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Testimony of H. Garry Gardner, MD FAAP

on behalf of the
American Academy of Pediatrics

before the Senate Commerce Science & Transportation
Subcommittee on Consumer Protection, Product Safety &
Insurance

“Oversight of the Consumer Product Safety Commission:
Product Safety in the Holiday Season”

Good morning. I appreciate this opportunity to testify today before the Commerce Science & Transportation Subcommittee on Consumer Protection, Product Safety & Insurance at this hearing, "Oversight of the Consumer Product Safety Commission: Product Safety in the Holiday Season." My name is H. Garry Gardner, MD, FAAP, and I am proud to represent the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 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 chair the AAP's Committee on Injury, Violence and Poison Prevention, which is responsible for advising the Academy and drafting its policies on a wide range of injury prevention issues, including consumer product safety. I have been in private pediatric practice since 1973 and am a Professor of Clinical Pediatrics at Northwestern University Feinberg School of Medicine.

Creating Safe, Healthy Products for Children

The AAP was pleased to work closely with the Members and staff of this committee and subcommittee over the course of the development and passage of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Over a period of close to two years, the AAP provided expertise and input on a range of child health and safety issues, including the proposed limitations on lead content and the definition of a children's product. As passed, the CPSIA ultimately rejuvenated a flagging Consumer Product Safety Commission (CPSC), gave it additional tools and authority to achieve its mission, and helped improve the safety of consumer products for children.

Today's hearing provides a valuable opportunity to discuss the CPSIA two years after its signature into law. Many of the directives under the law have already been implemented, either in whole or in part, while others remain to come. The AAP appreciates this opportunity to reflect on the successes of the CPSIA to date and opportunities for improvements in the coming months and years.

Let us take a moment to reflect back upon the state of product safety and the CPSC during the 2007 holiday season. Our nation had just experienced a flood of product recalls, including several involving some of the best-known and most-loved brands and toys. Many Americans were shocked to learn that the majority of toy safety standards were voluntary, not mandatory, with few or no consequences for violation of those voluntary standards. Even for a highly toxic substance like lead, the federal limit was an unacceptably high 600 parts per million, and applied only to paint on children's products. The CPSC was struggling to perform its mission with limited statutory authority, an atrophied staff, and a budget of \$62 million – less one-quarter of what Congress allocated for the Hubble Space Telescope that year, and slightly less than was spent on Pacific coastal salmon habitat restoration.

Three years later, the state of consumer product safety is very different. The CPSIA has already created a range of new safety standards for toys and other children's products, including strict limits on lead content in all materials. The CPSC has increased its staff, and its budget has almost doubled. Manufacturers will soon be required both to test for and document compliance with a range of safety standards, giving retailers and consumers a high degree of confidence in

the safety of these products. Unsafe cribs have been recalled, and dangerous drop-side cribs will soon be banned.

These new safety standards are having a meaningful impact on the lives of children and families, though sometimes in all-but-invisible ways. We cannot readily see that a toy is lead-free, or that a dangerous feature on a stroller has been re-engineered to be safe. It may seem perhaps that these are unimportant changes that cause only minor or incremental improvements in safety. But it would be a mistake to fall into the trap of believing that small changes cannot also be significant. These changes save lives and prevent life-altering injuries. The loss of a few IQ points or a small increase in the proportion of children with behavioral problems in the population of U.S. children has marked impacts on educational spending and future potential.¹ Over my 37 years in practice, I have seen a dramatic change in the injuries suffered by my patients due to unsafe products. Many of the injuries that used to be relatively common simply do not occur any more. As a pediatrician, I am grateful to Congress and the CPSC for your ongoing work to make products safer for our children.

The CPSIA has allowed the CPSC to make strides in two particular areas I would like to highlight: lead and Safe Sleep. Additional work remains to be done with regard to cadmium and other heavy metals, as well as emerging hazards. The American Academy of Pediatrics would like offer the following comments on each of these subjects.

Limiting Children's Exposure to Lead

Lead is well-established as a potent neurotoxin and a particular threat to the developing brain of the fetus, infant, and young child, with documented negative effects on behavior and permanent loss of IQ points. Studies have shown that lead has no normal function in the human body, and that a "normal" blood lead level is zero. There is no "safe" level of lead exposure; no threshold for the toxic effects of lead has been identified. When lead accumulates in the body, it is tightly bound to bones and then released slowly over years or decades. Therefore, exposures that may be separated by significant gaps in time have an additive effect on the body's burden of lead.

