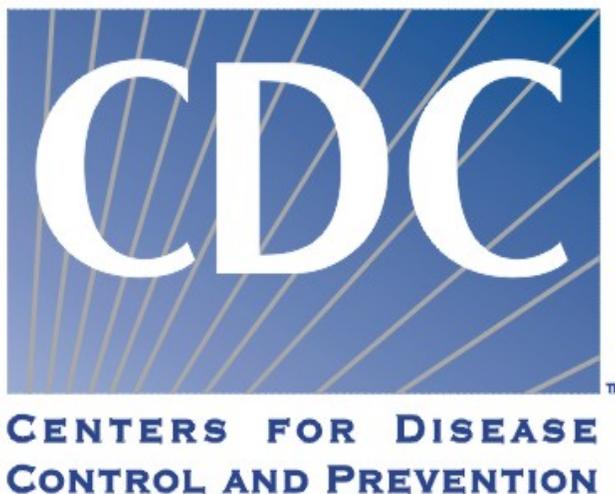


**DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR DISEASE CONTROL AND PREVENTION
National Center for Environmental Health/
Agency for Toxic Substances and Disease Registry
Lead Poisoning Prevention Branch**



**Advisory Committee on
Childhood Lead Poisoning Prevention
March 10-11, 2009
Atlanta, Georgia**

Record of the Proceedings

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ATTACHMENT 1

List of Participants

ACCLPP Members

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Dr. Deborah Cory-Slechta
[via conference call]
Dr. Sher Lynn Gardner
Dr. Kimberly Hansen
Ms. Linda Kite
Dr. Michael Kosnett
Dr. Jessica Leighton
Dr. Brenda Reyes
Dr. Megan Sandel
Dr. Gail Wasserman
Mr. Dana Williams, Sr.

Designated Federal Official

Dr. Mary Jean Brown, Chief
Lead Poisoning Prevention
Branch, CDC

Ex-Officio and Liaison Members

Dr. Walter Alarcon (National Institute for
Occupational Safety and Health)
Dr. Helen Binns
(American Academy of Pediatrics)
Ms. Margaret Easley (American Academy of
Nurse Practitioners)
Dr. Benjamin Gitterman
(American Public Health Association)
Mr. Steve Hays (American Industrial
Hygiene Association)
Dr. Ezatollah Keyvan-Larijani (Council of
State and Territorial Epidemiologists)
Ms. Jane Malone
(Alliance for Healthy Homes)
Mr. Ronald Morony (U.S. Environmental
Protection Agency)
Ms. Jacqueline Mosby (U.S. Environmental
Protection Agency) [via conference call]
Ms. Jodi O'Sullivan (American Academy of
Nurse Practitioners)
Dr. George Rodgers, Jr. (American
Association of Poison Control Centers)
Mr. Jonathan Wilson (National Center for
Healthy Housing)

CDC Representatives

Sara Browning (CDC Contractor)
Barry Brooks
Sharunda Buchanan
Ginger Chew
Kimball Credle
Gerald Curtis
Jay Dempsey
Karen Gavin
Oaiyim Harris
Jeffrey Jarrett
Taran Jefferies
Claudine Johnson
Jacquelyn Mason
Gerri Meadows
Paris Ponder
Marissa Scalia Sucusky
Connie Thomas
Tiffany Turner
Nikki Walker
LaToria Whitehead
Joyce Witt

Guest Presenters and Members of the Public

Maria Doa (U.S. Environmental Protection
Agency) [via conference call]
Ed Norman (North Carolina Division
of Environmental Health)
Adrienne Ettinger
(Harvard School of Public Health)
Jamie Ferman (U.S. Department
of Commerce) [via conference call]
Lisa Miller (U.S. Department of State)
Robb Morse (ESA Biosciences)
Kelly Parkhill (U.S. Department of
Commerce) [via conference call]
Bruce Ross (Food and Drug Administration)
[via conference call]
Anne Wengrovitz (Editor of the Lead and
Pregnancy Report)

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**ADVISORY COMMITTEE ON
CHILDHOOD LEAD POISONING PREVENTION
March 10-11, 2009
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), Lead Poisoning Prevention Branch (LPPB) convened a meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on March 10-11, 2009 at the Westin Atlanta North at Perimeter Hotel in Atlanta, Georgia.

Opening Session

Dr. George Rhoads, Chair of ACCLPP, called the meeting to order at 9:10 a.m. on March 10, 2009. He welcomed the attendees to the proceedings and opened the floor for introductions. The list of participants is appended to the minutes as Attachment 1.

Dr. Mary Jean Brown, Designated Federal Official of ACCLPP and Chief of LPPB, announced that voting members with a real or perceived conflict of interest related to any item on the March 10-11, 2009 ACCLPP agenda would be responsible for identifying these issues and recusing themselves from voting on these topics or participating in these discussions.

Dr. Sharunda Buchanan, Director of the Division of Emergency and Environmental Health Services at CDC, thanked the ACCLPP members for their continued commitment and contributions to childhood lead poisoning prevention. She also acknowledged Dr. Brown and the entire LPPB staff for their outstanding leadership and support of all of CDC's lead activities.

Dr. Buchanan confirmed that CDC's interim leadership is a strong supporter of LPPB's ongoing childhood lead poisoning prevention activities as well as its new healthy homes initiatives. She

encouraged ACCLPP to continue to provide solid advice and recommendations in these areas during CDC's transition to new leadership.

Update on LPPB Activities

Dr. Brown covered the following areas in her update. LPPB had three papers published in peer-reviewed journals in 2008 related to global approaches to reducing lead exposure and poisoning; lead exposures in U.S. children in 2008 and their implications for prevention; and risk factors for elevated blood lead levels (EBLLs) among African children in New Hampshire. LPPB's other three publications in 2008 focused on blood lead levels (BLLs) <10 µg/dL. The six papers were distributed to ACCLPP for review.

LPPB partnered with the CDC Division of Environmental Health Sciences and the Georgia Childhood Lead Poisoning Prevention Program (CLPPP) to conduct a study on screening rates and risk factors for lead poisoning in the city of Atlanta. The geographic information system (GIS) was used to produce maps to determine lead testing rates of children in at-risk neighborhoods.

The study showed that lead testing rates were higher among children in neighborhoods with far less lead paint hazards than children in neighborhoods with high-risk housing built before 1978. The only exception to this finding was in neighborhoods with a large number of children enrolled in Women, Infants and Children (WIC) programs. The study was recently published in 2009 in the *Journal of Pediatrics*. LPPB hopes the peer-reviewed paper will serve as a mechanism to advance efforts to reimburse WIC programs for lead testing of children.

LPPB's review of three National Health and Nutritional Examination Surveys (NHANES) from 1998-2004 was recently published in 2009 in *Pediatrics*. The study showed that EBLLs ≥ 10 µg/dL have dramatically declined in African American, Mexican American and white children over the past 20 years. Racial/ethnic differences among children with EBLLs ≥ 10 µg/dL are no longer statistically significant, but African American children still have a higher geometric mean BLL and more BLLs >2.5 or 5 µg/dL than Mexican American or white children. Tremendous progress has been made in reducing BLLs among children in all racial/ethnic groups, but stronger efforts are needed to achieve the *Healthy People 2010* goal of eliminating health disparities.

LPPB and New York State co-authored a paper that was published in the January 20, 2009 edition of the *Morbidity and Mortality Weekly Report (MMWR)* on the promulgation of the U.S. Environmental Protection Agency (EPA) renovation and repair rule. The regulation requires contractors to disclose lead paint hazards and conduct testing to assure the absence of hazardous lead dust. The study compared the percentage of lead-poisoned children who lived in homes that were renovated in 1993-1994 and 2006-2007.

