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H.R. ———, LEGISLATION TO REVISE THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT

HEARING

BEFORE THE

SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE

OF THE

COMMITTEE ON ENERGY AND COMMERCE
HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

FIRST SESSION

APRIL 7, 2011

Serial No. 112–34

Printed for the use of the Committee on Energy and Commerce
energycommerce.house.gov

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U.S. GOVERNMENT PRINTING OFFICE

67-423 PDF WASHINGTON : 2012

For sale by the Superintendent of Documents, U.S. Government Printing Office
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H.R. ———, LEGISLATION TO REVISE THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT

THURSDAY, APRIL 7, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON COMMERCE, MANUFACTURING, AND TRADE,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:05 a.m., in Room 2123 of the Rayburn House Office Building, Hon. Mary Bono Mack (chairman of the subcommittee) presiding.

Members present: Representatives Bono Mack, Blackburn, Stearns, Bass, Harper, Lance, Cassidy, Guthrie, Olson, McKinley, Pompeo, Kinzinger, Barton, Butterfield, Dingell, Towns, Rush, Schakowsky, and Waxman (ex officio).

Staff present: Gib Mullan, Chief Counsel; Shannon Weinberg, Counsel; Paul Cancienne, Policy Coordinator; Brian McCullough, Senior Professional Staff Member; and Alex Yergin, Legislative Clerk.

Mrs. BONO MACK. Good morning. It is with a sense of purpose as well as a sense of urgency that we gather here today to consider some sensible ways to make the Consumer Product Safety Improvement Act, also known as CPSIA, work better for all Americans. There is bipartisan agreement that CPSIA, while well-intentioned, has created a number of serious problems for manufacturers and retails. Today, we will examine some ways to make a good law even better.

The chair will now recognize herself for an opening statement. You can start me back at 5. Thank you.

OPENING STATEMENT OF HON. MARY BONO MACK, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

In our first hearing of the year, we heard about many of the problems associated with passage of CPSIA. Today, we will focus on a preliminary discussion draft, which offers a range of possible solutions.

One major area for reform relates to the regulation of children's products. In this area, we have the benefit of five unanimous recommendations from the CPSC. We also have draft legislation from last year and other CPSC suggestions in response.

The discussion draft aims to reduce the regulatory burdens of the law without undercutting consumer protection. A fundamental premise is that the Commission can actually protect consumers far better when it is allowed to set priorities and regulate based on risk. Where possible, we should spare the Commission from having to make time-consuming, case-by-case determinations, and let it spend more time on its bigger problems. This is especially true in our current budget climate where we have to make the best use of agency resources.

We need to strike the right balance and that is seldom easy. The discussion draft points to areas where we must decide important policy questions. I hope our witnesses today will help us to make wise choices by shedding light on these issues.

In Section 1, for example, the draft leaves open the age for defining the term "children's product." At our last hearing, my friend and colleague Mr. Dingell, the chairman emeritus of the full committee, reminded us that a lot of the problems with CPSIA originated in the Senate, but this is one that did not. The Senate-passed bill applied the lead content limits to products for children ages 7 and under. That age would have kept the focus on children who are at greater risk when it comes to lead, because very young children, according to the CPSC, are much more likely to put things in their mouth. The House set the top age at 12 years old because of the so-called "common toy box" concern. But by pushing the age to 12, we ended up regulating a huge number of products that are never going to be mouthed or even handled by young children. These include not only the well-known examples of ATVs, bicycles, and books, but also band instruments, scientific instruments, and clothes for older children, among other things.

Another key area is third-party testing. Again, the discussion draft tries to strike an appropriate balance. It preserves third-party testing for lead paint, cribs, pacifiers, small parts, and children's metal jewelry, all priorities that Congress explicitly set in CPSIA. For other standards, however, it gives the Commission discretion to decide what standards should require third-party testing. And it gives the Commission new authority and flexibility to require testing for only some portions of a standard or only for certain classes of products. It also asks the Commission to make sure that the benefits of third-party testing justify the costs before making it mandatory.

Another major area of reform is the CPSC's public database, which just recently began to post complaints. The discussion draft addresses some of the more significant problems that were brought to light in our earlier hearing.

First, the draft spells out in greater detail who can submit reports of harm for the public portion of the database. Among consumers, only those who have suffered harm or a risk of harm—as well as members of their family, legal representatives, or any person authorized by the family—could make public reports.

Second, the draft sets forth a process for improving product identification. The database cannot help consumers if they don't know which products have problems. The draft enlists manufacturers to help consumers provide better descriptions.

Third, the draft gives CPSC more options for solving claims of material inaccuracy. The fundamental premise here is that the database may do more harm than good if it misleads consumers based on inaccurate information.