Damage done by small amounts of lead may be hard to measure and even harder to understand. Children who accumulate lead in their body may not have any physical symptoms, but low lead levels cause a wide array of negative effects, including cognitive, motor, behavioral, and physical harm.² The vulnerability of children to lead poisoning during development of their brain and nervous system 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. 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 exposed to lead before the age of 3 years, IQ continued to fall even after the BLL had declined.³

The AAP has been supportive of CPSC's efforts to implement Section 101 of the CPSIA, which set the first-ever comprehensive limits on lead in children's products. The new lead limits are

being phased in over three years to allow manufacturers and retailers sufficient time to ensure that their products comply with the new rules. As of February 2009, products designed or intended primarily for children age 12 years and younger could contain no more than 600 parts per million (ppm) of lead. This standard was then lowered to 300ppm in August 2009. The AAP looks forward to the completion of the standard's implementation when the total lead limit drops to 100ppm in August 2011. Any children's product on the market that does not comply with the new lead standards will be considered a banned hazardous substance. The CPSIA, and Section 101 in particular, is a truly significant step forward in protecting children from the hazard of lead in toys and other products designed for children.

Creating Safe Sleep Environments for Infants and Children

Cribs, cradles, bassinets, and other infant sleep environments are designed for a parent or caregiver to leave a baby unattended safely for hours at a time. Unfortunately some sleep environments may pose a serious threat to a child's health and safety, thereby negating their intended purpose. Between November 2007 and April 2010, almost 150 fatalities and 1,675 injuries associated with full-size cribs and six fatalities and 28 injuries associated with non-full-size cribs were reported to CPSC. Since 2007, CPSC has issued 40 separate crib recalls involving more than 11 million products. Parents deserve the confidence of knowing the crib they purchase is held to the highest safety standards possible. The AAP has worked strenuously to reduce injuries and deaths from unsafe sleep environments by establishing guidelines for parents to use in evaluating these products and we fully support CPSC's efforts to establish strong, mandatory safety standards for cribs.

The AAP is pleased to have partnered with Chairman Tenenbaum and the CPSC on its Safe Sleep Initiative, a multi-faceted campaign aimed at reducing deaths and injuries associated with unsafe sleep environments. As part of this campaign, CPSC collaborated with AAP, Keeping Babies Safe, and journalist Joan Lunden to produce a video to be aired in hospital and physician waiting rooms providing recommendations and information to parents and families on safe sleep practices. In the video, AAP President O. Marion Burton, MD FAAP shared AAP's strong recommendation that all babies be put to sleep on their backs, which has helped reduce the rate of Sudden Infant Death Syndrome (SIDS) by 50 percent over the last 20 years. In addition, Dr. Burton highlighted the importance of never placing pillows, bumpers, sleep positioners, blankets or other fluffy items in cribs, and the need for cribs to have firm mattresses with tightly fitted sheets.⁴

Over the past year, CPSC has undertaken rulemaking processes to establish new mandatory safety standards for bunk beds, cradles, bassinets, full-size and non-full-size cribs, among many other categories of children's products as part of the Safe Sleep Initiative and as directed by Section 104(b) of the CPSIA. AAP strongly supports CPSC's efforts to establish mandatory safety standards for infant and children's sleep environments and has submitted extensive comments on each of these proposed rules.

The AAP has encouraged CPSC to make mandatory the new voluntary ASTM standard for full-size and non-full size cribs, which includes a requirement that sides of a crib be fixed in place, effectively banning drop-side cribs, (a crib design where the side of the crib can be raised and lowered). The AAP is extremely pleased that CPSC has proposed adopting this standard, as

failures in this product design have resulted in numerous infant injuries and fatalities. If this proposed rule is made final, it will be unlawful to sell, lease, or otherwise provide a full-size or non-full-size crib that does not meet mandatory CPSC standards. As a result, many establishments will be required to purchase new cribs and/or eliminate their inventory of noncompliant cribs, including child care centers (including family child care homes), hotels, motels and inns, resale and consignment shops, and crib retailers. While the AAP recognizes the demands the new safety standards may place on child care centers, retailers, and others, these considerations must be balanced against the cost to children, families, and society when preventable injuries and deaths occur in these cribs. The AAP supports CPSC in implementing the new mandatory safety standards in an expeditious, but sensible, timeframe.

Finally, the AAP was pleased that CPSC and the Food and Drug Administration (FDA) recently issued a warning to consumers urging parents not to use infant sleep positioners.⁵ Infant sleep positioners are flat mats with side bolsters or inclined (wedge) mats with side bolsters used to prevent an infant from rolling or turning while asleep. Over the past 13 years, CPSC and FDA received 12 reports of infants who died when they suffocated in sleep positioners or became trapped between a sleep positioner and the side of a crib or bassinet. These products represent a serious risk to the health and safety of sleeping babies. Sleep positioners do not prevent SIDS and in fact can increase the risk of infant suffocation. Manufacturers typically claim these products aid in food digestion to ease colic or the symptoms of gastroesophageal reflux disease and prevent flat head syndrome; however, these claims have not been reviewed and approved by the FDA. AAP has consistently recommended parents not to use these products and we fully

support CPSC and FDA's efforts to prevent further deaths or injuries as a result of using infant sleep positioners.