The study showed that the percentage of children who were exposed to renovation activities more than doubled between 1993-1994 and 2006-2007 and a large proportion of these children

had EBLLs >25 µg/dL. Contrary to the typical demographics of lead-poisoned children, most of the children in the study lived in rural or suburban homes owned by their parents. Results of the study emphasized the importance of EPA's renovation and repair rule and also underscored the need to continue and more strongly target educational efforts to persons who live in and remodel older housing. LPPB aired a podcast on the importance of taking precautions against lead poisoning when remodeling older homes. The podcast was presented to ACCLPP and is available for viewing by the public on the CDC web site.

LPPB conducted a cross-sectional study, one-time assessment in 2008 to quantify levels of mold, allergen and pesticide residue and air compounds in 34 green and 40 conventionally built apartments in Atlanta. The environmental sampling included vacuum dust sampling to collect allergens and mold, kitchen floor wipes to collect pesticides, and passive air diffusion badges to collect other chemicals. The study showed that pest allergens from mice in green built homes were statistically higher. Pest allergens from cockroaches were not statistically different between green and conventionally built housing.

Levels of dust mite allergens were extremely low and were not statistically different between the two types of housing. Visible mold was more likely to be seen in conventionally built housing. High levels of pesticides were observed in both types of housing. In terms of volatile organic compounds, acetaldehyde was detected in every green and conventionally built unit; high levels of isopropyl alcohol were detected in both types of housing; and statistically significant higher levels of formaldehyde were detected in green built housing.

LPPB conducted an investigation in 2008 in response to a request for technical assistance by the Allen County CLPPP in Fort Wayne, Indiana. The CLPPP expressed concern regarding EBLLs 30-60 µg/dL among Burmese refugee children who relocated from Thailand. The children purportedly were exclusively breastfed. Their mothers' BLLs were <5 µg/dL. The children also lived in lead-safe housing that was fairly recently built.

Of 207 children LPPB screened from 128 families, 199 were Burmese refugees. LPPB confirmed 14 EBLLs ranging from 10-29 µg/dL in one apartment complex, detected high levels of urinary arsenic in many of the children with EBLLs, and collected >100 product samples. The investigation is still preliminary at this point, but LPPB expects to report more findings later in the year.

LPPB is conducting an evaluation of the association between prenatal BLLs and auditory brainstem response (ABR) among newborns in two New York City hospitals. The two specific aims of the study are to (1) assess differences in newborn ABR wave data between low exposure of BLLs <10 µg/dL and high exposure of BLLs ≥10 µg/dL in maternal BLL groups and (2) evaluate whether the association between prenatal BLLs and newborn ABRs is modified in a dose-effect manner by the *APOE* polymorphism.

The study participants will include pregnant women and their term newborns seeking maternity health care at two urban hospitals in Elmhurst and Queens Hospital Centers in the borough of Queens, New York City. Pregnant women will be identified for enrollment into the study via a retrospective review of their medical records. The investigators hope to enroll ~300 children in

each maternal BLL group. The data collection process will be conducted from April 2009-April 2010.

The overarching goals of the study will be to strengthen understanding about the effect of lead on the developing fetus in terms of a hearing threshold and timing of exposure; emphasize the importance of maternal blood lead screening; identify an additional neonatal risk factor for hearing loss; assess low-level lead exposure; and focus on newborns rather than children.

LPPB is using a case study of childhood lead poisoning prevention in Savannah, Georgia to assess the influence of environmental justice organizations (EJOs) on public policies and identify the role of EJOs in advancing childhood lead poisoning prevention. LPPB is conducting the study in partnership with the Georgia CLPPP and the Citizens for Environmental Justice.

The study is designed to answer three key research questions: (1) How do EJOs influence changes in policy? (2) How do EJOs help communities that are at risk for lead poisoning to develop a working relationship with policymakers? (3) How do demographic characteristics of the Savannah population, such as race, income and housing factors, impact strategies that decision-makers implement to enforce childhood lead poisoning statutes, laws ordinances or regulations in Savannah?

LPPB sponsored its annual evaluation and training course with the Harvard School of Public Health with 24 students and CDC staff. The CDC/Harvard teams were assigned to assess activities in 12 programs. The Southern Nevada Health Department will evaluate the lead poisoning prevention program in Clark County prior to replicating these laws statewide. The Chicago Healthy Homes Program will evaluate the impact of education about indoor environmental hazards on residents and steps that residents can take to remedy the situation. The Baltimore Coalition to End Childhood Lead Poisoning will evaluate the effectiveness of family advocates in providing an array of available resources and services and creating a customized intervention package for each family.

The Connecticut Lead Poisoning Prevention Program will evaluate the effectiveness of new state legislation that requires annual blood lead screening of all children <3 years of age. The CDC Chemical Weapons Elimination Branch will conduct a program evaluation of its oversight of the closure process and destruction of chemical warfare agents and weapons stockpiles in the United States. The De-Lead Delaware Program will evaluate its \$12,000 per unit grant program that was designed to make homes safer from the hazards of lead-based paint. The state of Tennessee will evaluate its efforts to reduce childhood lead poisoning by providing outreach and education on EPA's lead-based paint regulations.

Kent County, Michigan will evaluate the effectiveness of a joint CDC/EPA program to build a healthy homes project serving an underserved community in Grand Rapids. The Miami-Dade CLPPP will evaluate its strategy of using different childcare centers to implement a healthy housing program. The Mississippi CLPPP will determine the impact, if any, of health education and outreach activities by sub-grantees on lead screening rates in high-risk counties.

The Kansas City Safe and Healthy Partnership will evaluate a demonstration grant by the U.S. Department of Housing and Urban Development (HUD) to provide home-based interventions and education to 300 families affected by either intermittent or persistent asthma. The Miami-Dade CLPP will evaluate the effectiveness of partnering with faith-based organizations to develop a healthy homes initiative.

LPPB submitted a proposal soliciting funding under the American Recovery and Reinvestment Act of 2009 to support the “Evidence-Based Environmental Interventions for Asthma and Healthy Homes Infrastructure” project. The proposal requests funding of \$50-\$100 million for up to four years. The purpose of the proposed project will be to hire and train a workforce within state and local health departments and non-governmental organizations (NGOs) to implement evidence-based asthma and other healthy homes interventions in homes, schools and workplaces.

The proposed project will help existing asthma program grantees to implement two recently developed sets of evidence-based guidelines for asthma management and control and also will assist in the coordination of housing interventions that address other home health and safety issues. If the proposed project is awarded, LPPB will allocate funding over the next two years as outlined below.

Funding of \$10 million per year will be allocated to train healthy homes workers to conduct environmental interventions. Funding of \$30 million per year for two years will be allocated to healthy homes awardees, such as eligible NGOs and state and local health departments. CDC’s existing competitive Notice of Funding Availability (NOFA) of \$600,000 will be used to hire and train healthy homes workers and coordinate activities with existing home visit programs.

Funding of \$2 million will be used for six CDC full-time equivalents to oversee and coordinate all aspects of the project. LPPB expects to receive a decision on its proposal from HHS within the next two weeks. If the proposal is funded, LPPB anticipates that the CDC Procurement and Grants Office will immediately release the NOFA on www.grants.gov with a deadline of ~6 weeks for the submission of applications.

