPA is doing a good job of recruiting people who are interested in moving to the Center. The Center leadership will have to find a way to ensure that the staff is looking out and up, and not in and down as they work to find computational solutions to Agency questions. Recommendations were made to broaden the Center's staffing in the areas of ecology and fate and transport.

There is a lot of computational science being conducted internationally, and it is important from a research and development (R&D) point of view that the Center staff stay linked to what is going on in the global theater. There are modeling experts and other disciplines that rely on computational toxicology throughout the Agency. The Subcommittee recommended that the Center form an informal "community of practice" within EPA, which can serve a networking function for interested scientists. Those individuals with technical expertise aligned with the Center's activities can be encouraged to contribute to Center activities while being housed in other organizations within ORD, EPA, or outside of the Agency. The computational toxicology program was linked to other partners such as the NIH and the National Institute of Environmental Health Sciences (NIEHS), but it was not evident to the Subcommittee that these relationships were formalized through some type of agreement (e.g., Memoranda of Understanding).

Dr. Johnson stated it was a good report and noted that communications were discussed on page 3. He was not certain that everyone would understand what "staff looking up and out and not down and in" means and asked that either alternative language be used or an example be provided to clarify the meaning of the sentence. Dr. Henderson asked whether there was a formal process by which EPA staff members can request assistance from this Center to address their own particular problems. Dr. Clark responded that the Center was not created to fulfill such a service function, rather it was established to ensure that the technology can be used where it is most appropriate. The Center was not developed to determine the best model to help resolve a problem in a particular region; instead, the Center is examining the problems faced by the regions and program offices to determine if there is the potential to use these more sophisticated computational tools to tackle the problems. Dr. Johnson suggested that the Subcommittee ask the Center to identify its customers and describe how its products will be developed. Are the products being created collaboratively or through some other process? Is the Center developing tools and encouraging their use by individuals to address their own specific problems?

Dr. Johnson asked for a motion to accept the report with the noted editorial corrections. Dr. Windom made a motion to accept the report, which was seconded by Dr. Duke. The report was approved by the BOSC Executive Committee, with the exception of Dr. Giesy, who recused himself from participation in this discussion and vote.

Ms. Kowalski, who also serves as the DFO of the Computational Toxicology Subcommittee, said she was searching for additional Subcommittee members. She asked the members to submit the names of candidates to her for consideration. She agreed to send the members a list of the areas of expertise that are needed.

Revised Mercury MYP Subcommittee Letter Report

Dr. Windom provided the members with the revised Mercury MYP Subcommittee Letter Report. Dr. Johnson noted that the word "members" should be deleted on page 1, line 13. A list of the Subcommittee

members was included on page 1, lines 41-46. There is now parallelism in the responses under each of the charge questions. Each charge question either contains a recommendation or it is noted as "none." Dr. Windom stated that the paragraph relating to the quality of science at ORD (page 2, lines 2-7) was changed. On page 8, lines 13-18, the comments related to outputs and outcomes were addressed. All other editorial corrections also were incorporated into the report. Dr. Johnson asked the members to review the report and be prepared to discuss it on Friday morning.

Dr. Johnson announced that the public portion of the day's agenda had been completed and the meeting was recessed for the day at 4:40 p.m. The BOSC Executive Committee met immediately following the recess in a closed administrative session.

Friday, June 3, 2005

Dr. Johnson reconvened the meeting at 8:30 a.m., and stated that discussion of the revised Mercury MYP Letter Report would be the first item on the agenda.

Revised Mercury MYP Subcommittee Letter Report

Dr. Johnson reviewed the changes that were incorporated into the letter report. Dr. Sayler stated that the report was much improved and Dr. Clark concurred. There were no additional comments from the members.

Dr. Johnson asked for a motion to approve the report with the addition of a closing statement to be added. Dr. Sayler made a motion to accept the report, which was seconded by Dr. Clark. The report was approved by the BOSC Executive Committee.

BOSC Issues

Dr. Farland thanked the BOSC members for their excellent work. At the January BOSC meeting, there was a discussion about the nature of the upcoming program reviews. He stated that there have been some very good outcomes from these reviews. He was proud of the way the BOSC has approached these reviews, worked with individuals from the outside scientific community, and provided some very good reports.

Dr. Farland addressed a few of the issues that Mr. Oppelt raised in his comments on Thursday. Mr. Oppelt mentioned his belief that Administrator Johnson would be supportive of Agency science because he comes from a science background. Less than 24 hours after Administrator Johnson took the oath of office, he visited the RTP laboratories, held an all-hands meeting, and toured the offices. He also followed up with some of the investigators conducting the exposure work at RTP. One of the big issues of his confirmation concerned EPA's exposure work, particularly the so called CHEERS Study that was conducted in Florida. This study was badly mischaracterized in the press and the subject was raised during the political deliberations for the Administrator's nomination. Because of the misinformation on the CHEERS Study, it was decided that a research activity of that type could no longer be conducted in Florida. Administrator Johnson wanted to be very clear to the investigators that exposure work on children and the kinds of observational studies in which the Agency looks at how individuals encounter pesticides and toxic chemicals in their home environments and other places are extremely important to EPA. He also wanted it clear that partnering with the American Chemistry Council (ACC) to support some of the analyses in that type of a study through a Cooperative Research and Development Agreement (CRADA) was something that should continue. EPA is continuing to deal with human study issues and

recognizes the importance of understanding exposures. Carrying out observational studies, particularly in populations of children, and understanding their behaviors at various ages is still a very important part of EPA's research program. Dr. Farland thinks that Administrator Johnson's legacy will be related to science and how science is used by the Agency. Specifically, under his leadership, there will be a better appreciation of the science that goes on at EPA, how it is used, and when it is used in decision making. Dr. Farland asked Dr. Johnson if he, and any of the other BOSC members, would be available to meet with the Administrator to discuss the activities of the BOSC. Dr. Johnson will work with Dr. Farland to identify a date for the meeting and he will notify the BOSC members once the date is determined.

Dr. Farland mentioned Mr. Oppelt's reference to the possibility that the House may provide a certain amount of funding for line items and the Agency will be able to decide what will be funded. Very often in EPA budgets, these line items will amount to $56 to $60 million. It is estimated that EPA will receive $40 million of line items in the 2006 budget. EPA is faced with the significant challenge of using less resources more effectively to fund those projects that are more relevant to EPA's programs. In the past, even the line items were subjected to peer review in terms of the science that was going to be done before EPA would fund those projects. Although the Agency may be able to tie some of the line item projects to its basic program, EPA may run the risk of alienating certain people on the Hill if some of the line item projects are not funded. Dr. Johnson stated that he thought other agencies were facing a similar situation; the Department of Energy (DOE) is doing something similar. DOE provides funding to the National Nuclear Security Administration (NNSA) and requires that the projects undergo peer review to ensure scientific quality and relevance to the strategic plan. Dr. Johnson offered to provide Dr. Farland with contacts at NNSA. Dr. Farland said that the overall outcome, if this happens, will be positive for EPA because it is more likely that line items in future budgets will link to the Agency's priorities and strategic direction.

