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CONSUMER PRODUCT SAFETY COMMISSION
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STATEMENT ON LEAD REGULATION UNDER THE CPSIA
COMMISSIONER ROBERT ADLER

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Introduction

I have been a Commissioner on the Consumer Product Safety Commission for roughly five months. During that time, the topic of lead has dominated the agency's (and my) agenda – consuming over half my time on far too many days. The reason is simple: in the Consumer Product Safety Improvement Act (CPSIA), Congress took a number of strong steps to regulate lead in children's products. Among other things, Congress (i) set extremely strict limits on permissible levels of lead in children's products and paint on consumer products, (ii) made these low lead limits retroactive, and (iii) established very narrow grounds upon which firms might seek an exclusion from the lead provisions in the CPSIA.

These provisions – which comprise only about five pages of a 60 page law – have been extremely controversial from the outset. They have triggered numerous complaints and objections from regulated industry and others, occupying large amounts of Commission time and attention.

As I have waded into the debate, I have encountered many thoughtful, sincere, and anguished concerns about the CPSIA. I have also heard numerous overheated arguments, scanned many bloviating blogs, and read great numbers of error-laden emails (and letters) commenting on the law.

As a former congressional staff attorney and as a former CPSC attorney-adviser, I find it hard to plead naiveté about how public policy is set in Washington, D.C. Nonetheless, I find it disturbing to see how the merits of the topic – the actual facts, hard science, and critical data about lead – have been casually used as weapons, not carefully developed as tools, in addressing the issue of regulating lead. As an academic who taught the need for due diligence and rigor in decisionmaking for the past 20-plus years, I find the hubbub to be less than helpful to me in my current role as a policymaker. Accordingly, I have

attempted in this statement to address as many concerns regarding lead in as thoughtful a manner as possible.

As I have shared my thoughts on lead with friends and colleagues, I have been repeatedly cautioned that parts of my statement will be taken out of context to support positions that I may oppose – and deplore. I understand this concern, but still feel an obligation to offer my best attempt at a thoughtful and balanced analysis on this critical topic.

Background

On December 16, 2009, the FY 2010 Consolidated Appropriations Act became law. This Act contained the FY 2010 appropriations for the U.S. Consumer Product Safety Commission. The Statement of Managers for the Appropriations Act directed the Commission to assess the lead provisions in section 101(a) of the recently enacted Consumer Product Safety Improvement Act (CPSIA) of 2008[1] and to recommend any improvements to the CPSIA to the House and Senate Appropriations Committees, as well as to the House Energy and Commerce Committee and the Senate Commerce, Science, and Transportation Committee by January 15, 2010. I am pleased to have joined in the Commission Report to Congress and fully support its recommendations.[2] I did not attach this statement to the Report because it is not a direct response to the questions in the Statement of Managers, but rather it is a broad exposition of my views on the issues generally.

The Consumer Product Safety Improvement Act: A Major Safety Step Forward

On August 14, 2008, President George Bush signed the Consumer Product Safety Improvement Act (CPSIA) into law. The Act passed in the House by a vote of 424-1 and in the Senate by a vote of 89-3. To say the least, such overwhelming majorities in a Congress otherwise split by deep partisan differences signaled extremely strong support for this legislation. I mention this because of recent broad attacks on the CPSIA from a variety of voices both inside and outside of government that claim to find almost nothing redeeming in the law. To the contrary, I believe the CPSIA was the right law at the right time. It represents a dramatic step forward in advancing consumer safety – a point that I fear may be overlooked amidst the clamor for modifying it.[3] Moreover, notwithstanding

[1] Public Law 110-314, 122 Stat. 3016 (August 14, 2008).
[2] My statement on the Report may be found at http://www.cpsc.gov/pr/adler01152010.pdf.
[3] Among the enhanced features in the new law: (1) expands staff levels for the agency, (2) restores the Commission to five-members, (3) shortens the time limits under section 6(b) of the CPSA from 30 days to 15 for manufacturers to submit objections to the public release of information identifying their products, (4) bans all but trace elements of lead in children's products, (5) requires testing of children's products by third-party laboratories before the products can be sold at retail, (6) requires manufacturers of children's products to place identifying labels on their products and packages to enable consumers and others to identify recalled goods, (7) requires the CPSC to assess the safety of current industry voluntary standards for durable infants' products and to promulgate mandatory safety standards for such products on a regular schedule, (8) makes mandatory the industry voluntary standard for toys and requires the CPSC on a regular basis to update the standard, (9) requires the Consumer Product Safety Commission (CPSC) to establish a user-friendly, publicly-accessible database on reports of harm from consumer products submitted by consumers, government agencies, health care providers, child service providers, and public safety entities,

the calls for narrowing the law's provisions, I believe that an equally compelling case for strengthening the CPSIA can be made.[4] For example, the CPSC is the only federal health and safety agency that must submit critical safety information to manufacturers for review before it can warn the public of product hazards.[5] Moreover, the requirements for extensive cost-benefit analysis contained in section 9 of the Consumer Product Safety Act (CPSA) continue to constitute an immense barrier to expeditious and effective rulemaking.[6] Further, despite the dramatic increase in CPSC funding in the past two years, the fact remains that the agency labors under a significantly broadened mandate with a staff roughly half the size that it had thirty years ago.[7]

Although one can debate the impetus for the CPSIA, I trace it back to a lengthy two-part expose (later awarded a Pulitzer Prize) published in early 2007 in the *Chicago Tribune* describing the death of a young child who had swallowed loose magnets from a toy regulated by the CPSC.[8] Among other things, the article alleged that the CPSC's limited

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(10) strengthens import protections and expands authority to halt the export of dangerous products, (11) bans 3-wheel All Terrain Vehicles (ATV's) and makes mandatory an industry voluntary standard on other ATVs, (12) prohibits the use of certain phthalates in children's toys and child care articles; also requires the study of other phthalates to determine whether they present a public health threat, (13) streamlines some CPSC rulemaking authority, (14) authorizes and directs CPSC to share safety information with state public health agencies and foreign governments, (15) authorizes state attorneys general to enforce CPSC rules through injunctive relief, (16) overrules the CPSC's attempt to preempt state common law tort claims for products complying with CPSC rules by barring the agency from construing any of its acts as preempting such claims, (17) provides whistleblower protections for private sector employees regarding alleged violations of any CPSC-enforced product safety requirements, and (18) increases civil penalties to $15 million for a related series of violations of CPSC laws, and enhances criminal penalties for such violations.

[4] I find it ironic that many of those most vocally opposed to granting the CPSC greater discretion in rulemaking and information disclosure vigorously support broadening our discretion to grant exemptions from the lead standard in the CPSIA.

[5] To be precise, section 6(b) of the CPSA requires the agency, not less than 15 days prior to publicly disclosing information that would permit the public to ascertain readily the identity of a manufacturer or private labeler of a consumer product, to notify and provide a summary of the information to the manufacturer and to provide the manufacturer with a reasonable opportunity to submit comments to the Commission regarding such information. The section further requires the Commission to take reasonable steps to assure, prior to public disclosure of the information, that the information is accurate, and that its disclosure is fair in the circumstances and reasonably related to effectuating the purposes of the Act. No other agency faces such a burdensome approach in releasing critical safety information to the public.

[6] I do not object to cost-benefit analysis. I object to placing extensive formal requirements for such an analysis in the CPSA because these provisions invariably lead to extensive judicial challenges to CPSC regulations based on frivolous objections that the agency failed to satisfy the Act's requirements. Satisfying the often duplicative and unnecessary requirements of section 9 invariably extends the time required to enact safety regulations.

