DEPARTMENT OF HEALTH AND HUMAN SERVICES

and

CENTERS FOR DISEASE CONTROL AND PREVENTION

convene the

ADVISORY COMMITTEE ON CHILDHOOD LEAD POISONING PREVENTION MEETING

San Francisco, California
October 15-16, 2002

RECORD OF THE PROCEEDINGS

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CENTERS FOR DISEASE CONTROL AND PREVENTION

ADVISORY COMMITTEE ON
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October 15-16, 2002
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Draft Minutes of the Meeting

The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) convened a meeting of the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP). The proceedings were held on October 15-16, 2002 at the Hyatt at Fisherman's Wharf Hotel in San Francisco, California. The following individuals were present to contribute to the discussion.

ACCLPP Members
Dr. Carla Campbell, Chair
Dr. Helen Binns
Dr. Birt Harvey
Dr. Richard Hoffman
Dr. Tracey Lynn
Ms. Amy Murphy
Dr. Sergio Piomelli
Dr. Kimberly Thompson

Designated Federal Official
Dr. Patrick Meehan

ACCLPP *Ex-Officio*/Liaison Members
Mr. Byron Bailey (HRSA)
Ms. Olivia Harris (ATSDR)
Mr. Steve Hays (AIHA)
Ms. Patricia McLaine (NCHH)
Mr. Ronald Morony (EPA)
Dr. George Rodgers (AAPCC)
Dr. Walter Rogan (NIH)
Mr. Robert Roscoe (NIOSH)

CDC Representatives
Ms. Linda Anderson
Mr. Robert Delaney
Ms. Crystal Gresham
Dr. Jeff Jarrett
Ms. Nicki Kilpatrick
Ms. Helen Kuykendall
Dr. Tom Matte
Ms. Susan McClure
Dr. Pamela Meyer
Mr. Timothy Morta
Mr. Gary Noonan
Mr. Kent Taylor

Guests and Members of the Public
Ms. Alise Cappel (CEHN)
Dr. Valerie Charlton (California DHS)
Mr. Sawyer Haig (CEHN)
Mr. Robert Putnam (CITE)
Ms. Renee Robin (CEHN)
Ms. Katie Silberman (CEHN)
Mr. Timothy Sparapani (DSMOD)
Dr. Michael Weitzman (University of Rochester) [via conference call]

***Opening Session*.** Dr. Carla Campbell, the ACCLPP Chair, called the meeting to order at 9:05 a.m. on October 15, 2002. She welcomed the attendees to the proceedings and particularly recognized Dr. Patrick Meehan, the new ACCLPP Executive Secretary. She also thanked Mr. Gary Noonan for serving as the former Designated Federal Official (DFO). Mr. Noonan was pleased to have served in this capacity. He commended ACCLPP on its continued effort to eliminate childhood lead poisoning. Dr. Campbell opened the floor for introductions.

***Update on National Center for Environmental Health (NCEH) Activities*.** Dr. Meehan reported that no ACCLPP member had a conflict of interest based on a review of all financial disclosure forms submitted. He announced that the Lead Poisoning Prevention Branch (LPPB) was recently moved to the Division of Emergency and Environmental Health Services (EEHS). The National Pharmaceutical Stockpile (NPS) is currently housed in EEHS, but the program will soon be transferred to the Office of Homeland Security. LPPB's new position in EEHS will fill the upcoming vacancy by NPS and allow emergency public health and terrorism activities to be more evenly distributed throughout NCEH.

The decision to relocate LPPB was also based on EEHS's strong focus on environmental health services. Lead poisoning has traditionally played a significant role in these types of initiatives. Ms. Linda Anderson will serve as the LPPB Acting Branch Chief until the position is permanently filled. Dr. Meehan presented an organizational chart to inform ACCLPP of LPPB's new location in NCEH and describe EEHS's six branches: Chemical Demilitarization, Emergency Preparedness and Response, Environmental Health Services, International Emergency and Refugee Health, NPS, and Vessel Sanitation.

EEHS is charged with providing technical assistance, guidance and support to front-line state and local environmental health service providers. Many new and emerging health issues are environmentally-related and require environmental health interventions. For example, lead poisoning, mold, injuries and indoor air quality are all components of housing and urban health. Of the 400,000 to 800,000 children with blood lead levels (BLLs) of 10 μg/dL or above, household income, age of housing and other common socioeconomic, demographic or housing risk factors have been detected. Clusters of these risk factors have provided NCEH with significant opportunities to identify high-risk areas from an epidemiological perspective.

As LPPB is more fully absorbed into EEHS, several activities will be conducted. First, high-risk children with elevated BLLs (EBLLs) will continue to be identified through screening. Second, partnerships with the Women and Infants Children (WIC) Program, U.S. Department of Housing and Urban Development (HUD), medical providers and other groups will be strengthened to reach at-risk children who have been traditionally missed. Third, a solid follow-up program will be designed to provide children with full case management services, *i.e.*, screening, provision of lead-safe housing and continued testing. EEHS will extensively use ACCLPP's case management guidelines and recommendations to implement follow-up activities.

Fourth, collaborative efforts will be undertaken with established partners at federal, state and local levels to identify high-risk and housing characteristics; immediately abate risks through primary prevention; take a holistic approach to housing and health issues; and develop local community-based lead elimination plans. EEHS will soon release the new lead poisoning prevention cooperative agreement; the new project cycle begins on July 1, 2003. FY'03 grantees will be required to develop lead elimination plans, more clearly analyze data to target high-risk areas, and illustrate more progress in eliminating lead poisoning. EEHS will circulate the draft cooperative agreement to outside groups for review and comment.