ACCLPP commended LPPB on its outstanding peer-reviewed publications, rigorous studies, innovative research projects, healthy homes NOFA and other activities that have been conducted over the past six months. The ACCLPP members made two key suggestions for LPPB to consider in advancing these initiatives.

First, LPPB should ensure that its educational and outreach activities on EPA’s renovation and repair rule are targeted to “do-it-yourself” home improvement retail stores, local health departments and code enforcement agencies issuing permit applications. Second, LPPB should use the study on the association between prenatal BLLs and ABR among newborns as an opportunity to examine the relationship between BLLs and spontaneous abortion. LPPB also should submit the study to the National Children’s Study as an adjunct research project. The National Children’s Study is currently accepting applications for adjunct studies.

Update by the Educational Intervention Workgroup (EIWG)

Dr. Sher Lynn Gardner, an ACCLPP member and chair of EIWG, reported that ACCLPP unanimously approved a motion to establish EIWG during the March 2008 meeting with the following charge: (1) compile existing evidence; (2) review Parts C and D of the Individuals with Disabilities Education Act (IDEA) and model special education regulations to provide guidance to state and local governments; and (3) describe specific action steps for parents, clinicians and educators.

ACCLPP also charged EIWG with identifying appropriate educational interventions for children with EBLLs; determining whether these interventions should be different from those of children with neurodevelopmental and cognitive delays of other etiologies; and determining if children with known EBLLs should be screened for deficits earlier.

EIWG convened a conference call and a face-to-face meeting in January and February 2009, respectively, with its diverse membership of CDC staff; ACCLPP members and liaisons; parents of lead-poisoned children; and external consultants with expertise in childhood lead poisoning, epidemiology, environmental health, special education, pediatrics and healthy housing issues.

To fulfill its charge, EIWG agreed to review and provide recommendations on revising CDC's 2002 publication, *Managing Elevated Blood Lead Levels Among Young Children*. EIWG also agreed that Chapter 5 of the publication, "Developmental Assessment and Interventions," would serve as the starting point for the review. However, EIWG identified a number of limitations in this section.

All of the citations referenced data that were collected prior to 2000 with the exception of a 2001 paper on succimer. Low-level lead exposure was not incorporated to clarify the slope of the dose-response relationship in BLLs <10 µg/dL. Emphasis was solely placed on IQ-related outcomes. A clear distinction was not made between differential effects and acute versus chronic lead exposure. Poverty, nutrition, and other features or confounders related to lead exposure were not clearly described.

EIWG acknowledged that additional information would be required to clearly define an "educational intervention," clarify the types of necessary educational interventions, and provide recommendations on the appropriate time to initiate an educational intervention. EIWG has taken initial steps to fill these three data gaps. EIWG defined an "educational intervention" as programs and services provided to children for the purpose of improving their ability to learn and succeed in life.

EIWG is still in the process of identifying the types of educational interventions that are needed. EIWG agreed that educational interventions for children with lead exposure should be initiated at the time the exposure is identified and also should include ongoing monitoring of progress to ensure cognitive deficits are addressed. EIWG identified data needs in other areas as well,

including an evidence-based list of known deficits associated with EBLLs, appropriate tools for assessments, and consensus on the appropriateness of specific educational interventions for certain deficits.

In terms of its charge to review existing laws, EIWG agreed that current regulations should provide the maximum benefit and support for children with deficits from EBLLs. As a result, EIWG recognized that its recommendations should be consistent with or potentially modify current laws protecting the rights of disabled persons. In this effort, EIWG extensively discussed two parts of IDEA. Part B of the federal grant program assists states in providing special educational services for children with disabilities in grades K-12, while Part C assists states in providing early intervention programs for infants and toddlers 0-2 years of age.

EIWG will attempt to answer several questions in its review of IDEA and No Child Left Behind (NCLB):

- What are the current implications of IDEA and NCLB?
- What is the impact on reauthorization of IDEA and NCLB?
- Are existing compliance with and current language of IDEA and NCLB sufficiently reflective to provide support for children identified with deficits caused by EBLLs?
- What sections of IDEA and NCLB are subject to negotiation, need clarification or vary in interpretation?
- What will be the impact of EIWG's recommendations on influencing new regulations or laws and including other groups of children?
- What are the practical implications of EIWG's recommendations, such as cost and the availability of specialists for assessments and interventions?

In addition to its review of existing laws, EIWG's next steps will be to focus on children 3-5 years of age who are not covered under IDEA; review the current literature on behavioral versus evidence-based approaches; and attempt to answer two additional research questions: (1) Does the etiology of the deficit make the expression of the deficit significantly different? (2) Do deficits caused by EBLLs improve following education? EIWG has explored the possibility of forming three subgroups to specifically address educational, clinical and legal issues.

Dr. Brown added that EIWG recognizes the need to take caution in making promises in the educational intervention paper. Parents have expressed concern that EIWG might serve as a mechanism for CDC to retract its historical position on the permanency of brain damage caused by lead. To address this concern, the paper will strongly support education and cognitive development of children with lead exposure.

ACCLPP commended EIWG on its tremendous progress since the October 2008 meeting in addressing the complex issue of educational assessments and interventions for lead-poisoned children. The ACCLPP members made several suggestions to assist EIWG in filling data gaps on the definition of "educational intervention," the types of educational interventions that are needed, and the appropriate time to initiate educational interventions.

- EIWG's proposed definition of "educational intervention" is too broad and applies to children in multiple situations. The definition should have a narrower scope and focus to identify specific types of children and describe certain medical treatments or interventions needed by the target population of children. The revised definition should be provided to schools and parents to clearly describe actions that can be taken by parents and school systems.
- Guidance on the types of educational interventions that are needed should include examples of models with a demonstrated track record of success.
- The educational interventions should be displayed in a user-friendly table with columns of different age groups of children, various neurocognitive areas and appropriate interventions to address each area.
- Consideration should be given to identifying the types of programs and services rather than interventions that are needed by the target population of children.
- EIWG should clearly define the goals, target population and expected outcomes of the educational intervention paper. The paper also should include a glossary to ensure that terms are clearly defined for various sectors and disciplines.
- EIWG's proposed definition of the appropriate time to initiate educational Interventions should be modified as follows: "For children with lead exposure, educational assessment and services as needed should begin at the time of exposure or suspected exposure to lead and include ongoing monitoring of progress to ensure cognitive and behavioral problems are identified and addressed early."
- EIWG's needed information should be changed to "appropriate tools for scientifically sound assessments" and "consensus on which scientifically sound educational interventions are appropriate for the identified deficits."
- EIWG should replace "EBLLs" with "lead exposure" in the proposed definition of the interface with current laws. The term "EBLLs" is limited and does not account for children who have deficits and IQ problems at lower BLLs. The definition should be modified as follows: "To ensure that the law provides the maximum benefit and support for children with current or past lead exposure."
- The educational intervention paper should attempt to demonstrate whether the provision of educational services to lead-poisoned children could reverse cognitive and other types of deficits. After this issue is addressed, the paper should recommend that a cost-benefit analysis of these services be conducted.
- The educational intervention paper should attempt to determine whether children with EBLLs and non-lead-poisoned children with the same delays respond comparably to similar interventions.
- EIWG should form four subgroups to specifically focus on clinical, educational, legal and advocacy issues. However, the scope of each subgroup should be clearly defined in terms of target audiences and the evidence base for recommendations.

Panel Presentation on Lead in Consumer Products

Dr. Michael Kosnett, an ACCLPP member and chair of the Lead in Consumer Products Workgroup (LCPWG), led a panel presentation on this issue. To provide a context for the panel presentation and ACCLPP's discussion, he described several case reports of lead in consumer products.