[7] The Commission has less than half of the staff of the Federal Trade Commission, which is an independent agency that also has the mission of protecting consumers. (FTC Performance and Accountability Report for 2009, available at http://www.ftc.gov/opp/gpra/2009parreport.pdf). Further, the CPSC has fewer total employees than the number of new employees requested by the Food and Drug Administration in its FY 2010 budget request. See Joshua M. Sharfstein, "Statement on FY 2010 Budget Request Before Subcommittee on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, Committee on Appropriations, U.S. House of Representatives" (May 21, 2009)(letter requesting 678 new employees for food safety and a budget increase of $259 million – both numbers more than the total at the CPSC).

[8] Patricia Callahan, "Toy Magnets Kill Young Boy," Chicago Tribune, May 5, 2007, and "Inside the Botched Recall of a Dangerous Toy," Chicago Tribune, May 7, 2007.

resources prevented the agency from following up on several reports of severe injuries associated with the product. Moreover, when the agency realized the extent of the danger, it found itself stymied by the information disclosure restrictions of section 6(b) of the CPSA. Even more dramatic news regarding the CPSC emerged that year as the agency began a series of widely publicized recalls of Chinese-produced toys containing high levels of lead, eventually culminating in over one hundred recalls involving roughly 20 million toys. As the recall count rose into the scores and media reports grew more alarming, Congress took note and began a series of hearings into the agency's operations and leadership. Congress eventually decided that a major overhaul of the CPSA was called for, leading to enactment of the CPSIA.

The Hazards of Lead

There is no question that the scores of toy recalls involving excessive amounts of lead brought the need for amending the CPSA to the attention of the Congress. Nor is it surprising that Congress took strong steps to address the risks associated with lead in toys and children's products.

While no one disputes that lead presents severe individual and environmental hazards, a brief history of lead regulation reveals that public health authorities – sometimes subject to industry obfuscation and delay[9] – have consistently underestimated the dangers of this heavy metal. Before 1970, astonishingly, "undue lead exposure" was commonly defined as blood levels above 60 micrograms per deciliter (or 60 µg/dL in scientific shorthand) – levels commonly associated with acute toxic reactions such as abdominal colic, anemia, encephalopathy, and, sometimes, death.[10] As the years passed and as thousands of new studies have confirmed, lead poses substantial risks even at much lower levels. In particular as recent research has shown, even low levels of lead are widely associated with learning disabilities, decreased growth, hyperactivity, impaired hearing, and brain damage.[11] Accordingly, over a twenty year period, the Centers for Disease Control

[9] See, e.g., David Michaels, "Doubt is Their Product," *Scientific American*, June 2005, Vol. 292 (6). See also, David Michaels, *Doubt is Their Product* (2008)[expanded discussion of points in the *Scientific American* article].

[10] See Bruce P. Lanphear, et. al, "Low-Level Environmental Lead Exposure and Children's Intellectual Function: An International Polled analysis," *Environmental Health Perspectives*, February, 2006, Vol. 114(2), A 85.

[11] See, e.g., Environmental Protection Agency, "Lead Poisoning and Your Children," EPA 747-K-00-003, October 2000; Kim Cecil, et. al., "Decreased Brain Volume in Adults with Childhood Lead Exposure," *PLoS Medicine*, May 2008, Vol. 5 (5) available at www.plosmedicine.org; Karn Koller, et. al., "Recent Developments in Low-Level Lead Exposure and Intellectual Impairment in Children, *Environmental Health Perspectives*, June 2004. Vol. 112 (9); Janet Raloff, "School-Age Lead Exposures Most Harmful to IQ," *Science News*, June 6, 2009, Vol. 175 (12) at 13; American Academy of Pediatrics, "Lead: Exposure in Children: Prevention, Detection, and Management, *Pediatrics*, October 2005, Vol. 116 (4), 1036-1046; Centers for Disease Control, U.S. Department of Health and Human Services, "Preventing Lead Poisoning in Young Children (August 2005)[hereinafter, "the CDC Report"]; and Integrated Risk Assessment Branch, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, "Development of Health Criteria for School Site Risk Assessment Pursuant to Health and Safety Code Section 901(g):Child-Specific Benchmark Change in Blood Level for School Site Risk Assessment," (April 2007[hereinafter, "the California Report"].

(CDC) and others have dramatically lowered their assessment of what blood measurements constitute "levels of concern."[12] In fact, although some authorities currently cite 10 µg/dL as an acceptable level of concern, a considerable body of recent research has cast doubt on even this low number.[13]

Today, science recognizes that even children who seem healthy can carry harmful levels of lead in their bodies. To say the effects are not directly observable is not to say that they are minor. In fact, small levels of lead have been demonstrated to have a significant negative impact on neural pathways, leading to measurable IQ losses, among other effects.[14] What makes the threat from lead so ominous is its effect on children. Children have proven to be more vulnerable to lead's effects than adults for several reasons: young children typically mouth things in the environment to a considerable extent, their gastrointestinal tracts tend to absorb more chemicals than adults, and their developing nervous systems are thought to be more vulnerable to lead than adult systems.[15]

Moreover, lead is a cumulative hazard, excreted at very slow rates from young bodies.[16] And since lead easily crosses the placenta, harmful exposures can occur even before children are born – prenatal exposure can cause reduced birth weight and premature

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[12] Here is a summary of the blood levels considered to be of concern by the CDC over the years:

- >40 µg/dL – 1971
- >30 µg/dL – 1978
- >25 µg/dL – 1985
- >10 µg/dL -- 1991

Lanphear, et. al. *supra* note 10.

[13] This point was specifically made in the report of the Senate Committee on Commerce, Science, and Transportation on the Consumer Product Safety Commission Reform Act of 2007 [later known as the Consumer Product Safety Improvement Act] in February 2007. ("Based on research conducted since 1991, evidence indicates that blood levels of less than 10 µg/dL can affect children's physical and mental development….") S. Rep. No. 265, 110th Cong., 2d Sess. 10 (2007). See, also, Helen J. Binns, et. al., "RN for the Advisory Committee on Childhood Lead Poisoning Prevention, Interpreting and Managing Blood Levels of Less Than 10 µg/dL in Children and Reducing Childhood Exposure to Lead: Recommendations of the Centers for Disease Control and Prevention Advisory Committee on Childhood Lead Poisoning Prevention, *Pediatrics*, Vol. 120 (5), November 2007 available at http://www.ncbi.nlm.nih.gov/pubmed/17974722?itool=EntrezSystem2.PEntrez.Pubmed.Pubmed_ResultsPanel.Pubmed_RVDocSum&ordinalpos=4 ; The California Report *supra*, note 11, at 1 ("It is becoming increasingly clear that the inverse relationship between blood lead concentrations and these health and developmental effects extends well below 10 µg/dL."); and Lanphear, et. al., *supra* note 10 ("The preponderance of experimental and human data indicates that there are persistent and deleterious effects of blood levels > 10 µg/dL on brain function, including lowered intelligence, behavioral problems, and diminished school performance."). As I understand it, CPSC staff has long considered blood levels of 10 µg/dL and higher to be of concern.

[14] Id. See, also, Todd A. Jusko, et.al., "Blood Lead Concentrations < 10 µg/dL and Child Intelligence at 6 Years of Age," *Environmental Health Perspectives*, Vol. 116(2) (Feb. 2008); Committee on Environmental Health, American Academy of Pediatrics, "Lead Exposure in Children: Prevention, Detection, and Management," *Pediatrics*, Vol. 116(4) October 2005; and R. Canfield, et.al., "Intellectual Impairment in Children With Blood Lead Concentrations Below 10 µg/dL," *New England Journal of Medicine*, Vol. 348 (2003).

[15] Koller, *supra* note 11, at 987 (citing these reasons).

[16] Lead has a half-life of roughly 35 days in the blood, but persists in bones for many years. See The California Report, *supra* note 11, at 4.

births.[17] Once exposed to harmful amounts of lead, children seem to suffer long lasting and perhaps permanent harm even if it can be removed from their system.[18]

Finally, to top off the list of lead's possible harms, the metal is suspected to be a carcinogen.[19] In sum, lead, along with things like cadmium, arsenic, and mercury, is one of the most toxic chemicals to which consumers are regularly exposed.

