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

BOARD OF SCIENTIFIC COUNSELORS
EXECUTIVE COMMITTEE MEETING

Washington, DC
September 23-24, 2002

Monday September 23, 2002

Welcome, Review of Agenda, Introductions

Dr. Jerry Schnoor (University of Iowa), Chair of the Board of Scientific Counselors (BOSC) called the meeting to order at 1:00 p.m. He welcomed everyone to the September meeting and mentioned that there are four new BOSC members, two of whom were present. Dr. Rogine Henderson (Deputy Director, National Environmental Respiratory Center) introduced herself and described her research interests and areas of expertise. She is an inhalation toxicologist and her research focuses on biomarkers. She mentioned that she has worked with Dr. Paul Gilman (AA/ORD) on numerous National Academy of Sciences (NAS) committees. Dr. George Daston (The Proctor & Gamble Company) is a developmental toxicologist whose research focuses on chemical teratogenesis and toxicogenomics. Dr. Schnoor mentioned that the other two new members would be introduced at the next BOSC meeting. He also announced that Dr. Gilman would be unable to attend today's BOSC meeting because of other commitments.

With regard to disclosures, Dr. Schnoor said that disclosures were discussed at the May 13-14, 2002 BOSC meeting, and would be discussed at the next BOSC meeting in January 2003. He noted that tomorrow's agenda includes a discussion of the new disclosure form that replaces the old disclosure form.

Dr. Schnoor quickly reviewed the meeting agenda. He mentioned that the Ad Hoc Communications Subcommittee has not met since the last BOSC meeting, and that Dr. Ann Bostrom (Georgia Institute of Technology) would provide an update on the Subcommittee's efforts. He asked the BOSC members to read the minutes from the May meeting and the draft of the mercury multiyear proposal as homework before tomorrow's session.

Measures of Success Report

Dr. Schnoor prepared a draft of the Measures of Success Letter Report, which was displayed on the overhead projector for the BOSC members to review and suggest changes. Dr. Dan Acosta (University of Cincinnati) noted that he had already submitted his comments on the report and they had been incorporated by Dr. Schnoor in this version. Dr. Jim Clark (Exxon Mobil Research & Engineering Co.) also had pointed out some misstatements that have been corrected in this version. Dr. Schnoor commented that Dr. Gilman seems to prefer shorter, hard-hitting reports, of which this is one. He pointed out that the report emphasizes that the Strategic Plans of the Laboratories and Centers should not lose focus and emphasis in the multiyear plans. Dr. Schnoor mentioned that several members of the BOSC liked the "LOGIC" model and there was agreement that it should be mentioned in the letter report.

Dr. Rae Zimmerman (New York University) suggested that a sentence be added to the section on qualitative indicators stating that these indicators, as well as the quantitative indicators, should be mapped onto the goals in the Laboratory, Center, or Division Strategic Plans. Further, it was agreed that the last sentence of the letter should encourage the Laboratories and Centers to put something in place and try it. Dr. Schnoor asked to BOSC to vote on the letter report so that it can be submitted to the AA/ORD. Dr. Clark moved to approve the letter report, and Dr. Acosta seconded that motion. The BOSC approved the letter report unanimously.

Future Meeting Dates

Dr. Schnoor asked the BOSC members about their availability for meetings in January and May 2003. Shirley Hamilton (EPA/NCER) proposed the following dates for the next two BOSC meetings: January 9-10, 16-17, or 23-24; and May 19-20, 15-16, or 22-23. She asked the members to check their calendars tonight so that the next two meetings can be scheduled during tomorrow's session.

Remarks of the NCER Director/BOSC Liaison

Dr. Peter Preuss (EPA/NCER) welcomed the new members to the BOSC. He mentioned that Dr. Gilman would like the BOSC to move in a new direction by providing more scientific consultation that utilizes the scientific expertise, as well as the science management expertise, on the Board. Dr. Gilman also wants the Board to provide input earlier in the planning process. Dr. Preuss noted that there will be a number of items in the future regarding which ORD will seek the BOSC's advice. He reported that EPA currently is working on many fronts, including the FY2003 budget, FY2004 budget, and various ideas and plans for the future. Dr. Gilman plans to discuss these efforts with the BOSC at the January meeting. When Dr. Preuss indicated that he would not be available to attend tomorrow's session, Dr. Bostrom asked if the BOSC could discuss the next steps for the Communications Subcommittee while Dr. Preuss is present, even though it is on the agenda for tomorrow's session. Dr. Bostrom reported that the Communications Subcommittee had been unable to schedule a site visit at NCER; however, she has read all five Laboratory/Center reports and believes that there is agreement within the Laboratories and Centers that more work is needed to effectively communicate research results. Dr. Bostrom asked if the Subcommittee should continue its attempts to schedule a site visit or if the Subcommittee should eliminate the site visit from its plans. Dr. Preuss explained that the site visit had to be postponed because of the ongoing intensive review of the STAR Program by NAS as well as his efforts as the technical lead on the state of the environment report for the EPA Administrator. He suggested that Dr. Bostrom speak with Dr. Gilman about the Subcommittee's charge and plans; he noted that Dr. Gilman is very interested in communications and may have a number of ideas on how the Subcommittee should proceed.

National Center for Environmental Research Draft Report

Dr. Schnoor asked Dr. Jim Johnson (Howard University) to describe the changes made to the NCER report since the last meeting. Dr. Johnson identified the minor changes that had been made to the report, noting that several changes were made to correct statements of fact in the report; some of the wording regarding NCER and NCER activities had been revised in response to comments at the May meeting. Dr. Bostrom mentioned that Dr. Johnson has been very receptive to suggested changes and has worked hard to improve the report. Dr. Johnson said that Dr. Preuss provided more current information for the report and offered many suggestions for improving it. Dr. Johnson noted that completion of the Center's Strategic Plan should be a high priority. He reported that all comments received to date had been incorporated into this draft of the report. Dr. Schnoor called for a vote on the report, and it was approved unanimously by the BOSC. Dr. Schnoor then thanked the BOSC members for the 18-months of effort devoted to the preparation of the five Laboratory/Center reports. Dr. Schnoor said that his goal is to submit the five Laboratory/Center reports to Dr. Gilman by October 1, 2002.

