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# 43rd EXECUTIVE COMMITTEE FACE-TO-FACE MEETING SUMMARY

**Marriott Metro Center**
**Washington, DC**

**February 4-5, 2010**[1]

## THURSDAY, FEBRUARY 4, 2010

### Welcome and Introductions

*Dr. Gary Sayler, University of Tennessee, BOSC Executive Committee Chair*

Dr. Gary Sayler, Chair of the Executive Committee of the Board of Scientific Counselors (BOSC), called the meeting to order at 9:00 a.m., and welcomed the BOSC members to the 43rd face-to-face meeting of the Executive Committee. He mentioned that although three Executive Committee members could not attend the meeting—Drs. John Giesy, Martin Philbert, and Henry Falk—there were enough members in attendance to provide a quorum. Dr. Sayler noted that the agenda is full but stated that he would do his best to complete most of the agenda today given the impending snow storm. He suggested that the members may want to try to book an earlier flight if possible.

Dr. Sayler mentioned that this would be Dr. Clifford Duke's last BOSC meeting because his term on the Executive Committee was coming to a close. Dr. Sayler stated that it had been a pleasure working with Dr. Duke for the past 6 years. Dr. Duke said that he had enjoyed being a member of the BOSC.

Dr. Sayler introduced Mr. Greg Susanke, the new Designated Federal Officer (DFO) for the BOSC Executive Committee. Dr. Sayler mentioned that Mr. Susanke had served as a DFO for some of the BOSC subcommittees, including the Homeland Security Research Program Subcommittee, which was chaired by Dr. Sayler. He noted one of the changes already implemented by Mr. Susanke—distribution of the premeeting materials electronically, with hardcopy of the materials distributed at the meeting in notebooks. Dr. Sayler asked the members to provide their feedback on this format and noted that it would probably continue for future meetings unless there were any objections.

Overview of the Agenda

Dr. Sayler reviewed the meeting agenda. The morning session includes a review of the September meeting minutes, the DFO's overview of administrative issues, the remarks of the new Assistant Administrator for the Office of Research and Development (AA/ORD), updates on the Drinking Water Program Review and Global Change Program Review, and presentation and discussion of the draft Letter Report from the Computational Toxicology Subcommittee. Drs. Giesy and Philbert were the vettors of this letter report. Following the lunch break, there will be an update on the EPA Science Advisory Board (SAB) activities, a presentation on the Decision Analysis Workgroup Report, and an update on the recommendations and changes for the program review process, subcommittee charge question revisions,

[1] Because of the snow storm that hit Washington, DC, on February 5, 2010, the BOSC meeting agenda was completed on February 4th and the second day of the meeting was cancelled. The DFO was present at the meeting location on February 5th from the planned start of the meeting through the planned public comment period and was available to take public comments.



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and the BOSC Guidance for Development of Program Review Reports and ORD Mid-Cycle Progress Reports. There also will be an open forum for discussing the future roles of the BOSC and related issues. Tomorrow's session includes the ORD update from Dr. Kevin Teichman, the ORD response to the Clean Air Program Review Report, and a continuation of the open forum discussion as well as future meetings and business. There will be time for public comment at 10:00 a.m. tomorrow.

Review of September 2009 Meeting Minutes

Dr. Sayler asked if the members had any corrections to the minutes from the September 15, 2009, Executive Committee meeting. When no comments were offered, Dr. Sayler called for a motion to accept the minutes. Dr. Charles Haas moved to accept the minutes of the June meeting, and Dr. Ken Demerjian seconded the motion. The minutes for September 2009 were approved unanimously by the BOSC.

## BOSC DFO Remarks

*Mr. Greg Susanke, U.S. Environmental Protection Agency, ORD, BOSC Designated Federal Officer*

Mr. Susanke, the new DFO for the BOSC Executive Committee, welcomed the BOSC members to the meeting and thanked them for their participation. He explained that the BOSC is a federal advisory committee that is subject to the requirements of the Federal Advisory Committee Act (FACA). Mr. Susanke reviewed the procedures that are required for all BOSC meetings. He stated that the BOSC provides independent, scientific peer review and advice to EPA's ORD, and it is his responsibility as the DFO to ensure compliance with all FACA rules.

In compliance with FACA requirements, all BOSC meetings are open to the public and time has been designated on the agenda for public comment. Mr. Susanke noted that although he received one request for the agenda, no requests for comment were received prior to the meeting. Time has been set aside on Friday's agenda at10:00 a.m. for public comment. He asked that comments be limited to 3 minutes each. An ORD contractor, Beverly Campbell from The Scientific Consulting Group (SCG), is present to take notes that capture the presentations and discussions. Following the meeting, she will prepare the meeting minutes, which will be made available to the public on the BOSC Web Site after approval by the Executive Committee and certification by the BOSC Chair.

As required by FACA, a notice of this meeting was published in the *Federal Register*. Mr. Susanke established an electronic public docket for the meeting on the Federal Docket Management System (FDMS), which can be accessed at http://www.regulations.gov. The number to search for this docket is EPA-HQ-ORD-2010-0013. The agenda was made available to the public in the docket and the materials are available upon request. As the DFO, Mr. Susanke ensures that the Executive Committee members receive annual ethics training and complete confidential financial disclosure forms. He asked members to notify him immediately if any potential conflict of interest arises during the meeting deliberations. He reminded the BOSC members and other participants to sign in at the registration desk if they had not done so already, and mentioned that Denise Hoffman is at the desk to help with any logistical needs.

Mr. Susanke said he appreciated the opportunity to meet the Board members in person after communicating with them by e-mail over the past several months. He noted that Ms. Lori Kowalski—the former BOSC DFO—had shared some of the e-mails she received from the Board members upon her departure. It was obvious from these e-mails that Ms. Kowalski was well liked and her hard work was appreciated by the Board. Mr. Susanke said he would do his best to take over her responsibilities and ensure that the BOSC receives the same high level and quality of support.

Dr. Sayler introduced the new AA/ORD, Dr. Paul Anastas, who was confirmed on December 27th. In an effort to help Dr. Anastas get to know the BOSC members, Dr. Sayler asked them to introduce themselves. A list of the Board members is attached to this summary.



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## AA/ORD Remarks

*Dr. Paul Anastas, EPA, ORD, Assistant Administrator for Research and Development*

Dr. Anastas greeted the BOSC members and expressed his pleasure to meet them. He explained that he had been confirmed as the new AA/ORD and he also serves as the EPA Science Advisor. Dr. Anastas said he was somewhat familiar with the BOSC and the crucial role the Board plays in evaluating ORD's research programs and providing guidance and direction to ORD. Beyond independent, external evaluation of ORD programs, the BOSC provides information needed by Office of Management and Budget (OMB) to assess program performance. Dr. Anastas stated that he was looking forward to learning more about the BOSC and interacting with the Board members.

Dr. Anastas provided some information on his background. He came from Yale University where he was on the faculty and served as Director of the Center for Green Chemistry and Green Engineering. He had a nice position at Yale so why would he leave it and move to Washington, DC? The mission of EPA is the reason he left Yale and came to EPA. To Dr. Anastas, the mission of the Agency is sacred. He has devoted his entire professional career to that mission. As a young boy growing up in Quincy, Massachusetts, he was inconsolable when a wetland near his home was replaced with an office park. His father, a high school biology teacher, explained to him that if he really wanted to protect the environment, it was important not only to care about it but to learn about it and understand it. With this sage advice, his father put him on the right track to being a scientist and an environmentalist. Dr. Anastas spent more than 10 years of his early career in EPA's Industrial Chemistry Branch of what is now the Office of Prevention, Pesticides, and Toxic Substances (OPPTS). From EPA, he went to the White House Office of Science and Technology Policy (OSTP), where he was the Assistant Director for Environment. His entire career has been devoted to this mission and he brings this perspective to his new challenge of serving as the AA/ORD and EPA Science Advisor.

When Dr. Anastas looks at EPA in 2010, he sees an Agency that began by tackling acute environmental problems in the 1970s, such as burning rivers and unbreathable air. The Agency did an extraordinary job in addressing those problems—it is one of the great success stories of the Federal Government. The challenges EPA now faces are more complex and subtle and much more difficult to define and explain. The mental frameworks currently in place do not always lend themselves to approaching and resolving these complex challenges. He acknowledged the difficulty of the work before him. How do we build systems thinking into an established framework with its own protocols? Dr. Anastas recognizes that it will take our best abilities to meet this challenge.

Before his confirmation, Dr. Anastas had several discussions with EPA Administrator Lisa Jackson. He was pleased that he did not even have to ask about her commitment, as well as that of President Obama, to maintaining the integrity of science at the Agency. That is essential to the scientific endeavor; anything that undermines science, undermines EPA's work and mission. The Administrator also is committed to transparency and Dr. Anastas confirmed that this one of his important priorities. Then he asked: How do we take on great environmental and health challenges in a way that is systematic and moves away from fragmented approaches, and at the same time meets our statutory and regulatory responsibilities? Dr. Anastas believes this will require innovative thinking. He pointed out that excellence and innovation are not the same thing. There can be innovation that is excellent but there can be excellence that is not innovative. The Agency will need to be innovative in the way it defines and approaches problems, such as gaining a better understanding of ecosystem vulnerability to the impacts of climate change. Dr. Anastas emphasized that the only reason to truly and deeply understand a problem is to empower a solution. A diagnosis is not the same as a cure. The Agency must empower the solution to the extent possible.

Dr. Anastas mentioned that the Administrator had identified seven priority themes for her tenure at EPA. These are: (1) taking action on climate change, (2) improving air quality, (3) assuring the safety of chemicals, (4) cleaning up our communities, (5) protecting America's waters, (6) building strong state

and tribal partnerships, and (7) expanding the conversation on environmentalism and working for environmental justice. Dr. Anastas stressed the strong verbs in these priority themes, pointing out that these priorities are not just about understanding the problem but are about acting on our understanding to address the problem. ORD has an important role to play in every one of the Administrator's priorities. Dr. Anastas explained that research, science, and technology are not listed among the Administrator's themes because they both view science and technology and research as essential components in each of these seven priorities. They see the work of ORD as essential and fundamental to the work of EPA.

Dr. Anastas shared some good news regarding the President's budget that was released earlier this week. In an era of increasingly difficult budget reductions, ORD fared pretty well. There will be budget increases in a few priority areas. He noted that this does not mean that all priority areas received budget increases. He was pleased to report that the budget for the extramural grants program—the Science To Achieve Results (STAR) Program—will increase by more than 40 percent (i.e., an increase of $26 million). This funding will be used for a number of priority areas. The budget for endocrine disruptors research will increase by $6 million and there will be an additional $2 million of funding for computational toxicology research. There also will be increases of $6 million for green infrastructure, $2.5 million for hydraulic fracturing research, and an additional $1 million for addressing electronics waste and electronics green design. Dr. Anastas pointed out that the increase in STAR funding will bring the program close to its historic highs. He also stressed the importance of the STAR Fellowship Program, noting that it is an important investment in the future. He was pleased to report that the increase in funding will bring the STAR Fellowship Program back to its historic high point.

