

ATTACHMENT B1

American Academy of Pediatrics Letter



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January 3, 2011

Carol E. Walker
Acting Reports Clearance Officer
Centers for Disease Control and Prevention
1600 Clifton Road, MS-D74
Atlanta, Georgia 30333

Dear Ms. Walker:

The American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, would like to express our strong support for the proposed Gulf Coast Children's Health Study at the Centers for Disease Control and Prevention's (CDC) National Center for Environmental Health.

The Academy is pleased the CDC has proposed undertaking a scientifically valid environmental epidemiologic study to assess the potential adverse health effects among children who resided in Federal Emergency Management Agency (FEMA) -provided temporary housing after Hurricane Katrina. The AAP continues to be concerned that children who resided in FEMA trailers may have been exposed to levels of formaldehyde gas and other indoor air pollutants that are hazardous to both their short-term and long-term health. The AAP hopes the proposed two-year Feasibility Study to investigate the association between residing in temporary housing units and adverse health conditions will result in a larger longitudinal study to investigate the ongoing health impacts experienced by children who resided in FEMA trailers.

Formaldehyde gas is known to cause a wide range of adverse health effects. The AAP handbook on pediatric environmental health acknowledges that "formaldehyde is a known respiratory irritant in the occupational setting and a common air pollutant in the home."ⁱ Numerous studies have found higher rates of asthma, chronic bronchitis, and allergies in children exposed to elevated levels of formaldehyde.^{ii,iii,iv,v} Formaldehyde is also a known carcinogen.^{vi} Formaldehyde is used in hundreds of products, but particularly in the resins used to bond laminated wood products and to bind wood chips in particleboard. Mobile homes and travel trailers, like the FEMA-provided temporary housing units, have small, enclosed spaces, low air exchange rates, and many particleboard furnishings, and therefore may have much higher concentrations of formaldehyde than other types of homes.^{vii,viii}

In order for the proposed Gulf Coast Children's Health Study to have the greatest utility, AAP urges CDC to consider mold exposure in addition to and in conjunction with formaldehyde exposure. It has been reported that many FEMA trailers had leaks and visible mold and the respiratory symptoms of mold and formaldehyde exposures will overlap. The omission of this potential etiology may seriously diminish the reliability of the study's results. In addition, because formaldehyde is a known carcinogen, CDC should consider including cancer rates among the measured long-term outcomes in the longitudinal study. Finally, in order to assure a sufficient study sample and to increase the information yield, CDC may consider obtaining medical records from primary care physicians' offices and local hospitals that treated the acute effects and symptoms of formaldehyde exposure. Billing records from insurance providers and Medicaid may also help indicate the rates of acute respiratory illness that occurred while children resided in FEMA trailers.

The AAP remains concerned for the current and future health of children in the Gulf Coast who are still recovering from Hurricane Katrina. From the dangers and hardship associated with evacuation and relocation, to respiratory problems and injuries immediately after the hurricane, to the ongoing concerns related to mental health effects and post-traumatic stress disorder (PTSD), the children of the Gulf Coast have borne an enormous amount of suffering associated with that disaster. This proposed study presents an opportunity to improve the health of children affected by Hurricane Katrina, but long-term follow-up and tracking will be necessary. The AAP hopes this study is only one component of a comprehensive, ongoing effort to improve the health and well-being of these children who experienced significant mental and physical trauma during and after Hurricane Katrina.

The AAP appreciates this opportunity to share our strong support for CDC's proposed Gulf Coast Children's Health Study, to assess the short-term and long-term health effects among children who lived in FEMA-provided temporary housing after Hurricane Katrina. If the AAP may provide assistance or information, please contact Cindy Pellegrini or Tamar Magarik Haro in the Academy's Washington Office at 202/347-8600.

Sincerely,



O. Marion Burton, MD FAAP
President

OMB:km

ⁱ American Academy of Pediatrics. *Pediatric Environmental Health*, 2d Edition. American Academy of Pediatrics, 2003.

ⁱⁱ American Academy of Pediatrics. *Pediatric Environmental Health*, 2d Edition. American Academy of Pediatrics, 2003.

ⁱⁱⁱ Wantke F, Demmer CM, Tappler P, Gotz M, Jarisch R. Exposure to gaseous formaldehyde induces IgE-mediated sensitization to formaldehyde in school-children. *Clin Exp Allergy*. 1996 Mar; 26(3):276-80.