Dr. Bostrom asked about the common themes among the reports. She mentioned that Dr. Schnoor had agreed to draft a page on the common themes. The BOSC agreed that Dr. Schnoor would look though his notes concerning the common themes and transmit this information in a letter report to Dr. Gilman.

Consultation on Biotechnology

Dr. Larry Reiter (EPA/ORD/NHEERL) indicated that he was pleased to see the "top-down, bottom-up" approach mentioned in the Measures of Success Letter Report because this is how ORD is approaching the development of the biotechnology and computational toxicology initiatives. The overall goal is to create a scientific framework that lays out issues and then to engage the scientists to map out specifics of the research programs. The regulation and monitoring of genetically modified crops has become an increasingly important issue for the Office of Prevention, Pesticides and Toxic Substances (OPPTS). However, both the OPPTS and the NAS agree that more science is needed to assess the risk of genetically modified (GM) crops to more effectively inform decisionmaking.

The FY2003 budget for biotechnology is $5 million. The focus of this work is geared to OPPTS' most pressing need—GM crops. Dr. Reiter informed the BOSC that he established a steering committee to create a top-down scientific framework for the work and to then oversee the bottom-up development of the program with research projects that best fit EPA's needs. To date, an R&D framework has been established, proposals have been solicited from the Laboratories and Centers, and the steering committee has met with other organizations involved in the biotechnology area to get their reaction to the developed framework. The organizations—U.S. Department of Agriculture (USDA), National Institute of Allergy and Infectious Diseases (NIAID), Food and Drug Administration (FDA), U.S. Agency for International Development (USAID), European Union (EU), and NAS—that have been solicited for advice thought that the proposed framework was on target in that it seemed to meet EPA's needs and it complemented the work going on elsewhere. Nothing in their comments led Dr. Reiter or the steering committee to think that the proposed program needed to be changed.

Dr. Clark wanted to know how this program would fit within ORD's Strategic Plan? Dr. Reiter responded that the program was being designed with the same philosophy as the plan by identifying high priority Agency needs and then applying the science to meet these needs. Because the program will not be initiated until FY2003, the specifics are not in the plan; nevertheless, the program is in the planning stages and work in this area will begin if and when Congress approves the work in the FY2003 budget.

Dr. Reiter identified three main areas of research: (1) assess the risk of allergenicity from genetically altered foods as a result of new proteins being introduced into food; (2) assess the possibility for gene transfer (hybridization and cross-fertilization) and the ecological risks associated with genetically modified organisms; and (3) manage gene transfer and resistance, specifically resistance of pests to Bacillus thurigiersus (Bt).

Dr. Daston wanted to know what GM pesticides have been introduced into plants for commercial use. Dr. Reiter answered that so far, only Bt has been inserted into plants and used commercially. The main concern is that pests eating the plants will develop resistance to Bt. This is of special concern to organic farmers whose main weapon against insects is Bt.

Dr. Reiter then presented five slides on problem formulation:

(1) There are no valid animal models to predict the dietary allergenicity and the long-term effects from consumption of GM crops.

(2) Regarding ecological effects, there is no standardized, verified assay to test for effect on non-target species.

(3) There needs to be investigation to understand the likelihood of gene transfer and how long modified genes persist in the environment. A major question is whether or not GM crops can cross-hybridize with wild-type organisms.

(4) Little data exist on whether pesticide resistance occurs in genetically modified crops under field conditions. The EPA, however, does have a strategy for dealing with pesticide resistance (i.e., the "High Dose Structured Refugia" strategy).

(5) There are no strategies to identify the key risks of concern nor are there effective risk management technologies to mitigate key risks.

Dr. Reiter mentioned that in the meetings with key officials from other agencies/organizations, Dr. Kim Waddell of NAS cross-mapped the problems formulated by EPA against the three NAS reports on GMOs and found that EPA's proposed program covers the major issues identified by the NAS.

Dr. Reiter then reviewed the allergenicity research goals. He noted that the proposed work in this area is complementary to the work being done by the NIAID. There are a number of factors that influence allergenicity, and they are reflected in the following research goals: (1) determine potency relative to known allergens, (2) identify windows of vulnerability during early development, (3) identify endpoints for use in an animal model, (4) relate digestibility to allergenicity, and (5) understand the mechanisms of allergenicity. Dr. Bill Chameides (Georgia Institute of Technology) asked what was meant by digestibility? Dr. Janet Anderson (EPA) replied that digestibility is the time to digestion, and in this context it also would refer to the time required to mount an immune/allergic reaction. Dr. Reiter stated that the products that will potentially result from this research are an animal model to assess the allergenicity of transgenic pesticide proteins and an understanding of the factors that contribute to susceptibility to sensitization to dietary allergens. Dr. James Bus (The Dow Chemical Company) wanted to know if EPA also would look at the dose-response relationship between allergenicity and the amount of transgenic protein ingested. Dr. Reiter responded that those types of studies would come later, after a model has been developed. Dr. Schnoor asked if it was correct to assume that studies measuring the risk of pesticides on humans have been performed. Dr. Anderson responded that for all approved pesticides, toxicity on humans has been evaluated.

Dr. Reiter then discussed the specific GMOs that will be studied initially. Bt corn and cotton crops will be used to study pesticide resistance. Bentgrass (its relatives include rye and fescue) and canola will be used to study gene transfer to non-GMO species. Bentgrass and canola make good models to study gene transfer because they are commercially important and they are grown in close proximity to non-GMO relatives. Dr. Bus asked if the studies would be extended to examine the ratio of saturated to unsaturated fats in canola oil. Further, could studies such as this be done in collaboration with the USDA? Dr. Reiter responded that although interesting, such studies were beyond the scope of the current proposal. There was a brief discussion regarding which agency (USDA, FDA, EPA) has regulatory authority over GM crops and if this should be a collaborate effort between these agencies. Dr. Schnoor stated that pest resistance is an EPA focus. Dr. Daston commented that this science may not be applicable to other agencies, given that it focuses on a pesticide problem.

Dr. Reiter then explained "High Dose Structured Refugia," the approach developed by OPP as a requirement for registrants using GM crops with plant incorporated protectants (PIPs). It is used to reduce the likelihood that gene transfer from the PIP to an insect will result in the development of resistance in a large population of insect pests. A small plot of non-GM crop is planted within the perimeter of a field planted with Bt GM crop. The pests will be present in the non-GM crop patch, but

not in the GM crop. However, if there are genetic changes resulting in Bt resistance in the pests, then there will be a concomitant change in the location of the pests.