Lead: No "Safe" Level

Virtually all experts say the same thing about lead's risks: there is no known "safe" level of lead.[20] Although a seemingly simple statement, it requires a thoughtful analysis to understand its nuances. It is not an assertion that all levels of lead exposure children experience are harmful nor, on the other hand, is it a suggestion that a "safe" level of lead eventually will be discovered. The statement, rather, is a careful phrasing of the current level of knowledge about lead's dangers – to wit, science has found definite and substantive evidence that lead is harmful to the outer limits of science's ability to detect harm. In recent years, for example, studies have demonstrated that very low levels of lead can produce measurable effects on IQ.[21] Moreover, new MRI (Magnetic Resonance Imaging) technology has permitted us to identify permanent damage in adults stemming from childhood lead exposures.[22] Beyond a certain point, however, we lack the tools for assessing subtle adverse effects of low levels of lead exposure.

I would describe the current situation with lead this way: every time we have developed (or refined) an approach that is capable of measuring the risks of lead, scientists have found negative effects. We may have currently reached the outer limits of our ability to

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[17] David Bellinger, et. al., "Weight Gain and Maturity in Fetuses Exposed to Low Levels of Lead," *Environmental Research*, Vol. 54, 151-8 (1991).

[18] American Academy of Pediatrics Report, *supra* note 11, at 1038 ("[The] data imply that the effects of lead exposure are long lasting and perhaps permanent.").

[19] Agency for Toxic Substance & Disease Registry, Department of Health and Human Services, "ToxFAQs for Lead," August 2007, available at http://www.atsdr.cdc.gov/tfacts13.html. ("The Department of Health and Human Services (DHHS) has determined that lead and lead compounds are reasonably anticipated to be human carcinogens and the EPA has determined that lead is a probable human carcinogen. The International Agency for Research on Cancer (IARC) has determined that inorganic lead is probably carcinogenic to humans and that there is insufficient information to determine whether organic lead compounds will cause cancer in humans.").

[20] See, e.g., The CDC Report, *supra*, note 11, at ix ("The data demonstrating that no "safe" threshold for blood lead levels (BLLs) in young children has been identified highlights the importance of preventing childhood exposures to lead."); The California Report, *supra* note 9, at 21 (noting that the OEHHA's recommendation for a benchmark incremental change in blood level is not an absolutely safe exposure level, "since no safe level has been definitively established."); American Academy of Pediatrics, "Lead: A Costly Burden on Children, Families, and Society," letter dated August 26, 2008 ("There is no known "safe" level of lead for children."); and Cincinnati Children's Hospital Medical Center, "International Study Finds No Safe Level of Lead in Children's Blood," press release (2005).

[21] See *supra* notes 10-13, and accompanying text.

[22] Kim M. Cecil, et. al., "Decreased Brain Volume in Adults With Childhood Lead Exposure," PLoS Medicine, available at www.plosmedicine.org, Vol. 5 (5), May 2008.

measure negative effects of exposure to small amounts of lead,[23] but that does not mean that no adverse effects are occurring. It basically means that we do not know.[24]

The immediate relevance of this to me as a policymaker is that I reject the term "*de minimis*" risk when applied to lead. To me, this implies either that a risk is known to be so minimal that one need not worry about it or that a risk is "safe." As I read the studies, neither proposition is correct. Instead of *de minimis*, if I had to choose a term to apply, I would describe lead's risks at very low levels as "not demonstrably harmful" or "not proven dangerous." These terms capture the sense that the technology of measuring harm has reached its limit for the moment, but that further research may clarify the risks – which may or may not be acceptable once better understood.

In the face of this uncertainty surrounding lead's risks at low levels, the public health community has wisely, in my view, advocated strongly for removing as much lead from the environment as possible, wherever possible. That said, given that lead remains ubiquitous and often unavoidable, policymakers, who are fully aware of lead's risks, have sought to determine some level that would be acceptable – at least until new information becomes available. California, for example, has recently established a new child-specific health guidance value (HGV) for lead in health risk assessments at school sites.[25] In setting this level, however, the California health authorities have cautioned that their number for tolerable lead "does not represent an absolutely safe exposure level, since no safe level has been definitively established."[26] As I shall discuss, I am open, in very limited circumstances, to employing this type of methodology to children's products subject to the CPSIA.

Lead Provisions in the CPSIA

Briefly summarized, Congress addressed lead in two ways in the CPSIA: First, Congress banned lead in any children's product[27] under the Federal Hazardous Substances Act

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[23] Id. Scientists still do not understand all of the ways that lead interacts in the body.

[24] Lead is not unique on this point. Other hazards, such as radiation, may present not-easily-measured risks at low doses. See, e.g., Robert Wagner, "Radiation and Cancer Risks: Is it Safe to Have X-Rays?" CancerNews at http://www.cancernews.com/data/Article/264.asp ("Most radiation models make the assumption that there is no safe dose of radiation and even the tiniest amount increases your risk of cancer."). Radiation has become controversial lately because of its use in X-ray scans at airports. See, Matthew Wald, New York Times,"Cancer Risks Debated For Type of X-Ray Scan, January 9, 2010, at A4 (noting that the new X-Ray scanners at airports may produce negligible risk to individual travelers, but "collectively the radiation doses from the scanners incrementally increase the risk of fatal cancers among the thousands or millions of travelers who will be exposed, some radiation experts believe.").

[25] The California Report sets, as an acceptable level, lead exposures that do not increase blood lead level beyond 1 µg/dL based on an increased daily intake of 6 µg/dL ingested soluble lead from soil or 5 µg of inhaled lead. This level derives from studies that show a change of one IQ point associated with increased blood levels of 1µg/dL. Levels below this show no demonstrable effect. The California Report, *supra* note 11, at 1. In a similar vein, EPA has recently set lower limits for ambient air quality standards (NAAQS) for the nation's air. See eNewsUSA, "EPA Finalizes New NAAQS for Lead at 0.15 µg/m3 (10Times Lower)" at http://enewsusa.blogspot.com/2008/10/epa-finalizes-new-naaqs-for-lead-at-015.html.

[26] The California Report, *supra* note 11, at 1.

[27] Congress defined a "children's product" as a "consumer product designed or intended primarily for children 12 years of age or younger." 15 U.S.C. § 2052(a)(2).

(FHSA) on a rolling retroactive basis. By that, I mean that Congress imposed increasingly more stringent limits on permissible lead levels in children's products over time and each instance in which the lead level dropped, any product introduced into commerce, whether manufactured before the effective date or after it, became instantly banned. As implemented, the permissible levels of lead dropped to 600 parts per million (ppm) 180 days after enactment of the CPSIA[28] and to 300 ppm one year after the Act became law.[29] To repeat: the lead bans are retroactive, i.e., any products on the market that exceed these levels become illegal to introduce or deliver for introduction into interstate commerce whether or not produced before the effective date of each new lead limit.[30]

Second, Congress substantially reduced the amount of lead permitted in paint. Effective one year after enactment of the CPSIA, all paint covered by existing regulation of the CPSC may contain no more than 90 ppm of lead, a drop from the previous permissible level of 600 ppm.[31]

As far as I can tell, these new limits represent the most stringent regulation of lead in the world. They demonstrate Congress's agreement with the public health community's claim that lead should be removed from the environment to the greatest extent possible.

