DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

CENTERS FOR DISEASE CONTROL AND PREVENTION NATIONAL CENTER FOR ENVIRONMENTAL HEALTH/ AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY

convene the

BOARD OF SCIENTIFIC COUNSELORS MEETING

May 19-20, 2005 Atlanta, Georgia

RECORD OF THE PROCEEDINGS

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EXECUTIVE SUMMARY

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a meeting of the Board of Scientific Counselors (BSC) on May 19-20, 2005 in Atlanta, Georgia.

CDC reported on recent developments under the Futures Initiative (FI), including the revised organizational structure of the Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), roles and responsibilities of CCEHIP staff, and FI successes. The Office of Strategy and Innovation (OSI) selected obesity, adolescent health, influenza and preparedness measurement as the initial priority areas for the goals management process. CCEHIP developed healthy places goals for communities, homes, hospitals and healthcare settings, institutional facilities, schools, travel and recreation, and workplaces.

CDC presented an overview of its agency-wide research agenda and described examples of environmental health themes that will be included. NCEH/ATSDR outlined several organizational changes at the center and coordinating center levels and provided an update on its recent accomplishments. ATSDR presented the updated draft dioxin soil policy guideline (DSPG) that was revised based on the BSC's previous comments. ATSDR described its asbestos activities, including community health projects in Libby, Montana; initiatives at non-Libby vermiculite sites; and investigations of naturally occurring asbestos.

NCEH/ATSDR gave two status reports on the CDC National Report on Human Exposure to Environmental Chemicals (NER). A plan was drafted to add and remove candidate chemicals from NER. The third NER will be released in June or July 2005 with a total of 148 chemicals. CDC described new rules HHS recently established for all advisory committees. The Program Peer Review Subcommittee (PPRS), Community and Tribal Subcommittee (CTS), and Health Department Workgroup (HDWG) reported on respective work plans, ongoing activities and future projects. NCEH/ATSDR will develop nomination packets for four of the 14 candidates who submitted applications to serve as new BSC members. The Chair opened the floor for public comments at all times as noted on the published agenda.

The BSC's deliberations resulted in several key suggestions to CDC.

• Revise the healthy places goals to more strongly reflect traditional prevention efforts that cross places and capture the built environment, transportation, and safe water, food and air.

- Further revise the DSPG based on the BSC's additional comments, particularly the suggestion to clearly delineate ATSDR's rationale for deleting the 1 ppb "action level." Allow ATSDR to decide whether the DSPG should be released for public comment at this time.
- Explicitly state the focus, goals and environmental public health role of ATSDR's asbestos projects because the initiative continues to expand with additional partners and activities without a defined direction.
- Invest more resources in applying environmental health data to risk assessment. Formulate strategies to capture infants and children, minority populations and other key subgroups in NER. Develop methods to use biomonitoring to examine exposures to these groups. For example, the National Health And Nutrition Examination Survey is an excellent indicator of the national average, but lacks sufficient representation of subsets of the population.
- Strengthen collaborations among BSC subcommittees.
- Define the "environmental health (EH) workforce" as a priority issue and separate this activity from the program peer review of the Environmental Health Services Branch.

The BSC's discussions also resulted in consensus recommendations, action items and agenda items. Both consensus recommendations were unanimously approved by voting members except where indicated.

Consensus Recommendations

- NCEH/ATSDR's report of ongoing and future activities to respond to PPRS's recommendations on the peer review of the Hazardous Substances and Emergency Events Surveillance Program is adopted. [One BSC member abstained from voting.]
- HDWG's recommendation to be established as a formal BSC subcommittee to continue its activities and representation to NCEH/ATSDR is approved.

Action Items

- Revise future presentations on FI. Include personnel and budget information on coordinating centers. Clearly state strategies and actions of FI goals.
- Provide the BSC with Dr. Lonnie King's slides on OSI.
- Provide the BSC with public comments that are submitted on the draft DSPG.
- Obtain information from Dr. Koenig on the healthy places model developed by the military and forward the materials to Dr. Baldwin.

- Provide the BSC with the white paper submitted by the Center for Regulatory Effectiveness that challenges ATSDR's asbestos activities at 28 National Asbestos Exposure Review sites. Include ATSDR's response to the challenge.
- Provide the BSC with the draft plan to add and remove candidate chemicals from NER.
- Inform the BSC about the availability of the third NER on the CDC web site and the date and time of the partners' conference call during which the major findings of the document will be presented.
- Inform the Special Consultants (SCs) that CDC will be distributing personnel forms, appointment papers and financial disclosure/ethics reports to be completed and submitted in accordance with the new rules for HHS advisory committees.
- Obtain information from Dr. Zenick on EPA's peer review model of the "overview poster session" and forward the materials to Dr. Wartenberg.
- Provide the BSC with CDC's report on state and local health departments that addresses issues related to the EH workforce and competencies.
- Provide the BSC with a one-page list of recommendations subcommittees will present for the BSC to consider, approve and forward to NCEH/ATSDR for action.
- Convene a conference call with the Chair and Designated Federal Official to distribute the research agenda to the BSC and SCs for review, compile comments and submit a coordinated BSC response to CDC.
- Revise future BSC agendas to decrease the number of presentations and increase discussion periods.
- Fill vacancies on subcommittees. Dr. Yang will serve as a new PPRS member, but the CTS still needs volunteers from the BSC to replace Dr. McDiarmid at this time and Dr. Harris in November 2005.

Agenda Items

- Presentation by CDC on strategies that will be implemented to successfully reach all of the customers targeted under FI.
- Overview by Dr. Walter Williams, Director of the Office of Health Equity.
- Update on the draft plan to add and remove candidate chemicals from NER with a focus on risk characterization and potential political issues.
- Progress report on CDC's research agenda.

The next BSC meeting will be held on November 17-18, 2005.

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Board of Scientific Counselors May 19-20, 2005 Atlanta, Georgia

Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR) convened a meeting of the Board of Scientific Counselors (BSC). The proceedings were held at CDC's Century Center offices in Atlanta, Georgia on May 19-20, 2005.

Opening Session

Dr. Patricia Nolan, the BSC Chair, called the meeting to order at 8:38 a.m. on May 19, 2005. She welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as <u>Attachment 1</u>.

Dr. Nolan regrettably announced the recent death of Mr. Terrance McManus, a BSC member, who made valuable contributions to NCEH/ATSDR, the BSC and environmental public health. The attendees engaged in a moment of silence to remember Mr. McManus.

Update on the CDC Futures Initiative (FI)

Ms. Ruth Martin, of the Coordinating Center for Environmental Health and Injury Prevention (CCEHIP), reported on developments under FI that have occurred since the

previous BSC meeting. CCEHIP is now staffed with ten personnel to conduct activities at a strategic rather than operational level. The roles and responsibilities of CCEHIP staff include liaisons to CDC's Office of Workforce and Career Development, Science Office, Office of Strategy and Innovation (OSI), and enterprise and communications function.

CDC originally planned to house NCEH/ATSDR, the National Center for Injury Prevention and Control (NCIPC), and the National Institute for Occupational Safety and Health (NIOSH) into CCEHIP. However, only NCEH/ATSDR and NCIPC will be located in CCEHIP due to tremendous concerns expressed by NIOSH constituents about the organizational change. No changes will be made to NIOSH's current operating procedures, organizational structure, budget and program personnel. CCEHIP will continue to collaborate with NIOSH on programmatic and scientific initiatives.

FI is a relatively new initiative, but CDC has already noted several successes. An agency-wide research agenda is being developed. More than 600 vacant positions and \$86 million were transferred to research and programs that directly improve health. New scientific collaborations were formed to focus on botulism toxin assays, holistic adolescent health goals and an integrated agency-wide obesity plan. Healthy places goals were established. Successful responses were provided to the West Nile outbreak, hurricanes and tsunami relief efforts.

A portfolio management initiative is being piloted in six states to provide better service and support to state health programs. Under this project, senior management officials from CDC will be placed in large states or regions to perform three key functions. State and local public health systems will be supported. Assistance will be provided on management issues related to procurement, funding, political or other challenges at the state level in conducting CDC activities. Efforts will be made to ensure that funding, partnerships and other state initiatives implemented with CDC dollars are appropriate.