During his first few weeks as the AA/ORD, Dr. Anastas has been visiting the ORD laboratories and centers; he has been very impressed with the commitment of the ORD staff to the Agency's mission. He has been listening to ORD staff members in the laboratories and centers describe their work and provide their thoughts on how they are helping the Agency accomplish its mission.

Dr. Anastas paused at this point to allow time for a dialogue with the BOSC. He encouraged the Board members to ask questions and offer their comments, noting that this was his first opportunity to hear from the BOSC.

Dr. Sayler thanked Dr. Anastas for his remarks and his willingness to have an open dialogue with the Board. He then asked if anyone had a question for Dr. Anastas.

Dr. Haas said that he had been working with EPA staff members for many years but he did not understand the role of the National Program Directors (NPDs) until he became a BOSC member. He asked for Dr. Anastas' thoughts on the role of the NPDs in balancing laboratory/center assets among research programs. Dr. Anastas said he would like to hear Dr. Haas' opinion on this issue. Dr. Haas responded that he remembers back to the time when the programs were clearly the responsibility of a single laboratory. The multidisciplinary, multimedia nature of today's programs, however, make that approach impossible. He suggested that ORD should revisit and possibly rethink the role of the NPDs. Dr. Sayler stated that the NPDs would play an important role in moving toward the systematic approach espoused earlier by Dr. Anastas. It often is difficult to get the researchers pulling in the same direction and that may be the most critical role of the NPDs.

Speaking from his perspective as a representative of the private sector, Dr. Dennis Paustenbach stated that during his 30-year career he has observed a tension between scientists outside the Agency and scientists inside the Agency. There currently is almost no dialogue between the private sector scientists and EPA scientists. In years past, EPA scientists would meet with private sector scientists to communicate about what needs to be done by the private sector (industry and academia) and what should be done by the public sector to address certain issues and improve our collective understanding of various problems. Would it be possible to bring back such a dialogue? He noted that there was a time when the rest of the



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world looked to EPA's efforts as the model but now many other countries and organizations are surpassing EPA and the United States. What can be done to correct this problem?

Dr. Anastas replied that he appreciated these comments and thought they were very important. He then asked if anyone remembered the subject of the first treaty with China, noting that the renewal of this treaty was the first communication between the United States and China after the long silence. Science is one of the best starting places when there has been limited communication and tension between two groups. Dr. Anastas acknowledged that there had been a great deal of polarization from science being dragged into politics; however, he agreed that it was important to engage in genuine scientific discussions. He believes that it is possible to make products that are of high value and do not harm the environment. It is a great design challenge but it is possible. It is essential to engage the people that will implement the solutions in a dialogue; they cannot be alienated from the discussion. Dr. Paustenbach thought Dr. Anastas was well positioned to open this dialogue with the private sector.

Dr. Demerjian reminded the BOSC members that the first ground-breaking action with the Soviet Union also concerned environmental issues. During the recent review of the Clean Air Research Program, the Subcommittee members expressed some concern about the NPD's lack of fiscal control. It appeared that ORD's original plan was to give the NPDs some fiscal control but for various reasons that has never happened. The Clean Air Subcommittee recommended that ORD rethink this approach. Dr. Demerjian noted that the proposed new ozone standard will present huge challenges to the Agency and thrust it into the global arena. If the Agency selects 60 ppb as the 8-hour standard, one-half of the United States will be in non-attainment in the summertime. EPA produces the tools that are used by the states to comply, and the scientific uncertainty becomes a real problem when getting down to these lower numbers. Is it realistic to believe that the tools will be adequate to meet the demand?

Dr. Anastas responded that scientific assessments are an essential building block but they are not risk management. He acknowledged the importance of increasing our depth of understanding and the elucidation of biological mechanisms; however, it is important to recognize that an assessment is not the same as risk management. The situation mentioned by Dr. Demerjian is a clear example of the difficulties the Agency faces when trying to blend scientific assessment with risk management.

Dr. Anastas asked for the BOSC members' perspectives on sustainability. The Agency has tremendous abilities and an excellent track record with many programs geared toward the scientific understanding of environmental and human health protection. Sustainability is all of that and more because it includes interactions and actions. What are the BOSC's thoughts on how ORD thinks about sustainability?

Dr. Sayler responded that ORD was a clear leader in this area a number of years ago with its efforts in life cycle analysis (LCA), energy analysis, systems integration, and pollution prevention. This leadership role, however, has been lost to the Europeans. Now, states are trying to lead the way. He noted that sustainability is a big issue in the U.S. Department of Energy (DOE), and that agency will be spending a great deal of money on this topic even though it may not be the most capable agency.

Dr. Anastas agreed that ORD had a wonderful foundation in LCA and it has maintained a sustainability program. He noted that sustainability often is not considered a separate program but something that cuts across all programs. Dr. Haas stated that sustainability is an important area but he expressed his concern that we are in danger of losing the meaning of that concept because the term "sustainability" has been overused. How do you operationalize sustainability? Only when sustainability is operationalized, does one get a sense of what needs to be done to get there.

Dr. Paustenbach suggested that ORD should determine an area of specialty within sustainability on which to focus. EPA should find a niche and be careful not to duplicate what is being done by the private sector, academia, and other countries. He suggested that the Agency find some connection between sustainability and enforcement.



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Dr. Duke stated that a key element of sustainability is being able to measure where we are and where we are going. Work has been done to develop such indicators. What is ORD's role in the Council on Environmental Quality's (CEQ) national system of environmental accounting, which is not dissimilar to EPA's Report on the Environment (ROE)?

Dr. Anastas responded that it is important for EPA to continue working with the CEQ on metrics and measures for sustainability and environmental improvement. This is one of the many reasons that the BOSC is important—it helps evaluate performance when it often is extremely difficult to quantify and measure. Dr. Anastas cautioned against confusing metrics with research goals. He noted that it can be very challenging to measure the achievement of goals. Unfortunately, the Agency often selects metrics based on what is easily measureable rather than what should be measured. The analogy of economic performance is useful here. When all you have is aggregate data, you often loose transparency and it can be difficult to determine where intervention is needed.

Dr. Demerjian asked about ORD's role to underpin the science to support the endangerment rule for $CO_2$. Dr. Anastas responded that this will be a very contentious discussion on the regulatory side, which will impact what ORD is called upon to do. There will be ongoing research but how that research will be tailored to meet the Agency's needs is something that Dr. Anastas needs to learn more about before he can provide an informed answer.

Dr. Barry Ryan asked if ORD should be the office within EPA that is "depoliticized." Does ORD have a role in accomplishing this and if so, what would that role be?

Dr. Anastas replied that the blurring of the lines between science and policy has been a challenge since the Agency was created. This affects how scientific analyses are put into policy frameworks that impact the political agenda. Dr. Anastas believes that the path forward is to increase environmental protection without economic burden through innovation. "No regrets pathways" are the fundamentals of sustainable design. Dr. Anastas acknowledged that there are legacy issues that will be contentious but he wants the regulators and the regulated to work together toward environmental and health protection that is economically profitable.

Referring back to Dr. Anastas' comments about the distinction between scientific assessment and risk management, Dr. Katherine von Stackelberg suggested that ORD should address this head on. She noted that it is impossible to separate the two; the scientist must interpret the science for the policy maker. Who is actually building the bridges between the scientists and the decision makers? Perhaps ORD should fill that void now.

In bringing the discussion to a close, Dr. Sayler thanked Dr. Anastas for responding to the BOSC's questions and comments, noting that this had been a great opportunity to share their thoughts.

## Subcommittee Updates

<u>Drinking Water Program Review</u>
*Dr. Charles Haas, Drexel University, Subcommittee Chair*

Dr. Haas reported that the process for identifying potential Drinking Water Subcommittee members is nearly completed. The Subcommittee will have a total of eight members and the chair when it is complete. A face-to-face review meeting has been scheduled for June 14-16, 2010, in Cincinnati, Ohio. Troy Rutkofske is the DFO for the Drinking Water Subcommittee.

Dr. Sayler mentioned that the charge questions for that review will reflect the changes discussed at today's meeting. In response to an inquiry regarding whether Dr. Haas had looked at the previous review



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reports for the Drinking Water Research Program, Dr. Haas responded that he had not looked at the report but he thought it was a good suggestion so he planned to do so before the review meeting. Mr. Susanke pointed out that the reports for all previous BOSC reviews are posted on the BOSC Website (www.epa.gov/ops/bosc).

Global Change Program Review
*Dr. Gary Sayler, BOSC Executive Committee Chair*

Dr. Sayler explained that because Dr. Falk was unable to attend the meeting, he would provide the update for the Global Change Subcommittee. This review was planned for July 2010, but for a number of reasons including commitments of the program, it has been postponed several months and probably will be held in fall 2010.

Dr. Kevin Teichman offered some additional information regarding why this review has been postponed. Dr. Joel Scheraga, the NPD for Global Change, has taken a position with EPA's Office of Policy, Economics, and Innovation (OPEI). Dr. Teichman said that although ORD is sorry to see Dr. Scheraga go to the policy side of the Agency, it is good to have someone at OPEI who understands the research program. In addition, Dr. Falk, who had volunteered to chair the Global Change Subcommittee, has recently agreed to serve as the Acting Director of the National Center for Environmental Health at the Agency for Toxic Substances and Disease Registry (ATSDR) in place of Dr. Howard Frumkin. Although Dr. Falk has not informed Dr. Teichman that he will be unable to serve as the Subcommittee Chair, this is a likely possibility. Therefore, it made sense to postpone the review until a new NPD for the program could be named and possibly a new Subcommittee Chair could be identified.

## Computational Toxicology Letter Report

*Dr. Dennis Paustenbach, ChemRisk, Inc., Subcommittee Chair*

Dr. Paustenbach stated that the two vettors for this letter report—Drs. Giesy and Philbert—sent him their comments prior to the meeting. None of the comments involved substantive changes to the report. They were primarily editorial comments.

Dr. Paustenbach clarified that Dr. George Daston actually served as the Subcommittee Chair for the Computational Toxicology Program review that was conducted in September 2009. Dr. Paustenbach succeeded Dr. Daston as the Subcommittee Chair following that review.

The Subcommittee did an outstanding job on the program review. It was an excellent group of reviewers. The face-to-face review meeting was held September 29-30, 2009, in Research Triangle Park, North Carolina. The meeting was attended by 80-100 people, and most of the attendees were EPA employees.

Overall, the Subcommittee members concluded that the program has made substantial progress toward meeting the original long-term goals (LTGs), and that the progress is appropriate given the duration of the program's existence and the resources involved. The program's LTGs are: (1) risk assessors use improved methods and tools to better understand and describe the linkages or the source-to-outcome paradigm, (2) EPA program offices use advanced hazard characterization tools to prioritize and screen chemicals for toxicological evaluation, and (3) EPA assessors and regulators use new and improved methods and models based on the latest science for enhanced dose-response assessment and quantitative risk assessment.