Dr. Piomelli urged CDC to emphasize the responsibility of local public health officers in identifying high-risk areas. Instead of writing prevention papers, CDC should strongly encourage public health officers to make field visits and report locations that are lead poisoned. He pointed out that the need for safe houses is omitted from ACCLPP's previous papers. During remediation, surrounding apartments or homes can become contaminated from lead dust. Dr. Piomelli's position was that ACCLPP should provide education on local residences where children can live during remediation of a lead-poisoned home. He encouraged CDC to support this outreach effort.

Dr. Binns inquired about LPPB's role in EEHS's existing branches and steps that will be taken to ensure lead continues to be a strong priority. Dr. Campbell was pleased EEHS will evaluate housing for risks to children and others. This activity will support ACCLPP's ongoing efforts in both primary and secondary prevention to improve remediation services for homes with environmental hazards.

Dr. Meehan made some follow-up comments in response to ACCLPP's deliberations. CDC will encourage Childhood Lead Poisoning Prevention Programs (CLPPPs) with HUD grants in their jurisdictions to use HUD funding for environmental evaluation and remediation for any low-income housing. These dollars can also be used to support field visits by public health officers in identifying high-risk areas. In EEHS, LPPB will continue to be structured as a separate entity with an independent branch chief and support staff. At $43 million, LPPB will have more funding than any other EEHS branch. LPPB will also be strengthened by the Environmental Health Services Branch and Healthy Homes Project. With LPPB's funding, considerable size and solid network of established partners, lead activities will continue to be a priority within NCEH.

Before opening the floor for the next presentation, Dr. Campbell presented plaques to recognize the diligent efforts and accomplishments of Dr. Birt Harvey, the Case Management Workgroup Chair, as well as Ms. Anne Guthrie-Wengrovitz, *in absentia*, and Dr. Richard Hoffman, the Medicaid Screening Workgroup Co-Chairs. The attendees applauded the achievements of these ACCLPP members. Dr. Campbell also acknowledged valuable contributions by ACCLPP members whose terms recently expired: Ms. Estelle Richman and Drs. Joel Schwartz, Michael Shannon and Michael Weitzman.

***Case Management Update*.** Dr. Harvey outlined the history of the workgroup's activities for the benefit of new members. ACCLPP acknowledged that a stronger focus should be placed on case management due to the collection of new data after the publication of CDC's case management guidance in 1991. Increased emphasis was also needed based on differences among case management recommendations by various cities and states. Experts were selected to advise the workgroup, collect supporting data and assist in developing updated case management guidelines. Drafts were presented to ACCLPP for review and comment and then revised based on this input. The final document was recently published and distributed.

To determine impact of the case management document, the workgroup agreed an independent contractor should administer surveys to case managers and program directors pre- and post-publication. The survey would be designed to identify case management activities at baseline, changes in practice several years after publication and problems with the document. The survey would also provide an opportunity for case managers to make recommendations on improving the document. However, the workgroup was informed that approval by the Office of Management and Budget (OMB) would be needed for a contractor to interview case managers. This process typically requires six to nine months to complete and would not allow baseline data to be gathered.

To overcome this barrier, a telephone interview was administered to only 60 program directors in the United States and was conducted by CDC rather than an outside contractor. The interview questions were refined by a contractor and reviewed by the workgroup. Each interview required one to 1.5 hours to complete and focused on five case management issues: nutritional, developmental, environmental, medical and educational. Since the interview was administered to program directors rather than case managers in the field, the workgroup acknowledges that responses may not be completely accurate. Key findings from the data analysis of 60 programs surveyed are as follow.

- 37% of programs do not evaluate zinc intake.
- 11 programs provide assistance in WIC enrollment.
- 14 programs conduct follow-up to determine whether WIC benefits were received.
- 11 programs never refer a child for a formal developmental assessment by a qualified professional. Of the 49 programs that make referrals, the majority are at BLLs which are inconsistent with the recommendations. Case management guidelines do not recommend referral unless the BLL is >20 μg/dL or other factors influence the child's development. Five programs routinely make referrals when the BLL is 10 μg/dL; eight programs make referrals when the BLL is 15 μg/dL.

- 18 programs do not consider any risk factors other than BLLs in deciding to evaluate a child, such as prematurity, substance abuse or single parenthood.

- 8 programs conduct follow-up after case closure to detect additional problems when the child enters school.

- 8 programs recommend that the primary care physician follow-up the child with surveillance after case closure.

- 17 programs do not address any further issues with the child after case closure.

- 27 programs allow case managers to develop written plans in association with care givers to manage a child with a significant EBLL.

- 19 programs recommend that care givers create barriers to keep children away from obvious sources of EBLL in the home; 41 programs recommend washing hands and toys; 42 programs recommend wet mopping floors; 26 recommend wiping window compartments; 11 recommend leaving shoes at the door; and 7 programs recommend placing floor mats at entryways.

- 41 programs list management of lead hazards in the home as a top priority.

- 36 programs believe a child's age is not a factor in prioritizing environmental assessment.

- 10 programs do not routinely collect dust wipes as a source of lead dust in the home; 53 programs routinely use XRF, which is far less important than dust wipes.

- 36 programs always obtain clearance by dust wipes before a child reenters the home; 7 programs almost always obtain clearance.