The **BSC** was pleased with the portfolio management pilot, but some members expressed concerns about other aspects of FI. The organizational chart does not reflect interactions with other HHS public health agencies. The customers are too numerous for CDC to effectively serve. CDC should replicate the ATSDR model in further development of the portfolio management initiative. Staff are located in each regional office of the U.S. Environmental Protection Agency (EPA) to closely collaborate with state and local health agencies and communities.

Overview of OSI

Dr. Lonnie King, the OSI Director, reported on OSI's role and functions. OSI was established to further implement FI; conduct a goals management process; identify innovations and strategies within a public health agency; and oversee CDC's transformation and organizational change. OSI is currently operating with a \$2.5 million budget and 13 personnel, but intends to recruit an additional 13 staff. OSI will engage a diverse cadre of federal partners, advisory bodies, the business community, private organizations, community groups and other constituents to achieve health goals across the life span.

One of the key features of OSI is the relocation of the Office of Health Equity (OHE), formerly the Office of Minority Health, from the CDC Office of the Director (OD). OHE requested this organizational change to strengthen and measure its progress in achieving health disparities, health equity and minority health goals. OSI's guiding principles to make a health impact and achieve goals include establishing objectives and priorities, aligning the budget and measuring progress based on performance. The goals management process focuses on people, preparedness and places. Global goals are currently being developed in partnership with other agencies. The first global health strategic plan is now being completed and vetted through the Department of State, HHS and other funding agencies.

OSI selected obesity, adolescent health, influenza and preparedness measurement as the initial priority areas for the goals management process and recently completed the first phase of each of the four projects. OSI will integrate activities across CDC in each priority area and strategically produce and measure outcomes for each stage of life. Funding is now being leveraged for the projects.

The **BSC** expressed concerns with some of OSI's focus areas. The life stage goals do not include the preconception period or unborn child, but this stage is one of the most vulnerable in the life span. The rationale for OSI's selection of the four initial priority areas for the goals management process is unclear, particularly since issues related to health disparities, children's environmental health, farm workers and other vulnerable populations are current topics of strong interest and focus.

OSI will face tremendous challenges in partnering with other preparedness agencies and groups. Innovation strategies to achieve the preparedness measurement goals directly contrast with activities by military-based incident management systems at national and local levels. OSI should address this concern by broadly communicating to other federal agencies its lessons learned and experiences in developing strategies and

integrating activities throughout CDC. The BSC noted its exclusion from providing input on OSI's selection of the four initial priority areas.

CDC's Healthy Places Goals

Dr. Grant Baldwin of CCEHIP reported that OSI charged CCEHIP with leading the development of healthy places goals due to several factors and problems. Places play an important role in overall health throughout the life span. Many significant public health achievements in the 20th century are linked to places. Each place has unique characteristics. Health improvement actions are specific to an individual place. The burden of disease is attributable to the environment and health is supportive of the environment. Specific sub-populations are at greater risk.

CDC's traditional focus on healthy places has been on lead, mercury, dioxin and other agents; air, water, soil and other media; and cancer, chronic obstructive pulmonary disease and other diseases. Under FI, however, CDC will shift its paradigm to focus on communities, homes, hospitals and healthcare settings, institutional facilities, schools, travel and recreation, and workplaces. The literature on home characteristics, for example, shows that ventilation and insulation, indoor air pollutants, environmental tobacco smoke, dust mites, cockroaches, lead-based paint and dust, volatile organic chemicals, household poisonings and pesticides, a water source or septic tank can contribute to asthma, allergies and injuries.

CCEHIP developed a specific process to define and measure the healthy places goals. Several technological and methodological advances were applied, including event surveillance, biomonitoring data, the Environmental Public Health Tracking project, computer modeling and geographic information systems (GIS). Teams were formed with leadership and support staff throughout CDC for each of the seven places. An overarching goal was established to protect and promote human health and eliminate health disparities in places where persons live, work, learn and play. Guidance was solicited from OSI to identify objectives, strategies and actions for each healthy place goal.

CCEHIP will take several steps to further advance this effort. Metrics for the healthy places goals and objectives will be proposed, developed and finalized. External and internal partners throughout CDC will be engaged to review the goals and objectives. The goals will be refined and piloted in one to two places. CCEHIP will allocate funding and other resources to achieve the healthy places goals, develop activities and programs based on priority areas, and measure progress.

The **BSC** expressed support of the overall concept of the healthy places goals, but some members were uncertain about the role of the goals in CDC's public health mission. The focus of the goals on unique characteristics of places rather than common themes may lead to challenges in designing efficient and effective prevention strategies. The BSC made several suggestions for CCEHIP to consider in further development and refinement of the healthy places goals.

- Revise the goals to more strongly reflect environmental health issues related to food, air, water, land use planning, social determinants of health, the built environment and prevention.
- Review existing healthy places models that have a demonstrated track record of effectiveness and success. For example, the military tracks the health of troops at all levels to determine deployment readiness.
- Structure the goals to highlight integration and interactions between indoor and outdoor impacts. For example, outdoor pesticides are tracked into homes and outdoor soil vapors intrude into homes from landfills.
- Ensure that the goals do not overlook communities and populations with no defined geographic "place," such as migrant workers.

CDC's Research Agenda

Dr. Robert Spengler is the Director of the Office of Public Health Research in CDC's Office of the Chief Science Officer. He presented an overview of activities that are underway to develop the new CDC-wide research agenda for both intramural and extramural projects. CDC established several roles for the research agenda. Research will be supported to achieve health protection goals for people, places, preparedness and global health. Critical evidence will be provided to improve existing or new programs and interventions. Broad research themes and focus areas will be identified to provide guidance throughout CDC. Assistance will be provided in planning, communicating and marketing CDC research. Progress toward achieving the research agenda goals will be monitored on an ongoing basis.

The research agenda will integrate CDC's goals, programs and research to accomplish goals, achieve health impact, and improve services, programs and response. This paradigm includes health protection goals for health promotion and community preparedness; public health services, response, research and other programmatic activities; and innovations for new priorities, threats and emergencies. CDC has taken several actions to develop the research agenda. Plans were formulated and approved by management, workgroups were formed, and input was gathered from internal and

external partners. An initial list of research themes and discussion topics was developed. Public participation meetings were convened throughout the country to obtain feedback from a diverse group of stakeholders and other customers.

Workgroups were formed with CDC leadership, staff and external partners to develop goals and focus areas for the research agenda that are consistent with CDC's coordinating centers and key offices. Research agenda priorities were defined based on criteria of public health need and importance; relevance to reducing health disparities; potential for broad impact; and contribution to CDC's mission and health protection goals. Research agenda categories were established, including promotion of health and well-being in every life stage; enhancement of community preparedness and response; ability to promote and sustain healthy places; partnerships for a healthy world; and support of innovation and infrastructure research. CDC is now synthesizing and prioritizing items to include in the research agenda and will soon release a draft for public comment. These comments will be used to revise and finalize the document.

CDC identified ~129 themes to incorporate into the research agenda. Examples of the environmental health themes are outlined as follows. Under "environmental risk factors," environmental causes of disease and disability will be assessed. Under "complex exposures," biomedical and modeling tools will be developed to evaluate exposures to chemical mixtures. Under "biomonitoring methods and tools," the use of biomonitoring technology will be evaluated in exposure assessments. Under "environmental health interventions," interventions to prevent environmental health threats and promote health will be designed, implemented and evaluated.

Under the "built environment and health," relationships among land use policy, the built environment, and human health and injury will be determined. Under "lead exposure and health," policy interventions will be developed and evaluated to eliminate elevated blood lead levels in the United States. Under "environmental data and information systems," methods and tools will be developed to link available environmental hazards and health outcome databases. CDC expects its centers to implement the research agenda at state and local levels. For example, NCEH/ATSDR will actively involve and closely collaborate with grantees to conduct initiatives under the new research agenda.

Other internal and external customers that will be engaged in the implementation of the research agenda include federal partners, CDC scientists, academic institutions, professional associations and other experts. CDC is continuing its direct outreach efforts, but has also created a web site at www.cdc.gov/od.ophr for the public to obtain additional information on the research agenda. The draft is being presented to the BSC

and all other CDC advisory committees. The public comment version and revised draft will also be shared with these groups before the document is finalized.

The **BSC's** suggestions for CDC to consider in further developing, revising and finalizing the research agenda are outlined below.