Dr. Farland indicated that EPA has received support from the House for Title 40 positions. These are meant to be high-level positions for individuals who are conducting or managing research. EPA's search for a physician investigator who has significant experience carrying out human studies was almost impossible because of the government's salary structure. The institutes that have used the Title 40 type of positions have benefitted because they could use a higher and more competitive pay scale and they also were able to carry these positions as 5-year term appointments.

Dr. Farland appreciated the comments from the BOSC that the NPDs were very helpful and cooperative during the program reviews. He requested the help of the BOSC in identifying individuals to fill the remaining NPD positions. He will provide copies of the recruitment materials to the BOSC and he asked the members to encourage qualified individuals to apply for the positions or to provide the names of potential candidates to ORD.

Dr. Farland mentioned the P3 awards and the opportunity for ORD to work closely with the National Academy of Engineering on this competition. This activity went beyond EPA's expectations in terms of both the numbers and the enthusiasm of the students who applied for the awards. Following the Science Forum and the P3 awards, EPA held an international meeting on sustainability in Washington, DC, that was well attended. One of the results of the meeting was the perspective on approaches to defining sustainability by demonstrating what kind of practices really are sustainable, which is being viewed as best practices around the world. EPA is continuing with the idea of some pilots to demonstrate sustainability through partnerships with communities and other federal agencies, and with development and application of tools that can continue to support this idea of a sustainable environment with attention paid to economic success.

Dr. Farland stated that he will try to act quickly on the BOSC nomination recommendations so that new members can be in place before the September Executive Committee meeting. Within the past month, he solicited additional nominees from the ORD laboratories, centers, and Office Directors; these nominees will be considered along with the nominees provided by the BOSC. Dr. Johnson asked EPA to provide the rationale behind the decision if the Agency selects members who were not on the list generated by the BOSC. Dr. Farland agreed and stated that ORD will not be going outside of the discipline areas.

Dr. Farland briefly commented on the survey results mentioned on Thursday. The results provided ORD with good information on the workings of the BOSC. He stated that ORD would appreciate receiving this type of information more frequently and asked the BOSC members to feel free to submit their comments. The survey does not have to be the only mechanism for feedback. ORD has made an effort to be more responsive to the BOSC in terms of the turnaround of materials and responses to reports. Dr. Johnson commented that he was going to collect informal comments from the members on the five lowest ranked questions as a way of determining how well things are going as improvements are made.

Dr. Farland stated that the BOSC has been very effective in conducting the program reviews. The Board has met and exceeded expectations from many in the programs. ORD will continue to do program reviews because they are used to refine the programs and can be used as input for the PART reviews. The current approach is for ORD to provide a list of nominated programs to OMB that it would like to see undergo a PART review next year. Typically, OMB asks for specific programs to be reviewed. Last year, however, ORD was successful in convincing OMB to conduct PART reviews of the programs that were undergoing program reviews. There are plans to do this again for next year. ORD would like to nominate the global, air toxics, water quality, and land (waste and contaminated sediments) programs for PART reviews. The global program already is undergoing a program review, but the other three program reviews would have to be conducted next year. Dr. Farland wanted to know if this would fit with the BOSC's agenda; if not, then ORD will need to develop independent external peer review panels to review these programs. There have been a number of opportunities to have parts of the STAR fellowship program reviewed. The fellowship program is highly competitive and ORD has received comments in these reviews that it is a very positive and worthwhile program, but the entire program has never been subjected to a formal review. This would not be a review of the scientific program, but more a review of the effectiveness of the program in filling the pipeline of good, trained scientists who will either have a better appreciation of the work that EPA does or will come to work for the Agency in the future.

Dr. Farland mentioned another possible area for review. The BOSC previously reviewed the advanced monitoring initiative and its relationship to the Global Earth Observation System of Systems (GEOSS),which has become a very large issue within the federal government. EPA continues to play a key role in how such tools are developed and applied—from remote sensing using satellites all the way down to ground level, modeling, monitoring, and understanding forecasting based on some of these kinds of approaches. There has been a push to expand these efforts across the Agency beyond ORD and to take an active role in the interagency activities. This might be an interesting area for the BOSC to consider for additional briefings and possibly some sort of consultation or review.

Dr. Farland thanked the BOSC members for their hard work and stressed the benefits ORD has received from the advances made in terms of the way ORD and the BOSC work together. He thanked Ms. Kowalski and all of the DFOs for the excellent jobs they have done.

Dr. Johnson asked whether the NPDs would receive any budgetary authority. Dr. Farland responded that in ORD, there is one senior budget officer who answers to the Agency in terms of the budget. The NPDs have budget responsibility and can make budget recommendations on a par with the Laboratory and Center Directors. The expectation for the NPDs is that their recommendations will flow through the

senior leadership in ORD. He suggested that the Laboratory and Center Directors attend a future BOSC meeting and discuss budget issues and the balance between intramural and extramural programs.

Dr. Lambert asked what could be done to stop the negative spin on the CHEERS Study. Dr. Farland responded that a large number of press interviews have been conducted. EPA is going to hold a workshop to discuss the ethical issues, but it will not be in the context of the CHEERS Study. It will be the broader issue of how EPA does its research. There are significant ethical issues relating to the kind of responsibility that investigators take when they do these types of projects. For example, what is the investigator's responsibility if he/she sees flaking paint or frayed wires? The National Academy of Sciences (NAS) has a study, which will be available this summer, that looked at ethical issues of studies of children in urban environments

Dr. Sayler asked whether nanotechnology, biotechnology, or homeland security would be reviewed in the future and Dr. Farland responded that biotechnology and nanotechnology are not large enough to qualify for a program review. Reviews of their strategies or MYPs could be conducted.

Dr. Giesy asked if the budget was restored for the ecology program and Dr. Farland responded that the House proposal for 2006 suggests funding for ecology and EDCs and a couple of other areas that had been reduced. Dr. Giesy wanted to extend his thanks for the opportunity to serve on the program reviews. The DFOs are great, they know their jobs and they do them very well. The program staff are very dedicated. Dr. Henderson concurred with Dr. Giesy's comments. She was extremely impressed with her program review and the enthusiasm and dedication of the people involved. It was a great and very positive experience.

Dr. Johnson expressed the need to meld several ongoing processes. As ORD develops the next generation of strategic plans, would it be possible to roll the regulatory mandates, budget realities, EPA's strategic plan, and emerging issues into one document. The strategic plan for ORD is disconnected from probable budget realities. It is likely that EPA will have close to a flat budget for the next 4 to 5 years. Some members have indicated that there is a need to look at emerging issues before they come to the BOSC and there might be a self-initiated study that the BOSC may want to undertake. The BOSC should provide advice to ORD in a proactive way before something gets out of control.

Dr. Johnson thanked Dr. Farland for his comments.