- 52 programs never use power sanding equipment to control lead in the home. Since this method is inappropriate, the 8 programs that use power sanding equipment must be educated.

- 48 programs follow up BLLs of 10-14 μg/dL.

- 22 programs recommend a complete history and physical for BLLs <20 μg/dL. Unless other risk factors have been identified, this practice is inappropriate according to the case management guidelines.

- 19 programs routinely test a child for anemia if the BLL is >20 μg/dL.

- 46 programs do not recommend long-bone x-rays; 50 programs do not recommend urinalyses and kidney function tests.

- 20 programs recommend that chelation be undertaken for BLLs <45 μg/dL. This practice is inappropriate according to the case management guidelines.

- 10 programs recommend hospitalization at BLLs <45 μg/dL; 17 programs recommend hospitalization at BLLs 45-69 μg/dL; 9 programs do not recommend hospitalization at any BLL.

- 41 programs follow up with primary care providers at case initiation; 26 programs submit summaries of initial evaluations to primary care providers; 17 provide primary care providers with case closure reports; 26 programs alert primary care providers to the potential for future problems.

Overall, the majority of programs adhere to most case management guidelines, but the rationale for non-compliance with other case management recommendations should be determined. Programs appear to lack solid communication with primary care providers. The survey results emphasize the need for ACCLPP to educate program directors and case managers about appropriate actions to take during the case management of children.

Dr. Pamela Meyer of NCEH reported on activities to disseminate the case management document. Advance copies were distributed to the authors, CLPPPs, various organizations, as well as ACCLPP members, liaisons and *ex officio* representatives. Although 2,000 copies were printed in June 2002, additional requests warranted a reprinting of 3,000 copies in July 2002. The document was also posted on the CDC web site. To publicize the document, communication staff created and distributed advertisements to professional journals with a request that the notices be published.

CDC made presentations on the case management guidelines during a lead conference and a five-day training session by the Louisville, Kentucky lead program. The case management presentation will be repeated during regional lead conferences, the annual program manager training session and other upcoming events in FY'03. CDC has contracted Battelle Memorial Institute (Battelle) to develop a training curriculum, but the tool will first be piloted with 30 participants during three initial training sessions. The curriculum will then be evaluated, revised and refined based on input and more widely launched during five additional training sessions. The workshops will be held in various regions throughout the country to allow both program directors and case managers to attend.

The eight-hour training sessions will cover the five case management areas highlighted in the document. During each workshop, participants will have an opportunity to self-

assess individual case management practices in small groups and compare current activities with the new guidelines. Responses to questions and concerns raised during training sessions will be posted on the CDC web site. Training materials will be developed into a train-the-trainer guidance manual and circulated to all grantees. CDC expects to obtain input on the draft work plan within the next two months, pilot the training curriculum in January 2003 and conduct additional training sessions in March 2003. CDC is also considering the possibility of designing a web-based training program in the future to more effectively meet training needs of grantees.

To determine current case management practices and evaluate impact of the document, Battelle will conduct a survey in the next year with a revised version of the telephone interview. Based on the time-line for OMB approval, two surveys may be administered to case managers.

ACCLPP weighed in regarding CDC's case management activities. Dr. Piomelli expressed concern about the manufacturer's recommendation to use Chemet while a child resides in a lead-contaminated home. He questioned whether the case management document clarifies that a child may absorb more lead while taking an oral chelator. Dr. Harvey confirmed that the document clearly recommends removing a child from a lead-contaminated home if significant renovations will be made. Dr. Binns encouraged CDC to require grantees under the new lead poisoning prevention cooperative agreement to integrate the case management document into programs. She also advised CDC to incorporate the case management training sessions into existing activities rather than develop an isolated eight-hour module.

Ms. McLaine emphasized the importance of adding language in the new lead poisoning prevention cooperative agreement to address funding and resources, particularly for Medicaid-eligible children. Dr. Thompson mentioned that development of online case management training sessions could be an additional requirement under the new cooperative agreement to address the issue of turnover among case managers. Dr. Hoffman suggested that a feedback graph be designed to allow programs to compare and contrast individual practices versus the guidelines. The chart could be tailored and distributed to each of the 60 CLPPPs.

Ms. Murphy added that the CDC project officer should conduct the assessment in conjunction with the program director. When work plans are submitted, the project officer can write specific objectives to address case management deficiencies that were detected in a particular CLPPP. Dr. Thompson inquired whether the survey allowed CDC to capture variability among CLPPPs and identify the most effective programs in reducing BLLs in children. She noted that obstetricians and gynecologists were excluded from the case management document dissemination plan. These providers are in a position to educate women on lead risks prior to giving birth.

Dr. Meyer replied that the telephone interview was anonymous in an effort to obtain honest responses. Although this survey design will not allow CDC to provide input to each individual program, general feedback and comments will be distributed. Dr.

Harvey hoped Battelle's refined survey will capture variability in practices among programs, but he welcomed suggestions from ACCLPP members to further address this issue. Dr. Hoffman acknowledged that this methodology is flawed since many program directors may not recall their responses and therefore would not apply CDC's recommendations.

Dr. Valerie Charlton, of the California Department of Health Services, was interviewed and announced that some survey questions were confusing, particularly dust wipes versus XRF. She also noted that legitimate disagreements or issues can surface from the case management guidelines. For example, the California lead program would conduct a complete history and physical on a child with a persistent BLL of 15 μg/dL, but the guidelines do not recommend this practice on BLLs <20 μg/dL. Nevertheless, she thanked ACCLPP and CDC for developing, distributing and evaluating the case management document. Dr. Rogan suggested that CDC apply the immunization model or use other data as a basis to measure best practices in case management.