In case 1, a woman 31 years of age presented to an emergency department (ED) in California with nausea, vomiting and abdominal pain. The patient had a spontaneous abortion two weeks prior to the ED visit and was hospitalized one week later with severe and persistent microcytic anemia with basophilic stippling. The patient had a BLL of 112 µg/dL and a history of taking nine different ayurvedic remedies over a two-month period to increase fertility. Of the nine remedies, four contained lead with an overall lead content of 73,900 ppm. The patient discontinued these remedies following an abnormal fetal ultrasound one month prior to the ED visit. The case was published in the *MMWR* in 2004.

In case 2, a child four years of age was a recent immigrant to California from Oaxaca, Mexico with a history of ceramic use and consumption of Mexican candies. The child had a BLL of µg/dL, but the environmental investigation was negative. The Mexican candy wrapper was found to have a lead content of 16,000 ppm. The case was published in the *MMWR* in 2002.

In case 3, a child two years of age in California had a BLL of 36 µg/dL and had eaten ~4 ounces of chapulines over the past few days. The chapulines were found to have a lead content of 2,300 ppm. Subsequent testing of other Oaxacan chapuline samples showed lead content ranging from 0-2,500 ppm. The case was published in the *American Journal of Public Health* in 2007.

In case 4, a child four years of age with a history of developmental delay presented to an ED in Minnesota with vomiting and was discharged with a diagnosis of viral gastroenteritis. The patient was hospitalized two days later after returning to the ED with intractable vomiting, a sore stomach and listlessness. The patient had seizures and respiratory arrest on the following day. The CT scan showed cerebral edema and the x-ray displayed "heart-shaped" metallic density in the abdomen.

Testing for heavy metals was requested, but the patient died the following day with a BLL of 180 µg/dL. A heart-shaped charm that was removed from the patient's stomach during the autopsy contained 99.1% of lead. The manufacturer eventually recalled 300,000 similar charms that were made in China and supplied with children's footwear. The case was published in the *MMWR* in 2006.

In case 5, an infant four months of age in Boston was screened for lead before moving into an apartment that had recently underwent lead paint abatement. The infant's BLL was 46 µg/dL and the mother's BLL was 29 µg/dL. The mother prepared her tea and the infant's formula in an imported Iranian samovar made with lead solder. Unboiled water in the samovar had a lead content of 4,000 µg/L after 15 minutes. The case was published in *Environmental Health Perspectives* in 1998.

Dr. Kosnett noted that the panel presentation would focus on four topics. One, what initiatives have been launched to reduce the importation of lead-contaminated consumer products, medicines and food? Two, what strategies can be implemented by U.S. public health officials who discover these hazards to reach out to international partners to prevent distribution in the United States and host countries? Three, what approaches can be used to ensure that lead poisoning prevention expertise from CDC and state and local programs contributes to a worldwide solution? Four, what options are available for multiple government agencies to collaborate on this issue?

Mr. Bruce Ross, Acting Director of the Food and Drug Administration (FDA), joined the meeting by conference call. He explained that FDA's regulatory authority includes responsibility for ~80% of food products as well as human and veterinary drug medical devices, cosmetics, dietary supplements and other products. Overall, FDA is responsible for ~\$1 of every \$5 spent in the United States in terms of regulating products.

FDA centers conduct activities that focus on food safety and applied nutrition, evaluation and research of drugs and biologics, devices and radiologic health, veterinary medicine, toxicology research, and regulatory affairs. FDA's Office of International Programs (OIP) conducts activities at bilateral, regional and multilateral levels and develops common rules to review and regulate products. OIP's primary responsibility is to provide leadership across all FDA centers and serve in a coordinating function for FDA's interactions with international countries.

OIP also collaborates with foreign regulatory authority counterparts, provides technical cooperation and assistance, operates an extensive capacity building program to respond to specific requests, manages FDA's foreign offices, and maintains international memoranda of understanding, confidentiality agreements and other formal arrangements to share pre-decisional data on product reviews, decisions and actions with regulatory authorities.

FDA has placed stronger emphasis on addressing challenges and unique regulatory problems related to globalization over the past decade. The dramatic increase in the manufacturing of products outside of the United States, inclusion of foreign sources or ingredients in products, volume of imported goods, and number of international trading companies has required FDA to change its traditional process of regulating food and medical products. This trend also has presented additional opportunities for fraud, mismanagement, contamination and inconsistency of products.

FDA acknowledged the need to increase its presence and engagement overseas to be more effective in regulating products in the United States in the 21st century. Most notably, many international countries have no or limited capacity to oversee product regulation and minimal ability to monitor the testing of exported goods. FDA also recognized that its traditional approach of regulating products within the U.S. borders was outdated, ineffective, dangerous and irresponsible.

Over the past two years, FDA has focused on developing the "Beyond Our Borders" initiative to increase its overseas staff, strengthen its global presence in five different regions of the world, and implement a prevention, intervention and response strategy for all aspects of the

manufacturing cycle. FDA is taking a number of actions to advance the Beyond Our Borders initiative, such as:

- expanding regulatory capacity building activities;
- engaging other counterpart agencies and governments;
- strengthening partnerships with international standards development organizations to harmonize regulations;
- increasing the number of foreign inspections in pre-approval, post-market and good manufacturing practice processes;
- developing strategies to receive and use inspection reports provided by foreign counterpart regulatory agencies or authorities to guide decision-making;
- involving third-party certification to obtain quality information regarding the competency of manufacturing firms; and
- improving information technology capacity and databases throughout FDA to more easily share data.

FDA designed the Beyond Our Borders initiatives with seven key objectives:

1. Increase in-country knowledge about the production and transport of products to the United States.
2. Collaborate with trusted counterpart agencies overseas to leverage resources related to science, inspections and other issues.
3. Involve counterpart agencies to build capacity when requested.
4. Engage trusted third parties from both public and private sectors with known capabilities to provide helpful information about regulated compliance and FDA standards.
5. Engage regulated industries to provide clearer information about their expectations and standards as well as those of FDA.
6. Partner with U.S. government (USG) agencies that are working overseas with a mission that is complimentary to FDA.
7. Strengthen capacity to perform more overseas inspections of high-risk facilities.

The overarching goal of the Beyond Our Borders initiative will be to ensure that products meet USG standards before reaching the ports of the United States. To successfully implement the initiative, FDA determined that its international offices would need to be located in China, India, Europe, Latin America and the Middle East. FDA is aware that these five geographic regions represent the major sources of food and drug products imported to the United States.

Although consumer product safety at the global level was incorporated into FDA's statutory mission in 1997, political will and funding were only recently aligned in FY2008 for FDA to develop and implement the Beyond Our Borders initiative. This change reflects a matured global marketplace for FDA's products; helps solve emerging problems related to the shift in the manufacture of drug products and active pharmaceutical ingredients to China and India as well as the development of the generic drug industry in the developing world; and implementation of clinical trials in non-regulated third world countries. Overall, FDA expects the Beyond Our

Borders initiative to meet the USG mission by enhancing the global knowledge base and leveraging resources overseas.

Mr. Kelly Parkhill, Acting Director of Policy in the U.S. Department of Commerce (USDOC), joined the meeting by conference call. He described USDOC's four primary agencies. The International Trade Administration has responsibility for international agreements that focus on import safety issues via standards or bilateral agreements. The National Oceanic and Atmospheric Administration has responsibility for seafood issues. The National Institute of Standards and Technology has responsibility for consumer products. The Patent Trademark Organization has responsibility for intellectual property rights protection.