Risk Assessment Workshop Update

Dr. Henderson, Chair of the Risk Assessment Work Group, reported that the Workshop on EPA Chemical Risk Assessment Principles and Practices was held February 2-3, 2005. The members of the work group included Drs. Henderson, Daston, Duke, and Giesy, and Ms. Kowalski. The focus of the workshop was Chapter 4 of the Risk Assessment Principles and Practices Staff Paper. She noted that Chapter 4 focuses on the use of default and extrapolation assumptions. The goal of the workshop was to review the methods used by EPA and suggest alternative methods that could improve current practices. Dr. Farland spoke at the beginning of the workshop and Dr. Peter Preuss was the concluding presenter. The workshop included three sessions, which were chaired by Drs. Henderson, Duke, and Daston. Each session began with a presentation by EPA, followed by three speakers who suggested ways to improve the current process. The speakers for the three sessions are listed below by session:

Use of Default Assumptions and Uncertainty Factors
- ✧ Dr. Rita Schoeny, EPA
- ✧ Dr. Hillary Carpenter, Minnesota Department of Health

- ✧ Dr. Mike Dourson, Toxicology Excellence for Risk Assessment (TERA)
- ✧ Dr. Jennifer Sass, Natural Resources Defense Council (NRDC)

Extrapolation from High to Low Doses
- ✧ Dr. Weihsueh Chiu, EPA
- ✧ Dr. Rory Conolly, CIIT Centers for Health Research
- ✧ Dr. Tom Starr, TBS Associates
- ✧ Dr. Lauren Zeise, California EPA

Extrapolation Between Species
- ✧ Dr. Kerry Dearfield, EPA
- ✧ Dr. Mel Andersen, CIIT Centers for Health Research
- ✧ Dr. Jim Bus, Dow Chemical Corporation
- ✧ Dr. Susan Sumner, RTI International

There was time for questions and discussion following each presentation and again at the panel discussion at the end of each session. The speakers submitted extended abstracts, which will be published in the journal *Environmental Science and Pollution Research – International* (ESPR). The authors had an opportunity to revise their papers before publication. A summary of the workshop discussions will be incorporated into a proceedings document that will be posted on the BOSC Web Site. The purpose of posting the proceedings on the Web site is to make it available to the general public. The summary for each of the session's discussions was sent to the speakers for their review and comment. Dr. Giesy stated that he serves on the editorial board of *ESPR* and he arranged for the extended abstracts to be published in the journal. *ESPR* has asked the work group to conduct the reviews of the abstracts. A publication date has not been finalized. Dr. Henderson thanked Drs. Giesy, Duke, and Daston as well as Ms. Kowalski for their help in organizing and conducting this workshop.

Ms. Kowalski clarified that she was listed as an organizer, not as a DFO, because this was not a FACA meeting. It was a workshop that served as a way to gather information. She suggested that it would be helpful if the BOSC would review the proceedings document and make recommendations to the Agency, similar to the format that was used for the Communications Report. Dr. Johnson responded that, at the January meeting, it was suggested that the work group do a post-workshop review and part of that review can be a draft letter report to the Agency.

Dr. Farland commented that he was indebted to NAS for providing the venue for the workshop. He suggested that the BOSC send them a thank-you letter for their assistance. He mentioned that this workshop is just one of a number of activities related to that staff paper. The next meeting on the white paper will be focused on approaches to using probabilistic methods in risk assessment, which the Society of Toxicology (SOT) is co-sponsoring, along with ACC, EPA, and others. This meeting will be held in Washington, DC, the last week in July and there is a link to the meeting on the SOT Web Site. Dr. Farland is anticipating a consultation with the SAB in the fall to discuss the activities related to this staff paper. Dr. Lambert, the liaison to the SAB, can report back to the BOSC on the SAB's reactions.

Dr. Sayler asked if the synopsis of the proceedings would be available to other journals if they were interested in publishing it. Dr. Giesy responded that arrangements could be worked out.

Dr. Johnson thanked Dr. Henderson and the work group for an outstanding job on the workshop.

Open Access

Dr. Giesy stated that he had brought up the issue of open access at a past meeting as something that the BOSC might want to review, find out how ORD is dealing with the issue, and what the BOSC might be able to do to help them come up with a policy. A copy of an article on open access published by the American Chemical Society and a document titled *Are Chemical Journals Too Expensive and Inaccessible?* published by the National Research Council of the NAS was provided to the members. Dr. Giesy is interested in this issue because he is an editor for a journal and serves on a number of other editorial boards. He works most closely with Elsevier and they recently had a workshop on open access. NIH plans to establish a policy on open access and that policy is going to be that if the government paid for it, everyone has to have free access to it. This has set off a debate in the publishing world. ACS is a big publisher and sees this policy as a threat because the journals are large money makers to support the society. Historically, there was a need for someone to collect the information, run the peer review process, and print the journals, which was difficult, time-consuming, and expensive. A lot of journals were run by societies, but that is not the case anymore. There also used to be a lot of publishing houses, but now there are just a few. These many changes have led to this debate.

Dr. Giesy stated that Elsevier was making about $1 million profit on *ESPR* alone. People started looking at the bottom line of some of the publishing houses. Last year, Elsevier, which controls more than 2,000 journals, had a profit margin of 47 percent. People looked at the publishing houses and realized that they are making a lot of money, authors are not getting paid, the government is subsidizing the research, and the public paid for the research so they should get free access.

Historically, access was obtained by paying subscriptions; now payment must be made up front to get the information out to the public. The cost structure does not change that much. Someone still has to pay. The issue is who pays and when. The key processes are peer review, editing, publication, and archiving. The model that evolved was that private enterprise did this and they expected to make a profit. Now people want to change the model. NIH is moving to codify its position. Congress and various agencies in the Executive Branch are saying that they are willing to pay for the peer review process and archiving, and they think they can do it faster and cheaper than the publishing houses. They want to control the access so that it is free to everyone. One of the big issues is that the government is willing to pay for peer review and archiving, but it is not willing to pay for the programs that a society might want to fund with proceeds from its journals.

Dr. Giesy asked a number of questions. What is ORD going to do? Will EPA follow NIH or develop its own policy? Is there anything the BOSC can do to help gather information or form the issues to help in that process?

Dr. Johnson commented that from what he had read, NIH had the ability to organize information by topic to allow users to search across many journals for one topic. Dr. Giesy responded that the publishers would argue that you can do that now through ScienceDirect and other search engines. He commented that as an educator, one of the issues is that it is practically impossible for him to make copies of any published materials for his students.

Dr. Farland thanked Dr. Giesy for raising the issue. He commented that this is something that is being discussed in many science circles right now. ORD has not yet looked at this issue. Dr. Farland is a member of the editorial board for *Environmental Health Perspectives* (EHP), which is a monthly journal

published by NIEHS. *EHP* went to open access several years ago. The decision was made to have the government foot the bill. NIEHS did not receive any additional funds for the journal so the money had to be taken out of its existing budget. NIH and other groups are now struggling with this same issue. Dr. Farland said that it is extremely important to ORD and EPA that there are information quality quidelines, peer review of information used for regulatory purposes, reputable journals, and a system that assures some quality to the publication of scientific information. He worries about the implications of these issues in whatever system is used. For peer review, it becomes a question of availability of the information to people outside of the Agency. One of the drivers has been that when EPA uses science to support regulatory activities, people want to be able to go back and look at the original papers and in many cases they do not have free access to them. The proposal that there would be a government-funded archive of literature is very attractive if there is a way to ensure that the peer review is as rigorous and trustworthy as it is in good, reputable journals. Dr. Farland did not know if there is any specific forum for discussion of this issue at the Agency.

