STATE OF NEW YORK
OFFICE OF THE ATTORNEY GENERAL
Writer's Direct No.
(212) 416-8287

ELIOT SPITZER
Attorney General

PETER H. LEHNER
Environmental Protection Bureau

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U.S. Environmental Protection Agency
Document Control Office (7407M)
Office of Pollution Prevention and Toxics
Attention: Docket ID No. EPA-HQ-OPPT-2006-0397
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

U.S. Consumer Products Safety Commission
attn: Chairman Hal Stratton
4330 East West Highway
Bethesda, MD 20814

Re: Sierra Club's TSCA Section 21 Petition Concerning Lead in Toy Jewelry, 71 Fed.Reg. 30921 (May 31, 2006), EPA Docket EPA-HQ-OPPT-2006-0397

Dear Sir/Madam and Mr. Stratton:

The Office of the New York Attorney General (NYAG) submits the following comments in support of the Sierra Club's petition under section 21 of the Toxic Substances Control Act (TSCA), requesting that the Consumer Products Safety Commission (CPSC) and Environmental Protection Agency (EPA) take action on toy jewelry containing lead.

The Sierra Club petition asks the CPSC to declare lead-containing toy jewelry a banned hazardous substance under the Federal Hazardous Substances Act (FHSA). The petition also asks that EPA, until the CPSC acts and to encourage action by the CPSC, exercise its authority under TSCA to: (1) require the submission of health and safety studies from manufacturers, importers, and processors of lead and lead salts; (2) report to the CPSC that toy jewelry containing more than 0.06% lead by weight presents an unreasonable risk of injury to health or the environment, and request that the CPSC act under FHSA to reduce or prevent this risk; (3) determine that the incorporation of lead into toy jewelry is a "significant new use" requiring 90-day notice before any business manufactures or imports such items; and (4) issue quality control orders to any manufacturer or processor of toy jewelry containing lead in excess of 0.06% by weight, requiring those entities to revise their procedures until lead in their products reaches the accepted level.

The NYAG has worked on many fronts to protect the citizens of New York from hazardous exposure to lead, including lead in consumer products. For example, the NYAG reached an agreement last fall with a major wholesaler of vinyl lunch boxes containing unlawful

120 Broadway, 26th Fl. New York, N.Y. 10271-0332 • Tel (212) 416-8450 • Fax (212) 416-6007
email: simon.wynn@oag.state.ny.us

levels of lead, recalling those items and halting their further distribution in New York.[1] The NYAG thus supports the Sierra Club's call for CPSC and EPA action on the severe and well-documented risks of lead in toy jewelry. A ban on lead in toy jewelry, backed by mandatory pre-market testing and vigorous enforcement against importers and distributors of such products, would provide reasonable protection to the public from this completely unnecessary source of exposure to lead. Such measures are long overdue, especially in light of recent cases of lead poisoning (one fatal) among children ingesting toy jewelry, as well as research suggesting that the use of lead in toy jewelry is widespread and that even minimal environmental exposure to lead poses a significant hazard to children.

The Presence of Lead In Toy Jewelry

There have been at least three recent instances of serious lead poisoning caused by toy jewelry. In February 2006, a 4-year old boy came to a Minneapolis hospital complaining of vomiting. He was quickly released, but returned two days later with intractable vomiting, "sore tummy," and listlessness. Ten hours later, the boy suffered respiratory arrest and was placed on mechanical respiration. The next day, tests revealed that he had a blood lead level of 180 micrograms per deciliter (μg/dL), 18 times the Center for Disease Control (CDC)'s "acceptable" level of 10 μg/dL. He died shortly thereafter. The culprit, as the CDC reported in March, was a heart-shaped "Reebok" charm found in his stomach, with a lead weight content of 99%.[2] Similarly, in Oregon in 2003, doctors retrieved a toy medallion from the stomach of another 4-year old boy suffering constant vomiting and abdominal pain. The toy medallion, which consisted of 39% lead by weight, had elevated the boy's blood lead level to 123 μg/dL.[3] In San Jose in December 2004, a 6-year old girl who had merely sucked on the charms of a homemade necklace was found to have elevated levels of lead in her blood.[4]