Dr. Bus was concerned about whether NCEA had the expertise to perform these types of studies. Dr. Reiter ensured the BOSC that NCEA has the expertise to perform these experiments and he pointed out that bridges would be formed among NERL, NCEA, and NRMRL to perform the studies. Furthermore, NCER's STAR Program also might be used to fill potential gaps.

Dr. Reiter stated that the next steps are to finalize the research plan and to hold a workshop to present the program and solicit feedback. He asked the BOSC members for their reaction to the program. Dr. Clark praised the proposal, but expressed concern that $5 million would not be sufficient for a program of this magnitude. He though it may take closer to $500 million to implement the program presented. Dr. Reiter suggested that $5 million is sufficient for FY2003. Dr. Bostrom asked about the level of federal funding that currently is being directed to research on GMOs. Dr. Reiter replied that in the discussions with other federal agencies, the sense was that there is not much money being spent on this area; he noted, however, that there might be sizeable programs in other federal agencies that did not participate in the discussions. The USDA and FDA currently support 90 projects totaling $16 million; therefore, $5 million is a respectable amount of funding. In contrast, the European Union has spent a total of about $17.5 million on GMO research. Dr. Bostrom wondered if the Department of Energy (DOE) is supporting any research on GMOs.

Dr. Daston commented that the areas of proposed research were chosen well, but he also did not think that $5 million was enough funding to cover the proposal. He suggested that ORD approach this research by looking at the "worst case scenario." If that scenario was found to be without effects, then there would be no need to pursue research in that area. For example, if there was no substantial gene transfer between species, then that issue could be set aside as a priority and ORD could move on to other priorities. Dr. Reiter expressed concern over trying to prove the negative (i.e., the worst-case scenario). Dr. Henderson wondered how one would even go about determining the worst case scenario. Dr. Chameides asked if industry was conducting research on GMOs. Dr. John Glaser (EPA/NRMRL) commented that a consortium of seed companies for Bt corn recently met in St. Louis, MO. Dr. Anderson said that industry has chosen to plant GM crops only in regulated areas, rather than fund the research. Dr. Chameides suggested that industry should be involved at future workshops. Dr. Schnoor commented that ORD was wisely looking at the regulatory issues, but how might those change with the outcome of the research? Dr. Reiter answered that information will come out of the research that will allow OPPTS to determine if they are on the right course with regard to pesticide resistance. Dr. Bus commented that this is the bold approach that is needed to evaluate the ecological impact over time as more crops are created on which the EPA must make regulatory decisions. Dr. Anderson mentioned that Bt crop resistance has been monitored since 1995, and there is no sign yet of pests developing resistance. Dr. Bostrom asked Dr. Reiter if the workshops would contribute to the prioritization of spending. Dr. Reiter replied that the purpose of the workshops is to sharpen the focus and prioritization of the research, so that a critical path is maintained as research programs are being developed.

Dr. Schnoor asked Dr. Reiter if he would like the BOSC to prepare something in writing in response to this presentation. Dr. Reiter said that feedback from the BOSC regarding the program would be greatly appreciated. Dr. Bostrom asked if EPA has any written products outlining the program. Dr. Reiter said that there is a framework document that he can provide to the BOSC. He mentioned that this document has been revised several times; the fourth draft currently is available. Dr. Schnoor said that the current draft would be fine and the BOSC was provided copies of that draft. He then asked the members of the BOSC what they envisioned happening next. Dr. Chameides said that the BOSC should read the EPA framework report and discuss it at the next meeting or during a conference call. Dr. Schnoor thanked Dr. Reiter for his presentation and promised to provide feedback on the program.

Conceptual Report from ORD in Computational Toxicology

After the break, Dr. Reiter described to the BOSC a conceptual framework on computational toxicology. He stated that this program is an important new initiative for EPA. The computational toxicology program is a visionary one, and it may very well change how ORD does business in the future. Furthermore, the goals of this program go beyond the EPA, and the program provides a model of how science being developed along several pathways can all feed into one program.

Dr. Reiter commented that EPA needs to understand the cascade of events that occurs from source of a stressor to an adverse outcome. EPA's approach is to do quanitative risk assessments and then develop risk management options for prevention and/or control. The trend has been to evaluate a single chemical at a time, which informs our understanding of this continuum.

Dr. Reiter noted that there are several programmatic challenges. There are already a number of priority lists in the queue, but there is not a risk-based criterion for setting testing priorities. Each authority comes with different testing requirements, which boils down to what you are going to test and how you are going to test it. There is not a scientific basis for flexible testing approaches. Finally, there is a lack of data to reduce the many uncertainties faced in quantitative risk assessments (e.g., extrapolations). Dr. Reiter indicated that genomics and proteomics have been making major breakthroughs, which promise to lead to the creation of an important set of tools which ORD can begin to apply.

Dr. Schnoor asked if the computation would be associative or predictive. Dr. Reiter responded that the application of computation would go in both directions. If one looks at a continuum then it seems that genomics is a lynchpin. He suggested that the BOSC think about this issue in terms of generating an understanding of genomic pathways at the cellular level, the tissue level, the organ level, and finally at adverse outcomes in the whole organism. If we can understand genetic changes and how they relate to outcomes, then we can use genomic profiling in a predictive manner. Dr. Reiter said that the idea behind the computational toxicology program is to integrate modern computing and information technology with molecular biology and chemistry to improve EPA's prioritization of data requirements and to improve risk assessment for toxic chemicals. Further, if genetic changes are predictive of toxic outcomes, genomic changes can be used to measure target dose and therefore provide a way to link physiologically based pharmacokinetics (PBPK) models with biologically based dose-response models.

There are many applications for this research , including but not limited to, delineating toxic pathways, extending cross- and within-species extrapolation, identifying genomic endpoints for quantitative structure-activity relationship (QSAR) models, identifying genomics-based exposure biomarkers, and understanding cross- and within- species variations on pharmacokinetics.