Dr. Paustenbach said that he did not know much about this program prior to participating in this review. He had done some work on physiologically based pharmacokinetic (PBPK) cancer modeling and did not realize until this review that the program has moved way beyond that point. The Computational Toxicology Research Program (CTRP) has the potential to have a huge impact on prioritizing chemicals.



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During its inaugural funding period, the program has built the infrastructure necessary to bring computational tools to risk assessment; assembling the data and building the tools that are needed to collect the high-throughput screening (HTS) data. Dr. Paustenbach commented that the program is on the first phase of a long journey. He noted that some of the tools from this program likely will be embraced by the toxicological community but some will not. In response to Charge Question #1, the Subcommittee recommended the following:

- ✧ Several CTRP projects have undertaken structuring, standardizing, and organizing the data so that they can be more easily subjected to comprehensive meta-analyses. At this point, the CTRP should obtain some public feedback on how people are using and interpreting the available data.

- ✧ Acceptance of products, methods, and databases by the risk assessment community is the key to success. Hence, the National Center for Computational Toxicology (NCCT) should organize an annual or biannual conference that brings together the data generators, data users, and risk assessors/managers—the ultimate users of these alternative methods/models.

- ✧ As more data from high-throughput assays and computer models become available, the NCCT should provide guidance on how to interpret this information in the context of more traditional testing and scientific examination so that risk assessment practitioners in the EPA program offices can apply these findings.

With respect to Charge Question #2, which focused on the program's use of internal and external partnerships to foster its goals, the Subcommittee found that the program has engaged a number of EPA laboratories, including EPA's National Health and Environmental Effects Research Laboratory (NHEERL), National Exposure Research Laboratory (NERL), National Risk Management Research Laboratory (NRMRL), and National Center for Environmental Assessment (NCEA). The program also has collaborations with the National Institutes of Health's (NIH) National Institute of Environmental Health Sciences (NIEHS) and Chemical Genomics Center. The Subcommittee noted that absence of collaborations with the National Science Foundation (NSF), DOE, and the National Library of Medicine, particularly the National Center for Biotechnology Information. The Subcommittee also noted the lack of strong relationships with various U.S. and international universities as well as partnerships with other scientific and regulatory bodies outside the United States. The Subcommittee recommends that the program:

- ✧ Continue to interact with other scientific bodies, regulatory agencies, and universities both in the United States and globally so as to insure that work conducted elsewhere can be "built upon." One possible benefit of this interaction is that it may promote harmonization regarding the organization of historical data that currently are being assembled, as well as new data. This would eliminate the time-consuming task of extracting data from original studies and then entering them in the databases.

- ✧ Routinely (perhaps biannually) sponsor some sort of exchange of information with risk assessment practitioners both inside and outside EPA (corporations, consultants, and government scientists) to be sure that the end products of the Program's work are both reliable and of use to the future users.

- ✧ For the next BOSC review, develop a table that presents the level of effort dedicated to specific projects, by year. This table would contain the number of CTRP FTEs, as well as the approximate level of "collaborative" effort (from other EPA laboratories and other partners and consultants). In-kind support and "hard" dollars also should be presented.



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Dr. Paustenbach mentioned that some Subcommittee members thought the program was duplicating work being done by other organizations; the recommendation concerning the information exchange arose from this concern.

There was some disagreement among the Subcommittee members with respect to Charge Question #3. Some of the members think that computational toxicology tools will replace toxicological testing, but others think that they will be "science forcing." The Subcommittee agreed that the program will establish a methodology that can be relied upon by researchers around the world for quickly identifying those chemicals that "have a red flag." The Subcommittee's recommendations were to:

- ✧ Keep the statisticians and mathematical modelers involved in assay evaluation so that they can move from qualitative prediction to quantitative prediction of outcomes from exposure data.
- ✧ Conduct an unbiased evaluation of the usefulness of particular assays to achieve prediction beyond a single class of compounds and to define knowledge gaps for new assay design.
- ✧ Develop case studies that demonstrate a strategy for incorporation of CTRP tools/research into the risk assessment process.

Dr. Sayler asked about the last paragraph on page 7 of the report, which mentioned the virtual liver and virtual embryo projects. What progress has been made in these areas? Dr. Paustenbach responded that some of the members think the virtual liver project has made good progress and it is extremely important; other members think it is a dream that is yet to be realized. Most members agree that the virtual embryo project is much more complex and difficult to implement. More than 300 chemicals, mostly pesticides, have been run through the system.

Dr. Paustenbach mentioned that one of the pharmaceutical companies collaborating with the program participated in the review meeting, adding that he had not seen such close collaboration with the private sector in a long time and he thought it would be beneficial to both parties. He suggested that the program should consider collaborating with five or six major chemical companies (both U.S. and international), adding that much of the chemical toxicity research has moved overseas. Dr. Paustenbach suggested that he add the recommendation about collaborating with chemical companies to the letter report. Dr. Sayler asked if he thought it was worth the effort of going back to the Subcommittee to get the additional recommendation approved. Dr. Paustenbach thought it might be adequate that the comment has been made at this meeting and will be captured in the minutes. Dr. Teichman assured Dr. Sayler that ORD will respond to both written and verbal recommendations.

Dr. Robert Kavlock, Director of the NCCT, stated that the program currently does not have any formal agreements with commodity chemical companies because of potential conflicts. He added that the program has had some dialogue with BASF and discussions with ATC and CropLife but there is no formal agreement with any of these companies. Dr. Paustenbach asked Dr. Kavlock if he was on the telephone during the discussion with Dr. Anastas when he asked about the tension between the private sector scientists and EPA scientists. Dr. Paustenbach commented that there should be no conflict of interest if the discussions are strictly science. Dr. Teichman pointed out that the current collaborations with the pharmaceutical companies focus on chemicals that passed the animal toxicity testing but then did not go as expected in the clinical trials. The pharmaceutical companies want to figure out if there is a tool that could have predicted these failures. Dr. Sayler asked if it was necessary for the Agency to have a "Chinese wall" between EPA and regulated companies because of conflict of interest. Dr. Teichman replied that the Agency encourages working with industry through the Federal Technology Transfer Act (FTTA). He was not aware of anything on the research side that would prohibit ORD from working with industry. He noted that it would be better to work with several companies rather than one company and to include environmental organizations as well so that everyone trusts the research results. Dr. Paustenbach



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said he would like to believe that there could be closer communications between EPA and the private sector.

Charge Question #4 concerned the contribution of the intramural and extramural research to achieving the goal of providing high-throughput decision support tools for screening and assessing chemical exposure, hazard, and risk to human health. The Subcommittee was very impressed with the training dimension of the management plan; the number and quality of the post-doctoral fellows being trained by the program were very impressive.

It was clear that exposure is not the primary focus of the program. As the CTRP continues to progress, there should be a higher priority on incorporation of ecological receptors and greater focus on assessment of exposure factors. The Subcommittee noted an absence of ecological health as an endpoint for the high-throughput decision support tools for screening and assessing chemical exposure, hazard, and risk. The CTRP will have to move into the field of ecological risk assessment at some point if it is to become fully integrated and supportive of the Agency's regulatory activities. Acknowledging this need and developing a forward plan to incorporate it as part of the CTRP should be part of the longer term plan.

Dr. Paustenbach stated that the nine recommendations under this charge question were to:

- ✧ Be more integrative, both internally and externally, to ensure all parties are working from common assumptions, data development schedules, and deliverable planning.
- ✧ Expand outreach to the broader community, both within EPA and in the extramural community. This is not to say that the CTRP has not been effective in building a strong outreach program, but only that this needs to be a priority, and possibly a higher priority.
- ✧ Detail specific roles for the STAR Centers as part of the integrated approach to managing the Program's mission.
- ✧ Place a higher priority on incorporation of ecological receptors and greater focus on assessment of exposure factors.
- ✧ Develop a forward, longer term plan to incorporate the field of ecological risk assessment as part of the CTRP.
- ✧ Expand the ExpoCast program to include real exposure and outcomes data, as well as the additional development of software resources to take advantage of these data for exposure and outcome predictions. This should be a priority of the Center.
- ✧ Continue training postdoctoral fellows because these scientists have the potential to be ambassadors to the rest of the community to help extend the understanding and acceptance of the types of computational tools the CTRP is trying to develop, and in doing so, ultimately help to improve those tools and their efficacy.
- ✧ Highlight quality assurance for software and models with a specific testing approach augmented with a sophisticated evaluation approach that probes how the systems produced work in the hands of users.
- ✧ Promote "user-centered design," an approach that grounds the process of design in information about the people who will use the product.

Dr. Paustenbach mentioned that the program should work with groups generating data (e.g., REACH) so that the data will be provided in a format that can be used by the program. Perhaps these organizations



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can reach an agreement on the format. This is an important issue because the program staff spends considerable time rebuilding data sets.

Dr. Sayler asked if there was any discussion of the program's use of advanced statistical approaches that are becoming available to make analyses more robust. Dr. Paustenbach responded that he was not sure if that was discussed because the Subcommittee met in small subgroups to discuss different charge questions. He thought pages 9-11 of the report touched on that subject. He asked Dr. Kavlock to comment on whether the program keeps up with advanced statistical techniques. Dr. Kavlock replied that they do keep abreast of analytical advances and incorporate them into the program. Dr. Sayler then asked Dr. Kavlock if the program is embracing the Collaborative Cross mouse model that is available at the University of North Carolina. Dr. Kavlock answered that the STAR Program and the Human Susceptibility Branch are working with that model.

In response to Charge Question #5 regarding continuation of the NCCT, Dr. Paustenbach stated that the Subcommittee strongly supports action to make the Center a permanent component within ORD. The Subcommittee recommends that the CTRP: (1) establish performance metrics that track the development of tools and resources for informing chemical prioritization, toxicity testing, and risk assessment; and (2) continue to meet with customers, clients, and stakeholders on a regular basis to ensure that the program is meeting the needs of risk assessors and risk managers in the Agency.

Dr. Paustenbach mentioned that he had discussed the work of the CTRP with the past three presidents of the Society of Toxicology. They think this work could have a great impact on the toxicology profession; they stressed the importance of validating the computational toxicology tools to assess their accuracy in predicting toxic effects.

Dr. Sayler thanked Dr. Paustenbach for his presentation and asked if there were any questions or comments on the letter report.

Referring to line 4 on page 4 of the draft report, Dr. Haas noted the words "database development is seen as a fairly mundane task." He pointed out that what the program is building is really going beyond a database. His colleagues use the terms "knowledge warehouse" or "knowledge repository" to refer to a more complex array of data, such as what the CTRP is constructing. Dr. Sayler recommended revising the wording in the report to the following: "…it is the foundation of the knowledge base on which much of the CTRP… ." Dr. Paustenbach agreed to make this change.