Dr. Giesy commented that when he gets a grant from EPA it includes the cost of university overhead, a large portion of which is for access to the library. Under the new system, should the overhead rates be reduced? His administrators would not like to see that happen. For each of his EPA projects, he publishes six to eight papers. This would be an estimated $3,000 to $3,500 per paper. Such a change has implications on overhead and how this cost is covered. It would have a huge impact on extramural funding and it could directly impact ORD's programs. If $35,000 of the grant funding has to be used to publish the work, there is no way that the research can be done. Dr. Johnson commented that the direct cost of $35,000 is actually closer to $50,000 (loaded with indirect rates).

Dr. Clark commented that in his world of industrial research, his only claim to credibility is to get something published in a peer reviewed journal research, otherwise it carries a bias of industry research. It seems that the definition of what is open research will feed the possible solutions. There are avenues of free access available now through universities and the government. It may be more of an issue of timely access in that people do not want to travel to a university or a government facility to access the information.

Dr. Sayler commented on the global issue. When there is talk of open access and fees for publishing, the developing countries are immediately cut off. Some exceptionally good environmental research is going on in these countries. It would hurt us if we were unable to access the information generated in India, China, or Korea, but it also hurts their ability to publish in high-quality journals and gain the respect that comes from such publications. An open access policy could be harmful because it is a fallacy that only the United States is publishing the best quality environmental research that is conducted. Investments by the Europeans for the past 10 years have given Europe the lead in many areas of environmental research. The same thing is beginning to happen in China. If we prohibit other countries from publishing with policies that are far too expensive, then we will hurt our own access to the state-of-the-art information and ultimately the ability of agencies like EPA to make effective decisions based on the highest quality science.

Dr. Farland agreed that the international issue was very important. He commented that there has been a broader problem with respect to the international community. Investigators in some of the countries are successful in getting their research published, but they do not have access to the journals in which they are published. Dr. Sayler commented that electronic access has dramatically improved such access in developing countries.

Dr. Duke stressed the complexity of this issue. There is a wide range between tightly controlled copyright enforcement, as some journals are still doing, and the model used by the Public Library of Science. Each journal has a policy that makes its articles relatively freely available 6 months to a year after publication. Authors published in numerous journals can make their own articles freely available on Web sites, so there is quasi open access. There is a significant challenge to the funding issues. If the National Science Foundation (NSF) elects to adopt the same policy as proposed by NIH, there would be a big impact on ecological research publication. It will effect the way we do business.

Dr. Johnson thanked Dr. Giesy for bringing this issue to the attention of the BOSC and EPA. Dr. Farland has indicated that ORD is not formally looking at this issue, but individual scientists are concerned about it because it is important that they publish. The discussions have included open versus personal access and the global issues. Should the BOSC pursue this topic or is more information needed? Dr. Giesy commented that it is very complex and it is going to impact the way we do business including how we do science, how we do research, and how we get access. His opinion is that things will change. The questions are: How disruptive will it be and how long will it take? What impacts will it have on what EPA might do and could the BOSC take a leadership role to minimize those impacts or smooth the transition?

Dr. Farland agreed to query the National Center for Environmental Research (NCER) to determine if the Center is thinking about the cost for publication and impacts on overhead rates. This issue has come up in an interagency council that is looking at the business of how science is done. Jack Puzak, the Director of NCER, sits on that particular council. He has concerns about maintaining the quality of peer reviews and the transparency needed by EPA to allow the Agency to use the information for regulatory purposes.

Dr. Johnson suggested that Dr. Farland provide an update on his conversation with Jack Puzak at the September meeting. That update may be a definition of the posture of ORD (i.e., a leadership posture) in trying to pave the way for this change, or it could be one of anticipating the various pathways that change could follow and understanding the impact it could have on the Agency, or it could be one of just waiting to see what happens before establishing a policy. This briefing can be considered a consultation for which no report will be generated.

Public Comment

Dr. Johnson asked if anyone would like to make a public comment. No public comments were offered from meeting participants. Dr. Johnson read the following comment that was submitted through EDOCKET from B. Sachau of Florham Park, New Jersey:

"Science is missing out on protecting Americans from toxic chemicals. We need better research and protection in this area; cancer is all over the U.S. and it is environmental poisoning."

Dr. Johnson stated that an acknowledgement would be sent that this comment was read into the record.

SAB Activities Update

Dr. Lambert distributed a table of the FY 2005 Advisory Projects for the SAB and its committees and a table of SAB "Self-Identified" Advisory Projects Supported by the SAB Staff Office. He noted that the SAB plans to hold its meetings in the different EPA regions to learn about regional emerging issues.

There was an SAB meeting held May 11-12, 2005, in Dallas, Texas (Region 6). The Nanotechnology Workshop was held in December 2004, and the report was distributed to the SAB at the May meeting. On February 17-18, 2005, the SAB gave its annual Congressional briefing on the EPA budget and the report on that testimony is being finalized. The report on the Drinking Water MYP was approved by the SAB and was scheduled to be submitted to the EPA Administrator in May. The Ecological Processes and Effects Committee formed a subcommittee to work on a few of the issues related to the Methodology for Identifying U.S. EPA Region 5 Ecologically Significant Areas. The Contaminated Sites and Resources Conservation and Recovery Act (RCRA) MYPs were reviewed and approved by the SAB, and they were scheduled to be submitted to the Administrator in May. Dr. Henderson, who serves as the Chair of SAB's Clean Air Scientific Advisory Committee (CASAC), noted that the National Ambient Air Monitoring Strategy Implementation Report was approved and a letter was transmitted to the Administrator. She reported that the PM Review Panel completed the criteria document in fall 2004, and the report on the staff paper is being prepared. The Ozone Review Panel has examined the first draft report on criteria pollutants. Dr. Lambert reported that the SAB will undergo a PART review in 2008.

Dr. Giesy noted the shaded lines on the table and asked why those projects will be resubmitted. Dr. Farland responded that the Agency submits a list of activities to the SAB. In some cases, the SAB does not have the time to do all of the activities on the list. In other cases, they schedule an activity for this year and then EPA is not ready, so the activity is moved to the next year.

Dr. Clark asked if the SAB participated in the Gallup survey. Ms. Kowalski responded that all of the 23 EPA FACA committees were sent the survey. Dr. Johnson asked if EPA paid for the survey and Ms. Kowalski responded that she did not know.

Dr. Johnson asked the BOSC members to review the tables of SAB projects to identify any that could result in a collaboration with the BOSC. Dr. Johnson thanked Dr. Lambert for the update on the SAB.

