American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Thursday, April 7, 2011

Testimony of
Dana Best, MD, MPH, FAAP

On behalf of the
American Academy of Pediatrics

Before the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade
Discussion Draft of a Bill That Would Revise the Consumer Product Safety Improvement Act of 2008

American Academy of Pediatrics • Department of Federal Affairs
601 13th Street NW, Suite 400 North • Washington, DC 20005
Tel: 800.336.5475 • E-mail: kids1st@aap.org

Thank you, Mr. Chairman, for this opportunity to testify today before the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade about children's product safety. My name is Dana Best, MD, MPH, FAAP, and I am pleased to represent the American Academy of Pediatrics (AAP), 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. I am an Associate Professor of Pediatrics at George Washington University School of Medicine here in Washington, D.C. and served for six years on the AAP's Committee on Environmental Health, which is the primary body within the AAP that handles lead and other environmental health issues.

The American Academy of Pediatrics strongly supported the provisions of the Consumer Product Safety Improvement Act of 2008 (CPSIA) that were designed to make children's products safer, primarily by reducing exposure to lead and other hazards, and requiring manufacturers to demonstrate safety before products could be sold. The AAP is therefore deeply concerned that the Subcommittee is considering legislation that would profoundly alter the CPSIA and could reverse the progress toward safer toys and children's products.

My testimony will cover four areas under discussion by the subcommittee: the scope of children's products covered by the law; limitations on lead in children's products; concepts of risk assessment; and the need for third party testing.

The Scope of Children's Products Should Protect Children Up to Age 12

The CPSIA defines a children's product as "a consumer product designed or intended primarily for children 12 years of age or younger." The AAP recommended that this law cover products for children up to age 12 years based on both developmental and pragmatic concerns.

With regard to developmental issues, the mouthing behaviors that cause the most concern for exposure to hazards like lead are most prevalent among young children, peaking in the toddler years and tapering off throughout school age. However, it is not unusual for school-age children to still place toys and other objects in their mouths, and it may in fact be fairly common for them to mouth or suck on items like jewelry or writing instruments. For some groups of children, such as children with developmental delays, mouthing behaviors may persist even longer.

Another key concern was the fact that toys are often shared among multiple children in the same household, regardless of whether those items are age-appropriate. While most parents work hard to keep toys meant for older children away from younger siblings, it is inevitable that young children will at least occasionally gain access to toys meant for their older brothers and sisters. It is therefore important to ensure that toys are as safe as possible for all children in a household.

Lead is a Potent Neurotoxin

Lead has been recognized as a potent neurotoxin since the time of the Roman Empire, although the mechanisms by which it inflicts brain damage have only been explored and understood in the past century. The brain damage caused by lead exposure is permanent and irreversible. Few options exist for treating lead exposure at high levels, and these treatments have potentially dangerous side effects. No options exist for treating lead exposure at low to moderate levels.

Exposure to lead is amply documented to cause the loss of intellectual capacity. 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.

In addition to these impacts on IQ, lead exposure has documented effects on behavior, with higher rates of behavioral problems reported in young children, teens and adults exposed to lead during childhood. Associations between lead exposure and increased aggression, commission of crime and antisocial or delinquent behaviors have been identified.[3,4,5,6] Children with elevated lead are more likely to have problems with attention deficit and reading disabilities, and to fail to graduate from high school. Other effects include abnormal balance, poor eye-hand coordination, longer reaction times, and sleep disturbances.[7,8,9]

With all of this information in mind, it is critically important to note that lead bioaccumulates. A percentage of lead will be excreted by the body, and the rate of clearance is dependent on a number of factors, including nutritional status. But a percentage of lead is also stored in the body, primarily in bone. These body stores persist over decades. When a woman becomes pregnant, her body draws upon its calcium stores to help create her fetus's bone structure. If lead has been stored in the bone, the developing fetus will be exposed to doses of lead throughout pregnancy.[10]

The costs associated with lead exposure are tremendous. Health economists estimate that every time average blood lead level increases by a small amount[*] across the children born in any given year, $7.5 billion is lost in potential earnings for those children.[11] Other studies have estimated the annual cost of lead poisoning in American children at $43.4 billion.[12] Costs are borne by our health care, education, and justice systems, among others.

Lead is naturally present in our environment at low levels. Human activities have raised those levels through contamination, whether by adding lead actively to products like paint or gasoline or producing it as a byproduct of activities like burning coal. Lead is present at low levels in our air, soil, and water, but often very difficult to remediate in those cases. It is therefore critical to restrict lead exposure in environments directly under our control, such as consumer products.