Mr. Timothy Morta is an LPPB project officer for the lead poisoning prevention cooperative agreement. He stated that the programs are waiting to receive the new guidelines since case management will have a stronger emphasis in the FY'03 language. CDC will more closely monitor and track case management activities and provide technical assistance based on requests by grantees in quarterly reports. CLPPPs are closely collaborating with HUD, the U.S. Environmental Protection Agency (EPA), community-based organizations and other local groups to leverage additional funding and undertake secondary prevention efforts. LPPB expects the programs to make dramatic changes based on the survey results.

***Primary Prevention Update*.** Ms. Amy Murphy, the Primary Prevention Workgroup Chair, outlined the history of the workgroup's activities for the benefit of new members. Since November 2001, the workgroup has convened several face-to-face meetings and conference calls. During these meetings, the workgroup developed a draft primary prevention document that is targeted to childhood lead poisoning prevention and housing programs at the local level. One of the most significant challenges the workgroup faced was appropriately addressing housing versus other sources of lead exposure.

Based on data from the National Housing And Nutritional Examination Surveys and other sources, housing was found to be the major lead exposure source for children and will be the primary emphasis of the primary prevention document. However, other sources will be incorporated into the document as well. After the draft is finalized, a strategy will be designed for local programs to effectively implement the document. The final document will be published in professional journals to summarize primary prevention recommendations to various audiences, including pediatricians, family practitioners and public health professionals. A web-based questionnaire has also been created and will be distributed to lead poisoning list serve members (to collect information about active primary prevention programs).

The document will contain a living appendix to illustrate concrete approaches programs take to implement primary prevention or use secondary interventions to transition into primary prevention. The workgroup expects to add this component to the document by the next ACCLPP meeting. The workgroup hopes the document will establish a federal infrastructure to sustain primary prevention at the local level and create a sense of urgency to meet the 2010 goal of eliminating lead poisoning.

For the benefit of new members, Drs. Campbell and Meehan explained the roles of workgroups and ACCLPP. ACCLPP members evaluate and discuss issues that require increased emphasis or updated guidance. Recommendations are then made by ACCLPP to establish and charge a workgroup to gather data on a particular issue. Because ACCLPP is the parent committee, information collected by workgroups is presented to all members for review and comment during public meetings. Any recommendations or documents developed by workgroups are considered as ACCLPP products. ACCLPP members volunteer to serve on workgroups, but outside experts, consultants, liaisons and *ex officio* representatives can serve as well.

Although workgroups are limited to a small number of individuals, a chair is still appointed to lead activities. ACCLPP convenes meetings twice a year, but workgroups generally meet by conference calls or face-to-face meetings on a more frequent basis. ACCLPP is a discretionary committee that is chartered to provide advice to the HHS Secretary and CDC Director. The operation, management and activities of ACCLPP are supported by CDC/NCEH/LPPB. CDC justified the need for ACCLPP by emphasizing the importance of receiving expert advice on childhood lead poisoning prevention. The floor was opened for ACCLPP to provide input and recommendations on the primary prevention document.

<u>General Comments</u>

- Develop a more concise and succinct document by decreasing the number of pages from 19 to five. Explain the rationale, briefly describe the context of primary prevention and list recommendations. Move all other text into an appendix.

- Use the case management document as a model and incorporate introductory pages that highlight key points and recommendations for each chapter.

- Describe the magnitude of childhood lead poisoning in more detail to reach audiences that may not be familiar with this issue. For example, clearly explain why childhood lead poisoning is “a major public health problem” at the beginning of the document. Use more basic terminology such as “prevention of lead poisoning of children who live in older housing” rather than “primary prevention.”

- Cite references, solid research and data needs to support key statements, models and strategies described in the document, such as the HIV Testing

Survey that compares prevalence-wide screening data and door-to-door samples. Include epidemiological evidence on EBLLs by region and age of housing to strengthen the rationale for focusing the document on housing as the primary source of lead exposure. Present rigorous evidence on lead dust exposure and other risk factors in children who develop EBLLs to compensate for the lack of data on interventions.

- Explicitly state that variability exists in communities at local, national and international levels and between urban and rural environments. For example, some programs may not view housing as a major problem in lead exposure.

- Outline a strong approach that authorizes entry into lead-contaminated homes and mandates repairs. Place this language in the "Regulatory Infrastructure and Incentives" section. Reference Massachusetts and other states that take civil or criminal actions to enforce compliance with lead-safe housing standards. Add these examples to the living appendix.

- Ensure that ACCLPP's position on primary prevention is emphasized in the document by listing recommendations on a particular issue at the end of each chapter.

- Acknowledge that primary prevention efforts will differ based on variability among private, public or rental housing stock.

- Recommend that fiscal incentives be provided to property owners who reduce risks by complying with lead-safe housing standards.

- Develop a transparent process to clearly identify homes with lead hazards when a regulatory public health approach is taken.

- Take a strong primary prevention position by advocating the elimination of lead into the environment by industries that can economically and viably make substitutions.

- Clearly identify target audiences, messages, expected outcomes and the most effective delivery methods of the document. For example, target the document to reach legislators who protect children.

- Maintain a narrow focus on housing as the primary source of lead exposure; create a companion document to focus on non-housing sources.

- Recommend that pediatricians be an active component in the primary prevention process when birth certificates are issued or when high-risk housing with children has been identified.