The Economic Impact of the CPSIA Lead Bans

Congress seems to have realized that these new lead limits would have a significant impact on the manufacturing community. To lessen the economic hit to producers, Congress included several ameliorative provisions in the law. First, Congress provided a six-month month grace period before the 600 ppm ban became effective and an additional six-month period before the 300 ppm ban took effect.[32] Second, for certain products, such as electronic devices (including devices with batteries) where compliance would be particularly difficult or impossible, Congress gave the CPSC discretion to withhold the ban provided that the use of lead was necessary for the proper functioning of a component part of an electronic device.[33] Third, Congress provided an exclusion provision for products with inaccessible parts[34] and one for products that the Commission determined would not present any absorption of lead into the human body nor have any other adverse impact on public health or safety.[35]

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[28] Section 101(a)(2)(A) of the CPSIA.
[29] Section 101(a)(2)(B) of the CPSIA. Effective August 2011, the limits drop to 100 ppm unless the Commission determines that a limit of 100 ppm is not "technologically feasible" for a product or product category. Section 101(a)(2)(C).
[30] Congress specifically provided that the bans be considered a regulation under section 2(q) of the FHSA. Unless made prospective, bans under this section are automatically retroactive. See section 101(g) of the CPSIA.
[31] Section 101(f)(1) of the CPSIA.
[32] As noted in the Senate conference report on H.R. 4040, "[The lead bans] are implemented responsibly to give manufacturers time to adapt, without compromising safety." 154 Cong. Rec. S7877 (daily ed. July 31, 2008).
[33] Section 101(b)(4) of the CPSIA.
[34] Section 101(b)(2) of the CPSIA.
[35] Section 101(b)(1) of the CPSIA.

Considerable debate has swirled around the extent of the economic impact of the CPSIA lead bans. That there would be some disruption is unquestionable. Any change as dramatic as the new lead levels in the CPSIA, applied retroactively, would undoubtedly have a major impact on those who manufacture consumer products. Although one would wish it were not so, it is likely that some firms, facing these significant new requirements, would choose to stop manufacturing children's products and go out of business or move to non-children's products. The critical question for me is whether any unanticipated costs of the lead bans in the CPSIA went beyond the law's social benefits such that some adjustment in the Act is warranted. Sadly, the data that would fully answer this question seems difficult, if not impossible, to obtain. It is true that I can find numerous stories in the media and on heated blogs about the economic consequences on individual manufacturers or particular industries, but these stories, while extremely compelling if not heart-breaking, are essentially anecdotal. Unfortunately, as a former faculty colleague of mine once quipped, "the plural of anecdote is not data."

Accordingly, despite my desire for better information, I accept that it is not forthcoming and turn to doing the best I can in the face of significant factual uncertainty.[36] On balance, based on numerous discussions with as many sources in industry, consumer groups, and other data sources as I can track down, I believe that the economic impact of the CPSIA was substantial and far-reaching, but I cannot put a reliable number on it.[37] The exact extent will probably never be known because some of the losses attributed to the CPSIA no doubt stemmed from the nation's deep recession, and not the Act.

Notwithstanding the lack of precise economic data, I see a problem and consider myself open to the idea of adjustments to provide some relief to those adversely affected by the law. I am particularly receptive to modifications that would benefit small businesses and low-income consumers. Needless to say, I oppose changes in the law that would place consumers at any significant risk from lead.

The CPSC's Implementation of the Lead Provisions of the CPSIA

Before discussing my views regarding possible modifications of the law, I would like to discuss the CPSC's implementation of the lead provisions of the CPSIA.[38] In my short tenure as a CPSC Commissioner, I have been extremely impressed by the thoughtful and measured way the agency has implemented the law in an effort to accommodate industry's concerns. For example, when faced with widespread industry confusion and

[36] To see that this is not a new dilemma, one need only type in the words "decision making in the face of scientific and factual uncertainty" in Google. I got 684,000 hits when I did this.

[37] The CPSC staff attempted to do so in a letter to Congressman John Dingell, but made clear that its data were anecdotal and not verified. See CPSC Staff, Letter to the Honorable John D. Dingell responding to questions submitted regarding implementation of the Consumer Product Safety Improvement Act (March 20, 2009). See, also, Joseph Pereira, "Makers are Pushing Back on Toxic-Toy Law," *Wall Street Journal*, March 5, 2009 (citing industry estimates of the impact of the CPSIA).

[38] Even before passage of the CPSIA, the Commission had issued guidance on lead in consumer products that called for companies to take strong measures to reduce this metal. See Consumer Product Safety Commission, "Guidance for lead (Pb) in consumer products," 16 C.F.R. § 1500.230 (1998).

turmoil regarding the law's requirements, the Commission issued a series of stays of enforcement regarding testing and certification to the new lead standards,[39] giving firms additional time to adjust their production processes to comply with the law. Although I continue to have qualms about possible unintended consequences of the stays,[40] on balance, I have supported the stays, and recently – reluctantly – voted to extend them.[41]

Most of the firms who have complained about the CPSIA's stringency and inflexibility point to three areas of concern: (1) the new requirements for testing and certification, (2) the challenge of seeking exclusions from the law's sweep, and (3) retroactivity of the law's provisions.

Testing and Certification Requirements: Under the CPSIA, Congress mandated that manufacturers of children's products subject to CPSC safety rules must submit their products to third-party laboratories[42] "recognized"[43] by the Commission to be tested for compliance with CPSC rules.[44] Once the products are tested and approved, manufacturers are then obligated to make certificates available to all parties in the distribution chain demonstrating compliance with the agency's safety rules.[45] Moreover, the CPSIA directed the CPSC to establish, within 15 months, protocols and standards for ensuring that children's products, once tested and approved, thereafter be tested periodically for compliance.[46]

Many manufacturers, particularly small firms, have claimed that these testing and certification requirements are a major challenge because of the scarcity of third-party labs willing to do lead testing at a reasonable cost. One group of manufacturers, the

[39] The Commission issued a stay only as to testing and certification, not as to compliance with the specific requirements of the lead bans. 74 Fed. Reg. 6396, 6398 (February 9, 2009).
[40] My biggest concern is that I fear that less-than-scrupulous manufacturers, freed from the obligation to test their products to the standard, would make no effort to determine whether their products violate the lead standards – potentially flooding the market with noncomplying goods. On the other hand, more ethical manufacturers likely would test their products to be sure they complied with the standard whether or not legally required to do so. A truly perverse outcome to be sure.
[41] "Statement of Commissioner Robert Adler Regarding the Stay of Enforcement of Certain Testing and Certification Requirements," December 17, 2009, available at http://www.cpsc.gov/PR/adler12172009.pdf.
[42] Section 102(a)(2) of the CPSIA. The precise term used in the statute is "third party conformity assessment body." For purposes of convenience, I shall refer to them as "third party testing labs."
[43] I use this term because the CPSC generally has not undertaken accreditation directly. Under the statute, the CPSC may either accredit directly or approve labs accredited by an independent accreditation organization designated by the Commission. Adopting the latter approach, the CPSC has selected the Independent Laboratory Accreditation Cooperation (ILAC) as its approved accrediting body. See Section 102(a)(3)(C) of the CPSIA.
[44] Needless to say, no firm need submit its products for testing to a specific standard until the CPSC has provided for the accreditation of the third party testing labs to that standard. Congress set out a schedule for accrediting labs in section 102(a)(3)(B) of the CPSIA.
[45] Section 102(a)(2) of the CPSIA.
[46] This provision of the CPSIA, known colloquially within the agency as the "15 month rule," has prompted a strong reaction from some manufacturers because of their concern that it could be implemented in an onerous and expensive fashion.