Dr. Reiter indicated that in FY2002, EPA began to do proof of concept for computational toxicology while building an integrating research framework for the overall program—$4 million appropriated by Congress to develop alternatives to animal testing. Dr. Reiter noted that endocrine disruptor chemicals (EDCs) will be used as a first approach for computational toxicology for several reasons: (1) EDCs are a high EPA priority, (2) these are mechanistically driven outcomes, (3) EDCs allow EPA to integrate health and ecology, and (4) EDCs are an area of high animal use and computational toxicology approaches could significantly reduce the number of animals required for testing. Dr. Schnoor wanted to know if the EPA tracked the use of animals in research. Dr. Reiter responded that EPA does track the use of animals, but he was not firm on whether the use of animals in EDC research is specifically tracked.

Dr. Reiter presented a slide, which demonstrated the intersection of *in silico*, *in vitro,* and *in vivo* research assays, the combination of which offers the promise to lead to an understanding of the cascade of events from target dose to adverse outcomes. Dr. Henderson expressed her amazement at some computation work in proteomics that does not require detailed understanding of what gene/protein is being analyzed.

For example, in a recent report in the journal *Lancet,* a group examined pollutants and used gene changes to predict ovarian cancer. They knew very little about the detailed biology, the results were based on software that detected changes in patterns. Dr. Reiter mentioned that Dr. Henderson was speaking more about informatics, into which the ORD will eventually invest more effort. Dr. Reiter agreed that there currently is a lot of work on developing pattern recognition programs, and ORD is doing some work on pattern recognition and analysis of changes in the pattern of gene and protein expression. He noted, however, that there can be considerable noise in the system that can cloud interpretation of the results. Dr. Gary Foley (EPA/NERL) mentioned that his Laboratory is leading the research effort in this area; he is speaking with IBM, Sandia National Laboratories, and other agencies within the federal government to find potential partners in the area of bio-informatics. Dr. Daston added that if the discriminant analysis is so good then one could make the determination between one group and another without needing the mechanistic information. However, the odds of that happening in toxicology are low, so one needs the mechanistic information to explain variation from the model. Further, information on dose is needed to understand the cascade leading from exposure to adverse outcomes.

To illustrate the concept, Dr. Reiter's next slide showed how reproduction might be impaired in various ways by impacting estrogen pathways, androgen pathways, and thyroid pathways, and combinations of *in silico*, *in vitro*, *ex vivo*, and *in vivo* assays would be used to understand pathways leading to altered development.

Dr. Reiter then presented the Xenopus Metamorphosis Model for Thyroid System Disruption. First, scientists look at the gene changes on a molecular level in the hypothalamus. Then, on the cellular level, they look at circulating hormone levels, and how they relate to changes in thyroid histology on the tissue level. Finally, the scientists look at the altered morphology of the Xenopus on the organismal level. Combining results in such a way provides a basis for understanding toxic pathways and developing predictive models. Such a framework will be needed before any computational toxicology model is ready to go "prime time." Several questions remain however. How can we take what we are doing and expand it to be useful to inform decisionmaking at EPA? What are the areas of highest priority? Dr. Reiter presented a slide outlining examples of research areas that will support FY2003 base realignment including toxicogenomics of drinking water contaminants, genomics of aquatic organisms, and genomic biomarkers from surrogate tissues.

Dr. Reiter noted that the goal of genomics research in aquatic organisms is to integrate exposure/effects of EDCs in common organisms. The concept is that an understanding of development patterns as related to endocrine pathways, will provide the means to begin to integrate SAR models. This will allow us to refine the fathead minnow test and make it more predictive, providing a bridge between gene regulation across androgen dose and time. Dr. Foley commented that this research also provides possible opportunities to define susceptibility and exposure-dose relationships. Dr. Zimmerman wanted to know if any of this research feeds back into the ORD exposure handbook, and Dr. Reiter replied that it does. Further, as these areas develop, they will have a tremendous influence on how ORD performs these experiments.

Dr. Reiter's next slide concerned genomics research in aquatic organisms; he indicated that the major challenge is the need for gene discovery. Dr. Daston replied that it is not simply the lack of genomic data, but also the creation of transgenic animals and banks of mutagenized animals that limit the research. Dr. Daston asked why EPA was using the fathead minnow when there appears to be so much more information on the zebra fish. Why not use the zebra fish instead of developing the information on the fathead minnow? An audience member commented that zebra fish are not very hardy, and therefore, not a good experimental model. Dr. Daston wondered whether there are more hardy strains of zebra fish that could be used for the experimental model. Dr. Schnoor mentioned that work could be done on both organisms—while genomic data are being gathered on the fathead minnow.

In concluding his presentation, Dr. Reiter stated that the next steps for this program are to: (1) develop a strategic plan for computational toxicology, (2) hold peer consultation workshops, (3) coordinate and collaborate with other agencies, (4) develop a research implementation plan, and (5) subject the computational toxicology plan to peer review. Although ORD has a general roadmap for the program, there is a need to prepare a written plan of action.

Dr. Reiter pointed out a number of challenges to this type of approach. Computational toxicology has the potential to change how the EPA evaluates the risk of chemicals. A big challenge will be matching the needed expertise in genomics, proteomics, and high-performance computing with capabilities to do so. This will involve coordination with others to meet the computational toxicology objectives. EPA will not solve these problems alone, but the Agency brings to the table an understanding of the context in which many of these decisions have to be made. Dr. Reiter stated that interpretation of the data will be the key. It is easy to generate a lot of genomics data, but one has to interpret what changes mean in terms of outcome or to what organisms are being exposed.

Dr. Schnoor asked if there were any questions or comments on Dr. Reiter's presentation. Dr. Henderson asked that ORD keep in mind protein changes and not just changes in genes as it builds its program. Dr. Daston expressed his enthusiasm for this project. He mentioned that he has been working on genomics; about $250,000-$400,000 has been spent by Proctor & Gamble on generating genomic data. He said that he could share these data with EPA, and although these data are significant, they are just the tip of the iceberg. Collaboration and cooperation will be needed to make progress in this area.

Dr. Clark thought this was a great program and that EPA is moving in the right direction. He also liked the fact that both human health and ecological issues were being addressed. Dr. Bostrom wanted to know the amount of ORD resources that currently are dedicated to genomics. Dr. Reiter replied that he is not certain because EPA has not yet completed the inventory; however, he mentioned that these techniques are really permeating the Laboratories and Centers. Dr. Reiter also commented that the Agency is still grappling with issues regarding scope; if care is not taken, everything could be considered computational toxicology. He noted that it will be important to create this type of crosscutting research without disrupting the critical path of the individual Laboratories on other key areas of research needed to meet EPA's needs.