Dr. Duke asked if there was a typographical error in the last line on page 6, referring to "providing the laboring ore." Dr. Paustenbach responded that the report should read "providing the laboring oar." He agreed to correct that typographical error.

Dr. Demerjian asked if there was a systematic program to conduct animal testing on 10 percent of the outcomes to evaluate the accuracy of the tools and to ensure that they are performing as expected. Dr. Kavlock stated that the program refers to that as "targeted testing." The CTRP is partnering with the National Toxicology Program (NTP) to test several of the chemicals for which the program has made predictions to see if the predicted pathway and outcomes can be validated. The program also has done some work on ranking endocrine disruptors; the first list of chemicals to be screened in the Endocrine Disruptor Screening Program has been completed and there will be testing data in a few years to compare to the CTRP's predictions. Dr. Paustenbach mentioned that the program's predictions will be validated over the next 2-5 years. Dr. Demerjian asked if the program has considered randomly selecting 10 percent of the predictions for testing, including all outcomes. This approach would remove the bias in the selection process. For 10 percent of the predictions, use traditional analysis in animal models to determine how well the computational toxicology model performed. That is the best approach for building confidence in the technique. Dr. Paustenbach liked this suggestion and said he would be glad to add it to the letter report. Dr. Kavlock responded that they were selecting quite a few chemicals for the



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NTP to study; he stressed the importance of being thoughtful about the chemicals selected for testing. Dr. Demerjian noted that the CTRP may want to consider testing some chemicals for which the program predicted no toxic activity to verify that they were not false negatives. Dr. Kavlock stated that they plan on testing some chemicals that have a low probability of testing positive as well as chemicals that have a high probability for testing positive. He explained that the chemicals for validation testing are not selected randomly; they are selected based on potential but all outcomes are included.

Dr. Sayler noted that a few modifications to the report will be made by Dr. Paustenbach based on the comments from the vettors and this discussion. He called for a motion to approve the letter report with these changes. Dr. Ryan made a motion to approve the report and Dr. Duke seconded the motion. The report was unanimously approved by the BOSC Executive Committee and it will be finalized for submission to ORD.

**Future Business**
*Dr. Gary Sayler, BOSC Executive Committee Chair*

Next Executive Committee Meeting

Dr. Sayler stated that the spring meeting of the Executive Committee would be held in Corvallis, Oregon. He noted that ecosystem services would be an appropriate topic to add to the agenda for that meeting. Traveling to Corvallis will involve flying into Portland and then driving about 90 minutes to Corvallis. He encouraged the Executive Committee members to coordinate their arrival times so that they could car pool from the airport in Portland to Corvallis. Dr. Ryan mentioned that the other option is to fly to the airport in Eugene, which is much closer to Corvallis.

Dr. Sayler asked about possible dates for the spring meeting. He asked about members' availability the second half of June. Several members had conflicts in early and late June and Dr. Haas mentioned that the Drinking Water Subcommittee meeting was scheduled for June 14-16. Dr. Sayler then asked about availability in early July. Most Executive Committee members indicated that they were available Monday and Tuesday, July 12-13, which would mean flying out on Sunday, July 11. After polling the members, Dr. Sayler stated that the two best options for the spring meeting are June 7-8, 2010, and July 12-13, 2010. Mr. Susanke will work with members to finalize the date for the spring meeting.

Future Work

Dr. Sayler pointed out that the work load for the BOSC is relatively light for 2010. There are only a couple of program reviews in place, but the review schedule picks up in late 2010 and early 2011. The Drinking Water Program review will be completed in 2010 and the Global Change Program review has been pushed to October 2010. The mid-cycle progress reports from the NPDs for the Human Health, Safe Pesticides/Safe Products, and Human Health Risk Assessment Research Programs will be presented at the June/July meeting in Corvallis. Mr. Susanke hopes to distribute these progress reports to the Executive Committee members prior to the Corvallis meeting.

Another item for the spring meeting in Corvallis will be an update from the Decision Analysis Workgroup's review of the methods and procedures that were used during the Nanomaterials Case Study Workshop to identify and rank the nano research priorities. The workgroup will review the methods and procedures before the June/July meeting and be prepared to discuss their findings with the Executive Committee at the meeting in Corvallis.

Dr. Sayler mentioned that Drs. Haas and Philbert have offered to work with ORD to think about informatics in a more structured fashion and to develop a more integrated, efficient strategy. Dr. Sayler suggested inviting an informatics expert to make a presentation at the Corvallis meeting. The BOSC could take a look at the informatics area and where the field is going with respect to knowledgebase



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models, statistical tools, etc. Dr. Haas reminded the Executive Committee that this offer to help ORD originated from the bibliometrics issue. Dr. Sayler suggested that the BOSC could take a broader approach. He added that this is a cross-cutting topic that fits well with the system within a system concept that Dr. Anastas spoke about earlier. Dr. Haas said he would give some thought to this suggestion, adding that it may merit further discussion later in the afternoon if time allows. He noted that this topic may be helpful to ORD in capturing the expertise that will be leaving the Agency as senior staff members retire. Dr. Haas said he would also try to identify some speakers for the Corvallis meeting. Drs. Sayler, Haas, and Philbert will work together to schedule one or two expert presenters for the Corvallis meeting.

Dr. Sayler mentioned that there may be an Executive Committee conference call scheduled in April if necessary, but there currently are no agenda items for that call.

Mr. Susanke asked if there were any additional comments on the BOSC's work schedule. He has been working with EPA staff to set up a tour of the Corvallis laboratory for the BOSC members. It looks like there will be a full agenda for the 1 ½-day meeting in Corvallis. He added that there may be some new Executive Committee members by the spring meeting. Mr. Susanke explained that the Agency is revising its federal advisory committee member identification and selection process. Consequently, the BOSC package for new members had to be revised to comply with the new procedures, which requires broader solicitation for new candidates and more transparency in selecting members.

Dr. Paustenbach asked about the maximum number of Executive Committee members and Mr. Susanke replied that the current BOSC charter limits the number of members to approximately 15. The BOSC charter must be renewed in May 2010, and it may be possible to increase that total number. He noted that there are five vacancies on the Board that need to be filled. Each member is appointed for a 2-3 year term and can serve a total of 6 years on the BOSC.

Dr. Sayler pointed out that there will be time in the afternoon session devoted to open forum discussion. That offers the members a good opportunity to ask Dr. Teichman how ORD plans to utilize the BOSC in the future. Given the lighter work schedule, the Board may want to take on some topics that would be of value to ORD. One such topic may be sustainability. This is an opportunity for the BOSC to redefine its relationship with ORD.

Dr. Paustenbach said that the BOSC's activities are quite different than he expected them to be before he became a BOSC member. He thought the BOSC would give conceptual advice to the AA/ORD rather than boring down into the research programs. He anticipated that the BOSC might look at what others outside the Agency are doing and offer advice to ORD on what areas are not being addressed.

Dr. Sayler responded that the BOSC's role is to look at the science to ensure that ORD is doing the right science and that they are doing it correctly. He added that the SAB provides the Agency conceptual advice at a higher level than that of the BOSC. Dr. Sayler noted that the SAB values the work of the BOSC. Dr. Paustenbach pointed out that the SAB also addresses some very specific topics. Dr. Sayler suggested that this discussion be resumed later during the open forum session.

## EPA Science Advisory Board (SAB) Activities

*Dr. Vanessa Vu, U.S. EPA, Director SAB Staff Office*

Dr. Vanessa Vu, Director of the SAB Staff Office introduced herself to the BOSC members. She is a toxicologist by training and worked at the National Cancer Institute (NCI) conducting research on carcinogens before coming to EPA. Prior to her years at NCI, Dr. Vu worked at Georgetown University. For the past 8 years, she has served as the Director of the SAB Staff Office. She recalled coming to a BOSC meeting when Dr. Jerry Schnoor was the Executive Committee Chair. Dr. Vu said that she knows many of the BOSC members because they also serve on the SAB or one of the SAB committees.



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Dr. Vu explained that her presentation would cover the statutory authorities and mission of the SAB as well as the committee structure, membership, and Fiscal Year (FY) 2010 advisory topics. The mission of the SAB is to provide the EPA Administrator with independent peer review and advice on scientific and technical matters underlying major environmental policies and risk management actions. There are three separate advisory groups: the Clean Air Scientific Advisory Committee (CASAC), the Advisory Council on Clean Air Compliance Analysis (Council), and the SAB.

The CASAC was established in 1977 under the Clean Air Act Amendments (CAAA) to provide advice to the Administrator regarding air quality standards of criteria air pollutants, research related to air quality, sources of air pollution, and strategies to attain air quality standards and to prevent significant deterioration of air quality. The Council was established as mandated by the 1990 CAAA to provide advice to the EPA Administrator regarding the Agency's analyses of the impacts of the CAA on public health, the economy, and the environment. Dr. Vu mentioned that a report on the successes of the Agency in reducing air pollution will be released as part of EPA's 40th anniversary celebration. The SAB was established in 1978 by the Environmental Research, Development, and Demonstration Authorization Act (ERDDAA) to provide independent advice to the Administrator on scientific and technical matters underlying key environmental policies and risk management decisions.

The SAB has 40 chartered members and 6 standing subcommittees. The CASAC has 7 chartered members and one subcommittee. The Council has 17 chartered members and 3 subcommittees. *Ad hoc* committees and panels are created as needed.

The EPA Administrator appoints members of the CASAC, Council, and SAB (including the members of the six standing subcommittees). The members are drawn from academia, governments, industry, and non-governmental organizations (NGOs). The SAB Staff Office Director appoints consultants to augment expertise on committees and panels as needed. Presently, there are about 120 appointed members and more than 200 consultants serving as Special Government Employees (SGEs). The members and consultants are subject to the ethics requirements of SGEs.

The SAB coordinates with a number of other advisory committees including the CASAC; the Council; the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel; the Children's Health Protection Advisory Committee; ORD's BOSC; the National Drinking Water Advisory Council; and the National Advisory Council for Environmental Policy and Technology (NACEPT).

Six types of advice are provided by the SAB, including:

- ✧ Consultation—non-consensus advice at the early stage of the Agency's works.
- ✧ Advisory—advice as the Agency's works are in progress.
- ✧ Peer Review—review of the Agency's completed work products.
- ✧ Original Study—original work on an emerging or overarching topic of importance to EPA.
- ✧ Commentary—unsolicited advice on an important technical or emerging issue in the form of a short communication.
- ✧ Rapid Consultative Advice—collective advice from individual experts in an emergency context.

The advisory topics considered by the SAB vary depending on the EPA office requesting the advice. Some examples follow:

- ✧ OPEI—Economic Methods and Guidelines



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- Office of Air and Radiation (OAR)—Economic Analysis, Model Reviews, Criteria Air Pollutants, Radiation Guidance, Indoor Air Guidance
- OPPTS—Chemical Assessment, Models
- ORD/Office of the Science Advisor—Risk Assessment Guidelines, Integrated Risk Information System (IRIS) Assessment of Environmental Contaminants, Homeland Security Technical Issues, Modeling Guidance, Science and Research Priorities and Budget, Awards Program for EPA Scientific Publications
- Office of Solid Waste and Emergency Response (OSWER)—Chemical-Specific Guidance Technology
- Office of Water (OW)—Guidelines for Water Quality, Water Infrastructure and Security, Drinking Water Chemical and Microbial Contaminants
- Regions—Assessment Tools and Methods.