Handmade Toy Alliance, points to its many members who generate very low annual revenues who assert they cannot afford to pay the listed fees of various testing labs.[47]

To the extent I can determine, a number of industry's stated concerns are valid. I believe the Commission has heard them and adjusted its implementation of the CPSIA to try its best to accommodate these concerns. In addition to staying enforcement of many of the lead provisions of the CPSIA,[48] the Commission has gone out of its way to provide what I consider to be extremely helpful guidance to manufacturers regarding the agency's implementation of its lead requirements, stressing very reasonable approaches – most recently, the Commission's approval of firms relying on the testing and certification by the suppliers of the components they use in making their products to meet the requirements of the CPSIA.[49]

Moreover, with respect to ongoing testing and certification under the so-called "15-month rule," the Commission has made clear in its proposed guidelines that its approach is not to impose a massive national quality assurance regime on manufacturers, but rather only to provide common-sense guidelines for manufacturers to follow to ensure that the public is not exposed to dangerous children's products. On this point, one proposal that I generally favor is testing requirements designed for "low-volume" producers.[50] Under this approach, if adopted by the agency, once a manufacturer's product has been approved by a CPSC-recognized third party test lab, the manufacturer will not have to conduct additional third party testing until at least 10,000 units of that product have been produced.[51] For those small manufacturers who produce at most a few hundred (or a few thousand) products annually, the "low-volume" producer provisions should dramatically lower their costs of complying with the law.

In short, despite some very heated rhetoric regarding the burdens imposed by the CPSIA, the Commission has taken what I consider to be a number of major strides in addressing industry's legitimate concerns regarding the burdens of complying with the Act's lead provisions.

Exemptions Under the CPSIA: Congress carved out several exclusions in section 101(b) to the lead bans in section 101(a) of the CPSIA. One obvious exclusion pertains to

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[47] See Handmade Toy Alliance, "Petition for CPSC Rulemaking and Other Actions to Preserve Small Batch Children's Product Manufacturers Under the Consumer Product Safety Improvement Act (CPSIA)," filed October 25, 2009.

[48] Not all lead requirements have been stayed: the lead-in-paint provisions in section 101(f) and the ban on lead in children's metal jewelry remain in effect.

[49] 74 Fed. Reg. 68593 (December 28, 2009)("Interim Enforcement Policy on Component Testing and Certification of Children's Products and Other Consumer Products to the August 14, 2009 Lead Limits").

[50] See Consumer Product Safety Commission, "Guidance Document: Testing and Certification Requirements Under the Consumer Product Safety Improvement Act of 2008," November 3, 2009, available at http://www.cpsc.gov/ABOUT/Cpsia/sect102.html#requirements.

[51] Unless there has been a material change in the product – in which case, new testing would be required by section 14(d)(2)(B)(i) of the CPSA, as amended by section 102(b) of the CPSIA. At the moment, I remain undecided whether this approach, without more, is sufficient. I might add a provision limiting the provision to "low-revenue" manufacturers and to require testing every 10,000 units or every year, whichever comes first.

inaccessible component parts of products subject to the lead bans. If, after subjecting a product and its component parts to reasonably foreseeable use and abuse, a manufacturer determines, based on a specific CPSC protocol, that a part of the product containing lead cannot be accessed by a child, the manufacturer need not meet the lead standard of the CPSIA for that component.[52]

A second exemption applies to certain electronic devices, including devices containing batteries. Here Congress permitted the CPSC to exclude the accessible lead-containing components of electronic devices where the agency concluded that it would not be "technologically feasible" to comply with the lead bans.[53]

By far, the most controversial exclusion provision of the CPSIA is found in section 101(b)(1). This section states:

> (1) The Commission may, by regulation, exclude a specific product or material from the [banned lead levels] if the Commission, after notice and a hearing, determines on the basis of the best-available objective, peer-reviewed, scientific evidence that lead in such product or material will neither –
>
> (A) result in the absorption of any lead into the human body, taking into account normal and reasonably foreseeable use and abuse of such product by a child, including swallowing, mouthing, breaking, or other children's activities, and the aging of the product; nor
>
> (B) have any other adverse impact on public health or safety.[54]

What makes this provision so controversial is that it is the primary route for an exemption under the CPSIA, i.e., if any manufacturer of consumer products (other than electronic devices) wishes to obtain an exclusion from the Act's lead bans, it must do so under this section. Yet, the obstacles to gaining an exemption are formidable. Only after an elaborate regulatory proceeding requiring peer-reviewed scientific, objective evidence may the Commission consider granting an exemption and no exemption may be granted unless the Commission determines that lead in the product will not result in "any" absorption of lead into the human body nor have any other adverse impact on public health or safety.[55]

The Commission's determinations under this provision demonstrate how stringent this language is. In proceedings where industry has applied for an exemption for certain parts of youth All-Terrain Vehicles,[56] and for children's bicycles,[57] the agency has denied the

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[52] Section 101(b)(2)(A) of the CPSIA.

[53] Section 101(b)(4) of the CPSIA. As I read the exclusion language, Congress provided the exemption grudgingly. Should the agency grant an exclusion, Congress directed us to establish a schedule to bring any exempted electronic device into compliance. Section 101(b)(4)(A). Moreover, Congress directed the agency periodically – no less often than every five years – to review its lead regulations and to revise them to make them more stringent as long as it was technologically feasible to do so. Section 101(b)(5).

[54] Section 101(b)(1) of the CPSIA.

[55] Id.

[56] Consumer Product Safety Commission, "Ballot Vote on Stay of Enforcement of Lead Content Limits for Certain Youth Motorized Recreational Vehicles; Request for Extension of Time," July 9, 2009.

petitions on the basis that some, albeit small amounts, of lead might be absorbed into children's bodies. Most recently, the Commission denied, on a 4-1 vote,[58] a request for an exclusion pursuant to section 101(b)(1) of the CPSIA by a manufacturer that used brass collars on toy tractors which exceeded the Act's lead limits,[59] leading to the question of whether the number of products eligible for an exclusion under this section might constitute a null set.

My answer is that if the section's provisions do not constitute a null set, they are so close to it that for all practical purposes they provide little relief to manufacturers. Therefore, I am convinced that a modest expansion in the amount of discretion granted to the Commission to provide exemptions from the lead bans in the CPSIA is justified.

Retroactivity of the CPSIA: As a general proposition, I am not a big fan of retroactivity either in legislation or regulation. Retroactivity imposes penalties for past behavior otherwise permissible at the time the behavior occurred – with no ability to modify the actions deemed impermissible. This is strongly disfavored in the law.[60] In fact, the

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[57] Consumer Product Safety Commission, "Request from the Bicycle Product Suppliers Association for Exclusion from Lead Content Limits under Section 101(b)(1) of the Consumer Product Safety Improvement Act (CPSIA), May 6, 2009 (Ballot Vote Sheet and Staff Briefing Package).

[58] One of my colleagues, in a very thoughtful dissent, argued that the Commission should have not read the term "any" in this section as meaning zero. My colleague offered several canons of statutory interpretation in support of the position that Congress would not have placed language in the statute that led to the "absurd" result of nothing qualifying for an exclusion. As tempted as I was to agree on policy grounds in this case, I could not. My reading of the Act's legislative history leads me to the conclusion that the exclusion language was designed to eliminate almost everything for which an exclusion might be sought, but not everything. As originally drafted in the Senate, this section applied only to lead crystal in jewelry and to nothing else. See H.R. 4040 as amended by the Senate, March 6, 2008, available at http://www.senate.gov/legislative/LIS/roll_call_vote_cfm.cfm?congress=110&session=2&vote=00193. As I understand it, during the bill's pendency, members of the jewelry industry had argued that no lead would leach from lead crystal even if swallowed, leading to this provision (which was later broadened but which mainly focused on lead crystals). Unfortunately, when tested, lead crystal did leach lead. So, the statutory language might not permit any exemptions, but not because Congress necessarily contemplated or intended that result. Moreover, I start from the long-standing and fundamental proposition that where the terms of a statute are clear, one must interpret a statute according to the plain language of its provisions. *Consumer Product Safety Commission v. GTE Sylvania*, 447 U.S. 102,108 (1980) and *Caminetti v. United States*, 242 U.S. 470 (1917). In this instance, the language of the statute is clear as evidenced by the consistent interpretation of the Commission that "any" means "any." Finally, I note that were I tempted to read the statute's words as ambiguous and, therefore, to choose a more relaxed interpretation of the statute, the CPSC's repeated determinations to the contrary would bar such an interpretation. See *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984)(holding that the courts can defer to an agency's interpretation of a statute where the wording is ambiguous and the agency's interpretation is reasonable).