[*] "Small amount" is defined here as 1 mcg/dL increase in blood lead level.

The CPSIA's Limits on Lead Should Not Be Relaxed

During the development of the CPSIA, the AAP was asked by Congress to recommend a limit for levels of lead in children's products. The Academy engaged in a rigorous scientific process, including a review of the pertinent literature, and ultimately recommended that lead in children's products be limited to 40 parts per million (ppm). You will find attached to my testimony a letter to then-Energy and Commerce Committee Chairman Henry Waxman explaining the AAP's calculations in detail with appropriate references.

Briefly, the AAP's experts determined that the appropriate goal of a standard should be to prevent a child from losing one IQ point. For close to two decades, the U.S. Food and Drug Administration (FDA) has recommended a daily intake of no more than 6 micrograms (mcg) of lead per day for children age 6 years and younger.[13] Scientific models of lead ingestion indicate that daily consumption of 6 mcg of lead would increase a child's blood lead level by 1 mcg/dL. The medical and scientific literature are in substantial agreement that an increase of 1 mcg/dL in blood lead level is capable of causing the loss of approximately one IQ point in children whose blood lead level is under 10 mcg/dL.[14,15] It is important to note, however, that the FDA's recommendation refers only to dietary intake and does not take into account other potential exposures to lead, such as paint. FDA officials explicitly stated, "These numbers will need to be adjusted downward to allow for other anticipated exposures to lead."[16]

The Consumer Product Safety Commission's 2005 interim guidance on lead in children's jewelry states that an item with more than 600ppm of lead would be capable of raising a child's blood lead level from 2.2 to over 10 mcg/dL.[17] Given that the AAP's goal was to prevent an increase of 1 mcg/dL, the total of 600ppm was divided by 7.8 to reach 77ppm. Recognizing that most children are exposed to other sources of lead and that lead is bioaccumulative, the AAP recommended roughly a two-fold margin of safety and reduced the recommendation from 77 to 40ppm. The level of 40 ppm was also selected to fall above the naturally-occurring background levels of lead seen in most parts of the United States.[18]

It is the considered judgment of the AAP that there is no scientific basis for establishing a "de minimis" exposure level for lead in children's products. As one study summarized, "With the recent evidence demonstrating an inverse association between blood lead levels and cognitive function in children exposed to low levels of lead, there is no safety margin at existing exposures."[19] To date, science has not been able to identify a threshold below which lead ceases to damage a child's brain or body.

Risk Assessment Is Not an Appropriate Method for Limiting Lead Exposure in Children's Products

The discussion draft before the Subcommittee appears to contemplate shifting from measurement of total lead in children's products to a framework based around risk assessment. The AAP urges you to leave intact the straightforward, predictable total lead standard in the CPSIA rather

than introducing the considerable uncertainty and unpredictability that is often associated with risk assessment.

The fundamental premise of risk assessment is that some degree of risk is acceptable. For example, in medicine, the expected benefit of a given drug or device is considered against the possibility of side effects. In the case of lead, however, the known benefit is zero, while the known risk is significant. If the CPSIA's standard is to be altered, Congress would first need to determine what level of IQ loss is considered acceptable across the exposed population.

In addition, risk assessment should – but often fails to – take into account factors related to both the object and the subject, in this case the product and the child. It has been suggested that product-related risk assessment might consider the amount of lead in the product, its physical accessibility, and the size of the item involved. Factors related to the child should also be considered, such as the age and developmental stage of the child who may be reasonably expected to encounter the product. It is also critically important to note, however, that key groups of children will have additional vulnerabilities that risk assessment fails to take into account adequately. Children with poor nutritional status or certain genetic traits will absorb higher levels of lead. Children who already have an elevated blood lead level may lose IQ points more readily than those with no detectable blood lead level. Standards should protect not only the "average" child, but also those children at higher risk for the adverse consequences of lead exposure. This is best accomplished with the lead limits currently in the CPSIA.

The AAP is deeply concerned that a risk assessment framework would require the CPSC to shoulder an untenable burden in attempting to perform or confirm risk assessment on various products. It is unclear who would bear the ultimate responsibility for determining risk, or what the process would be for reconciling differences in risk assessment between the agency and a manufacturer. For all of these reasons, the AAP urges you to reject calls for risk assessment related to individual products and the amount of lead that should be permitted in them.

The discussion draft proposes to distinguish between lead exposure from items that can be sucked on versus licked, or which can versus cannot be placed in a child's mouth. The AAP urges you to avoid setting different standards for lead in children's products based on any such distinction. From a scientific perspective, there is no basis for differentiating between a child licking versus sucking on an object. Children demonstrate a marvelous ability to bring to their mouths and keep there all manner of objects. The preferred term would be "mouthing" and would cover all related behaviors.