- Cite the recommendation in the case management document that supports temporary relocation of families when a home is being remediated and a child has been identified with an EBLL.

- Obtain CDC's full endorsement of the document to ensure credibility, support, cooperation and implementation by EPA, HUD and other agencies. For example, ACCLPP could present its primary prevention guidelines to the Federal Interagency Task Force on Children's Environmental Health.

- Incorporate guidance to empower individuals to identify risk factors and immediately become involved in the primary prevention process.

- Delete "secondary prevention" and "tertiary prevention" throughout the document. Focus on the window of opportunity to prevent lead exposure during a young child's development.

- Add strong and clear recommendations from ACCLPP about the need for local housing programs and non-HHS agencies to provide adequate resources for primary prevention.

- Ensure that the FY'03 lead poisoning prevention cooperative agreement contains language for CLPPPs to play a leadership role in both primary prevention and overall childhood lead poisoning prevention. Achieve this goal by providing CLPPPs with adequate information to make appropriate decisions and evaluate priorities at the local level.

- Add "health departments" and other appropriate agencies to each reference of CLPPPs in the document.

- Add supporting data to illustrate the cost effectiveness of primary prevention interventions described in the document.

<u>Specific Comments</u>

- Page 1: Develop and include a three-page executive summary to highlight the key points of the document for non-technical audiences.

- Page 3: Review data cited in the second and third paragraphs because this information is not consistent with data previously reported by Dr. David Jacobs of HUD.

- Page 4: Delete references to the Treatment of Lead-Exposed Children Trial since the study demonstrated no changes in outcome.

- Page 4: Add “were chelated” after the first phrase in Section II(2) to make a complete sentence.

- Page 4: Include comparative data to the finding of a ”24% decline in children’s BLLs after paint abatement was completed.”

- Page 4: Revise the “Rationale for Primary Prevention” section to focus more on the importance of prevention exposure, *i.e.*, longevity of lead in the human body and the inability to reverse damage caused by lead.

- Page 4: Describe effective strategies to strengthen the “Rationale for Primary Prevention” section. Revise the text to be evidence-based.

- Page 10: Delete paragraphs 2-5 under the “Options for targeting high-risk families with young children” section. Detailed descriptions of these programs are unnecessary for a primary prevention document; the options can be summarized in one sentence.

- Page 12: Decrease the “Existence of Comprehensive Secondary Interventions” section from three paragraphs.

- Page 12: Modify ACCLPP’s recommendation for “HHS and DOA to fund research and demonstration projects” to encourage CDC to immediately undertake this activity in the FY’03 lead poisoning prevention cooperative agreement.

- Page 12: Add language to more strongly emphasize condition of paint, maintenance, housekeeping and other basic housing factors in the “Development of an Evidence-Based, Cost-Effective Lead Safe Housing Standard” section.

- Include data in the “Development of an Evidence-Based, Cost-Effective Lead Safe Housing Standard” section to assist CLPPPs or health departments in making a stronger case when requesting resources from other agencies. For example, the information could contrast costs for primary prevention versus treatment of EBLLs.

- Page 17: Revise the “Collaboration with Multiple Stakeholders” section to be more realistic. CDC can achieve this goal by convening a primary prevention workshop with potential collaborators to discuss interests, issues, lessons learned and best practices of local groups.

- Other: Add an appendix citing the scientific literature to support the “Rationale for Primary Prevention” section on page 4.

On behalf of Dr. Richard Jackson, the NCEH Director, Mr. Robert Delaney welcomed ACCLPP members, liaisons and *ex officio* representatives to the meeting. He emphasized the importance of ACCLPP and recognized its valuable contributions, guidance, efforts and recommendations in preventing childhood lead poisoning. To further contribute to the significant reduction of the childhood lead poisoning burden in the United States, CDC has undertaken collaborative efforts with federal agencies, industry, professional organizations and advocacy groups.

However, established partnerships must be strengthened to reach special populations of children who remain a major public health concern, *i.e.*, those living in older housing with lead paint and lead-contaminated dust and those who are still at high risk for lead exposure. These partnerships must also be maintained to apply the best science, strengthen current programs and develop new strategies to eliminate childhood lead poisoning as a threat to children in the United States. Childhood lead poisoning will remain a top priority within NCEH. CDC looks forward to its continued collaboration with ACCLPP in significantly contributing to one of the most important public health success stories of the decade.

***Federal Advisory Committee Act (FACA) Procedures*.** Ms. Helen Kuykendall, of the CDC Management Analysis and Services Office (MASO), explained that FACA was enacted on October 6, 1972 under Public Law 92-463 as a system to create and operate advisory committees in the Executive Branch of the federal government. Congress created FACA to enhance accountability of advisory committees to the public; protect against undue influence of special interest groups; and reduce wasteful expenditures of public funds. Advisory committees are defined by FACA as "any committee, board, commission, council, conference, panel or task force established or utilized by the federal government for the purpose of obtaining consensus advice or recommendations on issues or policies."

Three types of groups can be chartered under FACA. A discretionary committee is established at the discretion of the agency head; a non-discretionary committee is mandated by legislation or statute; and a presidential committee is created by the President or Congress. Committees subject to FACA are established or controlled by the federal government; have other than full- or part-time federal employees; provide consensus advice; and have a specific purpose, organized structure and fixed membership. "Consensus advice" has not been defined by FACA or the General Services Administration (GSA) Final Rule. For purposes of HHS advisory committees, however, consensus is generally defined as a common viewpoint among members rather than advice from one individual.

