American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™

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January 21, 2009

The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce
2125 Rayburn Office Building
Washington, DC 20515

Dear Chairman Waxman:

The American Academy of Pediatrics, a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults, appreciates this opportunity to respond to your inquiry for more details on the development of our recommendations for limiting lead content in children's products.

Lead and Children's Health

There is no "safe" level of lead exposure. The vulnerability of children to lead poisoning during development of their brains and nervous systems has been amply demonstrated, and the literature is very consistent. On average, children whose blood lead levels (BLLs) rise from 10 to 20 micrograms per deciliter (mcg/dL) lose two to three IQ points. More recent studies have shown an even greater impact on IQ of BLLs under 10 mcg/dL. Key studies reported a loss of 4 to 7 IQ points in children whose lead levels rose from 1 mcg/dL to 10 mcg/dL.[1,2] These studies suggest that "low" levels of exposure – meaning BLLs less than 10 mcg/dL – cause proportionately greater harm than higher levels. The effects of lead on health do not stop once the child's brain and nervous system mature or the BLL falls. A recent study found that in a group of 7 year old children who had experienced a BLL of 20-44 mcg/dL around age 2 years, the concurrent BLL (i.e., BLL taken at age 7 years when the IQ test was administered), was more closely associated with IQ at age 7 years that BLL at age 2 or age 5 years.[3]

Another important lasting effect of lead exposure is on behavior, with higher rates of behavioral problems reported in teens and adults exposed to lead during childhood. Children with elevated lead are more likely to have problems with inattention and reading, and are at higher risk of failing to graduate from high school.[4] Investigators have identified associations between lead exposure and increased aggression, commission of crime and antisocial or delinquent behaviors.[5,6,7,8] Studies have suggested that several nations which began reducing lead exposure aggressively in the 1970s experienced corresponding decreases in crime rates two to three decades later.[9] Other effects include abnormal balance, poor eye-hand coordination, longer reaction times, and sleep disturbances.[10,11,12]

Lead is easily absorbed by ingestion or inhalation. The most common route of exposure of children is through ingestion, usually by putting hands and other objects in their mouths. Both hand-to-mouth exploration and playing on floors are typical behaviors for children, especially younger children. Studies using videos to record oral behaviors of young children report hand or object in mouth activities 20 or more times per hour.[13,14] If hands or objects placed in the mouth have lead, these usual childhood activities deliver doses of lead.

Once lead enters the body it remains there for years. Lead is similar to calcium from the elemental perspective. This means that our bodies "see" lead as calcium, absorb it into blood and then store it in bone. These stores of lead can be released years later, when bone changes occur or demands on calcium stores are made.[15] Another consequence of storing lead in bone is that exposures separated by months or years have an additive effect on the body's burden of lead and can exert effects over decades. Acquisition of lead in the body even in small amounts (i.e., amounts that result in BLLs less than 10 mcg/dL) contributes to this accumulation of lead. This means that even short term or small cumulative exposures can have lasting negative effects.

Over the past 30 years, average BLL has declined dramatically in the U.S., due largely to the elimination of lead from gasoline and mandated restriction of lead content in paint. At the same time, however, elevated BLL is still not uncommon. Eliminating elevated blood lead levels was established as a key goal under the federal Healthy People 2010 initiative.[16] The AAP believes firmly that our nation must continue efforts to reduce childhood lead exposure and its pernicious impacts. In the past three years alone, the AAP has pushed the Environmental Protection Agency to reduce airborne lead emissions under the National Ambient Air Quality Standards; urged the Food and Drug Administration to eliminate lead in imported candies and their wrappers; and continued our long-term engagement with the Department of Housing and Urban Development to reduce children's exposure to lead paint in older housing and through home renovation activities. We intend to sustain these efforts to ensure that children's potential for exposure to lead is reduced as much as possible and new avenues of exposure are not created.