The AAP urges Congress to resist calls to set different standards for lead in children's products based solely on subjective assessments of the likelihood of mouthing or ingestion. Given the extreme toxicity of lead, its bioaccumulation, and the permanent, irreversible nature of the damage it causes, the concept of setting different levels of lead for various types of toys or other children's products is troubling.

Third-Party Testing Is Necessary to Ensure the Safety of Children's Products

In 2007, the nation experienced a rash of product recalls that opened our eyes to the previously-unrecognized prevalence of lead in children's products. Numerous companies, including several that made some of the best-known and most-loved brands and children's products, were found to have sold items posing a range of hazards, from high lead levels to toxic chemicals to small, powerful magnets that could perforate the intestines if more than one was swallowed.

The voluntary system of product safety had failed in a very public and visible way. In response, the CPSIA required that all children's products undergo independent testing for safety before appearing on store shelves. Third-party testing was the solution designed to give parents the peace of mind that their children were not serving as test subjects for potentially unsafe products. It was also a necessary step to ensure that children's products imported from other countries compiled with U.S. safety standards.

The discussion draft proposes to make significant changes to the third-party testing requirements in the CPSIA, dramatically reducing the number and types of products subject to independent testing. This proposal would essentially return us to the pre-CPSIA state of affairs, where consumers were expected to make their best guess as to whether the toys and children's products they purchased were actually safe. Some have noted that recalls have dropped in recent years – a welcome trend, and one which the AAP applauds. Compliance with these still-voluntary standards is not, however, a justification for repealing those rules. The AAP urges the Subcommittee not to rescind requirements for third-party safety testing for children's products.

Non-Compliant Cribs Should Not Be Permitted in Child Care Facilities

The discussion draft proposes to permit child care facilities to continue using fixed-side cribs that do not comply with the recently-approved CPSC crib safety rule. Passed unanimously by the five bipartisan CPSC commissioners, this rule bans drop-side cribs and made several other important changes to the crib safety standard. The AAP is sensitive to the challenges this rule poses for child care providers who must replace noncompliant cribs and urged CPSC to provide a substantial phase-in period for crib replacement, which the agency did. We urge Congress not to alter this important rule and its implementation.

In conclusion, the AAP has profound concerns that many of the concepts in the discussion draft before the Subcommittee would roll back important child health safety protections. The CPSIA was passed in response to significant deficiencies in our nation's product safety system, which had allowed for the widespread sale and distribution of products dangerous to children's health. We urge you not to weaken the CPSIA's protections against lead and other hazards as you consider ways to improve the ability of manufacturers and businesses to comply with this important law.

The American Academy of Pediatrics appreciates this opportunity to offer comments on the discussion draft before the Subcommittee to amend the Consumer Product Safety Improvement Act of 2008. We look forward to working with you to protect the health, safety and wellbeing of all our nation's children.