FACA requires advisory committees to have a charter, public access and balanced membership in terms of points of view represented and functions to be performed. Advisory committee meetings must be announced in the *Federal Register* at least 15 days prior to the proceedings. The public must be allowed to speak or file written statements during these sessions. Detailed minutes must be created and maintained for each advisory committee meeting. The documents must contain the meeting date

and location; an attendee list; complete and accurate descriptions of discussions and conclusions; and advice or recommendations provided by the committee. Meeting minutes must be completed and submitted to the CDC Committee Management Office (CMO) within 90 days after the proceedings.

Verbatim transcripts are also created and maintained for some advisory committees, but this document is not required by FACA and cannot substitute detailed minutes. Working papers, transcripts, drafts and all other materials shared among an advisory committee must be made available for public inspection as long as the group exists. ACCLPP is a discretionary committee chartered to (1) provide advice and guidance to the HHS Secretary, HHS Assistant Secretary for Health (ASH) and CDC Director regarding new scientific knowledge, technological developments and practical implications for childhood lead poisoning prevention efforts; (2) review and regularly report on childhood lead poisoning prevention practices; and (3) recommend improvements in national childhood lead poisoning prevention efforts. MASO is responsible for assisting ACCLPP in conducting its business and meeting FACA objectives.

ACCLPP is governed by FACA, the GSA Final Rule and departmental and agency policies. FACA requires advisory committee charters to be renewed every two years or the group will be terminated. MASO consults with HHS, GSA and the Office of General Counsel (OGC) to explain the need to continue ACCLPP and describe a plan to ensure fairly balanced membership. Charter renewals must be filed with the GSA Secretariat, standing committees of Congress with legislative jurisdiction over agencies and the Library of Congress. The renewal notice must be published in the *Federal Register* when filed.

In addition to the parent advisory committee, subcommittees or workgroups can be established to conduct business. Subcommittees are members from the advisory committee who report to the parent committee and are subject to FACA procedures. Non-members can serve as consultants to subcommittees if additional expertise is needed. Workgroups are two or more members from the parent committee or subcommittee who gather information, conduct research, analyze facts or address an issue on a short-term basis. Workgroups report to the parent committee or subcommittee and are not subject to FACA requirements. However, all workgroup activities must be presented to the parent committee or subcommittee and discussed in an open session.

Advisory committees are structured with three components. First, the DFO or Executive Secretary supervises day-to-day operations of the advisory committee; approves meeting agendas; attends all committee meetings; and ensures all meeting notices are published in the *Federal Register*. Second, the chair presides over committee meetings; determines the operation of meetings in conjunction with the DFO; ensures public participation; and certifies the accuracy of meeting minutes. The chair is selected by the agency or members and also serves as a committee member. Third, committee members represent fairly balanced points of view; are appointed as special government

employees (SGEs) and must comply with conflict of interest statutes. Members serve overlapping four-year terms up to four years.

FACA defines an SGE as a private citizen appointed by the agency head, HHS Secretary or President. Appointments are based on an individual's expertise that will contribute to the objectives of the advisory committee. Members serve with or without compensation for 130 days or less per year. Members are appointed to express personal opinions only, but are held legally accountable for ethical issues and financial interests. Members must complete and update all required appointment papers and financial disclosure forms; review and comply with standards of ethical conduct for employees of the Executive Branch; attend all meetings; and actively contribute to advisory committee discussions, deliberations and recommendations.

The membership of advisory committees can also contain other individuals. An *ex officio* is typically a federal employee with full voting rights unless prohibited by statute. ACCLPP *ex officios* are currently non-voting members, but voting rights will be granted to these members when the charter is renewed in 2003. Liaisons represent a particular organization on an advisory committee and have no voting rights. Special consultants are invited to serve on advisory committees if additional expertise is needed. In terms of FACA management and communications, working relationships are established between the advisory committee and DFO; CMO and DFO; and OGC and CMO. Recommendations of advisory committees are communicated to the CDC Director and eventually forwarded to the HHS Secretary. Annual reports of advisory committees are submitted to Congress by GSA.

A videotape was presented to further orient the new members on conflict of interest, legal responsibilities of SGEs, financial disclosures and other FACA procedures. Additional information on FACA as well as meeting minutes and annual reports for ACCLPP and other advisory committees can be accessed at www.gsa.gov/committeemanagment. Annual reports outline operating costs, projected expenditures, membership and frequency of meetings. Chapter 9 of the HHS *General Administration Manual* contains policies governing advisory committees and can be accessed at www.psc.gov/hhsmanuals.html.

Dr. Meehan confirmed that he would closely collaborate with Dr. Campbell to more effectively communicate, disseminate and implement ACCLPP's recommendations throughout HHS. ACCLPP guidance is typically submitted to the HHS Secretary and returned to the DFO for a response. With the new process, recommendations will also be forwarded to the CDC Director and HHS ASH. For example, Dr. Meehan plans to telephone the HHS ASH and discuss ACCLPP's document on targeted screening for young children enrolled in Medicaid. At the invitation of the HHS ASH, Dr. Meehan, an ACCLPP member and a representative from the Centers for Medicare and Medicaid Services will discuss the document in more detail during a face-to-face meeting. In the future, ACCLPP communications will be submitted on CDC letterhead since EEHS recently learned that ACCLPP letterhead is in violation of FACA policies and procedures.