- Explicitly note on the web site the role of the BSC and CDC's other advisory committees in providing input and guidance.
- Review existing and new science, data and computational technologies.
 For example, the "virtual epidemiology" article on smallpox in the March
 2005 issue of Scientific America would serve as an excellent resource to
 CDC because the paper is consistent with all of the environmental health
 research themes in the research agenda.
- Use the research agenda as an opportunity to broadly influence an integrated approach to filling significant data gaps.
- Develop a formal mechanism for the BSC and CDC's other advisory committees to provide input on the research agenda as a collective group rather than individual members.

NCEH/ATSDR Update

Dr. Thomas Sinks, the BSC Designated Federal Official (DFO) and NCEH/ATSDR Acting Director, made several administrative announcements. Evaluation forms were distributed in the notebooks for the BSC to provide input on whether the presentations were meaningful and useful. NCEH/ATSDR will review the comments to improve future BSC meetings. Ms. Georgi Jones, Director of the NCEH/ATSDR Office of Policy, Planning and Evaluation, will retire in June 2005. Ms. Priscilla Patin, the former Committee Management Specialist for the NCEH Advisory Committee to the Director, has accepted a position in OD. Certificates signed by the CDC Director were presented to recognize the tenures of three BSC members whose terms have expired: Drs. Joxel Garcia, David Gaylor and Ngozi Oleru. The participants applauded the valuable input and tremendous contributions of the outgoing BSC members and NCEH/ATSDR staff.

Dr. Sinks reviewed several organizational changes at the center and coordinating center levels. One, a search is underway to permanently fill the position of the NCEH/ATSDR Director. CDC expects to make the appointment by July 2005. Two, CCEHIP now has a liaison to OSI and point of contact for environmental justice (EJ) and health disparities issues. However, NCEH/ATSDR division directors will still be responsible for implementing health equity and EJ activities at the program level and producing

deliverables in these areas. NCEH/ATSDR has requested that each division director submit a portfolio of health equity initiatives and asked the Community and Tribal Subcommittee to evaluate and provide input on the inventory.

Three, ATSDR's Office of the Chief Medical Officer, GIS Program and Division of Health Education and Promotion were abolished, but the major functions of these offices were maintained and transferred to other programs or divisions. Four, the budget and staff of NCEH/ATSDR OD were decreased because Congressional appropriations will be directly allocated to programs to implement projects. Under the new budget structure, ODs in CDC centers can no longer tap program dollars to obtain operating income. NCEH/ATSDR OD will serve as a facilitator and point of contact for the environmental health budget, policies and activities and also provide leadership, support and scientific oversight to cross-cutting initiatives.

Six, state cooperative agreements are being closely examined to identify potential areas for synergy because this effort represents the largest amount of NCEH/ATSDR's extramural funding. The Health Department Workgroup will be asked to provide assistance and guidance in this effort. Seven, information technology governance will be enhanced across all NCEH/ATSDR programs.

Dr. Sinks provided an update on NCEH/ATSDR's recent accomplishments. NCEH/ATSDR provided testimony to Congress and two state legislatures on its chemical demilitarization program; investigation of an acute outbreak of hydrogen sulphide gas emitted from a landfill in Warren, Ohio; and activities in Eldorado County, California related to naturally occurring asbestos. NCEH/ATSDR is coordinating public health efforts with both internal and external partners to address safe drinking water, food safety and air pollution. NCEH/ATSDR will designate a single point of contact for these issues across all divisions.

NCEH/ATSDR will leverage opportunities for the new people, preparedness and places goals under FI, but will still focus on its existing projects in these areas. These initiatives include biomonitoring, the National Exposure Report, newborn screening, quality assurance and quality control of laboratories, environmental emergency services and global efforts. NCEH/ATSDR will officially open its new chemical laboratory building on September 12, 2005 and move to its new offices in December 2006. Dr. Sinks asked the BSC to consider holding its next meeting for two full days for the members to spend a half-day touring the new laboratory and seeing demonstrations.

Public Comment Period

Mr. Kip Howlett of the Chlorine Chemistry Council (CCC) and Ms. Lesa Aylward of Exponent, Inc. made public comments regarding ATSDR's draft dioxin soil policy guideline (DSPG). They urged the BSC to reject any proposed change to the action level due to the following reasons. ATSDR's proposed revision is a significant policy change that is not supported by science. The National Academy of Science (NAS) formed a panel to review EPA's draft dioxin reassessment in response to a Congressional mandate. The panel expects to complete its review by December 2005.

Mr. Howlett and Ms. Aylward also asked the BSC to make two recommendations. ATSDR should reevaluate the scientific basis for its proposed revisions to the final DSPG in light of the NAS findings. ATSDR should submit a modified draft DSPG, if necessary, after the NAS panel completes its review of the dioxin science. The full text of the public comments by Mr. Howlett and Ms. Aylward along with supporting data and references are collectively appended to the minutes as Attachment 2.

The **BSC** asked NCEH/ATSDR to provide Mr. Howlett and Ms. Aylward with the April 15, 2005 draft of the updated DSPG that was distributed in the meeting notebooks.

Update on the ATSDR Draft DSPG

The minutes reflect that Drs. Kim and Paustenbach recused themselves from this agenda item. **Dr. Mark Johnson**, of the NCEH/ATSDR Division of Regional Operations, reminded the BSC that the revision to the DSPG is being proposed because the "action level" of 1 ppb is often misinterpreted as a "screening level" and ATSDR and state health assessors need more appropriate guidance. Revisions to the DSPG are as follows. The 50 ppt "screening level" for dioxin in residential soils will be retained, but the 1 ppb "action level" to evaluate public health hazards or initiate public health activities will be removed. The 1 ppb level will be referred to as an EPA "regulatory level" on which to base cleanup decisions. The policy will only apply to direct ingestion of soil, but evaluation of other site-specific exposure pathways will be recommended.

ATSDR took several actions in response to comments the BSC made during the previous meeting. The DSPG was revised and restructured to be clearer and more user-friendly to health assessors, EPA, the general public and other interested stakeholders. A fact sheet was developed to communicate to the public the background

and objectives of revisions to the DSPG. The fact sheet also contains a summary table of each change and its impact.

Two BSC members were asked to guide the discussion on the draft DSPG. **Dr. Gaylor** was in favor of the current DSPG. Both the 0.05 ppb screening level to initiate an investigation and the 1 ppb action level to conduct more aggressive activities should be maintained. This approach provides a range of concentrations rather than a single number for different activity levels. He did not support the proposed change to remove the 1 ppb action level from the DSPG. This revision may be misinterpreted to mean that ATSDR now believes dioxin is 20 times more dangerous. He also did not agree with the proposed use of "regulatory level" because this term incorrectly implies that ATSDR has regulatory authority. Dr. Gaylor advised ATSDR to use terms other than "action level" and "regulatory level" to minimize confusion. He supported CCC's recommendation for ATSDR to delay revisions to the DSPG until after the dioxin report from the NAS panel is completed.

Dr. Koenig commended ATSDR on its tremendous efforts to address the BSC's previous concerns on the DSPG, particularly the insertion of "residential" in the title. However, his position was similar to those of Dr. Gaylor and CCC. Dr. Koenig was opposed to the proposed change to remove the 1 ppb action level from the DSPG. This revision may cause limited resources to be inappropriately applied to unnecessary actions at the lower screening level of 0.05 ppb. He advised ATSDR to review the NAS report and other papers that will soon be published before making changes to the DSPG. ATSDR may lose credibility with the public if two different sets of changes to the DSPG are released now and after the publication of new data.

Dr. Sinks announced that the proposed changes to the DSPG were provided to an interagency workgroup represented by NCEH/ATSDR, EPA, the Food and Drug Administration and other federal agencies. The interagency workgroup is responsible for charging NAS with the review of risk issues. EPA has not yet submitted formal comments, but none of the agencies expressed opposition to ATSDR revising and releasing the DSPG at this time. ATSDR plans to publish a *Federal Register* notice announcing the availability of the draft DSPG for public comment and will also post the document on its web site.