EPA Office of International Affairs

Dr. John Diamante, Senior Science Advisor for EPA's Office of International Affairs (OIA), described ORD activities with OIA. He introduced Mr. Doug Steele (EPA/OSP), who is the official ORD liaison with OIA. In providing an overview of OIA, Dr. Diamante explained that OIA and ORD are at parallel levels within the EPA organization, but OIA is a small organization compared with ORD. OIA has the following four offices:

- ✧ Office of International Environmental Policy
- ✧ Office of Management Operations
- ✧ Office of Technology Cooperation and Assistance
- ✧ Office of Western Hemisphere and Bilateral Affairs

OIA's mission is to protect U.S. human health and environment, and advance national interests through international environmental engagement. In addition to transboundary and global environmental issues, the international interests of concern to OIA include the broader foreign policy and national security aspects of environmental problems. OIA is responsible for environmental efforts on the U.S. borders with Canada and Mexico and the Arctic and Caribbean regions. The office is involved in the negotiations on environmental aspects of trade, marine pollution, and other international policy issues, and manages EPA's international technology diffusion and technical assistance programs. OIA also

manages EPA international travel and serves as the liaison with the State Department and U.S. missions abroad. In addition, OIA coordinates with ORD, EPA media offices, and EPA regions on global and international trans-boundary initiatives.

There are numerous ORD activities with OIA, including:

- ✧ EPA U.S.-Mexico Border Program—OIA has the overall programmatic lead for EPA. ORD has the overall scientific/technical lead for EPA for projects such as risk assessment, transfer of appropriate technologies, and trans-boundary pollution transports.

- ✧ NATO Committee on the Challenges to a Modern Society (CCMS)—OIA has the long-term program lead for EPA. ORD provides the technical lead for individual scientific studies and technical projects.

- ✧ Former Soviet Union Defense Conversion, Nuclear Non-Proliferation and Related R&D—State Department/Agency for International Development (AID) provides funding under a U.S. foreign policy umbrella. OIA provides overall program and financial management in EPA. ORD provides scientific and technical experts for individual projects. There are 15 active projects and 35 technical proposals this year.

- ✧ Mercury Fate, Transport and Transformation Processes in the Arctic—There is an official U.S. project under the Arctic Council, which is a multi-lateral organization, that involves cooperation between the United States and Norway, Russia, and other countries in the Arctic. OIA has the overall project management responsibility and ORD provides technical expertise and scientific equipment.

- ✧ Monitoring of Long-Range Trans-Pacific Transport of Mercury—This is a joint project between OIA and ORD. There are existing monitoring stations in Hawaii and Alaska, and a Norwegian site is being added. An international scientific meeting on trans-Pacific air transport also was sponsored under this project.

One of the new activities this year is the Agency's involvement with GEOSS, which is a government-wide international initiative. This effort falls under the auspices of the Science Policy Council (SPC), which is staffed by ORD. Another new activity under the SPC is strengthening science in international environmental decision making. It is supported by OIA, ORD, and the Office of Environmental Information (OEI). The first effort involves the North American Free Trade Agreement (NAFTA) Commission on Environmental Cooperation (CEC). ORD and OEI experts are supporting the transfer of sound science and information quality practices to CEC.

Mr. Steele stated that ORD participates in international activities by supporting U.S. foreign policy interests, collaborating on research projects, and providing technical assistance and training. These activities reflect ORD leadership in environmental research. He provided specific examples of ORD international activities.

Hal Zenick is the co-chair of the U.S.-Mexico Border 2012 Environmental Health Workgroup. This workgroup is committed to increasing collaboration between environmental and public health entities to identify and improve community health issues. A number of projects have been conducted in the border

region related to surveillance, research, training/education, and communication. In the last few years, the focus has shifted to look at the development and application of indicators to assess changes in specific human exposure and health conditions. There are 8 current studies and 19 completed studies. A list of the projects and their status can be viewed on the Web at http://www.epa.gov/ehwg/.

The Former Soviet Union Weapons Nonproliferation Program is a State Department funded program to support the engagement and permanent redirection of former weapon scientists. This work goes through two Science Centers in Moscow and Kiev. ORD has partnered on these projects since 2000. Thirty-one proposals have been submitted for FY 2005 funding. Information on this program can be viewed on the Web at http://www.state.gov/t/np/. Some examples of projects include environmental monitoring laboratory development, bioremediation techniques for mercury-contaminated sites, biological treatment of PCB-contaminated soils, pesticides effects on malaria incidence, and computer-aided analysis of river contamination risk posed by wastewater of industrial facilities.

Dr. Johnson asked if these projects involved the import of U.S.-developed technologies to solve a problem or if they involve the development of new technologies and techniques. Mr. Steele responded that it includes both types of projects. Dr. Harding asked if ORD and DOE collaborated on some of these projects. Mr. Steele suggested that she visit the International Technology and Science Center Web Site at http://www.istc.ru and click on partners to determine if DOE is a partner.

The NATO CCMS was created in 1969 by the North Atlantic Council with the initial aim of addressing problems affecting the environment of the nations and the quality of life of their peoples. CCMS supports pilot studies, short-term *ad hoc* projects, and international seminars. In 1995, CCMS established an Environmental Clearing House System (ECHS) through an electronic bulletin board. Some examples of NATO-CCMS ORD led projects include advanced cancer risk assessment methods, clean products and processes, use of landscape sciences for environmental assessment, and ecosystem modeling of coastal lagoons for sustainable management. Information on these and other projects can be found on the CCMS Web Site at http://www.nato.int/ccms.

ORD has been involved in a number of EDC research projects such as the Global Endocrine Disruptor Research Inventory, the WHO-International Program on Chemical Safety (IPCS) global assessment of the state-of-the-science of endocrine disruptors, and the Organisation for Economic Co-operation and Development (OECD) work on endocrine disruptor testing and assessment. The Global Endocrine Disruptor Research Inventory is a compilation of ongoing research projects related to EDCs. The inventory was developed following the process used for the 1996 Federal Research Inventory done by the United States. As of May 23, 2005, the inventory contains 778 projects. More information is available on these projects at http://oaspub.epa.gov/endocrine/pack_edri.all_page.

GEOSS is a new project for ORD. It is the comprehensive, coordinated, and sustained observation of the Earth system to improve monitoring of the state of the Earth, increase the understanding of Earth processes, and enhance the prediction of the behavior of the Earth system. GEOSS is a step toward addressing the challenges articulated by the United Nations Millennium Declaration and the 2002 World Summit on Sustainable Development, including the achievement of the Millennium Development Goals. At the Earth Observations Summit (EOS) III in Brussels, on February 16, 2005, 56 countries and 33 organizations approved the GEOSS 10-year implementation plan, containing 2-year, 6-year, and 10-year outcomes, and a permanent secretariat hosted by the U.S.'s World Meteorological Organization of Geneva. The U.S. is the North America co-chair for the workgroup to develop the implementation plan.

Information on the 10-year implementation plan can be found on the Group on Earth Observations (GEO) Web Site at http://earthobservations.org; the Strategic Plan for the U.S. Integrated EOS can be found on NASA's Web Site at http://iwgeo.ssc.nasa.gov/; and EPA's role in GEOSS is described at http://epa.gov/geoss/.

Since 2003, ORD has demonstrated leadership in GEOSS through the intergovernmental *ad hoc* GEO, as Co-Chair of the User Requirements and Outreach Group, and played key roles in the first two Earth Summits. ORD continues its international GEOSS leadership role in the GEO User Interface Panel, established after the third Earth Summit in February 2005.

In conclusion, Mr. Steele stated that OIA and ORD work closely together to identify international research needs and opportunities. ORD scientists are encouraged to participate in international activities, and the ORD career ladder includes recognition of international contributions. The international research that ORD has done has contributed to Agency decisions. Working with OIA and the State Department, ORD gets involved in collaborative activities that support U.S. foreign policy objectives.