***Public Comment Period*.** A letter from Ms. Renee Robin, the California Director of the Children's Environmental Health Network, was submitted into the public record. The letter expresses the group's disappointment and concern that the HHS Secretary overruled CDC's recommendations for ACCLPP nominees. The document is appended to the minutes as Attachment 1.

Dr. Charlton announced that a bill was recently passed in California which makes the presence of deteriorated lead-based paint, lead-contaminated dust, lead-contaminated soil and other lead hazards violations of the housing code. Local environmental and health agencies have been authorized to distribute cease and desist orders in relation to these lead hazards. The new law does not specify age of housing. The legislation can be accessed at www.leginfo.ca.gov.

Dr. Piomelli submitted a letter from Attorney David Schoenbrod into the public record. The document asks ACCLPP to reconsider the definition of "lead poisoning" as childhood BLLs >10 μg/dL. The letter is dated April 24, 1996 and was addressed to Dr. Henry Falk, the ACCLPP Executive Secretary at that time. Dr. Piomelli reported that the letter was never distributed to ACCLPP. The document is appended to the minutes as Attachment 2.

There being no further discussion, Dr. Campbell adjourned the ACCLPP meeting at 5:15 p.m. on October 15, 2002.

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***Update by the Review of Evidence for Effects at Low BLL Workgroup*.** Dr. Campbell reconvened the ACCLPP meeting at 9:00 a.m. on October 16, 2002 and opened the floor to the first presenter. Dr. Michael Weitzman, of the University of Rochester, joined the meeting via conference call. Although his term has expired, he will continue to chair the workgroup that was charged by ACCLPP to review existing data on potential adverse effects in children from lead exposure at levels <10 μg/dL. The workgroup has maintained constant communication and was successful in engaging all outside experts who were asked to assist in this effort. The workgroup welcomes input and recommendations from ACCLPP on the process that has been established to review evidence on low BLL effects.

Dr. Tom Matte of NCEH clarified that neither ACCLPP nor the workgroup is charged to take action on BLLs <10 μg/dL. To date, the workgroup has compiled its membership; identified outside experts to answer scientific questions; and selected Battelle to manage the literature, retrieve data, facilitate logistics, summarize results and support other activities. The workgroup members represent expertise in clinical pediatrics, neuropsychological assessment, environmental epidemiology, lead-related developmental neurotoxicity, biostatistics, quantitative risk assessment and laboratory science. During the literature retrieval process, the workgroup primarily focused on human studies and identified data that included participants with BLLs <10 μg/dL.

The workgroup agreed that animal studies will not sufficiently answer questions related to dose response at a specific range of BLLs. Evidence the workgroup collected to date measures one or more health outcomes. The initial bibliography was limited to toxicological profiles developed by the Agency for Toxic Substances and Disease Registry, but the database is now being supplemented with additional literature searches and studies that are in press or will soon be published. To fulfill its charge and evaluate dose response, the workgroup has focused on high-relevance articles with a large number of study participants with BLLs <10 μg/dL.

To date, only a small number of studies have published results that are directly relevant to health effects at BLLs <10 μg/dL. Other data clearly show a large number of children in the population with BLLs <10 μg/dL, but these published reports do not include statistical analyses to differentiate between children with BLLs greater or less than 10 μg/dL. The workgroup will focus on "type A" studies or published data. No plans have yet been made to focus on "type B" studies in which investigators may be able to access raw data. The workgroup will review and classify the quality of data from cross-sectional or cohort studies.

During the workgroup's two conference calls in August 2002, several scientific issues were discussed, but not resolved. These challenges include a process to summarize highly relevant evidence; an effective methodology to identify age, secular and seasonal trends of BLLs; and the time-line of the workgroup's published report or policy recommendations versus activities by a consortium that has been assembled to conduct a pooled re-analysis of raw data from cohort studies and other investigations.

Both CDC and the National Institute of Environmental Health Sciences are providing funds to support the pooled re-analysis group. Dr. Bruce Lanphear serves as the principal investigator of the consortium; Drs. David Bellinger and Joel Schwartz serve on the group as well. The workgroup will continue to hold monthly conference calls and will also convene a face-to-face meeting in November 2002 to review high-relevance type A articles identified to date. The workgroup hopes to complete an outline of a draft report in February 2003 and then finalize and present the document to ACCLPP in late spring 2003.

ACCLPP commented on the workgroup's activities. Dr. Binns was pleased the workgroup is separating studies in which BLLs were measured in very young children versus older cohorts. This approach will be key in answering scientific questions. She suggested that the workgroup advance beyond the development of an ACCLPP report and generate a paper citing current published data on adverse effects at low BLLs. Dr. Matte confirmed that the workgroup is charged with generating an ACCLPP-endorsed product suitable for publication in the peer-reviewed literature.

In terms of challenges, Dr. Binns encouraged the workgroup to continue its progress in finalizing a summary statement by late spring 2003. The time-line should not be influenced by activities of the pooled re-analysis consortium since this group may not be

in a position to publish results for quite some time. On the one hand, several ACCLPP members agreed with Dr. Binns that the workgroup should maintain communication with the pooled re-analysis consortium and be aware of its activities without compromising or delaying the workgroup's independent effort. This goal can be achieved by inviting members of the pooled re-analysis consortium to present a status report at a future ACCLPP meeting.

On the other hand, Dr. Hoffman saw the benefit in ACCLPP reviewing data collected by the pooled re-analysis consortium prior to publication. He indicated that some ACCLPP members may be asked to write an editorial or serve as peer reviewers of the pooled re-analysis. Dr. Meehan explained that any ACCLPP member can serve in this capacity so long as views are expressed from an individual rather than committee perspective.