---

[1] Canfield RL, Henderson CR, Jr., Cory-Slechta DA, Cox C, Jusko TA, Lanphear BP. Intellectual impairment in children with blood lead concentrations below 10 microg per deciliter. *N Engl J Med.* 2003;348(16):1517-1526.
[2] Lanphear BP, Hornung R, Khoury J, et al. Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. *Environ Health Perspect.* Jul 2005;113(7):894-899.
[3] Dietrich KN, Ris MD, Succop PA, Berger OG, Bornschein RL. Early exposure to lead and juvenile delinquency. *Neurotoxicol Teratol.* Nov-Dec 2001;23(6):511-518.
[4] Ris MD, Dietrich KN, Succop PA, Berger OG, Bornschein RL. Early exposure to lead and neuropsychological outcome in adolescence. *J Int Neuropsychol Soc.* Feb 2004:261-270.
[5] Burns JM, Baghurst PA, Sawyer MG, McMichael AJ, Tong SL. Lifetime low-level exposure to environmental lead and children's emotional and behavioral development at ages 11-13 years. The Port Pirie Cohort Study. *Am J Epidemiol.* Apr 15 1999;149(8):740-749.
[6] Nevin R. Understanding international crime trends: the legacy of preschool lead exposure. *Environ Res.* 2007;104(3):315-336.
[7] Centers for Disease Control and Prevention. *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention.* Atlanta, GA: Centers for Disease Control and Prevention; 2002.
[8] Bhattacharya A, Shukla R, Dietrich KN, Bornschein RL. Effect of early lead exposure on the maturation of children's postural balance: a longitudinal study. *Neurotoxicol Teratol.* 2006;28(3):376-385.
[9] Chiodo LM, Covington C, Sokol RJ, et al. Blood lead levels and specific attention effects in young children. *Neurotoxicol Teratol.* Apr 21 2007.
[10] Schnaas L, Rothenberg SJ, Flores MF, et al. Reduced intellectual development in children with prenatal lead exposure. *Environ Health Perspect.* 2006;114(5):791-797.
[11] Salkever D. Updated Estimates of Earnings Benefits from Reduced Exposure of Children to Environmental Lead. *Environmental Res.* 1995: 70:1-6.
[12] Landrigan PJ, Schechter CB, Lipton JM, Fahs MC, Schwartz J. Environmental pollutants and disease in American children: estimates of morbidity, mortality, and costs for lead poisoning, asthma, cancer, and developmental disabilities. *Environ Health Perspect* 2002;110:721-8.
[13] Carrington CD, Bolger PM. An assessment of the hazards of lead in food. *Reg Tox Pharma.* 1992;16(3):265-72.
[14] Carlisle J, Dowling K. Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment. Integrated Risk Assessment Branch Office of Environmental Health Hazard Assessment California Environmental Protection Agency. April 2007. Available at http://www.oehha.org/public_info/public/kids/pdf/PbHGV041307.pdf.
[15] Environmental Protection Agency. National Ambient Air Quality Standards for Lead: Final Rule. EPA-HQ-OAR-2006-0735, *Federal Register* 73(219), 66964-67062.
[16] Carrington CD, Bolger PM. An assessment of the hazards of lead in food. *Reg Tox Pharma.* 1992;16(3):265-72.
[17] Consumer Product Safety Commission. Interim Enforcement Policy Lead Levels. 2/1/2005. Available at http://www.cpsc.gov/BUSINFO/pblevels.pdf.
[18] U.S. Geological Survey Professional Paper 1648. Geochemical Landscapes of the Conterminous United States – New Map Presentations for 22 Elements. Figure 17. November 2001. Available at http://pubs.usgs.gov/pp/p1648/p1648.pdf.
[19]Koller K, Brown T, Spurgeon A, Levy L, 2004 Recent Developments in Low-Level Lead Exposure and Intellectual Impairment in Children. *Environ Health Perspect* 112(9): doi:10.1289/ehp.6941.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

AAP Headquarters
141 Northwest Point Blvd
Elk Grove Village, IL 60007-1098
Phone: 847/434-4000
Fax: 847/434-8000
E-mail: kidsdocs@aap.org
www.aap.org

Reply to
Department of Federal Affairs
Homer Building, Suite 400 N
601 13th St NW
Washington, DC 20005
Phone: 202/347-8600
Fax: 202/393-6137
E-mail: kids1st@aap.org

Executive Committee

President
David T. Tayloe, Jr, MD, FAAP

President-Elect
Judith S. Palfrey, MD, FAAP

Immediate Past President
Renée R. Jenkins, MD, FAAP

Executive Director/CEO
Errol R. Alden, MD, FAAP

Board of Directors

District I
Edward N. Bailey, MD, FAAP
Salem, MA

District II
Henry A. Schaeffer, MD, FAAP
Brooklyn, NY

District III
Sandra Gibson Hassink, MD, FAAP
Wilmington, DE

District IV
Francis E. Rushton, Jr, MD, FAAP
Beaufort, SC

District V
Marilyn J. Bull, MD, FAAP
Indianapolis, IN

District VI
Michael V. Severson, MD, FAAP
Brainerd, MN

District VII
Kenneth E. Matthews, MD, FAAP
College Station, TX

District VIII
Mary P. Brown, MD, FAAP
Bend, OR

District IX
Myles B. Abbott, MD, FAAP
Berkeley, CA

District X
John S. Curran, MD, FAAP
Tampa, FL

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

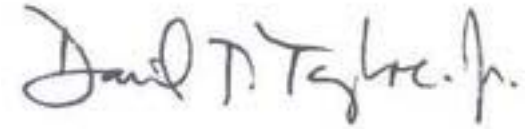
AAP collaborated on the development of legislative language that empowers the Consumer Product Safety Commission (CPSC) to accept and evaluate applications for such exemptions. This process will include possible exemption for inaccessible lead, although the definition of inaccessibility was the subject 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