The New York State Department of Health has identified two cases of elevated blood lead levels in children in recent years in which ingestion of jewelry containing lead was suspected. In 2005, a young Cayuga County girl was found to have an elevated blood lead level. The girl was known to mouth her bracelet and at least one charm was missing therefrom. Laboratory testing revealed that the jewelry had a very high lead content. In 2004, a Monroe County child with a very high blood lead level was found to have swallowed a medallion that was too large to exit the stomach. It was thought that the jewelry had originally been gold plated, but the child's digestive acids had over time dissolved through the gold to the leaded base metal. This child had to undergo chelation therapy.

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[1] Press Release, NYAG, Vinyl Lunchboxes Containing Lead Recalled (November 29, 2005). http://www.oag.state.ny.us/press/2005/nov/nov29a_05.html

[2] CDC, *Death of a Child After Ingestion of a Metallic Charm,* 55 Morbidity and Mortality Weekly Report 340 (March 31, 2006). http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5512a4.htm

[3] CDC, *Lead Poisoning from Ingestion of a Toy Necklace*, 53 Morbidity and Mortality Weekly Report 509 (June 18, 2004). http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5323a5.htm

[4] Alan Gathright, *Metal Charms Containing Lead Recalled*, The San Francisco Chronicle, March 5, 2005, at B2.

While the Minnesota, Oregon and California incidents led to recalls by the importers or distributors of the particular items involved, after-the-fact reactions are insufficient to protect public health and are not adequate to remove these hazards from the marketplace. Indeed, even though the Oregon poisoning spurred a 2004 recall of 150 million pieces of vending machine jewelry,[5] other sources of lead-containing jewelry still exist, as made clear by the Minnesota poisoning. Also after that recall, a 2005 study of 311 pieces of jewelry in California found 169 with at least 3% lead by weight; 123 with 50% or more; and 36 with more than 75% lead. The children's pieces tested had an average lead content of 28%.[6] Moreover, a substantial proportion (16%) of items with exposed metal transferred 10 μg of lead or more after just twenty seconds of simulated handling; one item released a startling 7500 μg of lead. To put those numbers in context, the CPSC has banned toys and other consumer products bearing paint with a lead content exceeding 0.06% by weight.[7] The CPSC has also determined that children should ingest no more than 15 μg of lead per day in order to maintain an acceptable blood lead level.[8]

Toy jewelry containing lead continues to be sold in New York as well. In mid-2005, a Rochester, N.Y.-based environmental group made 17 random purchases of inexpensive jewelry from 11 local Wegman's, Big Lots, and Eckerd Drug stores[9] and found two charm bracelets with lead levels of 2.8% and 6.2%; a beaded necklace containing 4.6% lead; another bracelet containing 2.5% lead; and an "angel pin" with a lead level of 0.55%.[10]

Risks and Impacts of Lead Exposure in Young Children

Lead exposure in New York, though much reduced over the last twenty years, continues to pose a significant public health concern for citizens of the state. The last major state-level study of lead found that 1 in 37 upstate children (5,258 in all) had blood lead levels exceeding the

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[5] Press Release, CPSC, CPSC Announces Recall of Metal Toy Jewelry Sold in Vending Machines; Firms Agree to Stop Importation Until Hazard Is Eliminated (July 8, 2004). http://www.cpsc.gov/CPSCPUB/PREREL/prhtml04/04174.html

[6] R. P. Maas et al., *Lead Content and Exposure From Children's and Adult's Lead Jewelry Products*, 74 Bull. Environ. Contam. Toxicol. 437, 440-41 (Environmental Quality Institute, University of North Carolina-Asheville, 2005). The UNC-Asheville study concluded (at p. 443), "This research clearly shows that lead in low-cost jewelry is a significant threat to public health, and currently these items are being sold directly to the consumer without any form of warning."