[59] See "Request from Learning Curve Brands Inc. for Exclusion from Lead Content Limits under Section 101(b)(l) of the Consumer Product Safety Improvement Act (CPSIA)," October 7, 2009.

[60] *Bowen v. Georgetown University Hospital*, 488 U.S. 204, 208 (1988)("[r]etroactivity is not favored in the law…. [C]ongressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result.") See, also, *Landgraf v. USI Film Products*, 511 U.S. 244, 114 S.Ct. 1483, 128 L.Ed.2d 229 (1994) and *Kaiser Aluminum & Chemical Corp. v. Bonjorno*, 494 U.S. 827, 855, 110 S.Ct. 1570, 1586, 108 L.Ed.2d 842 (1990).

Consumer Product Safety Act expressly bars the agency from imposing safety standards retroactively.[61]

That said, I note that because the CPSC is a health and safety agency, Congress provided us with extraordinary power to protect consumers. In particularly compelling cases, the Commission has the authority to take regulatory action against unsafe products even though they violated no existing law or regulation at the time they were produced. Perhaps the most immediate example is section 15 of the CPSA[62] which permits the agency to seek recalls of products determined to be "substantial product hazards" even where the products violated no standard or regulation when originally made.[63] Congress's rationale for providing this power to health and safety agencies is the well-settled need for government to be able to protect consumers in highly dangerous situations – which trumps the due process concern of providing notice prior to taking action against a product.[64]

Under this rationale, Congress has provided the Commission the authority under the FHSA to ban products retroactively. In fact, as previously noted, this is what Congress did in setting the lead levels in section 101(a) of the CPSIA. That the Congress had the authority to impose retroactivity is unquestioned. Whether that constituted good public policy in this instance is a matter still being hotly debated. My own view is what any good lawyer says when asked a difficult question – it depends. In this case, it depends on the level of risk associated with the amount and accessibility of the lead in a given children's product. Had I been involved in drafting the CPSIA – which I was not – I doubt that I would have chosen the extremely broad application of retroactivity that was written into the Act. I would not necessarily have allowed any and all products in inventory to be sold, but I would have favored allowing some where the risks were small and the costs of compliance very high. I realize that this could have resulted in permitting some additional lead into the market, and I acknowledge that this could carry some enhanced risk to consumers, but that is the type of balancing that Congress and every regulatory agency must weigh on a daily basis.[65]

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[61] 15 U.S.C. §2058(g)(1) of the CPSA. ("In no case may the effective date [of a consumer product safety standard] be set at a date which is earlier than the date of promulgation. A consumer product safety standard shall be applicable only to consumer products manufactured after the effective date.").

[62] 15 U.S.C. § 2064 of the CPSA.

[63] The Commission can also seek to remove products from the market that present an "imminent and unreasonable risk of death, serious illness, or severe personal injury" under its imminent hazard authority in section 12 of the Act. 15 U.S.C. § 2061 of the CPSA.

[64] FDA cases have so held for many years and have provided a precedent for over a century. See, e.g., *Ewing v. Mytinger & Casselberry*, 339 U.S. 594, 70 S.Ct. 870 (1950); *North American Cold Storage Company v. City of Chicago*, 211 U.S. 306, 315, 29 S.Ct. 101, 104 (1908)("The right to so seize is based upon the right and duty of the state to protect and guard, as far as possible, the lives and health of its inhabitants, and that it is proper to provide that food which is unfit for human consumption should be summarily seized and destroyed to prevent the danger which would arise from eating it."); *United States v. Nine Barrels of Olives*, 179 F. 983 (E.D. Pa. 1910) (notice and hearing not a condition precedent to the bringing of a suit by the United States for violations of Pure Food and Drug Act); *United States v. Seventy-Five Barrels of Vinegar*, 192 F. 350, 353 (N.D. Iowa 1911) (providing notice and hearing after seizure not a violation of due process).

[65] The CPSC always has recall authority under section 15 of the CPSA that it may invoke if products presenting a substantial product hazard are found.

On this point, I note that most of the previous congressional and CPSC regulation of lead has been on a prospective basis. For example, the 1978 CPSC ban on lead in paint applied prospectively.[66] Moreover, when the agency banned candles with lead wicks, it did so prospectively.[67] In fact, most CPSC regulations have applied only to future production, with the result that products declared unreasonable risks of injury have generally remained on the market if they were produced or imported prior to the effective date of a regulation.[68] Moreover, even though the CPSC has the authority to apply FHSA bans retroactively, it has often not done so.[69] I repeat: prospective application of regulations is normal and routine not only for the CPSC, but for most health and safety regulatory agencies.

In the case of section 101(a) of the CPSIA, Congress took the decision away from the agency and mandated retroactivity. Notwithstanding my misgivings about the need for such a sweeping measure, I believe that this was a sincere and reasonable step. The fact is that reasonable minds can disagree, and this is one of those instances on which I humbly, partially, disagree.

That said, at this point, I would not support a broad repeal of the retroactivity provisions in the CPSIA. Given the considerable time since enactment of the CPSIA, I would oppose such a repeal.[70] In the months that have passed, many companies have incurred substantial costs in destroying large amounts of inventory and altering their production processes to meet the new restrictions. To reverse the policy now would penalize those who have conscientiously moved to comply with the law and perhaps put them at a competitive disadvantage vis-à-vis their less responsible peers. (These considerations have not yet kicked in with respect to the statutory mandate that the lead limits retroactively drop to 100 ppm in August 2011. Accordingly, I have joined my fellow commissioners in proposing that the move to 100 ppm be done prospectively, not

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[66] The regulation was required under the provisions of the Lead-Based Paint Poisoning Prevention Act 42 U.S.C. § 4831(c) (1971), which banned lead in paint in excess of 0.5 percent of the paint. See, also 16 C.F.R. § 1500.17 (a)(6)(B).

[67] 16 C.F.R. § 1500.17(a)(13)(i) and (ii) (2003). I suppose one might argue that retroactivity is more justified in the CPSIA because we know more about the hazards of lead now. While I think we know more about the hazards of small amounts of lead now – which is why the lead bans address lower levels of lead in children's products – we were banning higher levels of lead back then, and those hazards were quite well known. Yet, the bans were prospective.

[68] Some examples of prospective regulation: children's sleepwear flammability, architectural glazing materials, matchbooks, bicycle helmets, omnidirectional citizens band base station antennas, walk-behind lawn mowers, swimming pool slides, cellulose insulation, automatic residential garage door openers, multi-purpose lighters, bunk beds, unstable refuse bins, flammable contact adhesives, lead-containing paint and certain consumer products bearing lead-containing paint, consumer patching compounds containing respirable free-form asbestos, lawn darts, consumer products containing chlorofluorocarbons, all-terrain vehicles, flammability of clothing textiles, flammability of vinyl plastic film, flammability of small carpets and rugs, flammability of mattresses and mattress pads. These can all be found in 16 C.F.R., et. seq.

[69] Examples of prospective FHSA regulations include: candles with lead wicks, bicycles, rattles, pacifiers, dive sticks, baby cribs, and some fireworks devices.

[70] With one exception: children's apparel sold by charities to low-income consumers. I discuss that in the next section of my statement.

retroactively.)[71] Moreover, even though I believe that a more limited approach to implementing lead regulation would probably not have produced any significant increased risk, the fact remains that retroactivity has removed – at perhaps an unnecessarily large cost – some potential harm to children, and that safety step forward should generally be preserved.