[1] Canfield RL, Henderson CR, Jr., Cory-Slechta DA, Cox C, Jusko TA, Lanphear BP. Intellectual impairment in children with blood lead concentrations below 10 microg per deciliter. *N Engl J Med.* 2003;348(16):1517-1526.
[2] Lanphear BP, Hornung R, Khoury J, et al. Low-level environmental lead exposure and children's intellectual function: an international pooled analysis. *Environ Health Perspect.* Jul 2005;113(7):894-899.
[3] Chen A, Dietrich KN, Ware JH, Radcliffe J, Rogan WJ. IQ and blood lead from 2 to 7 years of age: are the effects in older children the residual of high blood lead concentrations in 2-year-olds? *Environ Health Perspect.* 2005;113(5):597-601.
[4] Centers for Disease Control and Prevention. *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention.* Atlanta, GA: Centers for Disease Control and Prevention.; 2002.
[5] Dietrich KN, Ris MD, Succop PA, Berger OG, Bornschein RL. Early exposure to lead and juvenile delinquency. *Neurotoxicol Teratol.* Nov-Dec 2001;23(6):511-518.
[6] Ris MD, Dietrich KN, Succop PA, Berger OG, Bornschein RL. Early exposure to lead and neuropsychological outcome in adolescence. *J Int Neuropsychol Soc.* Feb 2004:261-270.
[7] Burns JM, Baghurst PA, Sawyer MG, McMichael AJ, Tong SL. Lifetime low-level exposure to environmental lead and children's emotional and behavioral development at ages 11-13 years. The Port Pirie Cohort Study. *Am J Epidemiol.* Apr 15 1999;149(8):740-749.
[8] Nevin R. Understanding international crime trends: the legacy of preschool lead exposure. *Environ Res.* 2007;104(3):315-336.
[9] Ibid.
[10] Centers for Disease Control and Prevention. *Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention.* Atlanta, GA: Centers for Disease Control and Prevention; 2002.
[11] Bhattacharya A, Shukla R, Dietrich KN, Bornschein RL. Effect of early lead exposure on the maturation of children's postural balance: a longitudinal study. *Neurotoxicol Teratol.* 2006;28(3):376-385.
[12] Chiodo LM, Covington C, Sokol RJ, et al. Blood lead levels and specific attention effects in young children. *Neurotoxicol Teratol.* Apr 21 2007.
[13] Reed KJ, Jimenez M, Freeman NC, Lioy PJ. Quantification of children's hand and mouthing activities through a videotaping methodology. *J Expo Anal Environ Epidemiol.* 1999;9(5):513-520.
[14] Ko S, Schaefer PD, Vicario CM, Binns HJ. Relationships of video assessments of touching and mouthing behaviors during outdoor play in urban residential yards to parental perceptions of child behaviors and blood lead levels. *J Expo Sci Environ Epidemiol.* 2007;17(1):47-57.
[15] O'Flaherty EJ. A physiologically based kinetic model for lead in children and adults. *Environ Health Perspect.* 1998;106 Suppl 6:1495-1503.
[16] Centers for Disease Control and Prevention, Healthy People 2010. http://www.healthypeople.gov/
[17] Centers for Disease Control and Prevention. Preventing Lead Poisoning in Young Children. Atlanta: CDC; 2005.
[18] Centers for Disease Control and Prevention. Interpreting and Managing Blood Lead Levels <10 µg/dL in Children and Reducing Childhood Exposures to Lead: Recommendations of CDC's Advisory Committee on Childhood Lead Poisoning Prevention. *MMWR.* November 2, 2007; 56(RR08):1-14;16.
[19] Carlisle J, Dowling K. Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g): Child-Specific Benchmark Change in Blood Lead Concentration for School Site Risk Assessment. Integrated Risk Assessment Branch Office of Environmental Health Hazard Assessment California Environmental Protection Agency. April 2007. Available at http://www.oehha.org/public_info/public/kids/pdf/PbHGV041307.pdf.
[20] "Dangers of Lead Still Linger." *FDA Consumer*. U.S. Food and Drug Administration, January-February 1998. Available at http://www.cfsan.fda.gov/~dms/fdalead.html.
[21] Consumer Product Safety Commission. Interim Enforcement Policy Lead Levels. February 14, 2005. Available at http://www.cpsc.gov/BUSINFO/pblevels.pdf.
[22] Consumer Product Safety Commission. Interim Enforcement Policy Lead Levels. February 14, 2005. Available at http://www.cpsc.gov/BUSINFO/pblevels.pdf
[23] U.S. Geological Survey Professional Paper 1648. Geochemical Landscapes of the Conterminous United States – New Map Presentations for 22 Elements. Figure 17. November 2001. Available at http://pubs.usgs.gov/pp/p1648/p1648.pdf.