Dr. Vu noted that the regions rarely bring issues to the SAB because they generally require input in very short timeframes.

Dr. Vu referred to three tables that were included in the meeting notebook. One table identified projects for the CASAC, the second table identified projects for the Council, and the third table listed projects for the SAB. She explained that the SAB Staff Office includes five administrative personnel who are responsible for coordinating the logistics of the meetings as well as 12 technical scientists/engineers who manage the various activities of these committees. Dr. Vu noted that the EPA Administrator has given the SAB a considerable amount of work and the 2010 schedule is quite busy.

Dr. Sayler stated that BOSC members who are interested in participating in any of the activities listed in the tables distributed by Dr. Vu should notify him and Mr. Susanke of their interest. EPA will cover the expenses of attending the meeting and the member would be required to report back to the BOSC Executive Committee on the activity.

Dr. Vu mentioned that Dr. Jon Samet, who chairs CASAC, is a member of the SAB. There are current and former SAB members serving on the FIFRA Scientific Advisory Panel as well. Dr. Vu stated that the SAB would welcome a member of the BOSC to serve as liaison between the two advisory groups. This liaison could contribute the BOSC perspective to SAB discussions. Dr. Vu said that she hopes the new chair of NACEPT will join the SAB as well.

Dr. Paustenbach commented that he did not see much overlap between the activities of the SAB and the BOSC. How can the BOSC be useful in supplementing the work of the SAB? Dr. Sayler reminded the members that the BOSC's charge is to advise ORD.

Dr. Vu stated that the SAB has difficulty planning ahead because the requests for advice come from the Assistant Administrators and occasionally the Administrator, and the Board must respond. Most of the SAB's projects are of the peer review type. She explained that the SAB does not want to just react to Agency requests. That is why the Board offers different types of advice, some of which allow the SAB to provide input quickly. Some SAB projects take years to complete; for example, it took 6 years to complete the report Valuing the Protection of Ecological Systems and Services. The SAB is wrapping up a study that aims to make recommendations for a more integrated research program on reactive nitrogen and to identify opportunities of integrated research for nitrogen management. A recent study involves the evaluation of the extent to which scientific assessment practices are integrated into EPA's environmental decision-making processes. Dr. Vu mentioned that the SAB also provided unsolicited advice on perchlorate in 2009. Rapid consultative advice was initiated by the Board after Hurricane Katrina when



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the Administrator asked the SAB to provide technical advice on sampling. This type of advice allows a federal advisory committee to respond rapidly to requests for advice in emergency situations.

Dr. Vu noted that the SAB interacts with the BOSC with respect to the ORD portfolio. The BOSC gives ORD advice on how it can be more effective. She emphasized that the BOSC can augment the activities of the SAB committees. Another area of overlap is the role the SAB plays in advising the Agency on future directions of ORD science and research needs. The BOSC can reinforce this role. Dr. Vu expressed her belief that there are many opportunities for collaboration and coordination with the BOSC and she hopes there will be more interaction in the future.

Dr. Sayler asked if Dr. Vu would prefer that a BOSC member serve as the liaison between the two advisory boards. Dr. Vu confirmed that she would prefer to have a BOSC member participate on the SAB and serve as the liaison to the SAB. Dr. Sayler said he would query the BOSC members to determine if anyone will volunteer to serve as the liaison to the SAB. Dr. Paustenbach asked if that individual would attend SAB meetings. Dr. Vu responded that they would attend the SAB meetings, but not the meetings of the various committees and panels. She explained that the parent group—the SAB—must review and approve all SAB products so those meetings cover all SAB committee activities.

Dr. Paustenbach asked if SAB Executive Committee retreats still exist. Dr. Vu confirmed that there was a retreat last year and explained that these retreats are intended to improve the efficiency and transparency of the SAB process in light of the GAO 2001 report. At the retreat last year, the SAB decided to retain the standing committee structure but would offer more opportunity for the public to submit nominations of candidates to serve on panels to address “hot” topics. The list of candidates being considered by the Agency will be available to the public and then there will be an ethics review. Dr. Vu said that she believes in the FACA process and thinks it is effective in obtaining outside, independent advice. They will continue to review the process and take steps to make it better.

### Decision Analysis Workgroup Report

*Dr. Katherine von Stackelberg, Harvard University, Decision Analysis Workgroup Chair, BOSC Executive Committee*

Dr. von Stackelberg reported that the Decision Analysis Workgroup had completed the case studies and prepared the workshop report. To provide some context, Dr. von Stackelberg described why the workgroup was formed and what the workgroup had accomplished; she then described some next steps.

In September 2008, Dr. Fred Hauchman from EPA’s Office of Science Policy (OSP) gave a presentation to the BOSC on using value of information (VOI) techniques to prioritize research by more formally identifying the research that would most reduce uncertainty. OSP indicated that it would like to hear recommendations from the BOSC on the best way to proceed with respect to institutionalizing the use of VOI and other, related techniques to support research prioritization and decision making within ORD. Although VOI is appropriate for specific kinds of decisions, it is challenging to use it for basic research decisions because it is not known how the uncertainty will affect the ultimate decision and it is not always possible to quantify the benefits in that way.

Following Dr. Hauchman’s presentation to the BOSC, Dr. von Stackelberg met with Dr. George Gray, who was the AA/ORD at the time, to talk about how ORD wanted to use decision analysis techniques. Dr. Gray indicated that he wanted to implement a more formalized structure for many decisions ranging from the allocation of funding to programs to the selection of proposals in response to STAR grants. Two key questions that were discussed at this meeting with Dr. Gray were: Had ORD tried to use decision analysis techniques in the past? What was the outcome? Dr. von Stackelberg said the workgroup learned that ORD had tried to use such techniques in the past. They had the right people involved in the efforts and the uses were both focused and manageable but, for whatever reasons, these experiments did not



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work. It was important to find out why they failed and to hear about instances where they were used successfully by EPA or other agencies.

To better understand how decision analysis techniques would be applicable and useful to particular kinds of decisions, the BOSC decided to work with ORD's NRMRL to hold a workshop to hear from experts in the field and from those at other agencies who grapple with these issues on a daily basis. A 2-day workshop was held at EPA in Cincinnati, Ohio, on March 30-April 1, 2009. Day one of the workshop consisted of presentations from experts in the field and the second day consisted of a panel discussion based on the three case studies, representing different levels of decision making, to discuss the kinds of decisions that would be most appropriately addressed by specific approaches.

Case Study #1, the Ecological Research Program (ERP), involves making decisions at the strategic level over a 5 to 7 year timeframe. This level of decision making involves multi-year plans and setting priorities at a general level for research across ORD. Case Study #2, Nanoscale Titanium Dioxide for Water Treatment, focused on identifying research priorities within a specific research topic. Case Study #3 was an exercise in prioritizing proposals received in response to an extramural call for proposals.

To answer the question is there a need for the BOSC to address this issue, the workgroup looked at all of the recommendations made by the BOSC from 2005-2008. About one-half of these recommendations included a reference to clarifying or developing more explicit decision criteria that implicitly, if not directly, endorse a decision analytic approach to research program planning. The list of these BOSC recommendations is included as Table 1 in the workgroup report. This demonstrates why the BOSC undertook this task and why it is important to ORD.

Dr. von Stackelberg mentioned the 1999 National Research Council (NRC) report entitled, Decision Making in the U.S. Department of Energy's Environmental Management, Office of Science and Technology. The NRC found that a decision methodology should be employed to aid program planning in that institutional setting. The methodology should be structured using quantifiable attributes wherever applicable, but also should allow for managerial flexibility. The NRC report included the following recommendations:

- ✧ Understand, focus on, and monitor changes in customer needs and requirements.
- ✧ Agree on clear and measurable goals.
- ✧ Use a formal (i.e., common, consistent, structured, and rational) technology development decision-making process and apply it uniformly.
- ✧ Think strategically (i.e., long-term and high impact).
- ✧ Measure and evaluate to guide resource allocation.
- ✧ Communicate across organizational boundaries (i.e., with technology users).
- ✧ Continually improve the research and development (R&D) management process.
- ✧ Hire the best people possible and maintain expertise.

One such comparison of multi-attribute value theory and the analytical hierarchy process methodologies in the NRC report showed that the decision outcome depended to a lesser extent on which methodology was used and to a greater extent on issues associated with the way the problem was structured and valuations and weighting factors were elicited. As previously noted, the general recommendation of this report was for DOE's Office of Science and Technology should employ "a method with structure, documentation, and quantifiable attributes, without a recorded preference on which specific method with these attributes OST should adopt." The recommendation is primarily that decisions be structured, which means that the goals, factors, and criteria believed to influence the decision should be clearly specified.



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Records should be kept of the reasoning by which the deciding factors were evaluated, including whatever method(s) were used in their evaluation.

The results of the three case studies were presented at the September 2009 BOSC meeting and, at that meeting, Dr. John Giesy stated that he had been involved with efforts to use decision analysis approaches in the 1980s and found that the process was contentious and yielded a "ridiculous" answer.
Dr. von Stackelberg said that she did not know how to respond to Dr. Giesy's comment except that it is possible that they did not do the process correctly. She also noted that in the 1980s they were still working out the kinks in the process. Now, there is software available to do the calculations for decision analysis.

Case Study #3 was an example of prioritization and resource allocation of extramural funds. The workshop participants viewed this as the most straightforward of the three case studies. The Agency has an existing peer review process for evaluating proposals. Expert reviewers are asked to consider the merit of each application based on a set of criteria. Instead of a qualitative narrative review, the reviewers would be asked to assign a numerical rating for each criterion rather than just assigning one overall rating. Internal reviewers could be asked to do the same using the criteria applied for the internal relevancy review.

The analysis could be done using a simple Excel spreadsheet. Internal and external evaluations can be combined and weighted in different ways using this format. The most challenging issue faced through the use of this format is defining the expected benefit (ideally in monetary terms) with which to formally estimate a new expected return on investment.