USDOC has no direct regulatory authority on import safety, but is actively involved in this issue through close collaboration with other USG agencies and various programs. For example, USDOC is the lead agency on the Interagency Import Safety Workgroup because counterfeit goods are the primary source of import safety problems. USDOC has the most experience at the federal level with industry and business partners in maintaining product safety for both consumers and industry related to the integrity of brands.

USDOC partners with standards development organizations, the Asia-Pacific Economic Cooperation (APEC), World Trade Organization on sanitary measures, and technical assistance programs in Brazil, China and India. USDOC has a memorandum of agreement with FDA and other interagency agreements with the Consumer Product Safety Commission (CPSC) and U.S. Customs and Border Protection to better address and more quickly respond to issues related to food safety, medical and pharmaceutical devices, and import product safety. USDOC also collaborates with industry on food and toy safety issues and is currently exploring strategies to improve monitoring of imported products.

Ms. Jamie Ferman, of USDOC, joined the meeting by conference call. She explained that USDOC, APEC and CPSC are currently conducting a joint project on toy safety. Funding for the project will support two toy safety seminars. The first seminar will include representation by regulators of the 21 members of the APEC Economies in Singapore. This event will be used as a forum to share best practices on toy safety. CPSC will present its new lead regulations and other requirements under the Consumer Product Safety Improvement Act (CPSIA) of 2008. CDC, FDA, USDOS and other federal agencies are welcome to attend or make a presentation during the seminar.

The second seminar will be held in January 2010 in Hong Kong with representation by all sectors of industry to explain various requirements. USDOC plans to use this event to showcase the United States as a leader in toy safety and emphasize the need for harmonization of toy safety regulations. USDOC is currently compiling and will disseminate best practices on complying with the new toy safety regulations.

Ms. Lisa Miller, a Foreign Service Officer in the U.S. Department of State (USDOS), explained that USDOS is neither a regulatory nor a technical agency. USDOS's primary function in consumer product safety at the global level is to provide diplomatic support and coordination.

Although USDOS has not been actively engaged in lead in consumer products, this issue is extremely important to the agency.

USDOS has staff in numerous geographic regions in the world, particularly in locations where local regulatory and technical agencies have no personnel. USDOS uses its global presence to facilitate contacts and serve as a spokesperson to foreign regulatory governments and agencies. However, USDOS's primary barriers to increasing its overseas involvement in lead in consumer products is a severe staff shortage and an inability to demonstrate to leadership the importance of lead as an international public health issue.

USDOS asked ACCLPP, CDC, FDA, USDOC, and other federal partners and stakeholders to provide maps, lists of countries, study results and other data pinpointing the actual geographic locations where lead is an international problem. USDOS could use this information to influence leadership to address the health and technical aspects of lead. USDOS is currently attempting to strengthen its formal relationships with CDC and other HHS agencies in this effort.

ACCLPP applauded the USG agencies for taking innovative steps to prevent or minimize the importation of lead-containing consumer products into the United States. ACCLPP also commended Dr. Kosnett for his leadership of LCPWG. However, the members extensively discussed their concerns about the inability of USG agencies to enforce consumer product regulations overseas. Several ACCLPP members made suggestions for LCPWG to consider in its ongoing efforts to address this problem.

- The USG agencies should extensively engage political advocates, Ministries of Health and government staff at all levels in foreign countries to launch a public campaign about the dangers of lead in consumer products.
- The USG agencies should ensure that scientific data on lead in consumer products are appropriately translated in laymen's terms for use by advocates and policymakers in foreign countries.
- The USG agencies should develop and distribute a resource guide to local health departments in the United States as well as to counterpart agencies and other colleagues in foreign countries. The guide should contain contact information of appropriate agencies to contact for specific issues related to lead in consumer products and an algorithm or decision tree of actions to take.
- LCPWG should establish a long-term goal of providing a forum for USG agencies to jointly build relationships in foreign countries and change practices in the field regarding lead in consumer products.
- LCPWG should engage the Pan American Health Organization, non-governmental organizations (NGOs), professional associations, the World Health Organization (WHO) and other multilateral organizations in its activities. For example, WHO could provide a foundation for broader discussion and endorsement of a consensus-based standard on lead in consumer products. This approach also could elevate political attention to the problem.

Dr. Brown made a number of comments in response to the panel presentation and ACCLPP's discussion on lead in consumer products. First, CDC can provide case reports, studies, maps and other data to assist USDOC in making a strong case to leadership that lead is an international health problem. Second, CDC previously published a notice in the *Indian Physician Newsletter* regarding ayurvedic medicines and the importation of products from India. Although the notice was well received by Indian physicians at that time, the ayurvedic medicine community in India recently wrote a series of letters criticizing a CDC-sponsored investigator about the level of poison in Western medicines.

CDC also was criticized during a site visit to Mexico to discuss the lead content in Mexican pottery. The Mexican Minister of Culture accused American physicians of attempting to destroy the culture of Mexico. Dr. Brown supported ACCLPP's suggestion for USG agencies to jointly build relationships in foreign countries. Based on CDC's past experiences, however, she cautioned that the success or effectiveness of this effort might be limited. Third, an interagency workgroup has been discussing the problem of lead in consumer products for the past four years. With the formation of LCPWG, Dr. Brown was in favor of expanding the interagency workgroup at this time to include non-governmental representatives.

Overview of the Worldwide Phase-Out of Lead Paint

Dr. Maria Doa, Director of the National Program Chemicals Division at EPA, joined the meeting by conference call. She announced that a global partnership is being developed to phase-out lead paint. The effort was launched in response to a proposal by the International Forum on Chemical Safety and international NGOs that was submitted during the International Conference on Chemicals Management. The United States expressed an interest in this issue and asked to co-facilitate the development of an information document and a proposed action.

The draft information document made a strong case to support the worldwide phase-out of lead paint. The revised draft was distributed in February 2009 for comment by international NGOs and industry groups. The draft information document, proposed action and a comprehensive list of potential cooperative actions also were provided to ACCLPP for review, comment and suggestions for improvement. Dr. Doa requested ACCLPP's input at this time because the documents would be presented during the International Conference on Chemicals Management in Geneva in May 2009.

The ACCLPP members made three key comments to refine the draft information document on lead in paint.

- Figure 1 in the section on "Societal Impacts of Lead Poisoning in Children" is a hypothetical and misleading model that is not supported by data. The model assumes that the impact of lead is the same across the distribution of IQs, but this finding has not been necessarily demonstrated in nature. CDC should provide EPA with language to

clarify that the hypothetical curve and major assumption in the model might poorly represent deficits at the bottom of the distribution of IQs.

- Language should be added to Figure 4.9 to clarify that although lead exposure is ranked as number 16 of the 20 leading risk factors for burden of disease, this issue is extremely important. Alternatively, risk factors that are ranked as numbers 21-30 could be added to Figure 4.9 to place lead exposure in the middle rather than at the bottom of the graph.
- A new paragraph on lead exposure to women of childbearing age and the transfer of lead to the fetus should be added to the section on the “Magnitude of the Problem.”

Dr. Brown announced that she drafted a letter and a memorandum to CDC leadership regarding the global partnership to phase-out lead paint. The letter is addressed to Dr. Richard Besser, Acting Director of CDC, and would be signed by both Drs. Brown and Rhoads. ACCLPP’s comments on the letter are outlined below.