Dr. Lambert asked if there were any unrealized opportunities that the Agency has not been able to pursue because of lack of funding, administrative, or regulatory issues. Mr. Steele responded that OIA is vastly underfunded. There are a lot of opportunities for more involvement. On the other hand, EPA is a domestic, regulatory agency and ORD's primary mission is to conduct the research required to support the regulatory needs of the media offices. It is better if the collaborative international research somehow supports EPA's needs.

Dr. Duke stated that more focus has been on the United States reaching out internationally and getting our scientists involved in international organizations. To what degree does ORD or OIA work to try to facilitate the use and recognition by the United States of research that originates overseas to inform regulatory policy making and other issues? Dr. Diamante responded that OIA has had a small program, which is underfunded and under emphasized to look for technology transfer opportunities. The program is very small scale and does not receive much support within the Agency. Dr. Sayler asked if there was a mechanism for incorporating good quality international data into U.S. environmental decision making. Dr. Diamante replied that this is an area that is getting more intense scrutiny at the government level, particularly OMB and Congress. Dr. Farland commented that there is an expectation that when EPA does assessments and literature reviews it covers as much of the world-wide literature as possible; EPA has made concerted efforts to include international information. There also is an increasing trend to try to bring the international community into EPA's peer review process.

Dr. Sayler asked how OIA selects its projects/topics. Dr. Diamante responded that it is the reverse—the issues pick OIA. An example is global phenomena and trans-boundary issues. EPA knew that there were trans-boundary issues across the Pacific Ocean because the satellites showed images of plumes from sands over the Gobi desert crossing to the West Coast of the United States. There now is quantitative evidence that these plumes can impact the air quality standards on the West Coast. This is changing some of the emphases in EPA's regulatory offices; environmental quality is no longer just a domestic issue, but is driven by globalization and world industrialization.

Dr. Sayler asked whether EPA may be outsourcing research on global issues in the long term. Will the United States ever be in a position where it is not investing enough in research and ends up mining the

data generated by other countries such as China. Dr. Diamante stated that if you broaden the definition of outsourcing to the cooperative efforts he discussed in his presentation, it is increasing.

Dr. Clark commented that he had worked on a number of program reviews. One of the common recommendations to the ORD scientists is to track and become more involved in the international research in their specific area. Is there an international travel budget or do the scientists have to find the money to cover their travel in their programs and then coordinate with OIA? Dr. Diamante responded that the scientists must find the money to cover their international travel unless it is funded through another program (e.g., money transferred to OIA from the State Department or Department of Defense). Within EPA, there is no specific international travel fund.

Dr. Lambert commented that this was a good presentation that showed how much EPA is doing with a very limited budget. Does the BOSC have a role in assisting the Agency in looking at some of the international issues such as technology transfer, global monitoring, and linking the atmosphere and the oceans? Dr. Diamante responded that because research is a large focus of these issues, the BOSC should have a role to play. The Board's efforts should be coordinated with those of the SAB, which has a broader Agency-wide mission. Mr. Steele commented that during annual planning in ORD, the authors of research plans and MYPs have been asked to identify potential international opportunities or needs. If the BOSC has recommendations or suggestions concerning international issues that arise as the program reviews are conducted, he would like to hear them.

Dr. Johnson commented that it appears that there are opportunities for scientists to travel internationally. He suggested that the BOSC consider this presentation a briefing that becomes part of the information to be used in the program reviews. It relates to the charge question concerning how the various programs are integrating international work into their efforts. The BOSC should examine the barriers to international collaboration, recognizing that the extent of collaboration depends on the particular research program—some may have a significant international component and others may be very local-oriented. This is an Agency-wide issue and if the BOSC decides to pursue this topic further, its efforts should be collaborated with the SAB. He thanked Dr. Diamante and Mr. Steele for their presentation and Dr. Lambert for inviting them to speak.

ORD Management Multi-Year Plan

Mr. Peter Durant, Acting Director of ORD's Office of Resources Management and Administration ORMA), provided a presentation on the ORD Management Multi-Year Plan (MMYP). The MMYP was developed to identify the administrative management actions for the next 3 to 5 years to help ORD achieve the goals in its scientific MYPs. The goals are to: (1) provide exceptional administrative service; (2) attract, develop, and retain a talented and diverse workforce; and (3) design, evaluate, and communicate ORD's programs effectively.

Based on a Federal Human Capital Survey conducted by the Partnership for Public Service and American University's Institute for the Study of Public Policy in 2002, EPA was ranked the fifth best place to work in the federal government. The performance measure established for the MMYP is: ORD is ranked among the top 100 sub-agencies as one of the "best places to work in the federal government." As of the last ranking, ORD was not there yet. The MMYP themes and approaches are: (1) value of ORD-wide solutions; (2) expand time available to scientists for science by relieving them of administrative burdens; (3) mobilize ORD's administrative management community to assist; and

(4) ongoing commitment of the Management Council.

Currently, more than 650 ORD employees are actively involved in the management and oversight of extramural vehicles (including contracts, grants, and interagency agreements). They include staff from both the administrative and scientific side of ORD (e.g., project officers, work assignment managers, and bank card holders).

There are three FY 2005 focus areas that relate to the three goals. The first focus area is a comprehensive review of ORD administrative services by laboratory, center, and office teams. The scope of the reviews include budget/finance, extramural management, information management, human resources, accountability/oversight, and facilities management.

The second focus area is human capital initiatives. A small grant of $25,000 has been awarded for an ORD orientation program. ORD has offices across the United States and is involved in about 1,000 projects in environmental science and engineering. The ORD orientation program would provide new employees with information on ORD as a whole and how ORD works within EPA and outside of the Agency. A Diversity Marketing Plan is being developed that can be used to recruit the next generation of employees. Key aspects of the plan will be diversity in terms of gender and race and a strategy to attract and recruit people to work at the Agency. A Supervisors Workshop also will be conducted. The results of the past five or six surveys have identified improvement opportunities with supervision and management in ORD. People are very committed to their jobs, but there is a difference in how supervisors perceive the organization and its climate compared to the perception of the staff. In a meeting of the managers, it was suggested that there be communities of practice where similar problems could be solved if people worked as a team. Becki Clark (ORD/NCER) is taking the lead on this issue.

The third focus area is the design, evaluation, and communication of ORD programs. Mr. Durant stated that this is an area where the BOSC plays a significant role and he thanked them for all of their work. Last winter, the President elevated the research investment criteria, and the importance of the PART review was reflected when OMB reduced the funding for the pollution prevention and ecology research programs significantly because they did not score well on the PART. ORMA also is working to improve internal and external communications through improvements to ORD's Web Site.