The **BSC** commended ATSDR on its outstanding efforts to address the comments and concerns raised by members during the previous meeting. The updated draft clearly reflects the BSC's input to provide further clarification and explanation of the DSPG. However, some members were divided on actions ATSDR should take at this point. On the one hand, some members of the Board believed that ATSDR should delay the

release of the revised DSPG until the NAS panel completes its dioxin report around December 2005. They believed that the revised DSPG will create negative reactions from a policy perspective and result in legal issues at state and local levels. They suggested that a collaborative effort with NAS can facilitate CDC's efforts under FI to remove traditional silos, strengthen partnerships, and enhance interagency and intraagency collaborations.

On the other hand, other Board members stated that ATSDR should not delay the release of the revised DSPG because the NAS report will serve as a scientific review of the DSPG and will not focus on policy, process or communications issues for health assessors. They believed that ATSDR will lose credibility with the public with a decision to delay its efforts to revise the DSPG over the past 1.5 years merely on the basis of the NAS report. These Board members felt that ATSDR should follow CDC's precedent in which drafts are posted on the web site to quickly provide guidance to health departments and environmental agencies at state and local levels. Additional comments to ATSDR by the BSC are outlined below.

- Use the term "further study level" rather than "regulatory level." Use new language that is clearer and more appropriate than "action level."
- Revise the fact sheet as follows. Add text to the first paragraph to clearly delineate ATSDR's rationale for deleting the 1 ppb action level from the DSPG. Explain that the 1 ppb action level is confusing, often misinterpreted, inconsistent with EPA guidelines, and a source of contention for communities with dioxin pollution problems. Emphasize that the revised DSPG should serve as a tool for health assessors to more effectively conduct a site-by-site analysis and identify possible health risks.
- Maintain the 1998 summary table, but rename the "Action Level" column heading to "EPA Regulatory Cleanup Level." Include a reference to the EPA law in the text of the column.
- Clearly define and provide examples of "actions" that should be taken when soils above for 1 ppb of dioxin are encountered.
- Obtain formal input from health assessors and other groups that will be directly affected by the revised DSPG. For example, conduct a systematic review by administering a survey to health assessors to determine the use or misuse of the DSPG.
- Explicitly state in the DSPG that "1 ppb" is an EPA regulatory cleanup level governed by specific provisions in federal regulations and "0.05 ppb" is an ATSDR screening level. Clarify that all "actions" listed in the DSPG are not appropriate for or applicable to each site.

- Redefine the evaluation levels based on "site" or "health" issues.
- Further revise the DSPG based on the BSC's additional comments and distribute the updated version to a few Board members and health assessors for review and input. However, allow ATSDR to decide whether the document should be released for public comment at this time.

Update on ATSDR's Asbestos Activities

Drs. Vikas Kapil and John Wheeler of NCEH/ATSDR provided a status report on the role of asbestos in environmental public health and future directions in this area. ATSDR has several asbestos initiatives underway to better define the problem, assess sites, improve and contribute to science, and provide community health education. In Libby, Montana, a mine that operated from the 1920s-1990 produced the majority of the world's vermiculite and shipped contaminated ore with up to 25% asbestos to >200 U.S. locations. ATSDR conducted a PHA, mortality review and community medical screening; confirmed the usefulness of CT scanning; and established the Tremolite Asbestos Registry (TAR) in Libby to respond to health concerns.

TAR is designed to maintain contact information; recruit individuals as potential participants in future research studies; provide health education and communication to affected persons; disseminate information on potential therapeutic interventions in the future; and evaluate mortality due to asbestos-related outcomes of interest. ATSDR has enrolled ~3,500 persons into TAR to date and is continuing recruitment efforts. The Libby screening results showed an 18% overall prevalence of pleural abnormalities in all participants and a much higher prevalence of 51% and 48%, respectively, in workers and household contacts.

ATSDR developed the National Asbestos Exposure Review (NAER) to determine whether non-Libby sites posed a public health concern. Multiple potential exposure pathways of asbestos were identified, including workers, household contacts, waste rocks distributed to the community and ambient air. Although >200 locations throughout the country received contaminated ore from Libby, ATSDR is only focusing on 28 Phase I sites that were most heavily impacted at this time. NAER findings to date showed that previous public health hazards are likely for workers and household contacts. No significant or current community exposures were found overall, but may be a concern at specific sites. No evidence has been produced to date to demonstrate excess morbidity or mortality of asbestos-related disease in the community.

ATSDR has conducted several activities at non-Libby sites, including the publication of 12 health consultations and five health statistics reviews. A mesothelioma surveillance project is being piloted in New Jersey, New York and Wisconsin to obtain detailed exposure history on new cases and evaluate the association between Libby vermiculite and mesothelioma. ATSDR has interviewed 148 cases for the project since 2003. Disease progression is being examined in former vermiculite workers in Ohio with follow-up medical screening and comparisons to previous chest x-ray and spirometry results. Data from these tests are currently being analyzed. A mortality analysis will be incorporated into the project to identify causes of death among deceased workers.

ATSDR is focusing on exposures to naturally occurring asbestos (NOA) that are caused by non-mining, non-industrial or non-commercial use. Samples were taken and activity-based investigations of NOA were conducted at the Oak Ridge High School in El Dorado, California and a site in Alaska. ATSDR has identified several data gaps in the science of asbestos. Health impacts on former workers and household contacts at non-Libby vermiculite sites should be determined. Risk modeling capacity should be strengthened to identify health impacts from low-level, intermittent and short-duration asbestos exposures. Knowledge on the toxicology of amphibole asbestos and non-asbestos fibers should be strengthened. Exposure and disease biomarkers should be developed. Digital versus standard film radiographs for "B-reading" of pneumoconioses should be evaluated. Suspension modeling skills should be enhanced.

The **BSC** expressed general support of ATSDR's asbestos activities, but several members made comments to improve the initiatives.

- Acknowledge fiber length issues when taking samples by applying the standard sampling methodology established by the Occupational Safety and Health Administration (OSHA).
- Review the 2002 Hodgson and Darnton paper to obtain supporting data that amphibole asbestos is significantly more carcinogenic than chrysotile asbestos.
- Launch the tissue burden study at this time and obtain permission from families to take tissues when TAR participants die from any cause.
- Quantify short-term asbestos exposures, but limit the amount of attention given to this effort because differences in pathology will not be significant.
- Develop a strong methodology to examine non-asbestos fibers because this activity will result in the most solid data set that is available at this time and also lead to important contributions in the asbestos field.
- Establish a sub-panel to read film radiographs because data show that Breaders only concur on 50% of samples.

- Review findings from the classic cow herd model and its three sister models to accurately address issues related to suspension modeling.
- Conduct as many ratio studies as possible to identify the distribution of dust by fiber type, length, aerodynamics and mean diameter.
- Shift the focus of the asbestos projects from site-specific concerns to include broader issues. For example, incorporate a representative sample of non-U.S. sites in the asbestos projects because contaminated ore was also shipped from Libby to Canada and overseas locations. Establish collaborations with the World Health Organization in conducting asbestos activities. Implement these strategies to support CDC's stronger focus on global health under FI. Provide guidance to health departments and environmental agencies and widely disseminate information to the public. Create a cross-site database of lung disease, mesothelioma and other adverse outcomes that have been detected at vermiculite sites. Redesign health consultations to describe common outcomes and recommend long-term health actions that should be taken across sites throughout the country.
- Establish partnerships to focus on the sensitive technique of metabolomics that has been successfully implemented in Europe. Perform research in this emerging area to advance the field of biomonitoring and more effectively identify persons who develop pleural abnormalities.
- Form an independent advisory panel with experts from academic institutions and other non-governmental sources to provide creative and ongoing guidance on the asbestos projects.
- Clearly delineate the focus, goals and environmental public health role of the asbestos projects because the initiative continues to expand with additional partners and activities without a defined direction.

Update on the CDC National Report on Human Exposure to Environmental Chemicals (NER)

Dr. John OsterIoh of NCEH/ATSDR reported that CDC has been developing methods and conducting studies on biological monitoring for more than 30 years. CDC released two NERs in 2001 and 2003 containing 27 and 116 chemicals, respectively, developed a process, and established criteria in 2003 to nominate chemicals for biological monitoring that would be of interest to the public. The criteria were based on a chemical's changing, persisting or likely exposure to the U.S. population; seriousness of

known or suspected human health effects; need to assess the efficacy of public health actions; and existence of an analytical method.