[7] 16 C.F.R. 1303.

[8] CPSC Office of Compliance, *Interim Enforcement Policy for Children's Metal Jewelry Containing Lead* 1 (2005). http://www.cpsc.gov/businfo/pbjewelgd.pdf

[9] Corydon Ireland, *High Lead Levels Found In Jewelry Here,* Rochester Democrat and Chronicle, June 11, 2005, at 2A.

[10] Press Release, Rochesterians Against the Misuse of Pesticides, Citizens' Environmental Coalition, and New York Public Interest Research Group, High Levels of Toxic Lead Found In Children's Jewelry Sold at Rochester Retailers (June 10, 2005). http://www.cectoxic.org/lead-press-release.html

CDC standard of 10 μg/dL;[11] the Department of Health identified 36 ZIP codes in which more than 1 in 20 children had elevated blood lead levels, most of those areas having high poverty rates and large concentrations of older housing stock.[12] New York City alone reported 3,193 new cases of elevated blood lead levels in 2004,[13] and in 2003 identified 587 children with blood lead concentrations higher than 20 μg/dL.[14]

Federal and state legislative bodies have taken action to reduce lead exposure (especially lead paint) since the 1970s, as medical evidence has mounted regarding its highly toxic effects even at low blood concentrations. Lead is particularly harmful to children, because of their smaller build and because they retain higher proportions of ingested lead than adults.[15] Children exposed to high levels of lead may develop anemia, brain damage, severe kidney damage, severe gastrointestinal distress, and muscle weakness. Even small amounts of exposure to lead can slow mental development and impair intellectual performance.[16] Indeed, adverse effects of lead exist at concentrations lower than the current CDC benchmark of 10 μg/dL. A 2005 study of 1,333 children found a decline in IQ of almost four points associated with a rise in blood lead levels from 2.4 to 10 μg/dL, with an additional 3 points of IQ decline occurring as blood lead concentrations increased from 10 μg/dL to 30 μg/dL. These researchers concluded that "environmental lead exposure in children who have maximal blood lead levels < 7.5 μg/dL is associated with intellectual deficits."[17] The Agency for Toxic Substances and Disease Registry's

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[11] New York State Department of Health, *A Report of Lead Exposure Status Among New York Children: 2000-2001,* p. iii. http://www.health.state.ny.us/nysdoh/lead/exposure_report/index.htm

[12] *Id*, at 8.

[13] New York City Department of Health and Mental Hygiene, *City Health Information: Childhood Lead Poisoning,* Dec. 2005, at 59.

[14] New York City Department of Health and Mental Hygiene, *New York City Childhood Lead Poisoning Prevention Program: Annual Report 2003* 6 (2004).

[15] Agency for Toxic Substances and Disease Registry, *Draft Toxicological Profile for Lead* 8 (2005). http://www.atsdr.cdc.gov/toxprofiles/tp13.html

[16] *Id*, at 10.

[17] B.P. Lanphear et al., *Low-level Environmental Lead Exposure and Children's Intellectual Function: an International Pooled Analysis,* 113 Environmental Health Perspectives 894, 894 (2005). Canfield et al. reported results consistent with that finding in the *New England Journal of Medicine* in 2003; their study of 172 children found a 7.4 point decline in IQ as average blood lead concentrations rose from 1 to 10 μg/dL. They wrote, "These and other data suggest that there may be no threshold for the adverse consequences of lead exposure and that lead-associated impairments may be both persistent and irreversible." R.L. Canfield et al, *Intellectual Impairment in Children With Blood Lead Concentrations Below 10 μg/dL*, 348 New England Journal of Medicine 1517, 1525 (2003). Those two studies confirm a much earlier survey of studies by Schwartz, reporting a negative relationship between children's blood lead concentration and IQ at levels "well below" 7 μg/dL, and noting that the effect was largest at these low levels of exposure. J. Schwartz, *Low-level Lead Exposure And Children's IQ: A Meta-Analysis and Search for a Threshold,* 65 Environmental Research 42, 52-53 (1994).