Lead in Children's Products

As you know, prior to the passage of the Consumer Product Safety Improvement Act (CPSIA), our government had never set limits for acceptable lead content in children's products, with the exception of lead in surface paint. The restriction of lead content to 600 parts per million (ppm) dates back to 1978 and does not apply to any other material or component in toys or children's products. As a result, toys and children's products could have unlimited amounts of lead in areas other than surface paint without violating any mandatory standard. Further, the 600 ppm limit for paint does not represent a health-based standard.

Lead can find its way into toys and children's products as a naturally-occurring component of materials used or as a deliberate or incidental additive. Lead is used

directly in certain materials, such as to stabilize some vinyl compounds and in lead crystal. Lead may also be a contaminant in air, water or soil that comes into contact with materials or components during the manufacturing process. Regardless of its source, however, lead's toxic effect on the developing brain requires us to examine these processes and minimize exposure whenever possible. Because there is no "safe" blood lead level in children, the AAP focused attention on limiting lead to trace amounts that would not represent "added" lead to products.

Development of the AAP Lead Recommendation

In September 2007, the AAP was asked by the House Committee on Energy and Commerce to testify about the hazards of lead and to make specific recommendations for lead content that would be used in the development of product safety legislation. While the AAP had published guidelines on lead exposure prevention, detection and management in the past, we had never attempted nor been requested to provide specific targets for lead content in products. The recommendation delivered to Congress was an ancillary effort that builds upon but is not inconsistent with or contradictory to our previously published statements.

The AAP's recommendations were developed by our Committee on Environmental Health (COEH), which comprises 9 top pediatric environmental health experts serving in a volunteer capacity. While child health issues were their guiding principle, the COEH also went to great lengths to examine the associated practical issues involved to ensure that the final recommendations would be pragmatic and feasible. The primary considerations were: 1) no "safe" threshold for blood lead levels for children has been identified;[17] 2) lead negatively affects health and development at levels well below 10 micrograms per deciliter (mcg/dL) blood lead level;[18] and 3) lead is a naturally-occurring element and may therefore be present is a wide array of materials so "lead-free" status may not be achievable in some products. Therefore, children's exposures to lead in products should be severely limited, but some low level of exposure, a "trace" amount, could be expected.

The primary goal of the COEH in developing these recommendations was to establish a guideline based directly on child health issues, rather than the selection of an arbitrary number. After much discussion, the committee agreed that the appropriate benchmark for its recommendation should be the loss of 1 IQ point. Using California Office of Environmental Health Hazard Assessment analysis that evaluated the upper 97.5% confidence level of blood lead level associated with this effect, a 1 IQ point loss would be prevented by limiting a child's BLL increase to no more than 1 mcg/dL.[19] Supporting a rationale on 1 mcg/dL rise is the FDA upper limit for lead in food at 6 mcg/lead/day for children aged <6 years, which is expected to cause a child's BLL to rise by 1 mcg/dL.[20] There is no logical reason to accept a higher rise in blood lead level from product exposure than from food exposure.

The COEH's next task was to determine the amount of lead that would result in a child's BLL increasing by 1 mcg/dL from exposure to a child's product. This evaluation focused on information posted by CPSC evaluations.[21] The committee determined as follows:

- Based on the 1999-2000 National Health and Nutrition Examination Survey (NHANES), the average blood lead level of a child aged 1-5 years in the US in 1999-2000 was 2.2 mcg/dL.
- In developing its recommendation for lead in toy jewelry, the CPSC calculated that an extractable lead content of 175 mcg would cause an average child's BLL to rise to 10 mcg/dL over a 1 month exposure period. The agency determined that this level of exposure occurs at a level of 0.06% lead by weight (600 ppm, coincidentally, the same limit as the 1978 lead paint ban).[22]
- As noted above, however, the COEH had already determined that waiting for BLL to rise to 10 mcg/dL was not acceptable due to the neurological damage that would occur. In order to limit the BLL rise to 1 mcg/dL, the CPSC figures were divided by 7.8, which represents the rise in BLL from 2.2 mcg/dL to 10 mcg/dL, to obtain the figure that would correlate to a BLL increase of 1 mcg/dL. Accordingly, 600 ppm lead divided by 7.8 equals 77 ppm lead being capable of causing a BLL increase of 1 mcg/dL.