Limiting Cadmium and Other Heavy Metals

Recent press reports have brought to light the potential danger of another heavy metal in consumer products: cadmium. Cadmium is a soft heavy metal used in a variety of industrial and consumer applications. Like lead, with which it shares certain properties, cadmium causes a range of well-documented adverse human health effects. Oral exposure to cadmium is associated with effects on the kidney, liver, bones, immune system, blood and nervous system. Acute cadmium exposure can lead to vomiting, diarrhea and other effects. Long-term exposure to cadmium can cause kidney disease, developmental and neurological deficits, and bone fragility. Cadmium is a known carcinogen.

It appears that some manufacturers have begun adding cadmium to children's products because the CPSIA limited the use of lead. The presence of cadmium at high levels has been found in a range of children's products, most notably toy jewelry and drinking glasses. This is clearly a case of abiding by the letter but not the spirit of the law -- Congress hardly intended for companies to substitute one poison for another.

The ASTM's F-963 toy safety standard currently contains voluntary standards for eight heavy metals known to be highly toxic: antimony, arsenic, barium, cadmium, chromium, lead, mercury and selenium. As part of the CPSC's review of the adoption of the F-963 standard as a

mandatory standard, each of these standards* should undergo rigorous review, along with the associated testing protocols. The AAP urges the establishment of a systematic, transparent process by which the agency should review the literature and data, consult with experts, and update each of the heavy metal standards. This process should not be delegated to non-governmental entities or be inaccessible to the public or stakeholders. Moreover, the standards established should apply to all children's products, not solely toys. The AAP looks forward to engaging with the CPSC throughout such a process and making our members' expertise available to the agency.

Emerging Product Safety Hazards

As Americans prepare to exchange gifts this holiday season, we should all be able to have confidence in the safety of toys and children's products. As a pediatrician and injury expert, however, I also find myself anxiously awaiting the next emerging product safety hazard. Ensuring the safety of consumer products requires our constant vigilance as the marketplace changes and new products – and sometimes, new hazards – are created.

Small, powerful magnets continue to be a concern, as they can cause serious injuries if more than one is swallowed. These abdominal injuries tend to mimic stomach ailments or other minor illnesses, and can be difficult to properly diagnose. The CPSC is aware of this hazard and has recalled numerous sets of magnetic toys. Given that these magnets are being used in increasing numbers of children's products, however, continued attention to this problem is necessary.

* Not including lead, which is already covered by the CPSIA

AAP's Committee on Injury is also learning of increasing numbers of reported injuries caused by children's ingestion of so-called "button batteries." Roughly the size of a dime or nickel, these batteries closely resemble a coin when seen on scans. Unlike a swallowed coin, however, a battery must be removed from the body immediately to prevent serious harm. If lodged in the esophagus, severe tissue damage can occur in as little as two hours. Button batteries have been identified as the cause of 13 deaths. Between 1990 and 2008, 8,648 battery ingestion cases were reported, of which 62% were button batteries swallowed by children under the age of 6 years. Among children in this age group, 12% of those who ingest a 20 to 25mm battery can be expected to experience serious complications or death.⁶ The AAP is interested in working with the CPSC and industry to require secure closures for devices that require button batteries as well as appropriate packaging.

In conclusion, the AAP deeply appreciates the opportunity to offer testimony today on the implementation of the Consumer Product Safety Improvement Act of 2008. We commend you, Chairman Pryor, and the subcommittee for your leadership on consumer product safety issues, and we look forward to working with you to ensure the health and safety of all children.

¹ Bellinger DC. What is an adverse effect? A possible resolution of clinical and epidemiological perspectives on neurobehavioral toxicity. *Environ Res.* 2004;95(3):394-405.

² Bellinger D. Lead. *Pediatrics.* 2004;113(4 (Supplement)):1016-1022.

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 Video available online at <http://www.healthychildren.org/English/news/pages/A-Safe-Sleep-for-Babies.aspx>.

⁵ Announcement available online at <http://www.cpsc.gov/cpsc/pub/prere1/prhtml10/10358.html>.

⁶ Litovitz, et.al. "Preventing Battery Ingestions: An Analysis of 8648 Cases." *Pediatrics* 2010;125:1178-1183.