The Office of Management and Budget (OMB) asked CDC to formulate a plan to remove chemicals from NER in November 2004. An ad hoc workgroup with BSC representation was formed in February 2005 to undertake this effort and held conference calls to develop and revise quantitative criteria. The workgroup identified six issues to define the removal criteria. One, is the main focus on the magnitude of the exposure and change in levels? Two, are toxicological endpoints a necessary quality? Three, should characteristics of a chemical for removal serve as corollaries of factors for nomination? Four, are multiple characteristics necessary to remove chemicals from NER? Five, how should the removal process be designed? Six, can targeted monitoring serve as an alternative?

The workgroup's draft plan to add and remove candidate chemicals from NER is outlined as follows. A candidate list of chemicals will be developed, revised, and approved on the basis of interest or lack of interest, but resources and emerging public health issues can influence which chemicals are included in the *Report*. The inclusion and removal processes will be combined in a three-stage approach. Inclusion criteria will be similar to the original process established in 2003. Removal criteria will be based on whether the levels of a chemical declined, did not change, or are below the level of detection over three survey periods.

A chemical will also be removed from NER if a new replacement metabolite is more representative of exposure than the chemical currently being measured. A panel of outside consultants and experts will be established to prioritize categories. A BSC workgroup will assist CDC in matching capabilities and efficiencies (for example, trade-offs with respect to specimen-size limitations and cost issues). Federal Register notices will be published to solicit public comments and announce the final removal characteristics.

"The BSC was in accord with the DLS and Work Group draft plan for adding and removing candidate chemicals from the Exposure Report; further the BSC recommended the following:

- Advise OMB to place more emphasis on collecting the best data rather than removing chemicals from Exposure Report.
- Consider alternative approaches, in addition to the Federal Register Notices, to reach community groups about the criteria.

- Clearly communicate to the public CDC's rationale for excluding chemicals from NER.
- Explore the possibility of decreasing the time to remove chemicals from NER because "three survey periods" equal to six years.
- Address the discrepancy between the large number of chemicals that will be nominated and the smaller number to prioritize. For example, the approach of focusing on chemicals with known or suspected human health effects may not include all important chemicals of concern.
- Resolve the inconsistency in the characteristics. For example, chemicals
 with a persistent exposure are listed in both the inclusion and removal
 criteria, but these chemicals should continue to be monitored.
- Expand NER with the inclusion of naturally occurring and pharmacologic compounds and "quality of life" markers to address chemistry issues.
- Take more blood samples, improve the chemistry and implement other strategies to decrease the number of non-detects.
- Maintain the "need to assess the efficacy of public health actions to reduce exposure" as an inclusion characteristic and also add this language to the removal criteria to determine if interventions should be evaluated in the future.
- Develop a ranking system to make the process clearer to the public. For example, establish and score categories for each criterion based on the chemical's carcinogenicity, contribution to health effects and other factors.
- Obtain guidance from CDC on effectively addressing political issues related to children's health that may arise in the future.

Overview of the Third NER

Dr. James Pirkle of NCEH/ATSDR announced that the third NER contains 32 more chemicals than the second NER for a total of 148; participants from the 2001-2002 National Health And Nutrition Examination Survey (NHANES); blood and urine levels of chemicals and metabolites; and a sample size of 2,000-2,500, but more for cotinine, lead and cadmium. The public health uses of NER are to identify chemicals that enter the human body; determine the number of persons with elevated levels; obtain reference ranges to identify unusual exposures; specify the effectiveness of exposure reduction efforts; determine levels in women of childbearing age, children and other susceptible groups; and establish health research priorities.

The 32 new chemicals in the third NER include pyrethroid pesticides, aldrin, endrin, dieldrin, and additional polycyclic aromatic hydrocarbons, dioxins, furans, phthalates,

PCBs, pesticides and herbicides. CDC inserts two major disclaimers in all NERs. First, NERs are designed to provide new information on exposure rather than toxicology. Second, the ability to measure a chemical with limited health risk information should not be interpreted to mean the chemical is harmful.

Highlights of the third NER are outlined as follows. The findings will be extremely interesting to scientists who address issues related to risk assessment and protection from adverse exposures. The tables have a new format to include 2001-2002 NHANES data; exclude the 10th and 25th percentiles; combine the 50th, 90th and 95th percentiles on one page; and illustrate important changes or variations in demographic groups. Differences in median values and 95th percentiles by a factor of 200-1,000 in some instances may demonstrate that specific segments of the population receive much higher exposures than indicated by the 50th percentile.

A statistical analysis will not be included to show differences in demographic groups between 1999-2000 and 2001-2002 NHANES data because previous surveys were based on three years of data, but current surveys reflect two years of data. Data will be released on new priority chemicals before the fourth NER is issued, such as perchlorate, speciated arsenic, volatile organic compounds, polybrominated diphenyl ethers and perfluorinated compounds. The third NER is currently undergoing CDC's internal review and clearance process and is expected to be released in June or July 2005. The document will be posted on the CDC web site and also distributed in CD-ROM format upon request. BSC members will be invited to participate on a partners' conference call at which time CDC will present major findings of the third NER.

The **BSC** commended CDC on compiling a tremendous amount of data and improving the tables in the third NER, but several members made two key comments. First, zeros should be added to the figures to avoid misinterpretation by the public and ensure that ranges consistent. Second, CDC should clearly explain its rationale for separating Mexican Americans from other Hispanic/Latino subgroups. Strategies should be formulated to capture infants and children, minority populations and other key subgroups in NER. Methods should be developed to apply biomonitoring techniques in examining exposures to these groups. The BSC noted that NHANES is an excellent indicator of the national average, but lacks sufficient representation of subsets of the population.

With no further discussion or business brought before the BSC, **Dr. Nolan** recessed the meeting at 5:09 p.m. on May 19, 2005.

Changes to HHS Advisory Committees

Dr. Nolan reconvened the meeting at 8:15 a.m. on May 20, 2005 and yielded the floor to the first presenter. **Ms. Cathy Ramadei**, of the CDC Management Analysis and Services Office, described changes to HHS advisory committees that will impact the BSC. HHS previously required most members of a parent committee to serve on a subcommittee. The new rule states that all or some members <u>may</u> serve on a subcommittee, but only one member is <u>required</u>.

All subcommittee members may vote and count toward a quorum. Subcommittees may continue to invite non-members and ad hoc consultants to meetings, but these persons may not vote and will not count toward a quorum. Subcommittees must continue to adhere to guidelines related to a balanced membership. All subcommittee members who do not serve on the parent committee must be immediately appointed as special government employees and complete and submit personnel forms, appointment papers and financial disclosure/ethics reports to the sponsoring agency. The new rules do not apply to workgroups.

Subcommittee and Workgroup Reports

Program Peer Review Subcommittee (PPRS). **Dr. David Williamson**, of NCEH/ATSDR, described actions that were taken to respond to PPRS's recommendations from the peer review of the ATSDR Hazardous Substances and Emergency Events Surveillance Program (HSEESP). One, a strategic plan will be developed and implemented to make HSEESP more nationally representative. A meeting will be held in the summer of 2005 to begin formally developing a HSEESP strategic plan and formulating a research agenda that covers statistics, relevant publications and research opportunities. Another meeting will be convened in the fall of 2005 for a diverse group stakeholders to provide input on the HSEESP strategic plan, including representatives from federal agencies, industry and state departments of health and environmental quality.

Two, criteria, metrics and methodologies will be developed to evaluate HSEESP. A public health prevention service fellow was hired to create evaluation measures to assess the effectiveness of HSEESP's outreach activities in states. An evaluation study will be piloted in the fall of 2005 in partnership with the Consumer Products Safety Commission to obtain data on victims of chemical-related accidents or releases who present to hospitals. HSEESP data will be compared to hospital reports to evaluate the

completeness of or gaps in reports and identify data sources that will be most beneficial to state and local health departments and impacted community members. Each state will be asked to review 10% of data entered into electronic systems and submitted to HSEESP each quarter and compare this information to hard copies. This strategy will be used to evaluate the accuracy and completeness of data.

Three, interagency coordination will be strengthened with EPA, NCEH, OSHA, the Chemical Hazard and Safety Investigation Board and other groups to raise awareness about HSEESP and its value. These collaborative efforts will be used to enhance capacity and systematically share data on risk management, health and accidents, process safety management, environmental report cards, and investigations of chemical hazards and releases. The partnerships are expected to result in the dissemination of better prevention strategies and stronger messages to states and communities.