- The terms “phasing out lead in lead-based paints” and “completely phase-out lead in paint” are inconsistent, confusing, and should be modified with the following language: “phase-out lead from lead paint.”
- The last sentence in paragraph 2 should be modified to clarify that “paints containing lead are still widely manufactured and sold for residential, general and commercial use.”
- The following wording should be added as the last sentence in paragraph 2: “In fact, 60% of paint in one country has lead.”
- The last sentence in paragraph 3 should be changed to “paints that are sold in other countries regularly make their way to domestic markets.” The remainder of the sentence should be deleted.
- The wording in paragraph 4 should be changed to “childhood lead poisoning has dramatically fallen from over a million children ...”.
- Bullet 4 should be modified with the following language: “share information on national, state and local laws ...”.
- The following wording should be added as new bullets 6 and 7: “offer technical expertise in the design and implementation of blood lead prevalence studies” and “offer technical expertise to determine consumer products that contain lead paint.”
- The bullet on building laboratory capacity should be revised with the following wording: “to provide training to maintain high-quality testing in laboratories for lead paint.”
- The last bullet should be modified as follows: “contribute to communication messages and capacity building for healthcare providers, caretakers, parents, renovators, painters, and other professionals to minimize children’s exposure to lead paint.”
- The ending statement should encourage Dr. Besser to request that the HHS Secretary urge the Secretary of State to express U.S. support for the resolution to phase-out lead paint.
- The letter should be provided to the permanent CDC Director after this appointment is made.
- Dr. Doa should be copied on the letter in order to share the document with USDOS staff. Dr. Doa will ensure that the letter is stamped “draft” prior to distribution.

The memorandum is addressed to Dr. Howard Frumkin, Director of NCEH/ATSDR, and Dr. Henry Falk, Director of the Coordinating Center for Environmental Health and Injury Prevention. The memorandum would be from both Drs. Brown and Rhoads and would serve as a transmittal letter to introduce the letter to Dr. Besser. ACCLPP's comments on the memorandum are outlined below.

- The phrases "lead in lead-based paints" and "lead in paint" should be changed to "lead paint."
- The recommendation should be changed to "ACCLPP formally recommends."

Dr. Rhoads entertained a motion for ACCLPP to approve sending the letter and memorandum to CDC leadership with the revisions noted for the record. **The motion passed with a majority vote of 10 members in favor and 1 member opposed.**

Dr. Brown confirmed that the revised memorandum would be distributed to Drs. Falk and Frumkin, with a copy to Dr. Doa, no later than March 13, 2009.

Public Comment Session

Dr. Rhoads opened the floor for public comments; no participants responded.

With no further discussion or business brought before ACCLPP, Dr. Rhoads recessed the meeting at 4:30 p.m. on March 10, 2009.

Overview of the North Carolina CLPPP

Dr. Brown reconvened the ACCLPP meeting at 9:05 a.m. on March 11, 2009 and yielded the floor to the first presenter.

Mr. Edward Norman, of the North Carolina Division of Environmental Health, explained that North Carolina is the tenth most populated state with a population of ~9 million persons. The state is the number one producer of furniture, tobacco, brick and textiles in the country, but metalworking, chemicals, paper, agriculture and tourism are major industries as well. North Carolina had the fastest growing Hispanic population in the 1990s.

The CLPPP is housed in the Children's Environmental Health Branch with 15 staff, including six regional consultants, a field supervisor, program manager, nursing consultant, training coordinator, health educator, epidemiologist, data analyst, data manager and attorney. A state law was adopted as a result of surveys that were administered in the mid-1980s to determine whether clusters of high-risk children could be identified. The CLPPP was established in 1989 and integrated into the Division of Environmental Health. The CLPPP has a centralized data

system and an Ad Hoc Lead Advisory Committee with representation by health departments and other agencies at state and local levels.

The CLPPP allocates funding from its CDC grant to six local CLPPPs that are housed in health departments and the University and Affordable Housing Coalition, the Duke School of the Environment, and the Environmental Resource Program at the University of North Carolina-Chapel Hill.

The CLPPP has conducted a number of studies on important issues over the past few years, such as differences in BLLs between rural and urban areas, vinyl mini-blinds, GIS mapping of high-risk housing in collaboration with Duke University, and drinking water contamination in Greenville and Durham, North Carolina. The CLPPP is a new grantee of the HUD Lead Hazard Control Grant Program and is continuing its involvement in lead-bearing substances in consumer products and local ordinances.

North Carolina law requires laboratory reporting of all blood lead test results, investigation of confirmed lead poisoning and EBLL cases, and remediation of identified hazards for confirmed lead poisoning cases. The law defines “EBLLs” as BLLs ≥ 10 $\mu\text{g}/\text{dL}$ and “confirmed lead poisoning” as BLLs ≥ 20 $\mu\text{g}/\text{dL}$. North Carolina screening guidelines encourage universal assessment and targeted screening at 12 and 24 months of age or at first entry before 6 years of age. Blood lead testing is mandatory in the state for children enrolled in Medicaid, WIC and the Children’s Health Insurance Program. The state laboratory analyzes blood lead testing data at no charge.

The number of children 6 months to 6 years of age who were tested for lead poisoning in North Carolina increased from 87,895 in 1995 to 150,518 in 2008. The number of children 6 months to 6 years of age with BLLs 10-19 $\mu\text{g}/\text{dL}$ decreased from 718 in 1995 to 179 in 2008, while those with BLLs ≥ 20 $\mu\text{g}/\text{dL}$ decreased from 178 in 1995 to 36 in 2008. Of 682,503 children 6 months to 6 years of age who were tested for lead poisoning in 2004-2008, the prevalence of BLLs ≥ 10 $\mu\text{g}/\text{dL}$ was 0.8% and the prevalence of BLLs ≥ 20 $\mu\text{g}/\text{dL}$ was 0.1%. GIS mapping showed that eastern North Carolina accounted for the largest percentage of children 1-2 years of age with BLLs ≥ 10 $\mu\text{g}/\text{dL}$ in 2004-2008. This part of the state has the oldest housing stock, highest rate of poverty and largest minority population.

The CLPPP takes a multi-tiered approach to follow-up of children with EBLs. For EBLs ≥ 10 $\mu\text{g}/\text{dL}$, diagnostic testing, periodic retesting, a voluntary environmental investigation, health education and nutritional counseling, and case management are performed. For EBLs ≥ 20 $\mu\text{g}/\text{dL}$, a medical evaluation and mandatory environmental investigation and remediation are performed. For EBLs ≥ 45 $\mu\text{g}/\text{dL}$, chelation therapy is performed. CLPPP data collected from 1995 to 2007 showed that children enrolled in the screening program with confirmed EBLs ≥ 10 $\mu\text{g}/\text{dL}$ decreased at both the six-month and one-year follow-up.

The CLPPP replicated Wisconsin’s Medicaid report card project. In this initiative, report cards are mailed to healthcare providers who see at least 15 children 1-2 years of age enrolled in Medicaid over a one-year period. The report cards give providers their overall testing rate, individualized testing rate information, and performance in complying with Medicaid testing

requirements based on a comparison of screening rates in the best county. CLPPP data showed that of 128,237 children 9-35 months who were enrolled in Medicaid in 2007, 73.2% were tested for lead.

North Carolina law contains an innovative provision. The “Voluntary Lead-Safe Housing and Preventive Maintenance Program” targets older rental properties, provides limited liability relief to participants, and offers free risk assessments and clearance testing. The CLPPP is planning to conduct three major projects in the future to address BLLs <10 µg/dL, lead and pregnancy, and the transition to healthy homes.