Choosing Between "Bad" and "Worse": The Special Case of Apparel for Low-Income Children

One of the challenges of being a policymaker is doing the right thing in the face of limited and unpalatable choices. In a *60 Minutes* interview, President Barack Obama put it succinctly, "[a] lot of times, when things land at my desk, it's a choice between bad and worse."[72] I see such a dilemma with respect to apparel needed by low-income children.[73]

On the one hand, there is the need of low-income children for the necessities of life, including winter apparel.[74] Unfortunately, given the retroactive nature of the lead provisions in the CPSIA, product resellers, such as Goodwill and the Salvation Army, face a profound dilemma: used clothing, even if manufactured many years before enactment of the CPSIA, must comply with the lead limits in the CPSIA if the clothing is distributed or sold to consumers, however needy. And, despite the remote possibility of sanctions,[75] the fact is that any reseller of children's clothing, however desperate the need of their clients and however charitable the organization, faces the possibility of civil

[71] See Consumer Product Safety Commission, "Report to Congress Pursuant to the Statement of Managers Accompanying P.L. 111-117," January 15, 2010.
[72] CBS News Interview with President Barack Obama, *60 Minutes,*March 22, 2009.
[73] I note that I served as a legal services attorney when I graduated from law school. This meant that my entire clientele consisted of citizens enmeshed in poverty, forever sensitizing me to the plight of underserved populations and the incredible challenges of surviving in their day-to-day lives. Moreover, on another personal note, I should mention that my mother ran a thrift shop in a small town in Massachusetts that catered to low-income customers.
[74] One can find hundreds, if not thousands, of stories on the internet about the current need for winter clothing, especially given the current economic downturn and the harsh winter so far this year. See, e.g., Joseph Pereira, Wall Street Journal, *supra* note 38; Cindy Martinez Rhodes, "Thrift Stores Must Look Out For Lead in Children's Items," PE.com, February 17, 2009, available at http://www.pe.com/localnews/inland/stories/PE_News_Local_S_lead16.3fec3b3.html; News Channel 3, West Michigan, "Salvation Army Needs Winter Coats," March 11, 2009 at http://www.wwmt.com/common/printer/view.php?db=wwmt&id=1368893; Elisabeth Johns, The Hamilton Spectator, "Wanted: Winter Coats to Replenish Salvation Army's Stockpile" January 31, 2009, http://www.thespec.com/printArticle/505071; Aaron Aupperlee, Kalamazoo Gazette, "Share the Warmth: Salvation Army Needs Coats," November 5, 2009, Mlive.com; Philip Case, "Spectrum: Coats for Kids Needs Help," State-Journal.com, December 13, 2009, available at http://www.state-journal.com/news/printer_friendly/4728234; and Amesbury News, "Ruth's House Desperate for Winter Coats," November 19, 2009, http://www.wickedlocal.com/amesbury/town_info.
[75] The CPSC has not placed enforcing the CPSIA lead provisions against resellers as a high priority, but, as noted in the Report to Congress, "[o]ur efforts have been directed toward working with the resellers to educate them on the scope of the law and its purpose and not to sanction." Consumer Product Safety Commission, "Report to Congress Pursuant to the Statement of Managers Accompanying P.L. 111-117, January 15, 2010, at 4.

and/or criminal penalties if it sells noncomplying goods.[76] Given this reality, a number of risk-averse, law-abiding charities have severely curtailed what they sell – or have abandoned the resellers market altogether.[77]

On the other hand, I recognize the problem of low-income children wearing used clothing with noncomplying levels of lead. No one, especially me, wants that to occur, but therein lies the dilemma of choosing between bad and worse. Which choice is worse?

As I have studied the issue of whether an exception should be available for charitable resellers to distribute used clothing to low-income children, I have heard one argument raised again and again in opposition to such an exception. Why, it is argued, should poor children be the ones exposed to excessive levels of lead when more affluent children will not face such a risk? To say the least, it is an important question and one to which I have given much thought.

My answer is to challenge a hidden assumption in the way the question is framed. Implicit in its wording lies the notion that low-income children can easily obtain desperately-needed clothing that complies with the CPSIA lead levels. If that were so, the answer is obvious and easy: don't permit used clothing containing lead on the market. But, if it is not so, then one evidently believes that children should be denied life-saving coats and jackets simply to avoid any increased exposure to lead – a proposition that seems heartless to me.

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[76] Consumer Product Safety Commission, "CPSC Clarifies Requirements of New Children's Product Safety Laws Taking Effect in February: Guidance Intended for Resellers of Children's Products, Thrift and Consignment Stores," January 8, 2009, Release #09-086. According the press release:

> The new safety law does not require resellers to test children's products in inventory for compliance with the lead limit before they are sold. However, resellers cannot sell children's products that exceed the lead limit and therefore should avoid products that are likely to have lead content, unless they have testing or other information to indicate the products being sold have less than the new limit. Those resellers that **do** sell products in violation of the new limits could face civil and/or criminal penalties. (emphasis in original.)

[77] See, e.g., Mary Lancaster, "Thrift Shops Caught in Tough Spot With New Lead Law," The Nantucket Independent, March 18, 2009; Scott Thomas Anderson, "Toying With Trouble," Ledger-Dispatch, March 6, 2009 (There are no toys on the shelves at the Hospice of Amador and Calaveras Thrift Store. Looking around customers find no …. clothing for children under the age of 12."); Erin Snelgrove, "Led Astray by New Lead Law," Yakima Herald Republic Online, February 4, 2009 (noting that the owner of a store that sells "gently used children's clothing" closed her store because of the new CPSIA requirements); Brian Bingaman, "New Lead Laws Affect Thrift Stores, The Reporter Online, January 30, 2009 (noting that unlike major retailers, such as Wal-Mart, resellers don't have the resources for lead testing. "The potential damage to resale business – particularly Goodwill and Salvation Army, whose store proceeds go to helping the less fortunate – would be devastating."); Warren Wise, "Resale, Thrift Shops Fear Economic Effects of Law," The Post and Courier, January 26, 2009 ("For all its good intentions, the new Consumer Product Safety Commission Improvement Act has needled the nation's thrift and consignment shop industry so much that some have dubbed the act's effective date "National Bankruptcy Day.'"); Ann Vogel, "Will New Lead Law Imperil Kitsap Consignment Shops?" Kitsap Sun, January 18, 2009 (noting that at least one local children's consignment store, Perfect Circle in Bremerton, has been forced by the new law "to go out of business."); and David Crigger, "New Lead Law Has Some Sellers Fearing for Survival," Bristol Herald Courier, January 12, 2009.

I believe that the proper way to frame the issue is the most direct and honest: does the need of low-income children for clothing, especially warm apparel for cold winter days, outweigh the potential risk associated with the lead in used clothing? Phrased this way, one can fairly address the issue.

One might question the premise of my concern about the CPSIA causing a clothing shortage for low-income children. As usual, hard data are not available, but judging from many media reports I have seen, a number of charities have voiced, and continue to voice, a desperate need for warm clothing.[78] And there is no question that some charities have dropped the sale and distribution of used clothing in light of their fears about being penalized under the CPSIA for selling noncomplying goods.[79]

But there is a more important point to be made here: to the extent that resellers are able to continue distributing used clothing, it is only because the law is being lightly enforced against them and because most resellers have continued their business with no idea whether they are selling violative goods. This is not a trivial point because to the extent that noncomplying clothing has ever entered the market, there seems little doubt that resellers carry and sell it. Unlike a manufacturer who can control what it sells in the market, charitable resellers must take whatever comes in as a donation. And since each article of donated clothing likely differs from most others, the resellers will inevitably take in an extremely broad selection of clothes. Given this flood of disparate apparel, even well-intentioned resellers who might want to test for compliance would face almost insurmountable expense in doing so.[80]

As one who values pragmatism, I suppose that I should not object too strongly to this state of affairs, but this is a less-than-optimal approach to say the least. It still exposes charitable resellers to possible CPSC penalties or state attorney general injunctive actions. And it still exposes them to media investigations and possible local citizen group exposés. Moreover, notwithstanding the slight risk of enforcement against them, many conscientious resellers will continue to withdraw from the market, thereby limiting the availability of children's apparel to low-income consumers. Finally, to state the obvious, if one were to maintain the status quo, that would be the functional equivalent of accepting the widespread resale of noncomplying apparel by a group of well-intentioned charities unnecessarily turned into scofflaws.