Four, state capacity will be strengthened by fostering collaborations between state departments of public health and environment. ATSDR field staff housed in EPA regional offices will serve as a valuable resource in this effort. A project will be launched to determine HSEESP's potential role and contributions to site-specific activities under the 1043 state cooperative agreements.

Five, specific issues identified by PPRS during the HSEESP peer review will be addressed. Prevention efforts will be incorporated into program goals. Case definitions and inclusion criteria for events will be added. The program scope will be expanded. A process will be created to consistently collect and report data. A national strategy will be developed to examine events on a wider scale and disseminate prevention strategies for broad categories of industries or chemicals. The distribution of data will be improved with a web-based public use data set.

Dr. Sharunda Buchanan, of NCEH/ATSDR, announced that PPRS will conduct a program peer review of the NCEH Environmental Health Services Branch (EHSB) the week of May 23, 2005. EHSB's mission is to improve and ensure the quality and accessibility of EH services in the United States and develop and enhance skills of EH professionals who provide these services. EHSB fulfills its mission by providing support, technical assistance and guidance to state and local health departments in delivering services of the highest quality. Inquiries to EHSB are tracked on a daily basis. EHSB acknowledges that EH practice is outmoded, EH leadership is lacking in many programs, the role of EHS is not visible or well understood, the number of EH professionals has decreased, and performance standards are minimal. The number of students enrolled in accredited undergraduate programs declined 42% over the last ten years and the number of graduates decreased 52% in this same time period.

CDC convened a diverse group of external stakeholders and organizations throughout the country to obtain input on revitalizing EH services for the 21st century. The meeting resulted in the development of six goals to build capacity, support research, foster leadership, communicate and market, develop the workforce, and create strategic partnerships. EHSB is divided into three sections for training, evaluation and information; research and evaluation; and technical assistance. EHSB conducts several activities to achieve EH services goals. Capacity-building grants were awarded to state and local health departments and communities to build EH services around the ten essential public health services. The EH Services Network was established with a diverse group of experts to use a systems-based approach in examining environmental antecedents to outbreaks and disease investigations. Funds under this initiative have been awarded to eight states. An EH services community assessment tool was developed and disseminated for public health officials and communities to collaborate on eminent EH issues.

Programs and curricula are being created to strengthen the public health infrastructure, build and enhance core competencies, promote diversity among EH practitioners, facilitate educational opportunities for EH professionals, increase the number of accredited programs, and develop communications messages to highlight the importance of EH services. An evidence-based systems approach is taken to integrate science and EH services. A document was developed outlining core competencies in the EH services workforce. The EH Leadership Institute was recently launched to create leadership competencies that will be needed to address EH challenges in the 21st century and improve EH practice within state, local and tribal organizations.

EH services partnerships have been strengthened and expanded to include diverse groups in both public and private sectors. The development of an Environmental Public Health Service Corps is being considered in which CDC would train professionals and then assign these individuals to state health departments under an internship or two-year training program. Efforts are being made to create a program in which retired military personnel would be specifically trained in EH services and assigned to state and local health departments.

Dr. Daniel Wartenberg, the PPRS Chair, reported that PPRS is proposing the following changes to make the program peer review process faster, more comprehensive and positive for all participating groups. The questionnaire will be redesigned as a self-assessment tool that will improve the quality of the peer review process, communicate at all levels, focus more on customers, and provide ongoing assessment. Conference calls will be held before site visits for team members to define the peer review goals and

introduce themselves to program staff. Site visits will be restructured with a brief program overview and a meeting with senior management. Responses to the PPRS summary report will be solicited from the program. Follow-up will be conducted more frequently than five years to identify progress and changes the program made in response to PPRS's recommendations.

Community and Tribal Subcommittee (CTS). **Dr. Cynthia Harris**, the CTS Chair, reported that the CTS and Special Consultants (SCs) developed the 2005-2006 work plan with tasks, timelines, action items and responsibilities. In <u>Activity 1</u>, input, guidance and assistance will be provided on developing standards and criteria to evaluate NCEH/ATSDR's activities and public health impact. Community and tribal input will be provided to PPRS and other BSC subcommittees. The NCEH/ATSDR portfolio related to health disparities and EJ issues will be reviewed.

In <u>Activity 2</u>, community and tribal access to NCEH/ATSDR's public health information will be evaluated. The NCEH/ATSDR web site will be updated with a "community and tribal" page to increase access. The CTS brochure will be updated, revised, redesigned and translated into Spanish. A plan will be formulated to disseminate the brochure. Access to NCEH/ATSDR publications that would be of interest and relevance to communities will be increased. CTS participation in related public health conferences and workshops will be enhanced.

In <u>Activity 3</u>, eight PHAs will be selected from demographically diverse sites for review and evaluation to determine if the documents are consistent with items in the PHA checklist and understandable to communities. The CTS will begin developing the 2006-2007 work plan during its face-to-face meeting in November 2005. EJ, federal facilities and tribal initiatives will be the activities for the 2006-2007 work plan. The CTS noted that the end of BSC tenures and a staff reappointment will result in the loss of the CTS chair, DFO and one member over the next six months. The CTS and SCs also expressed significant concerns about the impact of the NCEH/ATSDR consolidation on health disparities and EJ issues.

Health Department Workgroup (HDWG). **Dr. Gayle Windham**, the HDWG Chair, reported that HDWG's three conference calls in January-April 2005 led to the members formulating several recommendations for the BSC to consider. HDWG should be established as a formal subcommittee rather than a workgroup. The "National Strategy to Revitalize Environmental Public Health Services," its six goals, and EHSB's ten-year plan to develop the EH workforce should be strongly supported. CDC should be urged to aggressively seek the appropriate level of financial and human resources to fully

implement EHSB's plan, including support for the EH Leadership Institute and Environmental Public Health Service Corps.

Several gaps should be addressed. The emphasis on testing, monitoring and other EH services is to the detriment of other health issues. Health and evidence-based training should be enhanced. EH training should include data-based skills to acknowledge the importance of tracking, surveillance systems and other large data needs. The focus on cross-communication and collaboration at the management level should be strengthened for training, EH, epidemiology, data management and similar efforts within CDC. The burden on local personnel who perform multiple duties should be minimized.

In addition to recommendations, HDWG's deliberations also resulted in the members proposing next steps for future activities. Dr. Julie Gerberding, the CDC Director, or Dr. Steven Thacker, Director of the Epidemiology Program Office, could provide an overview of CDC's plans to address EH workforce development issues. HDWG could provide advice or formally assess state workforce needs to formulate specific recommendations in this area. HDWG could begin to focus on its next priority issue and continue to address the BSC's areas of interest, including terrorism and response, improved surveillance systems, indoor and outdoor air quality, and the built environment.

The **BSC** acknowledged the diligent efforts, dedication and valuable contributions of PPRS, CTS and HDWG. The reports demonstrate that numerous activities have been conducted since the previous BSC meeting. The BSC made several suggestions for the workgroup and subcommittees to consider in refining the respective work plans.

PPRS

- Ensure that the redesigned questionnaire for program peer reviews is consistent with the OMB Program Assessment Rating Tool.
- Incorporate an "overview poster session" into the peer review process in which site team members and program staff engage in dialogue to ensure the purpose and importance of the review are understood.

CTS

- Prioritize the work plan activities to ensure time is sufficient to successfully and realistically complete each project.
- Clearly delineate the rationale and outcomes of the PHA review and evaluation. Develop and present a report during the next BSC meeting describing specific products that will be generated from the PHA review.
 For example, assess PHAs to determine if the documents are user-

- friendly to states. Select one PHA initially and extensively review the document for a specific purpose.
- Shift the traditional CTS focus from site-specific activities to a broader agenda of health disparities, health equity and EJ across all NCEH/ATSDR divisions. For example, the CTS could advise NCEH/ATSDR on strategies to incorporate health equity information into the third NER.
- Provide guidance to the BSC on community and tribal issues that should be considered by NCEH/ATSDR rather than take actual responsibility. For example, the CTS should ask the BSC to recommend that NCEH/ATSDR update its web site with a community and tribal page. The CTS could gather and submit data to the BSC to support this recommendation.
- Strengthen collaborations with PPRS. Provide input on the redesigned peer review questionnaire to ensure community and tribal issues are reflected. Assign CTS members to participate on peer review site visits.