For Case Study #1 (i.e., the Ecological Research Program case study), the decision analysis software ExpertChoice was used. This software provides an intuitive Web-based platform from which to include multiple stakeholders and to elicit stakeholder preferences in a consistent and transparent manner. For this case study, the LTGs were identified as specific objectives to be maximized (the criteria against which the alternatives are judged), and each of the Annual Performance Goals (APGs) were identified as potential alternatives to be funded. Using the Web-based stakeholder elicitation tool, a stakeholder group (which would consist of all individuals with input into the decision) was assembled. The purpose of the stakeholder group is to map the importance of the various objectives with respect to the overall goal, and to map the importance of specific alternatives with respect to achieving objectives. ExpertChoice uses the analytical hierarchy process (AHP) as the underlying method for weighting the objectives. This means that the stakeholders are asked to evaluate objectives in a pairwise fashion. Using these answers, the program generates the weighting scheme for each objective. For the alternatives analysis, participants were asked to rate each alternative (APG) with respect to achieving the LTG. The rating scale can be specified by the user or can be based on several default scales included in most software. The results then are compiled to identify weighting across objectives and alternatives. Results can be evaluated by individual, combined, or by individual as compared to the combined results. The next step is to incorporate the results of the stakeholder exercise with a resource allocation evaluation. Resources are allocated based on the weightings developed previously and subject to specific user-defined constraints, including budgets and dependencies (e.g., a particular alternative cannot be completed without significant input from another alternative and so on). The results are presented in a report that identifies each alternative, whether it should be funded or not, given the user-specified constraints and budgets, and required personnel requirements and constraints. Dr. von Stackelberg mentioned that this software also can be used to identify the best efforts to fund should the program receive additional funding.

The features of the AHP-based software include:

- ✧ Advanced Optimization Engine—selects the optimal combination of alternatives that maximizes the attainment of objectives while not exceeding specified budgetary and other constraints. It



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enables users to optimally align their resources in seconds, given complex constraints for millions of potential combinations.

- ✧ Custom Constraints—allows users to add constraints (e.g., types and number of staff), other than costs, to their model. It provides ultimate flexibility and control to optimize based on any type of constraint that is unique to their organization.

- ✧ Risk—enables users to easily factor risk into their optimization by discounting a project's benefit by its probability of success. Users arrive at a better balanced portfolio of projects by including real life factors into their consideration set.

- ✧ Dependencies—provide users a simple way to account for the dependencies that exist between projects. These include: Depends On (project A is not funded unless project B is funded), Mutually Dependent (both projects A and B must be funded or neither is funded), and Mutually Exclusive (funding project A precludes funding project B). This feature allows users to better manage the complexity that is inherent in selecting the optimal set of projects by handling project relationships in a simple way.

- ✧ Musts and Must Not Fund—force fund or unfund a project with the click of a button. This feature accommodates political considerations that are a part of all organizational decision making, and helps users understand and quantify the trade-offs when including political considerations.

- ✧ Groups—associate multiple projects together in a group and elect to fund projects within a group. The number of projects selected from the group has to be one of the following: $\leq 1$, $= 1$, or $\geq 1$. This feature improves control and enables, for example, the user to allow a division to nominate multiple projects for funding, but select one of the projects for inclusion in the final portfolio.

- ✧ Partial Funding—select projects that are eligible for partial funding (project can still deliver benefit even if it does not receive full funding) and the Resource Aligner will select the optimal project to receive the residual resources. This feature maximizes benefit by allocating all available resources.

- ✧ Funding Pools—enables users to optimize project funding across multiple funding or resource pools. Set a funding limit for each pool and the Resource Aligner will optimally pull funds from across the funding pools for each project. This feature optimizes across multiple funding sources by pulling the optimal amount or resources from each pool, maximizing benefit while keeping within set constraints.

- ✧ Increasing Budgets—provides an efficient frontier curve and optimal project portfolios for various budget levels. This feature quickly identifies optimal funding levels and rationalizes budget increases or decreases based on meaningful and defensible data.

- ✧ Relevant Constraints—shows which constraint is "binding" or relevant. This feature saves time and increases control by showing users the critical path to their decisions.

- ✧ Flexible Report Generator—enables multiple, printable outputs to reflect the users optimization model. This feature provides users with the tools they need to make their case and to share results with their teams.

Dr. von Stackelberg stated that it is clear that there are various decision analysis tools, methods, approaches, and software that ORD can use to formalize decision-making processes; she noted that ORD should be flexible and use more than one.



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Although she could not explain exactly why these techniques have not worked for ORD in the past, Dr. von Stackelberg emphasized that the key is communication. She pointed out that the process of reaching the decision is more important, or as important, as the decision itself. Because communication has improved since the 1980s, that improves our ability to use these kinds of tools.

The workgroup does not want to be prescriptive in the report to ORD. The Army Corps of Engineers has moved toward this kind of model, and they have indicated that it has been difficult to implement and successful implementation requires the commitment of senior management who decides that this is how the agency will make decisions. Should the BOSC recommend that Dr. Anastas make the decision and then begin implementing small pilots? She added that ORD will have to address the issue of the NPDs' lack of fiscal control. She also mentioned that the commitment to using decision analysis techniques will have to infiltrate the culture of the Agency.

The draft recommendations of the workgroup are:

- ✧ Use of decision analysis techniques to support research prioritization within ORD is feasible and recommended.
- ✧ ORD should resist the impulse to rely on one piece of software or an outside vendor or contractor to implement use of these techniques.
- ✧ Communication is the key. The staff has to be 100 percent engaged in the effort at every level.
- ✧ Develop case studies; begin the process in small ways.
- ✧ Evaluate extramural proposals using the criteria already established.
- ✧ Evaluate ways in which benefits can be defined.

Dr. Paustenbach commented that most people probably do not want group insight synthesized mathematically to tell them the optimum decision. Dr. Haas said that he thinks the process may be threatening to some people. Perhaps it would be less threatening if ORD used decision analysis tools to generate some subset of preferred possible choices from a large set of choices rather than one optimal option (go three-quarters of the way to a pure decision analysis framework). If the goal is to get more EPA employees to use these decision analysis techniques, this might be a less threatening approach.

Dr. Paustenbach asked if the workgroup prepared a list of the ways these techniques can be used. Dr. von Stackelberg replied that OSP has indicated that they would like these techniques to be used at nearly every level and stage. The workgroup did the three case studies as examples to show ORD how these techniques can be used to make different types of decisions at different levels. She added that Dr. George Gray wanted ORD to use decision analysis techniques to prioritize research projects based on their potential to reduce uncertainty. Dr. Paustenbach suggested that the workgroup develop a list of five possible "experiments" for the BOSC Executive Committee. The Executive Committee will recommend that the AA/ORD select one of these experiments to conduct an actual pilot. ORD should go through the entire process and then assess its effectiveness.

In response to Dr. von Stackelberg's question regarding whether the report should include the five potential pilots, Dr. Paustenbach confirmed that they should be included in the report. He volunteered to assist in developing the list of five potential pilots. If needed, Dr. Haas agreed to help as well.

Dr. Duke noted that the current draft recommends that ORD develop case studies and begin the process in small ways. He suggested changing the wording of that recommendation to "develop pilots" and include a list of five topic areas. Dr. von Stackelberg asked if the report should state that the AA/ORD has to



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make a decision to implement this approach. Dr. Paustenbach thought the report should include such a statement and Dr. Sayler said that the BOSC should request a response to this report from ORD.

Dr. Sayler indicated that there are two options for moving forward with this report. The vote for approval could be made during a conference call in April or it could be deferred until the June/July meeting. Dr. von Stackelberg preferred addressing the report on a conference call so that the BOSC can forward the report to ORD. Dr. Sayler confirmed that the Decision Analysis Workgroup report would be finalized and a vote would be taken during the April conference call. He noted that because today's meeting would be concluded early due to the impending snow storm, Dan Costa's presentation of the ORD response to the Clean Air Program Review Report also would be included on the agenda for that conference call.

Dr. Hauchman thanked everyone who worked on the Decision Analysis Workshop. His reaction is that the workgroup is on target and he agrees that the decision to implement such techniques will have to come from the top. He indicated that he has some ideas on how to do that. Dr. von Stackelberg noted that ORD will need to identify many little ways to engage people in the process. Dr. Hauchman mentioned that there is a lack of familiarity with these techniques among the NPDs, Assistant Laboratory Directors (ALDs), and others so implementing the pilots will not be a trivial task. Even if Dr. Anastas buys into the idea of implementing decision analysis approaches, these techniques are still a mystery to most ORD staff members. Some thought must be given about how best to educate EPA staff about these techniques.

Dr. von Stackelberg replied that there are a number of technical staff members at EPA who use these tools from different perspectives; they know and understand these methods. Therefore, EPA has some internal expertise on which to draw. In response to Dr. Sayler's question regarding the use of a contractor to do the training, Dr. von Stackelberg stated that it is important for the training to come from inside the Agency because the staff members have to believe it will make their jobs easier. Contractors could help implement the process.

Dr. Hauchman said that ORD appreciates the need for more transparency and the need to think through outcomes at the front-end of a program but most staff members just are not sure how to do this.

## Public Comment

*Dr. Gary Sayler, BOSC Executive Committee Chair*

At 2:45 p.m., Dr. Sayler asked if anyone present wanted to make a public comment. No comments were offered.

## Program Review Process: Recommendations and Changes

*Mr. Greg Susanke, EPA, OSP, BOSC Executive Committee DFO*

Mr. Susanke explained that many of the recommendations and changes in the table included in the meeting notebook were derived from the BOSC's activities over the last year or so. At the September meeting, OSP made a presentation on an analysis conducted on the program review process. That analysis has been completed. The goal of the assessment was to figure out how to optimize the program review process. A program review and a mid-cycle review had been completed for every ORD program so it was a good time to assess the process. The assessment included a review of the BOSC reports as well as interviews with the NPDs. The impetus of the assessment was to learn from the past 5 years of experience and to employ lessons learned to improve how the review process is designed and managed.

Many of the findings focused on the charge questions. The design of the charge questions is a major factor in the quality of the BOSC reviews. Of the 210 recommendations made by the BOSC on 12 program reviews between 2005-2008, they split about evenly between the two overarching questions: "Is ORD doing the right research?" (charge question categories: relevance, structure, and resources), and "Is



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ORD doing the research well?" (charge question categories: performance, quality, outcomes, coordination & communication, and leadership).

The findings of the assessment include:

- ✧ The charge questions can be simplified and reduced in number.
- ✧ ORD should identify the information being made available to address specific charge questions ("roadmap to better link questions with materials provided by ORD).
- ✧ BOSC reports that follow the structure of the charge questions are easiest for ORD to comprehend.
- ✧ Clearly identified recommendations, well differentiated from observations and general comments best communicate the BOSC's priorities.
- ✧ Each BOSC review should receive a performance evaluation to enable ongoing quality control and optimization of the BOSC review process.

Mr. Susanke noted that the BOSC Program Review Guidance indicates that the recommendations in the reports should be in bold text so that they are easily identified. There are several items still under consideration and ORD would like the BOSC's feedback on these issues. He asked if there were any questions or comments.

Dr. Demerjian stated that the "roadmap" provided for the Clean Air Program Review was excellent and it was beneficial for both the Subcommittee members and ORD. Dr. Sayler asked if the BOSC members had any comments on the number of recommendations. Mr. Susanke stated that it is difficult for ORD to respond to the review when the report contains a large number of recommendations. Perhaps it would be better for the BOSC to focus on priority recommendations. He suggested the possibility of including fewer but high level recommendations and relegate those less important recommendations as comments for ORD consideration.