Draft Toxicological Profile for Lead concludes, "No safe blood lead level in children has been determined."[18]

Comments on Petitioners' Proposed EPA Actions

Reports of widespread use of lead in toy jewelry, together with persuasive evidence that even minimal childhood exposure to lead has adverse effects on mental development, point to the conclusion that strong regulatory action is needed to curtail this completely unnecessary public health hazard. The optimal policy is a coordinated program of simple and stringent limits on lead content, preferably an outright ban, and mandatory product testing by importers, manufacturers, and distributors of toy jewelry.

Banning lead in toy jewelry, as proposed by Sierra Club and supported herein, is superior to the CPSC's current Interim Enforcement Policy for Children's Metal Jewelry[19] because it is simple to administer over a diverse set of products; ensures that no product hazardous to children, by accident or design, makes it to market; and recognizes the scientific reality that there is no known safe level of lead exposure for children.[20] The Interim Enforcement Policy tests "components" of jewelry (ill-defined, but essentially the separable parts of the product) and sets limits of 0.06% lead by weight and 175 μg of "accessible" lead for any tested component. As the Center for Environmental Health points out,[21] this standard – while an improvement over no guidance at all – unintentionally allows individual pieces of jewelry with a low *per-component* lead content, but high *overall* content, to evade enforcement. The Interim Enforcement Policy's lead weight limits are also based on an "acceptable" blood lead concentration of 10 μg/dL which many studies have begun to question (see note 17, above).

The NYAG recommends the "preventive" approach suggested by experts in the field of childhood lead exposure.[22] Toy jewelry should be as free of lead as possible before it reaches the market, not hastily recalled – often with poor effectiveness[23] -- once a previously unknown

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[18] Agency for Toxic Substances and Disease Registry, *supra* note 15, at 10.

[19] CPSC, *supra* note 8.

[20] Agency for Toxic Substances and Disease Registry, *supra* note 15, at 10.

[21] Center for Environmental Health, *Analysis of CPSC Policy on Lead-Tainted Children's Jewelry* (2005). http://www.cehca.org/jewelry.htm.

[22] *See, e.g.,* Canfield et al., *supra* note 17, at 1525. ("Because there is no effective treatment for children with moderately elevated blood lead concentrations, the collective evidence argues for a shift toward primary prevention of lead exposure in contrast to the current, almost exclusive emphasis on the treatment of children with elevated blood lead concentrations").

[23] *See* CPSC, *CPSC Focuses Attention on Recall Effectiveness,* CPSC Monitor, May 1, 2003 ("Historically, rates of return have been very low on most products. (As low as 16% in 1996.)").

hazard is discovered.[24] This approach would counsel a ban on lead in toy jewelry and a requirement that manufacturers of these items have their products independently tested before offering them for distribution. Tests for lead are relatively easy and inexpensive, and much less costly for the public (and for manufacturers) than dangerous products and large-scale recalls.

The NYAG fully supports the petition's request that the CPSC ban toy jewelry containing lead. Until such a ban, EPA should take the steps further requested in the petition. The NYAG offers the following observations on the proposed EPA actions, as a supplement to the arguments in the Sierra Club petition:

1. TSCA §8(d) Health and Safety Reports

With respect to the request that EPA seek health and safety reports from manufacturers, processors, and distributors of lead and lead salts under TSCA §8(d), we note that the term "processors" is defined in TSCA §3 to include any entity who prepares a chemical substance or mixture for distribution in commerce *as part of an article* containing that substance or mixture.[25] Thus EPA should ensure that it extends its health and safety data reporting rule to such manufacturers within its jurisdiction of toy jewelry incorporating lead. EPA should also use the results of this rule to inform its risk report and recommendation to the CPSC under TSCA §9 as requested in the Sierra Club petition.