HDWG

- Strongly encourage each PPRS member to thoroughly review the "National Strategy to Revitalize Environmental Public Health Services" prior to the EHSB peer review.
- Enhance collaborations between HDWG and PPRS to ensure that work plans of both groups are consistent.
- Define the "EH workforce" as a priority issue and separate this activity from the EHSB peer review.
- Refine the recommendations to ensure that guidance to NCEH/ATSDR will be effective. Circulate the revised recommendations to the BSC for review and a formal vote prior to the next meeting.
- Urge CDC to review successful and creative models to increase EH funding. For example, academic institutions throughout the country lobby Congress each year for continued funding and support of EH programs in the National Institute of Environmental Health Sciences.

Public Comment Period

Dr. Nolan opened the floor for public comments; no attendees responded.

BSC Open Discussion

Dr. Nolan opened the floor for the BSC to provide additional input to CDC on previous agenda items. Comments by the members are outlined below.

Healthy Places Goals

- Develop a matrix to illustrate the relationship between CDC's healthy places goals and Healthy People 2010 objectives.
- Include universities, faith-based institutions and other places in the goals where persons spend a considerable amount of time and can be impacted by environmental factors.
- Refine the goals to strongly emphasize that built, physical and social environments serve as integrating factors in healthy places.
- Review existing data from the Morbidity and Mortality Weekly Report and other sources to identify places where the most unhealthy events, morbidity and mortality occur. Use this information to prioritize the healthy places goals and appropriately allocate resources.
- Explore opportunities to apply the healthy places goals in areas other than the program peer review process.

Research Agenda

- Revise the biomonitoring research effort to examine chemical mixture issues from an analysis perspective.
- Request strong endorsement from the BSC on NHANES-type studies that are designed to obtain fundamental baseline data on chemicals in individuals.

BSC Business

Dr. Sinks announced that a call for new BSC members was published in the *Federal Register*. Of the 14 responses, one individual withdrew and no Native Americans submitted applications. NCEH/ATSDR will develop nomination packets for two primary and two secondary candidates.

Consensus recommendations, action items and agenda items raised by the BSC over the course of the meeting are outlined below. Both consensus recommendations were properly moved, seconded and unanimously approved by voting members except where indicated.

Consensus Recommendations

- NCEH/ATSDR's report of ongoing and future activities to respond to PPRS's recommendations on the HSEESP peer review is adopted. [One BSC member abstained from voting.]
- HDWG's recommendation to be established as a formal BSC subcommittee to continue its activities and representation to NCEH/ATSDR is approved.

Action Items

- Revise future presentations on FI. Include personnel and budget information on coordinating centers. Clearly state strategies and actions of FI goals.
- Provide the BSC with Dr. King's slides on OSI.
- Provide the BSC with public comments that are submitted on the draft DSPG.
- Obtain information from Dr. Koenig on the healthy places model developed by the military and forward the materials to Dr. Baldwin.
- Provide the BSC with the white paper submitted by the Center for Regulatory Effectiveness that challenges ATSDR's asbestos activities at the 28 NAER sites. Include ATSDR's response to the challenge.
- Provide the BSC with the draft plan to add and remove candidate chemicals from NER.
- Inform the BSC about the availability of the third NER on the CDC web site and the date and time of the partners' conference call during which the major findings of the document will be presented.
- Inform the SCs that CDC will be distributing personnel forms, appointment papers and financial disclosure/ethics reports to be completed and submitted in accordance with the new rules for HHS advisory committees.
- Obtain information from Dr. Zenick on EPA's peer review model of the "overview poster session" and forward the materials to Dr. Wartenberg.
- Provide the BSC with CDC's report on state and local health departments that addresses issues related to the EH workforce and competencies.
- Provide the BSC with a one-page list of recommendations subcommittees will present for the BSC to consider, approve and forward to NCEH/ATSDR for action.
- Convene a conference call with the Chair and DFO to distribute the research agenda to the BSC and SCs for review, compile comments and submit a coordinated BSC response to CDC.
- Revise future BSC agendas to decrease the number of presentations and increase discussion periods.

• Fill vacancies on subcommittees. Dr. Yang will serve as a new PPRS member, but the CTS still needs volunteers from the BSC to replace Dr. McDiarmid at this time and Dr. Harris in November 2005.

Agenda Items

- Presentation by CDC on strategies that will be implemented to successfully reach all of the customers targeted under FI.
- Overview by Dr. Walter Williams, the OHE Director.
- Update on the draft plan to add and remove candidate chemicals from NER with a focus on risk characterization and potential political issues.
- Progress report on CDC's research agenda.

Closing Session

Dr. Sinks was extremely pleased with the BSC's tremendous progress in serving as one consolidated advisory body and providing NCEH/ATSDR with valuable input on its activities. **Dr. Nolan** thanked Dr. Drue Barrett and Ms. Sandra Malcom, the BSC Committee Management Specialist, for their outstanding efforts in providing the BSC with more informative materials and distributing the previous meeting minutes in a more timely fashion.

The next BSC meeting will be held on November 17-18, 2005. With no further discussion or business brought before the BSC, Dr. Nolan adjourned the meeting at 12:19 p.m. on May 20, 2005.

| | I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete. |
|------|--|
| Date | Patricia Nolan, M.D., M.P.H. Board of Scientific Counselors Chair |

ATTACHMENT 1

List of Participants

BSC Members

Dr. Patricia Nolan, Chair

Mr. James Derouin

Ms. Becky Dunlop [via conference call]

Dr. Miguel Fernandez

Dr. Joxel Garcia

Dr. David Gaylor

Dr. Cynthia Harris

Mr. Scott Holmes

Dr. Nancy Kim

Dr. Harold Koenig

Dr. Ronald Laessig

Dr. Ngozi Oleru

Dr. Dennis Paustenbach

Dr. Daniel Wartenberg

Dr. Gayle Windham

Dr. Raymond Yang

Ex Officio Members

Dr. Allen Dearry (NIH/NIEHS)

Dr. Lee Sanderson (NIOSH)

Dr. Harold Zenick (EPA)

Designated Federal Official

Dr. Thomas Sinks

CDC Representatives

Dr. Grant Baldwin

Dr. Drue Barrett

Dr. Sharunda Buchanan

Dr. William Cibulas

Ms. JoAnn Cox

Mr. Andrew Dannenberg

Mr. Kenneth Davis

Ms. Diane Dennis-Stephens

Dr. Christopher DeRosa

Ms. Athena Gemella

Ms. Petunia Gissendaner

Ms. Ginger Gist

Mr. Hugh Hansen

Ms. Laura Harden

Ms. Olivia Harris

Ms. Arneta Herbert

Mr. Jerry Hershovitz

Dr. Heraline Hicks

Mr. Jim Holler

Dr. Mark Johnson

Ms. Georgi Jones

Dr. Vickas Kapil

Dr. Lonnie King

Mr. Nancy Levine

Mr. Shirley Little

Ms. Sandra Malcom

Ms. Ruth Martin

Dr. Susan Moore

Dr. Moiz Mumtaz

Mr. Ed Murray

Ms. Maureen Orr

Dr. John Osterloh

Ms. Priscilla Patin

Dr. James Pirkle

Dr. Hana Pohl

Dr. James Rabb

Ms. Cathy Ramadei

Mr. Renee Ross

Mr. Kevin Ryan

Dr. Robert Spengler

Dr. Terrie Sterling

Ms. Stacey-Ann Taylor

Ms. Jana Telfer

Ms. Carolyn Tylenda

Ms. Robin Wagner

Dr. John Wheeler

Dr. Sharon Williams-Fleetwood

Dr. Mildred Williams-Johnson

Dr. David Williamson

Members of the Public

Ms. Lesa Aylward (Exponent, Inc.) Ms. Molly Haining (Hunton Williams) Mr. Mark Harris (ChemRisk)

Mr. Kip Howlett

(Chlorine Chemistry Council)
Ms. Amanda Raziano (Association of State and Territorial Health Officials)

ATTACHMENT 2

Public Comments

Talking Points for ATSDR Board of Scientific Counselors Meeting and Proposed Changes to Dioxin Soil Policy Guideline

Kip Howlett

Good morning. My name is Kip Howlett. I am Executive Director of the Chlorine Chemistry Council, a trade association dedicated to addressing public policy issues affecting the chlorine industry.