Dr. Schnoor commented that this program is really shaking the foundations of risk assessment. Dr. Clark pointed out that maintaining such a program is costly. Does that mean the program would wind down in a few years? Dr. Reiter responded that ORD is being careful not to over promise. It is critical for management and Congress to see the importance of pursuing this program and to recognize that it will require a long-term commitment. Dr. Herbert Windom (Skidway Institute of Oceanography) asked how the ORD plans to engage scientists into this area. Dr. Reiter replied that they are using a number of approaches to engage the scientists. He noted that these approaches are still in the discussion stage; however, EPA's scientists appear to embrace the concept. Dr. Schnoor wanted to know if this would become a multiyear plan. Dr. Reiter responded that he hoped that it would, because this program needs to move forward and grow over time. Dr. Schnoor thanked Dr. Reiter for his presentations and reminded the BOSC members of their homework assignments.

Tuesday September 24, 2002

Review of Agenda and Approval of May BOSC Meeting Minutes

The meeting was reconvened by Dr. Schnoor at 9 a.m. There was a brief discussion of the May meeting minutes, and it was decided that the last full sentence of paragraph 4 in the May 13 meeting minutes (closed session) would be deleted. Dr. Johnson asked that term "work strategies" be changed to

"objectives" in the section regarding the Measures of Success Letter Report. He also had a question regarding the last paragraph of the May 13 meeting minutes, where it was noted that the ORD BOSC was now the EPA BOSC. Dr. Schnoor commented that this change reflected the BOSC's expanded domain to research and scientific issues as well as management advice, but clarified that the BOSC would still report to the AA/ORD. It was agreed that this sentence would be revised. With the suggested changes, the May meeting minutes were approved unanimously by the BOSC.

Final Discussion/Vetting of BOSC Subcommittee Reports

Dr. Chameides said that he vetted two of the reports—the NHEERL and NRMRL reports. Dr. Schnoor asked if there were any reports that needed more attention before they were submitted to Dr. Gilman. Dr. Zimmerman said that she had marked several small editorial changes in the NCEA report and given them to Beverly Campbell (SCG). Dr. Bostrom mentioned that the NERL report reads differently than the other four reports. In particular, the portion of the report that deals with communication only mentions communication between the PI and Laboratory Director. This and other differences make the report seem inconsistent with the others. Dr. Bostrom suggested that a checklist for the body of the reports be created in the future to maintain consistency among BOSC Subcommittee reports. Dr. Schnoor said that he would read the NERL report again before it is finalized and submitted to Dr. Gilman. He asked that Drs. Chameides and Bostrom also read the NERL report once more. Changes of a vetting nature should be sent to Beverly Campbell for inclusion in the final version of the report. Dr. Schnoor asked that any changes also be sent to Dr. Juarine Stewart (Clark Atlanta University) so that she can determine which changes to incorporate and how best to revise the report.

Dr. Johnson asked that the final Laboratory/Center reports be sent via e-mail to the members of the respective Subcommittees that worked on the reports. Dr. Schnoor agreed with this suggestion and asked Beverly Campbell to distribute the reports to the Subcommittee members. Dr. Bostrom pointed out that the reports could simply be posted on the BOSC Web site if one existed. Ms. Hamilton replied that she has been looking into the possibility of creating a BOSC Web site.

Dates for Upcoming BOSC Meetings

Based on the availability of the members, it was decided that the next BOSC meeting would be held on January 9-10, 2003. The meeting will begin at 10:00 a.m. on the 9th and adjourn at 2:00 p.m. on the 10th. The subsequent meeting will be held on May 22-23, 2003. That meeting probably will be held in Research Triangle Park, NC, and will begin early on the morning of the 22nd so that it can conclude around 12:00 noon on the 23rd.

Discussion of SAB Activities

Dr. Schnoor introduced Dr. Robert Flaak, the Acting Deputy Director of the Science Advisory Board (SAB), who provided an update on the SAB's activities. Dr. Flaak mentioned that Drs. Gilman and Schnoor will be attending the SAB executive meeting in October in Washington, DC.

Dr. Flaak presented a detailed outline of the SAB history and role. Congress established the SAB in 1978. The SAB includes 107 members, who are considered special government employees; 400 consultants; and a staff office of 18, 8 of which are Designated Federal Officers. The SAB averages 40 reviews a year, and the Board's agenda is set through the Science Policy Council (SPC). Dr. Flaak noted that a GAO review that was initiated 2 years ago resulted in a change in panel formation, disclosure/conflict of interest, and public review at the SAB. In response to GAO concerns, EPA developed a new 3110-48 conflict of interest form, which will be discussed by Dr. Angela Nugent later today. Dr. Flaak mentioned the requirement for annual ethics training, and reported that EPA is

developing a CD/online ethics-training course that could be used by the BOSC. He stated that the SAB advises the EPA through written reports that are generated during its quarterly meetings or through one or more teleconferences.

Another new initiative of the SAB is the stakeholder process where the public has an opportunity to comment on issues under consideration by the Board. Dr. Flaak reported that one public meeting has been held and there were press and industry representatives present. Dr. Henderson expressed some concern that the stakeholders who attend these meetings will be those geographically located in the Washington, DC, area. Dr. Flaak replied that individuals could attend these meetings via teleconference or via the Internet. Dr. Zimmerman asked how the meeting was advertised. Dr. Flaak replied that the meeting was announced in the federal register and through mailings. Dr. Flaak briefly discussed the new panel formation process and directed the BOSC members to the SAB Web site (http://www.epa.gov/SAB) for more information. Dr. Schnoor thanked Dr. Flaak for the informative review and asked if the BOSC members had any questions.

Dr. Schnoor asked if there were any projects on which the SAB and the BOSC could work together. Dr. Flaak replied that the SAB should work with the BOSC on the ORD projects. To address questions regarding the difference between the role of the SAB and the role of the BOSC, Dr. Flaak stated that the main difference is that the SAB looks across the entire Agency, and the BOSC looks specifically at ORD programs. Dr. Zimmerman inquired if the different SAB subcommittees work together and if there are inter-committee interactions. Dr. Flaak said that there are interactions between subcommittees on many projects, but he listed only the lead committee on the spreadsheet that he distributed to the BOSC members.