In its next step, the COEH took into account the fact that most children are exposed to lead from a variety of sources, which may include lead paint hazards in the home, airborne lead emissions, contaminated soil, and other consumer products. Since lead is bioaccumulative and highly persistent in the body, it is important to provide a margin of safety to ensure that exposure to a single toy or children's product cannot cause BLL to increase 1 mcg/dL.

In determining how to set this margin of safety, the COEH examined the practical issues associated with lead exposure. Lead occurs naturally in the environment, so setting lead content at zero was not deemed to be a feasible recommendation. The committee examined data from a variety of sources to learn about the natural geological occurrence of lead in the United States. The U.S. Geological Survey provides nationwide data on lead exposure, which illustrates that naturally occurring lead levels generally top out at 30 ppm.[23] The AAP confirmed this data with Geological Survey and independent geologists. Given this evidence, the COEH recommended a two-fold margin of safety for lead content in children's products, dropping the recommendation from 77 ppm to 40 ppm. You may note that this is considerably lower than the margin of safety mandated under other federal laws; for example, the tolerance for pesticide residue on food requires a ten-fold margin of safety (i.e., limit set at one tenth of the amount estimated to cause the negative effect) for vulnerable populations, including children.

Development of the CPSIA Standard and Exceptions Clause

Over the year that Congress spent working intensively on this legislation, the AAP engaged in a detailed dialogue with both House and Senate offices regarding the merit of various possible exemptions to the lead guidelines. In partnership with these offices, the

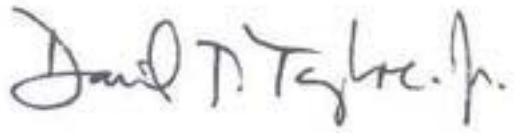
AAP collaborated on the development of legislative language that empowers the Consumer Product Safety Commission (CPSC) to accept and evaluate applications for such exemptions. This process will include possible exemption for inaccessible lead, although the definition of inaccessibility was the subject of much debate. For example, it was questioned whether lead would be considered inaccessible if it were covered by paint or electroplating, or included in a compound such as vinyl or lead crystal. In each of these cases, the COEH advised that lead was not inaccessible because barriers like paint and electroplating can be breached, vinyl deteriorates with time and use, and lead leaches from crystal in the presence of acid (including stomach fluids).

In the final legislation, the CPSC is specifically directed to examine the application of the lead standard to electronic products, including batteries, and to develop guidelines for minimizing children's exposure to lead that cannot be eliminated from these products. The AAP supported these proposals, which will allow for the transparent, science-based evaluation of proposals to permit lead in certain components of toys and children's products. The AAP anticipates offering our views and guidance to the CPSC as such applications are submitted and examined.

The AAP is acutely aware of the impact our recommendations can have, and we strive to ensure that all AAP recommendations are based on science and practical to implement. Led by the COEH, the AAP engaged in a thorough, evidence-driven review to develop our lead recommendations. Following that, AAP members and staff spent countless hours engaged with numerous Congressional offices to explore the issues associated with lead in children's products and to assist in crafting a final bill that would protect children's health through pragmatic, feasible standards. The AAP strongly supported this legislation and looks forward to working with the Consumer Product Safety Commission on its implementation in the coming years.

I hope this letter satisfies your request for information and gives you confidence that the AAP's recommendations represent an empirically-based solution grounded in science. If the Academy may be of further assistance, please contact Cindy Pellegrini in our Washington, D.C. Office at 202/347-8600.

Sincerely,



David T. Tayloe, Jr., MD FAAP
President

DTT:cp

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