Dr. Sayler said he did not think there was time to go through each recommendation in the table distributed by Mr. Susanke. He noted that in most cases, the views of the BOSC and the NPDs appeared to be complementary rather than opposed.

### Subcommittee Charge Question Revisions

*Mr. Greg Susanke, EPA, OSP, BOSC Executive Committee DFO*

Mr. Susanke stated that the charge questions have changed over the years and there has been a tendency to increase the number of questions. It was the consensus of the BOSC members and the NPDs that there were too many charge questions to be adequately addressed in a 1 ½- day meeting. Therefore, ORD has made a concerted effort to refocus the charge questions. This re-examination of the charge questions resulted in narrowing the scope of the questions to three main areas of program evaluation: relevance, quality, and performance. Although the other additional charge question categories used previously such as program structure, coordination and communication, and scientific leadership have been eliminated, some aspects of these questions have been incorporated into the revised charge questions. The total number of questions has been reduced from 16 to 7; however, additional charge questions for the program being reviewed can be developed to address specific needs of the program.

The revised charge questions are as follows:

<u>Relevance</u> (Are we doing the right research?)



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1. Are the intended users of the research results and products sufficiently identified, and are the intended uses of the research results and products clearly explained?

2. Is the rationale for conducting the research, as described in the documentation provided, scientifically sound; and does it address the most relevant scientific issues and needs of the users, given the resources available to the program?

3. Are the research program and identified LTGs and APGs appropriate for meeting the identified user needs with the best possible science?

Quality (Are we doing the research right?)

4. What is the perceived quality, in terms of being both technically and scientifically sound, of the Research Program's results and products as they relate to similar research and products produced in related fields?

Performance (Are the research results and products, timely, communicated, and useful?)

5. Are the Program's research results and products completed in an appropriate time frame given the nature and complexity of the output and the end-user needs?

6. How effectively are the Research Program's research results and products:
   a) targeted to the appropriate environmental decision-makers and scientific communities?
   b) conveyed and supported to easily allow the user to use the research products and results as intended?
   c) transferred/delivered for internal and external use?

7. To what extent are the Research Program's results and products:
   a) being used by environmental decision-makers?
   b) being used by and leading the broader scientific community?

Mr. Susanke stated that the NPDs are in agreement with these revised charge questions and ORD would like to pilot these questions for the Drinking Water Research Program Review. Feedback from the Subcommittee, BOSC Executive Committee, and NPD will be solicited following that review.

Dr. Duke commented that he remembers the BOSC and ORD taking great pains to ensure that the questions were phrased to avoid simple yes or no answers. They were worded to elicit more elaborate answers. Mr. Susanke thanked Dr. Duke for this feedback.

Dr. Sayler explained that the charge questions had evolved over time. ORD drafted the questions and the BOSC modified them so that the answers could be used to address OMB's Program Assessment Rating Tool (PART) process. Mr. Susanke commented that although PART is no longer being used by OMB, that they will continue to assess relevance, quality, and performance so ORD is confident that as long as the charge questions address these three areas, the BOSC reviews will be useful for future OMB reviews.

Dr. Sayler mentioned that efficiency was a topic that was added to program reviews in the past year. Is that still an issue? Mr. Susanke replied that efficiency is still important but there is a shift from investment efficiency to investment effectiveness. ORD has attempted to address this issue in the performance questions (Questions 5-7). He added that it was difficult to balance the two needs—obtaining technical input and evaluating the program. ORD has tried to include both in the revised charge questions but they may lean more toward the program evaluation side. He noted that the NPDs can develop program-specific questions to address technical issues of the program.



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Dr. Haas commented that none of the questions prompt consideration of the resources available to the program. Mr. Susanke replied that Question 2 includes the words "given the resources available to the program." The Subcommittee should consider resources when responding to Question 2. Dr. Haas said that he thought Question 2 was addressing LTGs and APGs rather than the execution of the program. He is not certain what category the question should be under but there should be a question that asks whether the research is being executed as well as it could be given the available resources. Dr. Demerjian said that this question relates to both quality and performance but perhaps more so to performance.

Dr. Sayler mentioned that none of these questions get at the issue of how the decisions are made. Dr. Demerjian indicated that one issue that the Subcommittee tried to address during the Clean Air Program Review was how the NPD gets ORD to spend more money on one area than another. He did not think that issue was addressed with these revised charge questions. Dr. Sayler noted that these new questions move away from the issue of how ORD selects the projects for funding in the first place. Dr. Demerjian pointed out that how the program decides to spend its resources is relevant to the review and that has been a "touchy" subject in the past.

Dr. Sayler expressed his surprise that the scientific leadership question was dropped. Mr. Susanke replied that the idea was incorporated to some extent in Question 7b, which asks if the results and products are being used by and leading the broader scientific community. Dr. Demerjian said he did not have any problem with reducing the number of charge questions, but he was concerned about eliminating the scientific leadership, coordination and communication, and program structure questions. Dr. Sayler asked if there were any comments about removing the questions about meeting the LTGs. Dr. Demerjian commented that if LTGs are no longer important to OMB then those questions would be less critical. He added that Questions 2 and 3 allow the BOSC to comment on the LTGs.

Dr. Ryan said he liked the idea of fewer charge questions, adding that it seemed the same answers were repeated numerous times in past reports. Dr. Sayler asked if the BOSC Subcommittees would continue to receive the fact sheet about the program that summarizes the origins of the program, what it does, and where it is going. This fact sheet provides a framework for the Subcommittee members and helps them get an immediate grasp of what the program is all about. He noted that the fact sheets were particularly useful for old Charge Question 10, concerning the logical framework. Dr. Demerjian agreed that these fact sheets are very helpful to the reviewers.

Dr. Paustenbach commented that he would like to believe that the reduction in the number of charge questions is for simplification purposes and not a message to the BOSC to offer less advice. Dr. Ryan said that he sees this as a simplification process, which does not restrict the BOSC Subcommittees from addressing everything they did before.

Dr. Demerjian proposed adding scientific leadership as Question 8, because scientific leadership is fundamental to the Agency's credibility. Is EPA viewed as one of the premier organizations in the field? Dr. Sayler suggested that scientific leadership could be added as Question 4b under quality.

In response to Dr. Sayler's earlier question about efficiency, Ms. Mya Sjogren from EPA's Office of Resources Management Administration (ORMA), stated that efficiency is not a priority at this point. Dr. Sayler said he was not concerned about eliminating the efficiency question because ORD had not been able to provide the Subcommittee the information they needed to answer that question.

Dr. Haas offered some wording to capture the scientific leadership question: What is the perceived quality of the research team and their scientific products as compared to others in related fields? He agreed to send this wording to Dr. Sayler.



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Mr. Susanke explained that the mid-cycle reviews have been replaced by mid-cycle progress reports from ORD. Two of these reports will be provided to the BOSC at the June/July meeting. ORD would like feedback on the proposed format for these progress reports. They want to ensure that the reports they provide meet the BOSC's expectations. They propose on using the original ORD response to the program review report and updating it; ORD will provide an updated response to the BOSC's recommendations. The report will explain the status of the program in implementing the recommendations and will offer an explanation if it is not on track. Mr. Susanke asked if this was what the BOSC expected. Drs. Demerjian and Sayler responded that such a report would be fine.

## ORD Update

*Dr. Kevin Teichman, EPA, ORD, Deputy Assistant Director for Science for ORD*

Before presenting the ORD update, Dr. Teichman offered a few comments on the afternoon's discussion. He stated that the reduction in the number of charge questions is not meant to limit the BOSC in any way from effectively evaluating ORD programs. The intent was to give the BOSC just what is needed to evaluate the program—no more and no less. If the Subcommittee needs information on post-docs and contractors or any other information to evaluate the program, ORD will provide that information. Dr. Paustenbach said that he did not think that information would be needed unless the Subcommittee is asked to assess efficiency.

Dr. Teichman commented that it is unknown what will replace OMB's PART process, but he stressed that the BOSC reviews are much more important to ORD than just to support OMB reviews. Dr. Paustenbach said he got the sense that ORD did not want the BOSC to comment on the use of public money. Dr. Teichman replied that if that is not in the revised questions, then it should be added because the Agency wants the BOSC's input on that issue.

Dr. Teichman thanked Mr. Lek Kadeli who served as the Acting AA/ORD for the 12 months prior to Dr. Anastas' confirmation.

Earlier today, Dr. Anastas quickly mentioned the EPA Administrator's seven priority themes. He went through them rapidly so Dr. Teichman distributed a handout that listed the priorities.

Dr. Teichman stated that the BOSC's Global Change review would be delayed, in part because Dr. Joel Scheraga , the NPD, has taken another position in EPA. Also, because of Dr. Falk's new responsibilities at ATSDR, Dr. Teichman thinks it is ikely that Dr. Falk will not be able to chair the Global Change Review.

Referring to Dr. Sayler's earlier comment about keeping a "Chinese wall" between EPA and industry, Dr. Teichman clarified that there is no such requirement. The FTTA encourages relationships between EPA and industry, although it is better to work with groups rather than individual companies. Dr. Teichman suggested a presentation on the FTTA at a future BOSC meeting.

Hydraulic fracturing is becoming an important issue within ORD. A report on hydraulic fracturing will be written in 2010, and more funding for this work has been included in the request for 2011. There are water and air emissions concerns associated with hydraulic fracturing and the Agency wants to avoid moving pollutants from one medium to another. NRMRL will be leading this effort but other ORD laboratories/centers will be providing support. ORD also recognizes the need to work with stakeholders both inside and outside the Agency on this issue. He stressed that EPA is well suited to address hydraulic fracturing using the risk assessment/risk management paradigm.

Dr. Paustenbach asked if this is clearly in EPA's purview. Dr. Teichman responded that the 2010 appropriations report directly authorizes EPA to do a study on hydraulic fracturing. OW and OAR will be involved; it will be an EPA study but input from other agencies on this topic will be obtained.



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Dr. Teichman mentioned the bipartisan Science for Policy Project report entitled, "Improving the Use of Science in Regulatory Policy," which was written by a group of people with a wide range of views, including Congressman Sherwood Boehlert and Donald Kennedy from *Science*. Dr. Teichman noted that, such a group can reach consensus, the report is worth reading. The report stresses that scientists need to understand that they are informing policy makers and science is not the only factor policy makers use in making decisions. Policy makers need to be more open and transparent about what factors, including science, they use to make decisions. He urged the BOSC members to look at this bipartisan report. The report is available on the Web at http://www.bipartisanpolicy.org/library/report/science-policy-project-final-report.

Dr. Paustenbach asked if the Agency has a policy that directs what government employees can say about issues. Dr. Teichman indicated that the Office of the Science Advisor (OSA) or OPEI should respond to that question because ORD employs only a small percentage of the Agency's scientists (about 1,300 of the Agency's more than 6,000 scientists are employed by ORD). He noted that ORD has been working on guidance that would allow ORD scientists to state their opinion as long as it is clearly identified as the scientist's opinion. The program offices will be notified of the scientist's opinion but they will not be able to force the scientist to change his/her opinion or prohibit the publication of that opinion.