Dr. Daston wanted to know if the new disclosure/conflict of interest procedures affected the timeline for convening a committee. Dr. Flaak responded that is takes about 1 month to generate a short list for a committee. That list then is posted on the Internet and comments are solicited from the public. This process now takes about 3 to 4 months. He pointed out that the review process is becoming more efficient and so the entire time required for the process (from convening the subcommittee to producing the report) has been reduced. Using a 3-day meeting structure, the subcommittee prepares the report at the meeting and it usually is approved within 1 month. Dr. Acosta asked how often a full member of the BOSC also is a member of the SAB. Ms. Hamilton stated that the BOSC agreed not to appoint members of the SAB to the BOSC; however, BOSC members can be SAB consultants. Dr. Flaak added that there are several individuals who serve on more than one SAB committee. He also said that they are trying to reduce the size of the committees to 8-9 members so that more expert consultants can be added to the committees. Dr. Chameides asked if the conflict of interest/disclosure forms could be completed online. Dr. Flaak said that they could be filled out electronically, but that the form then needed to be printed and signed, as there is no protocol for collecting electronic signatures. Dr. Flaak encouraged the BOSC members to call or email him if they have additional questions (202-564-4546 or Flaak.Robert@epa.gov).

Discussion of Confidential Financial Disclosure Form for Special Government Employees

Dr. Angela Nugent (SAB/EPA) provided an overview of the new confidential financial disclosure form developed for special government employees, which she helped to create. Dr. Nugent said that the new form is a tool to help DFOs do a better job of serving the committee and fulfilling their duties as a federal officer and to protect the committee members. She mentioned that the form can be downloaded from the SAB Web Site. The form enables EPA to collect the data it needs to evaluate conflict of interest and the appearance of lack of impartiality. Dr. Nugent noted that the old form did not collect data on grant funding sources, detailed consulting work, or relationship/leadership roles in nonprofit organizations. She pointed out that the SAB was previously criticized for not collecting that kind of information. Further, a GAO report (June 2001) indicated that the EPA was not collecting the right kind of information. The GAO compared the EPA form with those used by other organizations, such as journals

and peer review boards, and used those forms as the benchmark. Previously, EPA did not think it had the authority to collect that kind of information, but there was a change in thinking in the ethics office, so the new form was developed and approved. This new form represents a balance between a form that was too cumbersome to complete and one that did not collect enough information.

The first page of the new form explicitly defines conflict of interest and appearance of lack of impartiality. The appearance of lack of impartiality is a personal circumstance that would cause a reasonable person to question the special government employee's involvement in a matter. The special government employee is required to inform the DFO of these personal circumstances, such as a spousal activity, consulting activity, etc. Dr. Johnson about the difference between bias and conflict in regard to the new form. Dr. Nugent replied that the form only collects financial conflict of interest data; it does not collect information on bias. However, the SAB does try to ask potential committee members about their position and if there might be a bias on the particular subject which will be discussed by the committee. Dr. Nugent mentioned that the CD-ROM-based training on ethics includes a segment on conflict of interest. Ms. Hamilton mentioned that the BOSC members are required to receive annual ethics training, and she pointed out that it was time for that annual training. Dr. Schnoor said that he would like to have a discussion about bias and ethics at the next BOSC meeting.

Dr. Nugent then discussed the differences between the new form and the old one. The most significant differences are in parts 2 and 5 of the form, which focus on consulting work. Part 2 deals with consulting work for consulting firms by the individual or spouse. Part 5 has to do with consulting activities for academic and other institutions. Dr. Zimmerman asked where to indicate the consulting firm's clients. She also asked about the rationale for selecting $2,500 as the figure above which consulting contracts must be reported. Dr. Nugent replied that all contracts must be reported, but if the contract exceeds $2,500, then the box must be checked. Dr. Chameides commented that the purpose of providing this information is to give the Agency a general idea that there may be a conflict.

Dr. Nugent stated that part 4 is a new section in which the special government employee declares his/her research support and project funding. Part 6 of the form is the declaration of expert testimony. Dr. Acosta wanted to know what was meant by expert testimony. Dr. Nugent replied that expert testimony includes any deposition or testimony in a judicial context, or testimony to the Congress. She noted that it only includes testimony for which the individual was compensated.

Part 3 of the form also is a novel element dealing with non-compensated employment, excluding religious, arts, social, fraternal, or political entities or those solely of an honorary nature. For example, a scientist working for "Friends of the Earth" or the Chairperson of an NAS committee would be included in part 3. There was a debate as to whether membership on an NRC/NAS committee should be included. Dr. Nugent said that she would check with the lawyers, but that the idea is to report leadership roles, not membership roles. Dr. Chameides stated that he planned to enter "various NRC activities" on the form. Dr. Zimmerman asked if professional societies were included in the non-profit category. Dr. Nugent replied that professional societies are included as non-profits. She added that these forms are to be completed annually and before each new panel activity (i.e., each time there is a change in subject matter).

Dr. Nugent stated that part 9 is a new section that allows the individual to provide a personal narrative. Part 9 is meant for the special government employee to report anything that may be a conflict of interest with regard to the committee's activities.

Dr. Nugent pointed out that people's lives are very complex so it was difficult to engineer a universal form. The lawyers and the SAB staff thought that this new form was a good effort to focus on categories of information the individuals need to divulge.

Dr. Windom mentioned that he recently served on a panel; before the meeting began, the panelists were asked to discuss potential conflicts of interest. He thought this was a good mechanism to give individuals an opportunity to air concerns. Dr. Schnoor said that the new forms must be completed by each BOSC member and submitted to Ms. Hamilton by October 31, 2002. There was some discussion about how to save the completed form. Dr. Nugent said that it could be saved using enhanced Adobe Acrobat software; however, it cannot be saved if the individual is using the free downloadable version of Acrobat. Dr. Nugent also asked that comments about the new form be submitted to Ms. Hamilton. She noted that SAB is evaluating the form and soliciting feedback that will be used to revise the form.

Dr. Acosta asked if it was necessary to report the specific stocks that are included in a mutual fund. Dr. Nugent replied that only the stocks of diversified mutual funds need to be reported. She added that the name of the fund must be reported, not the family of funds. Dr. Schnoor thanked Dr. Nugent for her presentation and clarifications concerning the new form.