Update by the Lead and Pregnancy Workgroup (LPWG)

Dr. Jessica Leighton, an ACCLPP member and chair of LPWG, reported that ACCLPP’s feedback on the lead and pregnancy paper during the October 2008 meeting focused on the following sections: conclusions from the scientific literature on neurobehavioral development; the definition of EBLLs and the meaning of ≥ 5 µg/dL; screening, nutritional and breastfeeding recommendations; occupational exposure; and research, policy and health education needs.

Dr. Leighton conveyed that following the October 2008 meeting, LPWG developed language to address ACCLPP’s input. Her summary of LPWG’s proposed final revisions to the lead and pregnancy paper is outlined below.

Title

- Proposed Final Language: *Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women*

Neurobehavioral Development

- Proposed Final Language: Recent epidemiologic cohort studies suggest that prenatal exposure, even with maternal BLLs below 10 µg/dL, is inversely related to fetal growth and neurobehavioral development independent of the effects of postnatal exposure. Exact mechanism(s) remains uncertain.

BLLs >5 µg/dL

- Proposed Final Action: The term “EBLLs” will not be used to characterize pregnant women. The term “BLLs” will be used to guide specific clinical recommendations. A “bright line” will not be declared to describe health effects.

Screening Recommendations

- Proposed Final Language: In clinical settings where routine blood lead testing of pregnant women is not indicated on the basis of community-specific risk factors, healthcare providers should consider the possibility of lead exposure in individual pregnant women by evaluating risk factors for exposure as part of a comprehensive occupational, environmental, and lifestyle health risk assessment of the pregnant woman. Blood lead testing should be performed if an individual risk factor is identified.

General Nutritional Recommendations

- Proposed Final Language: All pregnant and lactating women should avoid the use of alcohol, cigarettes, herbal medicines, and any other substance that may adversely affect the developing fetus or infant.

Nutritional Recommendations for BLLs >5 µg/dL

- Proposed Final Language: In pregnant and lactating women with BLLs ≥ 5 µg/dL or with a history of lead exposure, dietary calcium intake of 2,000 milligrams daily should be maintained either through diet or in combination with supplementation. All pregnant and lactating women should be evaluated for iron status and supplementation provided in order to correct any iron deficiency.

Breastfeeding Recommendations

- Proposed Final Language: Mothers with BLLs <40 µg/dL should breastfeed. At maternal BLLs between 20-39 µg/dL, data do not exist to accurately weigh the risks of lead exposure from breast milk against the benefits of breastfeeding. Thus, a prudent course of action is for these women to initiate breastfeeding accompanied by sequential mother and infant BLLs to monitor trends so that adjustments can be made if indicated. Infants born to mothers with BLLs ≥ 5 µg/dL should be blood lead tested at birth and followed according to the schedule in Chapter 5. Mothers with confirmed BLLs greater than or equal to 40 µg/dL should begin breastfeeding when their BLLs drop below 40 µg/dL. Until then, they should pump and discard their breast milk. Breastfeeding should continue for all infants with BLLs below 5 µg/dL. For infants whose BLLs are rising or failing to decline, environmental and other sources of lead exposure should be evaluated. If no external environmental sources are identified and maternal BLLs are >20 µg/dL, then discontinuation of breastfeeding should be considered until maternal BLLs decline.

Occupational Exposure

- The section on occupational exposure was significantly revised with comments and data submitted by Dr. Kosnett. The section recommends medical removal of pregnant or lactating women with BLLs >10 µg/dL.

Research Needs: Biomedical

- Proposed Final Data Needs:
 - Long-term prospective studies on the effect of lead exposure during fetal development and disease risks later in life.
 - Follow-up studies of pregnancy outcomes and infant development in women with a history of lead exposure during pregnancy.
 - Studies on genetic susceptibility to adverse effects of lead exposure (gene-environment interactions).
 - Studies to determine whether BLL thresholds exist for specific adverse health effects due to lead exposure during pregnancy.

- Studies to determine the value of maternal biomarkers in predicting infant and childhood BLLs in the future.
- Studies on the biokinetics of lead in breast milk.
- Studies on the biokinetics of lead with nutritional supplementation or super-supplementation during pregnancy.
- Pharmacokinetics studies to determine the effectiveness of chelating agents during pregnancy and lactation.
- Studies on the role of educational and developmental support and intellectual stimulation in improving academic/life performance of children exposed to lead *in utero*.
- Studies on the identification and development of new therapeutic agents to remove lead from bone or tissue storage sites in women of childbearing age.

Research Needs: Health Services

- Proposed Final Data Needs:
 - Estimates for the number of pregnant women in the United States who should have blood lead tests and the costs and benefits associated with testing and follow-up care.
 - Guidance to validate risk questionnaires for pregnant women in specific clinical settings and subpopulations.
 - Determination on optimal timing for blood lead testing during pregnancy.
 - Characterization of risk factors for pica and clinical strategies to identify pica in pregnant and lactating women.
 - Identification of the effectiveness of interventions to reduce pica among pregnant women.

Policy Needs

- Proposed Final Data Needs:
 - Strategies to make current occupational standards stronger and more protective.
 - Regulation of alternative medicines and dietary supplements to ensure product safety and accuracy in labeling and marketing.
 - Regulatory authority to require lead safety in dwellings occupied by pregnant women and resources to control lead hazards in these units.
 - Reimbursement for testing and follow-up care for uninsured (immigrant) pregnant women and their infants.

Health Education Needs

- Proposed Final Data Needs:
 - Continuing medical education on lead and pregnancy.
 - Environmental health requirements in basic practitioner's curriculum.
 - Expansion of resources to support national centralized data collection and management facilities.

Dr. Leighton recognized Dr. Adrienne Ettinger, of the Harvard School of Public Health, and the other LPWG members for their diligent efforts in extensively revising the last iteration of the lead

and pregnancy paper. She also acknowledged Ms. Anne Wengrovitz for serving as the editor of the document.

Dr. Leighton noted that the most recent version of the lead and pregnancy paper was distributed to ACCLPP for review, discussion and input. She asked the members to submit final comments on the document no later than March 31, 2009 to her, Dr. Ettinger and Ms. Wengrovitz at anne.wengrovitz@gmail.com. After LPWG incorporated the comments in April 2009, CDC would e-mail the revised final draft and a voting form to ACCLPP in early May 2009.

ACCLPP agreed to submit additional comments in writing to LPWG on the form that was provided. ACCLPP also agreed to submit comments in a Microsoft Word document and reference the corresponding page and line numbers. LPWG would compile and distribute individual comments to the entire ACCLPP membership along with the disposition of each comment.

ACCLPP applauded LPWG on its outstanding efforts in developing the complex lead and pregnancy paper and harmonizing numerous comments and revisions over the past four years. The members made several suggestions for LPWG to consider in revising the final draft.