I am here to urge you to reject any proposed change to the action level in ATSDR's Dioxin Soil Policy - the next item on your agenda.

We oppose any change at this time for the following reasons:

- 1. The proposed change to the soil policy is deletion of the I ppb TEQ action level from the existing policy. This, although characterized by the proposed policy change as merely a "clarification," is, in fact a significant policy change. Deleting the I ppb TEQ action level will effectively result in a substitute of the 0.05 ppb TEQ screening level for the action level a 20-fold decrease. Such a change in policy must be supported by appropriate scientific evidence.
- 2. The existing policy is clear, and the current I ppb TEQ action level is appropriate, and importantly, it is also consistent with EPA's Superfund Dioxin Cleanup criteria of I ppb TEQ.
- 3. The proposed revisions to the policy do not add clarification; in fact, they will likely lead to more confusion, a result that is particularly hard to countenance because no new science has been published since the original policy was developed that would support the proposed changes. The lack of a scientific basis gives a change in the action level the appearance of representing an arbitrary shift in policy.
- 4. There is new science available since the policy was originally developed, but this new science does not support lowering the dioxin action level it actually supports maintaining the current action level. My colleague, Ms. Lesa Aylward, will briefly describe this new science in a few moments.

5. In any case, any modification to ATSDR's Dioxin Soil Policy Guideline is premature. Congress has mandated a review of EPA's Draft Dioxin Reassessment by the National Academy of Science. This panel, established last November, expects to complete its work by December 2005. It was set up in particular to "...ensure a coordinated approach to dioxin-related issues." The NAS review encompasses critical scientific aspects of dioxin hazard, exposure and risk assessment. In light of the scope and purpose of the NAS review, ATSDR should not propose any changes in policy until they have the benefit of the NAS review. Any change by ATSDR could be interpreted to undermine or circumvent NAS's scientific review. At the very least, it is inefficient of ATSDR to make a change at this time as it is likely this policy would need to be re-evaluated after the NAS report becomes available.

In conclusion, we urge the Board to:

- Reject any proposed change in the action level presented in the Draft DSPG at this time because it is a significant change in policy that is not supported by science and because it is premature in light of the NAS review process;
- Direct ATSDR to reevaluate the scientific basis for its proposed modifications of the Final DSPG in light of the NAS findings;
- Direct ATSDR to resubmit, if necessary, a modified Draft DSPG after the NAS has completed its review of the dioxin science.

Thank you for this opportunity to present comments to the BSC.

Lesa Aylward

I am Lesa Aylward, a Senior Managing Scientist from Exponent. I am here on behalf of the Chlorine Chemistry Council to present comments regarding the proposed changes in the ATSDR Dioxin Soil Policy Guideline (DSPG).

The current ATSDR DSPG was the result of a comprehensive analysis of the scientific data that were available at that time. The technical basis for the current DSPG was published in the peer-reviewed literature both as a draft (in 1997) and as a final document (in 1999), and the entire policy was given wide scientific review and consideration. There are significant new data since 1998 that affect both cancer and non-cancer hazard assessment and the assessment of background exposure levels. The NAS committee that is reviewing the USEPA Draft Dioxin Reassessment is

considering these data. If the DSPG is being evaluated for possible changes, such an evaluation should consider the new scientific data and should await the results of the NAS review.

The newly available data do not justify the proposed changes in the DSPG. I'd like to provide a brief overview of just a few of the key studies and data that should be considered before any change in the DSPG is adopted.

- 1. New data on background levels of dioxin exposure in the U.S. continue to show declines in both intake and body burden.
 - Based on 2001-2002 data from the U.S. FDA, dietary intake levels are about half of what was estimated by USEPA based on mid-1990s data, and more than 90% lower than estimated intakes in the 1970s (U.S. FDA 2004; Lorber 2002).
 - Body burdens continue to decline, and are historically low among young adults of reproductive age. Average body burdens in young adults are less than one-tenth the levels found in young adults in the early 1970s, and approximately one- fourth of the population "average" levels estimated by the USEPA in the 2003 Draft Dioxin Reassessment (Patterson et al. 2004; USEPA 2003).
- 2. New data on cancer risk from studies in laboratory animals and humans show lower potencies than previously estimated.
 - New, high-quality, cancer bioassay data from NTP on TCDD and two
 other major TEQ contributors show lower cancer potency for TCDD than
 previously estimated from older bioassays with fewer dose groups, and
 lower relative potency for 4-pentachlorodibenzofuran. The NTP studies
 also show highly non-linear dose-response, consistent with a threshold
 mechanism for cancer.
 - New data on elimination kinetics in persons with high dioxin exposures show that, like laboratory rodents, humans eliminate dioxin more rapidly at substantially increased body burdens. As a result, past estimates of occupational exposure have likely underestimated true exposures, and therefore, estimates of cancer potency from these studies are overestimates (Aylward et al. 2005; Aylward et al. in press).

- 3. New data related to developmental effects of dioxin may modify estimates of risk at low, chronic exposure levels.
 - The rhesus monkeys from the study used as the basis of the ATSDR MRL have been found to have significantly increased PCB body burdens compared to the control monkeys from that study more than 15 years after the last exposure to TCDD (Rier et al. 2001). These data prompted the European Commission Scientific Committee on Foods (ECSCF) and the FAO/WHO Joint Expert Committee on Food Additives (JECFA) to set this study aside as inappropriate for a quantitative extrapolation to humans, because the true TEQ exposure levels at the time of the study could not be determined but were likely to be substantially higher than the nominal TCDD dose (ECSCF 2001; JECFA 2001).
 - Detailed studies in rodents on materna1-fetal distribution of TCDD and other TEQ contributors have demonstrated that studies employing acute gavage administration of TCDD during gestation are likely to significantly overpredict the risk from environmental exposure patterns (chronic low-level exposure to a mixture of TEQ contributors with different pharmacokinetics and distribution characteristics) (Hurst et al. 2000a,b; Chen et al. 2001).
 - Recent data sets and analyses show more rapid elimination of TCDD and other congeners in infants and children than in adults (Kreuzer et al. 1997; Paustenbach et al. 2004; Leung et al. in press; upcoming data on Seveso children). This means that elevated exposures in infants and children (due to breast feeding or increased soil ingestion) do not accumulate in the body to the same degree as in adults.
 - Several international expert committees have established tolerable daily intakes in the range of 2 pg/kg-d for dioxins based on developmental effects data. These TDIs are consistent with but somewhat higher than the ATSDR MRL of 1 pg/kg-d (ECSCF 2001; JECFA 2001; UKCOT 2001).

This brief overview, while not comprehensive, illustrates both the volume and significance of the available new data. The Board of Scientific Counselors should ask ATSDR to wait for the results of the NAS review of the dioxin science before proposing any changes to the DSPG. If changes to the DSPG are to be considered, the available recent data should be included in the development of the proposed changes. Thank you for the opportunity to comment on this matter.

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ATTACHMENT 3

List of Acronyms

BSC — Board of Scientific Counselors

CCEHIP — Coordinating Center for Environmental Health and Injury Prevention

CCC — Chlorine Chemistry Council

CDC — Centers for Disease Control and Prevention

CTS — Community Tribal Subcommittee
DFO — Designated Federal Official
DSPG — Dioxin Soil Policy Guideline

EHSB — Environmental Health Services Branch

EJ — Environmental Justice

EPA — U.S. Environmental Protection Agency

FI — Futures Initiative

GIS — Geographic Information Systems HDWG — Health Department Workgroup

HHS — Department of Health and Human Services

HSEESP — Hazardous Substances and Emergency Events Surveillance

Program

NAER — National Asbestos Exposure Review

NAS — National Academy of Science

NCEH/ATSDR — National Center for Environmental Health/

Agency for Toxic Substances and Disease Registry

NCIPC — National Center for Injury Prevention and Control

NER — National Exposure Report

NHANES — National Health And Nutrition Examination Survey

NIOSH — National Institute for Occupational Health

NOA — Naturally Occurring Asbestos

OD — Office of the Director
OHE — Office of Health Equity

OMB — Office of Management and Budget

OSHA — Occupational Safety and Health Administration

OSI — Office of Strategy and Innovation

PHAs — Public Health Assessments

PPRS — Program Peer Review Subcommittee

SCs — Special Consultants

TAR — Tremolite Asbestos Registry