Dr. Piomelli acknowledged that the workgroup is addressing a controversial issue. He was disturbed that Drs. Bellinger and Schwartz serve on the workgroup, but have published data on adverse health effects at BLLs <20 μg/dL. Some conclusions reached in these studies have been criticized by many experts as "absurd," "non-scientific" and "unsupported by statistics." Dr. Piomelli strongly recommended that an individual be appointed to serve on the workgroup who does not believe, *a priori*, major adverse effects will occur at low BLLs. Four workgroup members are neutral on this issue; two are, *a priori*, in favor of the finding that adverse effects at BLLs <10 μg/dL are insignificant. He was concerned that if lead poisoning is defined as all children with BLLs <10 μg/dL, the population of children with actual lead poisoning will be forgotten.

Dr. Matte pointed out that some workgroup members are credible and established investigators with solid scientific credentials and extensive backgrounds in lead developmental neurotoxicity. Other workgroup members bring an innovative perspective to the field. He was confident that the workgroup represents balanced perspectives and will be able to support conclusions. Dr. Meehan added that Dr. David Savitz is a workgroup member who completed a seminal study on electromagnetic fields. In this investigation, Dr. Savitz was extremely objective on another controversial subject. Dr. Harvey clarified that the workgroup is only charged with summarizing and presenting data to ACCLPP. Recommendations on policy issues will be made by ACCLPP rather than the workgroup. No other ACCLPP member expressed concern with the workgroup members.

***ACCLPP Current Business*.** Drs. Campbell and Meehan provided a status report on recent ACCLPP communications. ACCLPP's August 23, 2002 letter to the HHS Secretary requested assistance in ensuring continued research to identify effective methods for reducing children's exposure to lead and other environmental hazards. ACCLPP also asked the HHS Secretary to fully support and be actively engaged in a study by the National Academy of Sciences (NAS). This activity will examine ethical issues that may arise while conducting research to eliminate housing-related conditions associated with childhood lead poisoning and other diseases or injuries.

A member of the NAS expert panel has been invited to attend a future ACCLPP meeting and provide a status report on this activity. Dr. Meehan will follow up with the HHS Secretary's office to determine the status of a response to ACCLPP's letter.

ACCLPP's September 23, 2002 letter to the HHS Secretary discussed the potential public health problem of lead poisoning among adopted and refugee children. To educate parents of immigrants and adopted children from overseas on the need for lead screening, ACCLPP asked the HHS Secretary to disseminate information to the U.S. Department of State and HHS agencies. To facilitate this process, ACCLPP attached to sample one-page letters that can be distributed to parents. (include info. below in same paragraph)Dr. Meehan reported that a response to the letter by the HHS Executive Secretary is forthcoming. He committed to submitting the letter to CDC's Division of Quarantine (DQ) to obtain feedback, background data and guidance on effective approaches to address this issue. DQ has responsibility for medical screening of refugees and immigrants.

ACCLPP's September 26, 2002 letter to the HHS Secretary contained evidence-based recommendations on targeted lead screening for young children eligible for Medicaid services. (include info. below in same paragraph)
Dr. Meehan asked ACCLPP to consider effective strategies to bring the recommendations to the attention of CMS. CDC policy staff will review CMS's original proposal for targeted lead screening as well as the December 2000 *Morbidity and Mortality Weekly Report* that contains ACCLPP's commitment to produce a document on this subject. The information will then be presented to CMS in an effort to identify next steps in the process. Dr. Meehan confirmed that he will contact CMS within the next 30 days.

***ACCLPP New Business*.** The members suggested several items to be placed on future agendas.

- Discussion of ACCLPP's definition of "lead poisoning."
- Discussion of ACCLPP's priorities.
- Overview by CDC on the 60 CLPPPs and LPPB's research priorities to ensure children not covered by CLPPPs are not being missed.
- Discussion or formal review on the impact of ACCLPP's guidelines and recommendations.
- An orientation to inform new members on the proper procedure to ask for presentations, respond to requests and select priorities.

Requests were also made for CDC to provide new members with the following information: the list of topics from which ACCLPP selected its priorities in 2001; a list of current ACCLPP members; and a description of current members and charges of workgroups. Dr. Campbell reported that core activities by the Case Management and Targeted Screening Workgroups are complete. The two workgroups no longer convene meetings since only follow-up activities are outstanding. The Primary Prevention and Evidence on Low BLL Effects Workgroups are active and made presentations during

the meeting. Updates from these workgroups will continue to be placed on future agendas until the respective charges have been fulfilled.

In addition to regular status reports by workgroups, other items are placed on future agendas by suggestions from members. Formal motions that are made and passed by voting members are eventually forwarded to the HHS Secretary. Other agenda items include updates on new data, results and interventions in the childhood lead poisoning prevention field. Dr. Campbell encouraged members to suggest future agenda items at least one month prior to a meeting.

Public Comment Period. The Chair opened the floor for public comments; no attendees responded.

Closing Session. The 2003 ACCLPP meetings will be held on March 18-19 and October 14-15. EEHS will confirm these dates by circulating an e-mail message to all members.

There being no further discussion, Dr. Campbell adjourned the ACCLPP meeting at 10:30 a.m. on October 16, 2002.

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

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Date

Carla C. Campbell, M.D., M.S.
ACCLPP Chair