Communications Ad Hoc Subcommittee Progress Report

Dr. Ann Bustrom provided an update on the progress of the Communications Ad Hoc Subcommittee. The Subcommittee met informally in Seattle, WA, and the members have participated in one conference call. Most of the Subcommittee communications have been via e-mail. Dr. Bostrom questioned whether the Subcommittee should try to reschedule the NCER site visit. She agreed, however, to talk to Dr. Gilman before solidifying the action plan for the Subcommittee.

Dr. Bostrom noted that the self-study questions distributed to each of the five Laboratories and Centers included the following question: How does the Laboratory/Center communicate its results within the organization, within ORD, within EPA, to outside agencies, and to the outside world? This question was posed to elicit a general overview of the state of communication of research results in the Laboratories and Centers, and to guide the BOSC Communications Ad Hoc Subcommittee in its selection of cases and questions for further study. Dr. Bostrom stated that the findings and recommendations from the Laboratory and Center revie to this and other questions, suggest that:

- ✧ Communicating research results is an (often self-identified) area of importance and desired improvement for the Labora
- ✧ The Laboratories and Centers have not formally identified, characterized, or prioritized the audiences for their research
- ✧ Ongoing documentation and assessment of the quantity and quality of research results communications, covering a rang and products, are lacking.
- ✧ Passive information provision (e.g., Web pages and journal publications) is central to current efforts to communicate res
- ✧ Several, if not all, of the Laboratories and Centers have insufficient communications expertise on their staff to improve results.
- ✧ There are specific cases of good communications practices that could be useful for the Laboratories and Centers to share

Letters were drafted to Dr. Peter Preuss at NCER, Dr. George Alapas at NCEA, Dr. Dan Costa at the PM Program, and Dr. Larry Reiter at NHEERL. These letters contain the self-study questions for the review. Dr. Bostrom indicated that the next steps for the Subcommittee are to: (1) complete the report on the relevant findings of the Laboratory/Center site visits, (2) discuss the Subcommittee's planned activities with Dr. Gilman, (3) send the letters and self-study questions to the Laboratories and Centers, (4) schedule site visits for January-February 2003, and (5) draft a Subcommittee report by April and distribute it to the BOSC members before the May meeting.

Dr. Schnoor said that there were excellent points in the initial draft report and there was a lot of good information with which to move forward. Dr. Clark asked what needed to be done to the report before it is sent to Dr. Gilman in October. Dr. Bostrom replied that she did not think the Subcommittee should send a report to Dr. Gilman; she suggested that the Subcommittee send him background information on the Subcommittee's plans and efforts. Dr. Windom wondered if the real problem is communication of the research plan, rather than communication of the research results. How does the Laboratory/Center ensure that the right research is being done, especially in the multiyear plans? How is communication with the stakeholders accomplished, so that the research they need is being done? Dr. Bostrom commented that, although these are interesting questions, they are beyond the scope of this Subcommittee.

Dr. Zimmerman noted that the communication objectives need to be spelled out; she noted that the question regarding how the Laboratories and Centers communicate is a very difficult one to answer. She wondered if there was a mechanism for inter-Laboratory communication or exchange, or a way to map e-mail communications. Dr. Bostrom replied that there are e-mail-mapping studies, but she noted that such an undertaking is beyond the scope of this Subcommittee. Dr. Daston followed up on Dr. Windom's question by asking if the ORD has a mechanism to inventory research projects. This may be a useful tool to understand what projects are being done. Dr. Schnoor replied that there is a catalog of ORD research projects. ORD does a good job of tracking its projects, but not tracking communication.

Mike Moore (EPA/ORD), Communications Director for ORD, pointed out that Dr. Gilman is very interested in communications, and his focus extends beyond ORD and encompasses the entire Agency. Mr. Moore also said that his office has a draft strategic plan, modeled in large part on the NCERQA Communications Plan. Mr. Moore said that he would share that draft with the Subcommittee. Dr. Schnoor asked if Mr. Moore also had a list of all ORD publications. Mr. Moore responded that a scientific inventory is being developed for all of EPA, and everyone has been asked to contribute to that inventory. Furthermore, his office has established a communication focal point in each Laboratory/Center that communicates by telephone once each week. Dr. Bostrom asked if she could have the list of communication contacts, and Mr. Moore agreed to provide that list, as well as additional information.

Dr. Schnoor asked the BOSC members if they believed that there was enough information for Dr. Bostrom to complete a letter report for submission to Dr. Gilman by October. Dr. Johnson said that the Subcommittee should review the letter report to ensure that it is factually correct. Dr. Bostrom asked Dr. Johnson to clarify his comment. Dr. Johnson said that the Subcommittee should ensure that the letter report does not recommend that ORD undertake actions that currently are being done or overlook some program that is meeting an identified need. Dr. Schnoor said that the Subcommittee should meet (face-to-face or by conference call) before the teleconference with Dr. Gilman. During this meeting, the Subcommittee members should be asked to identify and approve the preliminary findings to be included in the report. Dr. Zimmerman added that the report should define the types of communication that are being reviewed. Dr. Bostrom commented that the report addresses all types of communication; however, a handful of case studies that use different types of communication are being selected for more detailed examination.

Dr. Bostrom asked if the self-study questions should be sent out now, or if the distribution should be postponed until after the conference call with Dr. Gilman. Dr. Acosta thought that the Subcommittee should solicit Dr. Gilman's input before the self-study questions are distributed. Dr. Schnoor stated the a report of the Communication Ad Hoc Subcommittee's activities will be on the agenda for the January BOSC meeting.

Dr. Schnoor reminded Dr. Bostrom that the focus of the communications review is not limited to NCER. He stated that NCER is being singled out and criticized even though the Center was proactive in developing a communications plan. The BOSC members agreed that the Subcommittee should

reschedule a site visit with NCER. Dr. Bostrom summarized the next steps for the Subcommittee identified during the discussion: the Subcommittee will meet (face-to-face or via conference call) to discuss the preliminary findings and to approve the draft letter report, and a conference call will be scheduled with Dr. Gilman. It was agreed that the findings of the Subcommittee should be shared with the BOSC before they are presented to Dr. Gilman. Moreover, the self-study questions should not be sent out until Dr. Gilman has been consulted about the Subcommittee's plans. Everyone agreed that the Subcommittee needs a strong vision from Dr. Gilman before proceeding with the review.