Dr. Harding asked about the morale of Agency employees. She has heard that people in other agencies have resigned because they believe that the science is not being done properly or it is being distorted based on political views. Mr. Durant responded that ORD organizational surveys were initiated in 1996, and the five that have been completed indicate a positive trend with respect to this issue. In addition to these ORD organizational climate surveys, the U.S. Office of Personnel Management has conducted two government-wide climate surveys. As he stated previously, EPA was ranked as the fifth best place to work in the federal government based on the first survey. Last fall, a second Federal Human Capital Survey was conducted and nearly 150,000 federal employees responded to the survey. He does not have the data for EPA yet but federal-wide, 91 percent of the employees believe that they do important work, 83 percent like what they do, and 71 percent derive a sense of personal accomplishment from their work. Since 2002, the number of people who said they would leave their federal government jobs in 1 to 3 years has declined. Dr. Farland stated that many people come to work for EPA because of the Agency's mission and because they want to make a difference. It is more difficult than ever to keep good staff because there are many more job opportunities.

Dr. Stewart mentioned that EPA had a large number of retirement eligible scientists and asked how well the post doctoral program is helping to fill those positions. Dr. Durant responded that the program has been a great mechanism to continue to refresh ORD's set of skills. He thinks the program is one of EPA's smart human capital moves and the program should be sustained in the future. OMB has approved support for 20 additional FTEs.

Dr. Lambert suggested establishing a mentoring program to encourage people to go to conferences and to guide the scientists toward career development. Mr. Durant responded that a mentoring program was a very good idea and that there have been discussions to include a "buddy" program in the ORD Orientation Program.

Dr. Johnson thanked Mr. Durant for his presentation. He commented that the BOSC has gained an increased understanding of the MMYP, which may be useful in future program reviews as well as a review by the BOSC of the MMYP.

Future Business

Dr. Johnson reviewed the following accomplishments of the meeting:

- ✧ The Human Health Program Review Report was approved pending editorial changes.
- ✧ The PM/Ozone Program Review Report was reviewed and the Subcommittee was asked to incorporate changes. The report may be approved by conference call to be scheduled this summer.
- ✧ The Mercury MYP Letter Report was reviewed and accepted.
- ✧ The Computational Toxicology Letter Report was approved with minor changes.
- ✧ The open access discussion was considered a briefing. Dr. Farland will discuss the open access issue with Jack Puzak and provide feedback to the BOSC at the next meeting.
- ✧ Next steps were discussed for the Risk Assessment Workshop (extended abstracts journal publication, meeting proceedings, and letter report).
- ✧ The OIA presentation provided information to the BOSC that can be used during future program reviews.

Dr. Johnson asked if there were any comments on the response from the Agency on the Communications Letter Report. Dr. Stewart commented that it was an appropriate response; ORD stated how much it valued the BOSC's opinion and how it would use the recommendations. She suggested that the BOSC acknowledge receipt of the letter. Dr. Harding will prepare a short response and e-mail it to Dr. Johnson who will submit it to ORD. Dr. Johnson asked for a motion to accept the report. Dr. Harding made a motion to accept the report, which was seconded by Dr. Stewart. The report was approved by the BOSC.

Dr. Johnson asked if there were any comments on the minutes of the May 5, 2005, Conference Call. As there were no changes, Dr. Johnson asked for a motion to accept the conference call minutes as written. Dr. Clark made a motion to accept the minutes, which was seconded by Dr. Sayler. The minutes were

unanimously approved by the BOSC, with the exception of Dr. Henderson who abstained because she was not on the conference call.

Dr. Johnson stated that the BOSC has conducted six program reviews during the past year, and six reviews is the maximum that the BOSC can do each year. The Drinking Water and Global Climate Change Program Reviews are continuing; therefore, the BOSC can undertake four more reviews in the coming year. He stated that the four opportunities for new program reviews were: (1) air toxics, (2) water quality, (3) land (waste and contaminated sediments), and (4) the STAR fellowship program. He recommended that the Board undertake only three of the four opportunities and one of the three choices should be the fellowship program. He suggested limiting the selection to three because he was concerned about over commitment of the members' time and because the BOSC may wish to look at an emerging issue over the next year. For example, the BOSC may want to do a homeland security review before it is scheduled for a PART review, which may be in 2006 or 2007. After some discussion, the BOSC agreed to do all four of the new program reviews. There was a concern that if the BOSC only agreed to do three reviews, then Dr. Farland would have to convene an external panel to review the fourth one. The following assignments were made:

- ✧ Air Toxics Research Subcommittee—Dr. Giesy, Chair; Dr. Henderson, Vice-Chair
- ✧ Water Quality Research Subcommittee—Dr. Windom, Chair; Dr. Sayler, Vice-Chair
- ✧ Land Research Subcommittee—Dr. Clark, Chair; with a liaison from the SAB
- ✧ Fellowship Program Subcommittee—Dr. Stewart, Chair; Dr. Duke, Vice-Chair

Dr. Johnson stated that the Subcommittees would need to be formed by September 2005, and the program reviews will have to be completed and approved by the BOSC by April 30, 2006. Dr. Johnson asked Dr. Farland to provide draft charge questions to the four subcommittees as soon as possible. The draft charge questions should include a specific question about communication. The chairs and vice-chairs will need to identify the specific expertise needed for the subcommittees. They may consult with other BOSC members to identify the specific expertise, but never more than two members at a time to comply with FACA rules. Ms. Kowalski commented that the reviews that were recently completed were conducted in a very compressed time frame. The new reviews were brought up at this meeting to give the BOSC more time to prepare for and complete the reviews. She suggested that the face-to-face meeting be held before the end of the year and a draft report be ready for review at the January 2006 BOSC meeting. This means that the subcommittees should be formed by the end of the summer and ready to work by the fall. It takes a couple of months to finalize the reports after they are approved by the BOSC. She already has identified potential DFOs for each of the subcommittees. Dr. Clark commented that the BOSC should request a liaison from the SAB for the Land Research Program Review as soon as possible.

Dr. Johnson stated that the next BOSC meeting will be held September 12-13, 2005, in Cincinnati, Ohio. He asked that the agenda include a briefing on the advanced monitoring initiative and a follow up presentation on the National Homeland Security Research Center with a poster session on their research.

Dr. Johnson thanked everyone for their participation in the meeting. The meeting was adjourned at 2:40 p.m.

Action Items

- Dr. Johnson will follow up with Dr. Daston who was asked to draft a letter to ORD that acknowledges receipt of the response to the Biotechnology Research Letter Report.

- Ms. Kowalski will see if the accounting system can provide separate information on reimbursable expenses and inform the Board members regarding what she discovers.

- Dr. Johnson will work with Ms. Kowalski to develop a draft model report format and send it to the members for their review.

- The members will provide changes to their contact information to Ms. Kowalski.

- Dr. Klaunig will rewrite the section on page 2 of the Human Health Research Program Review Report to clarify that the change when the original LTG 1 was broadened to include more mechanistic work.

- Dr. Clark will obtain comments on the Human Health Research Program Review Report from Dr. Henderson and Ms. Houk and send a marked up copy to Dr. Klaunig.

- Dr. Henderson change the Particulate Matter Research Program Review Report to read fine/ultrafine particles.

- Dr. Henderson will include the original wording of the two LTGs in the Particulate Matter Research Program Review Report.

- Dr. Henderson will include the comment about terminating the ozone program earlier in the report, possibly on page 13. She will clarify or resolve the inconsistency in numbers that appear on page 17, lines 29-30, where there is a reference to 12 areas of emphasis proposed by the NRC, and on page 29, line 40, where there is a reference to 10 questions raised by the NRC.