- The renovation project that is referenced in the paper should be replaced with a citation of a better study to show that peeling paint does not affect pregnant women.
- The paper should highlight the longstanding problem of transferring information from the maternal to the infant medical record. As a solution to this issue, a new policy recommendation should be added to encourage the inclusion of maternal blood lead test results in electronic and other medical records that are available to pediatricians. A list should be provided of potential data elements to include in the maternal electronic medical record.
- The vitamin D section is outdated and does not include 2000-2004 data that were released in 2008. LPWG should consult with Dr. Helen Binns, the ACCLPP liaison to the American Academy of Pediatrics (AAP), to obtain the more recent data, references and AAP's recommendations on pregnant women.
- The recommendation for continuing breastfeeding should be modified as follows: "For infants whose BLLs are ≥ 5 $\mu\text{g}/\text{dL}$ and are rising or failing to decline, environmental and other sources of lead exposure should be evaluated. If maternal BLLs are >20 $\mu\text{g}/\text{dL}$, breastfeeding can be initiated, but the infant's BLL should be followed. If no external environmental sources are identified and the infant's BLL increases by more than 5 $\mu\text{g}/\text{dL}$, temporary interruption of breastfeeding should be considered." The text of the paper should emphasize that in this situation, one environmental inspection would not be sufficient and other sources of lead exposure should be reevaluated.
- The mining industry should be highlighted as an additional occupational source on page 27.
- The "Summary of Public Health Actions" in the Executive Summary should recommend a medical removal from occupational exposure for pregnant or lactating women with BLLs ≥ 10 $\mu\text{g}/\text{dL}$.

- The paper should be distributed to maternal/child health organizations and advocates for review and input before being finalized and published. This approach might minimize potential controversy with the recommendation to consider temporary interruption of breastfeeding with maternal BLLs ≥ 20 $\mu\text{g/dL}$. LPWG should engage Dr. Phyllis Stubbs-Wynn, the ACCLPP *ex-officio* member for the Maternal and Child Health Bureau in the Health Resources and Services Administration, to facilitate this effort.
- The biomedical research need to “determine whether BLL thresholds exist for specific adverse health effects due to lead exposure during pregnancy” should be deleted.
- “Research with some variation in study design compared to traditional cohort studies on blood lead” and “studies on adding materials to remove lead from breast milk after pumping” should be included as new biomedical research needs.
- The health services research need should be modified as follows: “estimates on the number and distribution of pregnant women in the United States who should have blood lead tests.”
- “Data collection and mandatory reporting of BLLs for all pregnant women” should be added as a new policy need.
- The Executive Summary should contain a statement to explain that the lead in pregnancy paper is not intended to address potential lead exposure in women prior to conception or in men.

ACCLPP Business Session

Dr. Brown made a series of announcements. An appropriations bill was signed on the previous evening to officially rename LPPB to the “Lead Poisoning Prevention and Healthy Housing Branch” and expand its mission to include healthy housing programs and holistic approaches to housing. However, CDC will continue its strong commitment to focus on lead poisoning prevention, address other lead issues, and institutionalize approaches to lead poisoning prevention in all of its funded lead and healthy housing programs.

Dr. Brown regrettably announced that Dr. Michael Shannon, a former ACCLPP member and a dear friend to her, ACCLPP and the entire LPPB staff, unexpectedly died on the previous day. After his four-year term on ACCLPP ended in the mid-1990s, Dr. Shannon later served as an external consultant to LPWG as a liaison to the American Academy of Pediatrics.

Dr. Shannon was a pediatrician at Children’s Hospital of Boston, a specialist in childhood lead poisoning, and a strong advocate for children both domestically and internationally. Dr. Brown had known Dr. Shannon since his residency at Boston’s Children’s Hospital and she stated for the record that she would deeply miss her friend and colleague.

Dr. Brown read the following statement into the record that Dr. Kosnett drafted in remembrance of Dr. Shannon:

“The CDC Advisory Committee on Childhood Lead Poisoning Prevention notes with sadness the passing of Dr. Michael Shannon of Harvard University. He was a renowned specialist in the field of pediatric emergency medicine and medical toxicology. Dr. Shannon was respected worldwide as an expert in childhood lead poisoning. Through his dedicated patient care to countless numbers of lead-poisoned children, his scholarly contributions to the medical literature, and his highly regarded efforts as a teacher of students and colleagues, Dr. Shannon was a towering figure in lead poisoning prevention efforts. He will be deeply missed.”

Dr. Brown announced that CDC would convene the 2009 National Environmental Public Health Conference at the Sheraton Atlanta Hotel in Atlanta, Georgia on October 26-28, 2009. The deadline for the submission of abstracts is May 8, 2009 and registration for the conference would open on June 1, 2009. The conference would be organized with tracks on healthy housing and other important environmental health issues.

Drs. Brown and Rhoads presented certificates of appreciation to Drs. Magaly Angeloni and Valerie Charlton, *in absentia*, whose terms end in May 2009. The participants joined Drs. Brown and Rhoads in applauding Drs. Angeloni and Charlton for their valuable service to ACCLPP and their commitment and dedication to the children of the United States.

Dr. Angeloni commended Dr. Brown for her unconditional commitment to lead and healthy housing as well as her leadership and proactive approach to obtaining Congressional approval to rename LPPB and expand its scope and mission to include healthy housing. Dr. Angeloni strongly urged ACCLPP to continue to provide solid guidance to LPPB during its transition. She asked ACCLPP to formulate strong recommendations on interventions and other activities grantees and health departments would need to conduct to successfully make the shift to healthy housing. She encouraged ACCLPP to extensively discuss this issue during the next meeting. Dr. Angeloni thanked CDC for providing her the opportunity to serve on ACCLPP.

Dr. Kosnett informed ACCLPP that he recently wrote a paper entitled *Health Effects of Low Dose Lead Exposure in Adults and Children, and Preventable Risk Posed by the Consumption of Game Meat Harvested with Lead Ammunition*. He planned to introduce this issue to LCPWG and present findings and recommendations to ACCLPP in the future. The paper was distributed to ACCLPP for review.

Ms. Jane Malone, the ACCLPP liaison to the Alliance for Healthy Homes (AHH), announced that AHH and the National Center for Healthy Housing (NCHH) co-authored a letter to Ms. Lisa Jackson, the newly appointed Administrator of EPA. The purpose of the letter was to assure the timely and effective implementation of EPA's lead renovation remodeling and painting rule by the April 22, 2010 deadline. The letter was distributed to ACCLPP for review.

Mr. Ronald Morony, the alternate *ex-officio* member for EPA, confirmed that EPA is taking steps at this time to implement the lead renovation remodeling and painting rule by the April 22, 2010 deadline. EPA has not identified any impediments to meeting the deadline. Mr. Morony also confirmed that he would convey ACCLPP's offer to provide technical assistance and expertise to EPA and the Ad Council on publicizing the rule and designing outreach messages.

Mr. Jonathan Wilson, the ACCLPP liaison to NCHH, added that CDC's role in publicizing EPA's lead renovation and remodeling rule should be to inform CLPPPs about the April 2010 deadline for implementation. Estimates show that ~240,000 contractors in the United States will need to be trained on the new rule over the next year. CDC also should educate CLPPPs about their role in widely publicizing the rule in local communities throughout the country, potentially providing space for training sessions or serving as trainers.

Public Comment Session

Dr. Rhoads opened the floor for public comments; no participants responded.

Closing Session

The next ACCLPP meeting would be held on October 21-22, 2009 in Washington, DC. Dr. Brown informed ACCLPP that this location was selected because the Surgeon General's Call to Action on Healthy Homes is expected to be released in June 2009. The new Surgeon General, if appointed by October 2009, would be invited to the next ACCLPP meeting.

With no further discussion or business brought before ACCLPP, Dr. Rhoads adjourned the meeting at 12:04 p.m. on March 11, 2009.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

Date

George G. Rhoads, M.D., M.P.H.
Chair, Advisory Committee on
Childhood Lead Poisoning Prevention

Public Comment Session

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Closing Session

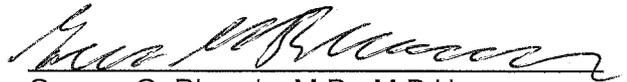
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