If, as I believe, most charitable resellers are likely selling noncomplying used clothing on a daily basis, it seems important to assess the risks attached to this activity. I note at the outset that clothing tends to present a lead hazard only with respect to items attached to

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[78] See *supra* note 73 and accompanying text.

[79] See *supra* note 77 and accompanying text.

[80] To be sure, resellers are not required to test the used clothing that they distribute, but that generally means that they have no idea about the lead levels in the clothing they sell. One cannot avoid a degree of cynicism in this situation. As the director of a local Goodwill Industries shop in Bristol declaimed, "To say you don't have to test for lead, but to say you can't sell it if it does have lead, now how stupid is that?") David Crigger, "New Lead Law Has Some Sellers Fearing for Survival," Bristol Herald Courier, January 12, 2009.

fabric – such as buttons, grommets, and zippers – not to the fabric itself.[81] I also note that the agency has had few, if any, recalls of these products for lead beyond occasional instances in which a button or zipper had a surface coating of paint.

The CPSIA has extended the lead limits beyond paint – to the underlying material itself. Here the issues get murkier. Most scientists who focus on lead hazards identify a risk that causes concern at the point where lead exposure results in an increase of 1µg/dL or more in a child's blood lead level.[82] Making a proper determination whether the risks associated with buttons, grommets or zippers cross this threshold is a challenge because there is no easy way to translate the amount of measurable lead in a product to a precise change in blood level. To assess the risk properly, one would have to determine how a child would be exposed to lead and the amount of exposure the child would experience.

I have consulted with CPSC and outside scientists to gain some insight to how one would measure the lead risks of a zipper that a child might mouth over time. I picked this example because zippers seem to present a worst-case (or at least a bad case) scenario in terms of exposure from clothing.[83] Zippers typically lie within easy reach of a child's mouth and they seem to be attractive items to suck on because they are often shiny. Unfortunately, as far as I can tell, no one has conducted tests on a representative set of zippers to determine the level of lead to which a child might be exposed, so any risk assessment would be, at best, a guess.[84] My best guess, based on my research and discussions with a number of CPSC and other scientists, is that the level of risk would be low given the small amounts of lead likely to be absorbed by even a dedicated zipper sucker – but one cannot quantify the risk at this point. In sum, I cannot state with certainty that a "safety"[85] threshold of, say, 1µg/dL blood level change would never

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[81] Fabric does not exceed the lead limits in the law. See Consumer Product Safety Commission, "Determinations Regarding Lead Content Limits on Certain Materials or Products; Final Rule," 74 Fed. Reg. 43031 (August 26, 2009).

[82] See, e.g., The California Report, *supra* note 11, at 21. Several studies have suggested that a change in blood level of one µg/dL can lower a child's IQ by 1 point. Id. Changes below this have shown no demonstrable adverse effects, leading to a rough scientific consensus that this could serve as a metric for acceptable risk.

[83] Clothing is not a significant source of lead poisoning. Far and away the greatest source of lead poisoning is lead paint in older housing, lead-saturated soil from gasoline emitted over the years from automobile exhausts, and lead-saturated dust (both from paint and gasoline). Koller, *supra* note 11 at 987-988, and accompanying text. See, also, http://www.epa.gov/lead/ (stating that the most common source of lead contamination is "deteriorating lead-based paint, lead-contaminated dust and lead-contaminated soil").

[84] It is not difficult to determine the level of lead in zippers, but that is only a first step in assessing their risk. One must next assess the amount of mouthing likely to occur with zippers. At the CPSC, staff determines the amount of lead released in a 6-hour extraction with a saline solution, and calculates the extraction rate in micrograms per minute. The staff assumes that each minute of extraction represents a minute of mouthing of the object by a child. A CPSC study of mouthing behaviors of young children estimated an average daily mouthing time of 37 minutes for typical objects, although the limited data regarding zipper mouthing suggested much lower time and much less frequent mouthing behavior. Celestine Kiss, U.S. Consumer Product Safety Commission, "A Mouthing Observation Study of Children Under 6 Years" (2001). After that, staff would still have to relate the results to a hazard assessment based on the most current science regarding lead risks.

[85] I use the word as shorthand for the proposition that there is no demonstrable harm from lead at this blood level change. I do not mean to suggest that this really is a safety threshold. See *supra* notes 20-26, and accompanying text.

occur from zipper sucking. In a population of tens of millions of children with differing play behavior, such an assertion would be a grand stretch.

The fact that I cannot say there is no risk is why I characterize the choice as between bad and worse. It is also why I would limit any exemption for used clothing as narrowly as possible.[86]

In short, based on the low, but potentially real, risk[87] of lead in clothing balanced against the very real need of low-income children for this basic necessity, I support some sort of exception from section 101(a) of the CPSIA for charities that sell and distribute used clothing to low-income children. Although I leave the details of how to do this to other, wiser minds, it seems there could be a variety of narrowly tailored remedies.[88] I would strongly oppose any extension of this exception to non-charitable resellers because the cost-benefit equation is different once one moves beyond low-income children.[89] There the choice is not between bad and worse; it is between bad and unnecessary – not an approach I favor.

Conclusion

Having explained my views on lead, I join in the Commission Report to Congress seeking additional discretion for the agency. As noted in my separate statement, I urge Congress, in modifying section 101(b), to keep three key questions in mind with respect to modifying this section:

- First, does the product, component, or material, for which an exclusion might be sought truly *need* the lead? Asked another way – is there a readily available, comparable substitute for the lead? Is it possible, without incurring undue expense or undermining a product's utility, to make the lead inaccessible?
- Second, does the accessible lead for which an exclusion is sought create a demonstrable adverse effect on public health or safety?
- Third, for how long does a firm (or industry) need an exclusion? At some point, technology surely will enable companies to make children's products without lead. Absent some limit on the length on an exclusion, they could

[86] In fact, I would be open to some tinkering to refuse an exemption for clothing with hanging metal parts or clip-on pieces or other obvious, easily-caught potential hazards.
[87] I do not view this as a *de minimis* risk approach because I do not take the position that I know that the risk is minimal. I take the position that the risk is probably low, but I do not know for sure. I believe that even if the risk is significant, the value of providing warm clothing to low-income children outweighs even a significant risk.
[88] I would, for example, support a requirement that all resellers exempted from the law post warnings to parents that indicate used clothing may contain lead in buttons, grommets and zippers.
[89] To be sure, I realize that some customers of charitable resellers are not low-income and, conversely, I recognize that some customers of non-charitable resellers are low-income. Every time one draws lines, circumstances like this may well appear. Nonetheless, I draw such a line because, on balance, I believe that it will benefit the most deserving people in the most beneficial way.

conceivably lock in outdated technology instead of encouraging industries to find new solutions to the problem of accessible lead.

I hope that Congress will consider these concerns in any modifications it makes to section 101(b). The Commission's Report acknowledges that there may be some instances where lead, though accessible, is necessary for a product to survive in the market. Doing so, however, should not take precedence over a demonstrable health risk to children.

As a final point, if Congress were to choose to provide more flexibility in granting exclusions under section 101(b) by adding the approach outlined above, it would be helpful if the Commission also gained greater flexibility in the process of granting exclusions. The current requirement that the Commission engage in elaborate rulemaking to grant section 101(b)(1) exclusions is potentially very burdensome to the CPSC and, if so, would inevitably lead to significant delays in providing relief to firms seeking an exclusion.