Mercury MMP Discussion

Dr. Schnoor stated that Norine Noonan, Henry Longest, and now Paul Gilman have requested that the BOSC review some or all of the Multi-Year Plans (MYPs. Sixteen MYPs have been drafted, and two have been formally reviewed by the SAB—the Pollution Prevention MYP and the Drinking Water MYP. Three more MYPs are targeted for review by the SAB—Air Toxics, Particulate Matter, and Contaminated Sites. The Mercury MYP would be the sixth MYP scheduled for review. Dr. Schnoor noted that review of the MYPs is an important part of the BOSC's FY2003 duties. He thought the members should discuss how the BOSC is going to handle the MYP reviews. He mentioned that the Board members may want to meet with Kevin Teichman, Office of Science Policy, as he is interested in the BOSC review of the MYPs.

Dr. Windom mentioned that he did not understand how the writers of the Mercury MYP arrived at the scientific questions listed on page 4 of the plan. Dr. Schnoor responded that those issues should be resolved in the actual review process. He asked the BOSC to focus on the charge regarding the MYPs. Is it doable? Dr. Daston said that he was not sure if there is enough information in the MYP to address that question. Dr. Zimmerman wanted to see a more direct charge statement and wondered if the MYP included stakeholder involvement issues. Who has input into the plan? Dr. Zimmerman also wanted to know how the authors prioritized the issues. Dr. Chameides asked about the meaning of question 5. Dr. Schnoor replied that the question concerns whether they are doing research that will accommodate the future. Are they looking ahead? Dr. Schnoor asked the BOSC members if they thought there was enough information to review this MYP.

Dr. Bostrom said that much of the data was out of date. For example, on page 5, none of the references are more recent than 2000. Is there a mechanism to update the documents? Dr. Schnoor suggested that OSP update the MYP before the BOSC reviews it. Dr. Chameides noted that the discussion of science in the MYP is weak. If the document is meant for scientists, there should be more background material provided. He believes the BOSC should review the Mercury MYP, but agrees that OSP needs to address these deficiencies before that review. Dr. Schnoor added that the Drinking Water MYP was more detailed and much more impressive than the Mercury MYP.

Dr. Acosta pointed out that the MYP indicated (on page 2) that it was reviewed by the Executive Council. Is the BOSC duplicating those efforts? Dr. Schnoor replied that the BOSC review would constitute an external review; the Executive Council is an internal review. Given that there are serious technical questions regarding the Mercury MYP, Dr. Schnoor asked if the discussion of this MYP should be tabled until a representative from ORD can be present to address the BOSC's concerns and to answer any questions. It was agreed that the discussion should be postponed. Dr. Schnoor agreed to provide the BOSC's preliminary comments about the Mercury MYP to the OSP. He will ask OSP also to provide information on who had input into this MYP and how it was developed, updated information, more background material, and results from the previous review by the Executive Council.

Dr. Chameides asked if Dr. Gilman chose this particular MYP for BOSC review. Ms. Hamilton responded that the BOSC asked to see an example of an MYP; the Mercury MYP was the next plan ready for review. Ms. Hamilton added that discussion of the MYP was premature given that Dr. Herman Gibb

was unable to attend the meeting and present the MYP to the BOSC. She suggested that the BOSC postpone discussing the MYP until there is a presentation that will provide the Board a better understanding of the MYP. Dr. Daston agreed that the BOSC should table the discussion for now, however; he noted that it would save considerable time if the BOSC's concerns about the plan were shared with Dr. Gibb prior to the next meeting. Dr. Bostrom mentioned that if the BOSC is to review this MYP, the Board should identify several mercury experts to add to the review committee. Ms. Hamilton encouraged Dr. Schnoor to call Dr. Gibb and share with him the BOSC's concerns about the Mercury MYP.

Wrap-Up

Dr. Schnoor asked the members if there were any additional items for discussion. Dr. Acosta asked about the term of each Board member. Ms. Hamilton replied that letters are being sent to each Board member stating the length of his/her term. Dr. Bostrom asked about other projects to be undertaken by the BOSC in 2003. Dr. Schnoor replied that the BOSC would be reviewing several MYPs. Both Drs. Acosta and Chameides mentioned that they would be interested in working on bioterrorism issues. Ms. Hamilton suggested that Dr. Schnoor discuss that possibility with Dr. Gilman. Dr. Schnoor asked for a motion to adjourn the meeting. Dr. Chameides moved to adjourn, and Dr. Windom seconded the motion. Dr. Schnoor adjourned the meeting at 1:45 p.m.

Action Items

The following action items were identified during the meeting discussion:

- Ms. Beverly Campbell agreed to revise and finalize the Measures of Success Letter Report and send it to Dr. Schnoor.
- Ms. Campbell will revise the May meeting minutes in accordance with the comments of the September meeting and send them to the BOSC Chair and the DFO.
- Ms. Campbell will finalize the NCER Report and send it to the NCER Subcommittee Chair for final approval.
- Drs. Schnoor, Bostrom, and Chaimedes will send changes to the NCEA Report to Dr. Juarine Stewart and Ms. Campbell so that the report can be finalized. Dr. Stewart will determine how best to incorporate the review comments.
- Ms. Hamilton agreed to investigate the possibility of creating a BOSC Web Site.
- The BOSC members will provide feedback to Dr. Reiter regarding the biotechnology and computational toxicology programs presented at the September meeting.
- Dr. Daston agreed to share his genomics data with EPA.
- Dr. Schnoor asked that all BOSC members complete the new conflict of interest and financial disclosure forms and send them to Ms. Hamilton by October 31, 2002.
- Dr. Bostrom will schedule a meeting or conference call for the Communications Ad Hoc Subcommittee. She also will schedule a conference call with Dr. Gilman to discuss future plans for the Subcommittee. In addition, she will reschedule the NCER site visit.

- ✧ Mike Moore agreed to provide copies of ORD's draft strategic communications plan with the Communications Ad Hoc Subcommittee. He also will provide Dr. Bostrom a list of the communications contacts in the Laboratories/Centers.

- ✧ Dr. Bostrom will share the findings of the Communications Subcommittee Letter Report with the BOSC prior to communicating them to Dr. Gilman on the conference call.

- ✧ Dr. Schnoor agreed to communicate the BOSC's concerns about the Mercury MYP to Dr. Gibb before the Mercury MYP is presented to the BOSC.

- ✧ Dr. Schnoor agreed to ask Dr. Gilman if the BOSC's input on bioterrorism issues would be helpful.

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