^{iv} Garrett MH, Hooper MA, Hooper BM, Rayment PR, Abramson MJ. Increased risk of allergy in children due to formaldehyde exposure in homes. *Allergy*. 1999 Apr; 54(4):330-7.

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- ^v Rumchev KB, Spickett JT, Bulsara MK, Phillips MR, Stick SM. Domestic exposure to formaldehyde significantly increases the risk of asthma in young children. *Eur Respir J*. 2002 Aug; 20(2):403-8.
- ^{vi} International Agency for Research on Cancer, "IARC Classifies Formaldehyde As Carcinogenic to Humans," Press Release No. 153, June 15, 2004, http://www.iarc.fr/ENG/Press_Releases/archives/pr153a.html
- ^{vii} American Academy of Pediatrics. Pediatric Environmental Health, 2d Edition. American Academy of Pediatrics, 2003.
- ^{viii} Spengler JD. Sources and concentrations of indoor air pollution. In: Samet JM, Spengler JD, eds. *Indoor Air Pollution: A Health Perspective*. Baltimore, MD: Johns Hopkins University Press; 1991.

ATTACHMENT B2

CDC's Response to American Academy of Pediatrics Letter



January 20, 2011

O. Marion Burton, MD, FAAP
President
American Academy of Pediatrics
141 Northwest Point Boulevard
Elk Grove Village, IL 60007

Dear Dr. Burton,

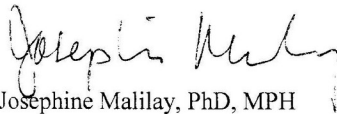
Thank you very much for your letter in response to the 60-day Federal Register Notice for the CDC Gulf Coast Children's Health Study. We greatly appreciate the American Academy of Pediatrics' (AAP) support for the study as well as the organization's recommendations to enhance the study. This letter provides additional information on the Feasibility Study data collection protocol that, we hope, will address the methodological issues raised by AAP. Regarding the recommendation for long-term follow-up, CDC will make a determination to proceed with a larger, longitudinal study upon the conclusion of the Feasibility Study. If a Full Study is implemented, an additional 2,700 children will be enrolled and followed prospectively for approximately 5 years.

We agree that mold is an important exposure to consider in addition to and in conjunction with formaldehyde. In addition to sampling for formaldehyde, the current study protocol includes the collection of a dust sample from each participant's current home. The dust sample will be analyzed for allergens, molds, and endotoxin. Potential mold exposure in the current home will also be assessed by a trained field investigator as part of a household walkthrough survey. Among children who are seven years and older, personal exposures to specific air pollutants will also be monitored to help provide information to understand the prevalence of ongoing adverse health outcomes. Specifically, the personal exposure monitors will measure particulate matter, formaldehyde and other volatile organics, endotoxin, 1, 3 β -glucan, and allergens. In addition to these environmental exposure measurements, questions from validated national surveys regarding exposure to mold in the current and previous homes are included in the baseline and follow-up surveys. We believe that information obtained from these multiple assessments will help to provide a more comprehensive understanding of the potential exposures and health impacts observed among these children.

Cancer is an important health outcome to consider when studying formaldehyde exposures. The baseline and follow-up surveys include a yes/no question regarding the diagnosis of cancer by a physician. In response to your letter and to ensure that we capture adequate information on cancer diagnoses, we plan to add additional questions to obtain data on cancer type, date of diagnosis, and physician contact information.

The ability to locate medical records is one of the objectives that will be measured during the Feasibility Study. The current protocol includes medical record abstraction for participants who reported one or more adverse health outcomes in order to validate the reported diagnoses and observations from the clinical assessment. Additionally, during the Feasibility Study, we will attempt to obtain and abstract medical records for a subset of participants who did not report an adverse health outcome in order to evaluate the degree of underreporting. While we concur that the ability to validate diagnoses using primary care provider and hospital records is important, we do not plan to use administrative or billing data bases to obtain population disease rates. We appreciate the AAP's continued interest in the health and well-being of children in the Gulf Coast who were affected by Hurricanes Katrina and Rita. We hope that this letter sufficiently addresses the comments and concerns raised by the AAP in regard to the CDC Gulf Coast Children's Health Study.

Sincerely,



Josephine Malilay, PhD, MPH
Associate Director for Science
Division of Environmental Hazards and Health Effects
National Center for Environmental Health

Cc: Fuyen Yip, PhD, MPH
Air Pollution and Respiratory Health Branch