2. TSCA §9 Report to the CPSC

The NYAG supports Sierra Club's request that EPA issue a risk report to the CPSC under TSCA §9 recommending action under the FHSA, and take appropriate regulatory steps under TSCA §9(a)(2) if the CPSC does not respond within 90 days.

As noted above, there is abundant evidence to provide the EPA with the "reasonable basis" required under TSCA §9(a)(1)[26] to conclude that lead in toy jewelry presents an "unreasonable risk of injury to health or the environment" and warrants stronger regulation under FHSA. In its TSCA report, EPA should recommend that the CPSC declare toy jewelry containing lead "banned hazardous substances" under the FHSA §2(q)(1)(B),[27] following the notice, hearing, and regulatory analysis procedures required under FHSA §3(f)-(i). Given the demonstrated human costs of past failure to regulate in this area, and the current widespread availability of inexpensive substitutes for lead in toy jewelry, EPA's recommended regulation should have no trouble satisfying the cost-benefit analysis required under FHSA §3(i)(1).[28] EPA should also recommend that the CPSC back up this regulation with a requirement that

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[24] *See* Kids in Danger, *Playing With Poison: Lead Poisoning Hazards of Children's Product Recalls, 1990-2004*, August 2004. http://www.kidsindanger.org/04v1/publications/reports/2004_playingwithpoison.pdf

[25] 15 U.S.C. §2602(10)(B) and (11) (2005).

[26] 15 U.S.C. §2608(a)(1) (2005).

[27] 15 U.S.C. §1261(q)(1)(B) (2005).

[28] 15 U.S.C. §1262(i)(1) (2005).

manufacturers and importers provide the agency with results of independent product testing by accredited laboratories, at least for an interim period.

If the CPSC does not act under FHSA in a way that reduces the risks that EPA identifies in its report, EPA has sufficient authority under TSCA §6(a)(2)[29] to enact a limit on lead in toy jewelry, as well as authority under TSCA §6(a)(4)[30] to require manufacturers of these products to "monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection."

3. Issuance of "Significant New Use Rule" Under TSCA §5(a)(2)

The NYAG supports Sierra Club's call for EPA to issue a significant new use rule under TSCA §5(a)(2), requiring firms which manufacture or import lead-containing toy jewelry to give 90-day notice to the Administrator before doing so. These notices could prove to be a valuable source of market information for EPA and the CPSC as these agencies regulate lead in toy jewelry.

4. Issuance of Quality Control Orders Under TSCA §6(b)

The NYAG supports Sierra Club's petition that EPA, if the CPSC does not issue a ban, exercise its authority under TSCA §6(b) to issue quality control orders to manufacturers of toy jewelry that contain lead. This action could reduce risks associated from unintentional lead contamination in toy jewelry due to poor quality control.

As the product tests cited earlier suggest, there is ample evidence of continued poor quality control in toy jewelry leading to extreme variability of lead content. After the lethal incident of lead poisoning in February of this year, for example, officials from the Minnesota Department of Regulatory Services collected identical "Reebok" charms with lead content varying from 0.07% by weight to 67%.[31] The Toy Industry of America has also recognized the importance of quality control, claiming that most cases of lead in its members' products result from suppliers who fail to meet manufacturing specifications. However, the problem persists despite promises from the industry association since 1998 that its members would eliminate lead from their products.[32]

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[29] 15 U.S.C. §2605(a)(2) (2005).

[30] 15 U.S.C. §2605(a)(4) (2005)

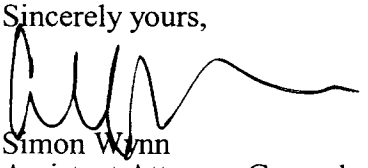
[31] CDC, *supra* note 2.

[32] Kids in Danger, *supra* note 24, at 12.

Conclusion

The NYAG appreciates the opportunity to comment on this important petition. Please contact the undersigned for further clarification if needed.

Sincerely yours,



Simon Wynn
Assistant Attorney General

On the comments:
Tomas Carbonell
law student assistant