- Dr. Johnson will provide his editorial comments on the Particulate Matter Research Program Review Report to Dr. Henderson.

- Dr. Henderson will change the Particulate Matter Research Program Review Report to more explicitly identify the communication efforts for the program. She also will clarify Recommendation 8.

- Dr. Henderson will review Recommendation 9 of the Particulate Matter Research Program Review Report to determine if it needs to be reworded with a better example.

- Dr. Henderson will split Recommendation 5 into two recommendations—one on funding for the intramural program and one on the termination of ozone health research.

- Dr. Johnson asked the individual BOSC members to send their comments on the Particulate Matter Research Program Review Report to Dr. Henderson as soon as possible.

- Dr. Henderson and Dr. Stewart will incorporate the review comments into the Particulate Matter Research Program Review Report and send the revised report to the BOSC members for review. An Executive Committee conference call will be scheduled to discuss the revised report.

- Dr. Duke will discuss with Dr. Clark his experiences in helping the external chair understand the BOSC and what is expected of the program reviews.

- Ms. Kowalski, as DFO of the Computational Toxicology Subcommittee, is looking for additional candidates to add to the Subcommittee. She asked the members to send her any suggestions for candidates. She will send the members a list of the areas of expertise that are needed for the Subcommittee.

- Dr. Johnson will work with Dr. Farland to identify a date for the meeting with the EPA Administrator and Dr. Johnson will notify the BOSC members of the arrangements.

- Dr. Johnson will provide Dr. Farland with a contact at NNSA so that he can learn more about how they ensure scientific quality and relevance to the strategic plan.

- Dr. Farland requested the help of the BOSC to identify individuals for the remaining NPD positions. He will provide copies of the recruitment materials to the BOSC and the members should encourage qualified candidates to apply or provide names of candidates to ORD for follow up.

- Dr. Farland will try to act quickly on the BOSC nomination recommendations so that new members can be in place before the September BOSC meeting.

- Dr. Johnson will collect informal comments from the BOSC members on the five lowest ranked questions on the Gallup survey as a way of measuring improvements.

- The Communications Work Group will review the proceedings document from the Risk Assessment Workshop and develop a letter report (with recommendations) to the Agency. The letter report will be reviewed by the BOSC at the next meeting.

- Dr. Henderson will draft a letter to the NAS thanking them for their assistance with the Risk Assessment Workshop.

- Dr. Farland will have a consultation with the SAB in the fall to discuss the activities related to the Risk Assessment staff paper. Dr. Lambert, as the liaison to the SAB, will report back to the BOSC on the SAB's reactions.

- Dr. Farland will discuss the issue of open access with Jack Puzak and report back to the BOSC on this conversation at the September meeting.

- Dr. Johnson will send an acknowledgment that the public comment from B. Sachau was read into the record.

- Dr. Johnson asked the BOSC members to review the tables of the SAB projects to identify any that could result in a collaboration with the BOSC.

- ✧ Dr. Harding will prepare a draft acknowledgment of the response received from the Agency on the Communications Letter Report and e-mail it to Dr. Johnson who will submit it to ORD.

- ✧ As Dr. Windom had to leave the meeting early, Dr. Johnson will send him an e-mail asking him to serve as the Chair of the Water Quality Research Subcommittee.

- ✧ Dr. Farland will provide draft charge questions to the four subcommittees as soon as possible. The draft charge questions should include a specific question about communication.

- ✧ The chairs and vice-chairs will identify the types of expertise needed for their subcommittees and send that information to Ms. Kowalski and the designated DFO for their subcommittees.

- ✧ Ms. Kowalski will work with the chairs and vice-chairs to form the four new subcommittees by September 2005, and to schedule the face-to-face meetings so that they are conducted before the end of the year.

- ✧ Dr. Johnson will request a liaison from the SAB for land program review as soon as possible.

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B • O • S • C

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June 2-3, 2005

Agenda

Thursday, June 2, 2005

8:00 a.m. – 8:30 a.m.	Registration	
8:30 a.m. - 9:00 a.m.	Welcome and Introductions ✧ Review of January Mtg Minutes ✧ Overview of Agenda	Dr. James H. Johnson, Jr. Chair, Executive Committee
9:00 a.m. – 9:15 a.m.	BOSC DFO Remarks ✧ FACA ✧ Survey Results ✧ Administrative Issues	Ms. Lori Kowalski, ORD
9:15 a.m. - 9:30 a.m.	AA/ORD Remarks	Mr. Timothy Oppelt, Acting Assistant Administrator for Office of Research and Development
9:30 a.m. – 11:00 a.m.	Subcommittee Reports ✧ Human Health Program Review	Dr. James Klaunig, Subcommittee Chair
11:00 a.m. – 11:15 a.m.	Break	
11:15 a.m. – 12:45 p.m.	Subcommittee Reports (Continued) ✧ Particulate Matter/Ozone Program Review	Dr. Rogene Henderson, Subcommittee Chair

12:45 p.m. – 1:45 p.m.	Lunch	
1:45 p.m. – 3:30 p.m.	Subcommittee Reports (Continued) ✧ Drinking Water Program Review ✧ Global Change Program Review ✧ Mercury Multi-Year Plan Review	Subcommittee Chairs Dr. Gary Sayler Dr. Cliff Duke (Vice-Chair) Dr. Herb Windom
3:30 p.m. – 4:00 p.m.	Break	
4:00 p.m. – 4:30 p.m.	Subcommittee Reports (Continued) ✧ Computational Toxicology	 Dr. Jim Clark, Subcommittee Vice-Chair
4:30 p.m.	Adjourn Public Meeting	
4:30 p.m. – 5:30 p.m.	Executive Committee Administrative Session (Closed)	

Friday, June 3, 2005

8:30 a.m. - 9:15 a.m.	BOSC Issues ✧ ORD Update ✧ New Program Reviews	Dr. William Farland, Acting Deputy for Science for Research and Development
9:15 a.m. – 9:45 a.m.	Risk Assessment Workshop Update	Dr. Rogene Henderson, Workshop Work Group Chair
9:45 a.m. - 10:15 a.m.	Open Access	Dr. John Giesy, Executive Committee
10:15 a.m. – 10:30 a.m.	Public Comment	
10:30 a.m. – 11:00 a.m.	Break	
11:00 a.m. – 11:30 a.m.	SAB Activities	Dr. George Lambert, SAB Liaison to the BOSC
11:30a.m. – 12:30 p.m.	EPA Office of International Affairs ✧ Presentation ✧ Discussion	 Dr. John Diamante, Senior Science Advisor for EPA Office of International Affairs Dr. George Lambert, SAB Liaison to the BOSC
12:30 p.m. - 1:30 p.m.	Lunch	

1:30 p.m. – 2:00 p.m.	ORD Management Multi-Year Plan	Mr. Peter Durant, Acting Director, ORD Office of Resources Management and Administration
2:00 p.m. – 2:30 p.m.	Future Discussion/Future Business ✧ Meetings in 2005 ✧ Nomination Subcommittee Update ✧ Ad Hoc Communication Subcommittee	Dr. James H. Johnson, Jr. Chair, Executive Committee
2:30 p.m	Adjourn	