Dr. Sayler asked if there were any questions for Dr. Teichman. He mentioned that the BOSC schedule for 2010 is a bit thin and there was some concern among Executive Committee members about the future role of the BOSC. Does ORD have a vision for additional or new responsibilities for the BOSC? He asked Dr. Teichman to give the Board an idea of where he sees the BOSC going in the future.

Dr. Teichman stated that the BOSC will continue to conduct program reviews. The Board's input is very valuable to ORD. Although there are only two program reviews scheduled for 2010, there will be more in 2011. He noted that Dr. Anastas' first briefing about the BOSC occurred on February 3; Dr. Anastas has some thoughts about using the BOSC to help him "drive" ORD. He may want to use the BOSC for consultations and for obtaining feedback on a wide range of issues. Dr. Teichman reminded the BOSC that 2010 is a transition year so the schedule is a little leaner than it has been in past years.

Dr. Sayler asked Dr. Teichman to update the BOSC on Title 42 hiring authority. Dr. Teichman explained that this is the authority given to EPA to make up to five, term appointments per fiscal year in ORD from FY2006 to FY2011. Dr. Sayler said that he was invited to talk to the National Academies panel that is conducting a review of EPA's Title 42 hiring authority. He was asked to provide the BOSC's perspective on how this hiring authority has impacted ORD. He told them that it has had a tremendously positive impact on the Computational Toxicology Research Program. In addition to Dr. Sayler, Drs. Teichman, Larry Reiter, and Peter Preuss, as well as Mr. Kadeli made presentations to the National Academies panel. Each gave their personal perspectives on why these Title 42 appointments were so important to ORD. Drs. Bob Huggett and Paul Gilman, both former AA/ORD, also were present at that meeting. Dr. Sayler expressed his hope that the results of that review will strengthen the use of this authority at EPA in the future. It is important to the Agency and ORD is the only EPA office that currently has this authority. Dr. Teichman added that ORD would not have been able to attract these top-notch scientists to EPA without this authority.

**Future Business**
*Dr. Gary Sayler, BOSC Executive Committee Chair*

Dr. Sayler mentioned to Dr. Teichman that Dr. Vu would like the BOSC to appoint a member who would serve as the liaison to the SAB. Dr. Teichman responded that this issue came up with Dr. Anastas yesterday and they are aware that the BOSC currently is shorthanded. He added that there are several BOSC members who are nearing the end of their terms and there currently are five vacancies on the BOSC. He said that Dr. Anastas thinks the BOSC is a vital group and he is committed to filling these



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positions with the best people to help guide ORD. Because the BOSC is shorthanded, it may be best for the SAB to identify a liaison to the BOSC rather than *vice versa*.

Dr. Sayler asked if there were any other questions for Dr. Teichman. When there were none, Dr. Sayler reminded the BOSC members that an Executive Committee conference call would be scheduled in April to cover Dan Costa's presentation of ORD's response to the Clean Air Research Program Review and to finalize and approve the report of the Decision Analysis Workgroup. He asked if there were any additional issues to discuss.

Dr. Demerjian asked if he could send the ORD response to the Clean Air Research Program Review to the Clean Air Subcommittee members and Dr. Teichman replied that he can send it because once it is distributed at a BOSC meeting it is available to the public.

Mr. Susanke thanked the BOSC members for their comments on the revised charge questions. He will review those comments and take another look at the questions. He noted that the BOSC members did not review the revised Draft Guidance for Development of Program Review Reports. He explained that this revised guidance came out of the discussions at the September 2009 Executive Committee meeting. This draft has a few new recommendations and some inappropriate items have been deleted. It instructs the Subcommittees to focus the reports on the significant recommendations.

Dr. Sayler stated that the BOSC did not have any problem with those changes. He pointed out that the guidance now reflects the new charge questions so if they change, the guidance needs to be updated.

Dr. Demerjian noted that ORD responds to recommendations even if they are not included in the Executive Summary. Dr. Sayler replied that ORD will respond to any item that is worded as a recommendation and is in bold text. He acknowledged that some recommendations are more important than others but found it difficult to have the Subcommittee members go through the process of eliminating less important recommendations. Perhaps these less important recommendations could be worded as considerations rather than recommendations so that they do not require an ORD response.

Dr. Sayler reminded the BOSC members that the next Executive Committee meeting would probably be held in July in Corvallis, Oregon. Mr. Susanke said he would try to firm up the date for the meeting as soon as possible.

Dr. Sayler adjourned the meeting at 4:04 p.m.

## Action Items

- ✧ Dr. Paustenbach will finalize the letter report for the Computational Toxicology Research Program Review, including incorporating the comments from the report vettors. In addition, he will reword the phrase "database development is seen as a fairly mundane task" in line 4 on page 4 of the letter report on the review of the CTRP. Dr. Sayler proposed the following wording: "…it is the foundation of the knowledge base on which much of the CTRP… ." He also will correct the spelling of "ore" at the bottom of page 6 to "oar."

- ✧ Mr. Susanke will send the CTRP review letter report to the contractor for final formatting and editing before it is submitted to ORD.

- ✧ Mr. Susanke will work with the BOSC members to select the best date (either June 7-8, 2010 or July 12-13, 2010) for the next Executive Committee meeting, which will be held in Corvallis.



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- ✧ Mr. Susanke will distribute the mid-cycle progress reports for the Human Health, Safe Pesticides/Safe Products, and Human Health Risk Assessment Research Programs to the BOSC members prior to the June/July meeting in Corvallis.

- ✧ The Decision Analysis Workgroup will review the methods and procedures used during the Nanomaterials Case Study Workshop to identify and rank the nano research priorities. The workgroup will be prepared to discuss its findings with the Executive Committee at the meeting in Corvallis.

- ✧ Mr. Susanke will add to the Corvallis meeting agenda an update from the Decision Analysis Workgroup's review of the methods and procedures that were used during the Nanomaterials Case Study Workshop.

- ✧ Drs. Sayler, Haas, and Philbert will work together to schedule one or two informatics experts to present at the Corvallis meeting.

- ✧ Dr. Sayler will query the BOSC Executive Committee members to determine if one will volunteer to serve as the liaison to the SAB. Dr. Teichman suggested, however, that the SAB identify a member to serve as the liaison to the BOSC.

- ✧ Dr. Paustenbach and Dr. Haas volunteered to assist Dr. von Stackelberg and the other Decision Analysis Workgroup members in developing five potential pilots for the AA/ORD to consider for implementation.

- ✧ Mr. Susanke will review the comments offered by the BOSC members on the new, simplified charge questions and will revise them as necessary (e.g., add a scientific leadership question to the new list of charge questions Question 4b). Consideration will be given to the following wording from Dr. Haas "What is the perceived quality of the research team and their scientific products as compared to others in related fields? "

- ✧ Mr. Susanke will consider including a presentation on the FTTA at a future BOSC meeting to help the Board members understand the relationships the Agency currently has with industry.

- ✧ Dr. Demerjian will send the ORD response to the Clean Air Research Program Review report to the Clean Air Subcommittee members.

All materials that were transmitted during and for this meeting are in the public meeting binder in the BOSC central files in Washington, DC.

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BOARD OF SCIENTIFIC COUNSELORS

**43rd EXECUTIVE COMMITTEE FACE-TO-FACE MEETING**
**AGENDA**
**February 4 - 5, 2010**

Marriott at Metro Center
775 12th Street, NW
Washington, DC 20005
Phone: (202) 737-2200

Teleconference: 866-299-3188
Code: 202-564-9945#

**Thursday, February 4, 2010**

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|---|---|---|
| 8:30 a.m. – 9:00 a.m. | Registration | |
| 9:00 a.m. – 9:15 a.m. | Welcome and Introductions<br>- Review of September Meeting Minutes<br>- Overview of Agenda | Dr. Gary S. Sayler, Chair, Executive Committee |
| 9:15 a.m. – 9:30 a.m. | BOSC DFO Remarks<br>- Administrative Issues | Mr. Greg Susanke, Designated Federal Officer (DFO), Office of Research and Development (ORD) |
| 9:30 a.m. – 10:15 a.m. | AA/ORD Remarks | Dr. Paul Anastas, Assistant Administrator for ORD |
| 10:15 a.m. – 10:30 a.m. | Break | |
| 10:30 a.m. – 10:45 a.m. | Subcommittee Updates<br>- Drinking Water Program Review<br>- Global Change Program Review | <br>Dr. Chuck Haas, Subcommittee Chair<br>Dr. Henry Falk, Subcommittee Vice Chair |
| 10:45 a.m. – 12:00 p.m. | Computational Toxicology Letter Report<br>- Presentation<br>- Discussion | Dr. Dennis Paustenbach, Chair, CompTox Subcommittee |
| 12:00 p.m. – 1:00 p.m. | Lunch | |
| 1:00 p.m. – 1:30 p.m. | EPA Science Advisory Board (SAB) Activities | Dr. Vanessa Vu, Director SAB |

| | | |
|---|---|---|
| 1:30 p.m. – 2:30 p.m. | Decision Analysis Workgroup Report | Dr. Katherine von Stackelberg, Workgroup Chair, Executive Committee |
| 2:30 p.m. – 2:45 p.m. | Break | |
| 2:45 p.m. – 3:15 p.m. | Program Review Process: Recommendations and Changes | Mr. Greg Susanke, DFO, ORD |
| 3:15 p.m. – 3:45 p.m. | Subcommittee Charge Question Revisions | Mr. Greg Susanke, DFO, ORD |
| 3:45 p.m. – 4:15 p.m. | BOSC Guidance for Development of Program Review Reports and ORD Mid-Cycle Progress Reports | Mr. Greg Susanke, DFO, ORD |
| 4:15 p.m. – 5:00 p.m. | Executive Committee Open Forum: Roles and Issues | Dr. Gary Sayler, Chair, Executive Committee |
| 5:00 p.m. | Recess | |

**Friday, February 5, 2010**

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| 8:30 a.m. – 9:00 a.m. | ORD Update | Dr. Kevin Teichman, Deputy Assistant Administrator for Science for ORD |
| 9:00 a.m. – 10:00 a.m. | ORD Response to Clean Air Report | Dr. Dan Costa, National Program Director, Clean Air Research Program |
| 10:00 a.m. – 10:15 a.m. | Public Comment | |
| 10:15 a.m. – 10:30 a.m. | Break | |
| 10:30 a.m. – 11:30 a.m. | Executive Committee Open Forum: Roles and Issues (cont'd) | Dr. Gary Sayler, Chair, Executive Committee |
| 11:30 a.m. – 12:00 p.m. | Future Discussion/Future Business<br>- EC Meetings in 2010<br>- Future Work | Dr. Gary Sayler, Chair, Executive Committee |
| 12:00 p.m. | Adjourn | |

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