Finally, the draft would strengthen the Commission's authority to investigate complaints. While some consumers may benefit from the ability to see safety-related complaints, a lot more consumers will benefit if the Commission can investigate complaints more quickly.

Congress must move quickly, too, because the clock is ticking. Unless we act soon, the 100 parts-per-million lead limit will take effect retroactively in August, and once again, millions of dollars worth of products will become illegal to sell, donate, or export.

We have an opportunity and an obligation to make CPSIA a law that benefits all Americans.

[The prepared statement of Mrs. Bono Mack follows:]

PREPARED STATEMENT OF HON. MARY BONO MACK

The committee will come to order.

Good Morning. Today, we turn back to the subject of the Consumer Product Safety Improvement Act of 2008, also known as CPSIA. In our first hearing of the year, we heard about the many problems associated with this law. Today, we will focus on a preliminary discussion draft, which offers a range of possible solutions.

One major area for reform relates to the regulation of children's products. In this area, we have the benefit of five unanimous recommendations from the Consumer Product Safety Commission. We also have draft legislation from last year and other CPSC suggestions in response.

The discussion draft aims to reduce the regulatory burdens of the law without undercutting consumer protection. A fundamental premise is that the Commission can actually protect consumers far better when it is allowed to set priorities and regulate based on risk. Where possible, we should spare the Commission from having to make time-consuming, case-by-case determinations, and let it spend more time on bigger problems. This is especially true in our current budget climate, where we have to make the most of scarce agency resources.

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Third, the draft gives CPSC more options for solving claims of material inaccuracy. The fundamental premise here is that the database may do more harm than good if it misleads consumers based on inaccurate information.

Last, the draft would strengthen the Commission's authority to investigate complaints. While some consumers may benefit from the ability to see safety-related complaints, a lot more consumers will benefit if the Commission can investigate complaints more quickly.

Congress must move quickly, too, because the clock is ticking—unless we act soon, the 100 ppm lead limit will take effect retroactively in August and once again millions of dollars worth of products will become illegal to sell, donate or export.

Mrs. BONO MACK. And now I would like to recognize the ranking member of the full committee, Mr. Waxman, for his 5-minute opening statement.

Mr. WAXMAN. Chairman Bono, thank you very much for recognizing me to give this opening statement and Mr. Butterfield to allow me to go ahead of him.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

I share your belief that some changes are needed to the toy bill that we passed in 2008. That legislation was an historic step forward for children's safety, but like most legislation, it was not perfect. It has had some unintended consequences and needs refinement. But the discussion draft before us, which is the subject of today's hearing, takes a wrecking ball to the law and would endanger young children. As the chair of the Consumer Products Safety Commission wrote us today, this draft would turn back the clock to an era when harmful products made their way into the stream of commerce and into the hands of innocent children.

In 2008 our committee led the way in passing a strong toy safety law. We held hearings at which we learned about children who died or were severely injured by lead in toys and small charms. We learned that other children suffered catastrophic internal injuries from magnetic toys that ripped through their intestines. And we witnessed record recalls and loss of confidence in the safety of children's products. Despite strong bipartisan support for the new law, implementation has not always been smooth. The ATV industry, the bicycle industry, the publishing industry, and makers of handcrafted toys have all raised valid compliance issues.

I know it is possible to address these concerns without gutting the law. When I was chairman of the committee in the last Congress, we initiated a stakeholders' process to produce the draft bill that gave targeted relief to industry while maintaining the most important health and safety protections in the new law. That draft legislation was supported by both industry and consumer groups. Although the Republican staff were consulted at every step in the process, Ranking Member Barton decided he would not support the bill and we never acted on it.

The discussion draft before us is a very different document. Democrats, consumer groups, and health experts were not consulted. The result is a one-sided proposal that provides relief to industry but sacrifices children's health and safety. According to the Consumer Federation of America and Consumers Union, this proposal undermines safety testing for children's products, undermines lead protections, undermines the effectiveness of the new crib safety standard, and undermines the new public safety product hazard database.

According to Chairman Tenenbaum and Commissioners Adler and Moore, this proposal would be a reversal of several of the core safety provisions in the law. Not only are they critical of the bill, but let me just state quite clearly, there is no chance that a bill this extreme could ever become law. It would not survive in the Senate, and if it did, it would be vetoed by the President. The result would be a lost opportunity. Many of the witnesses who will testify today have identified legitimate concerns but they will receive no relief if all we produce is a more partisan gridlock kind of legislation.

If we work together, I am confident that we can find a way to address most of industry's concerns without jeopardizing the important safety advances we made in the toy safety law. And I had a discussion with the chairman yesterday. I think there is an opportunity for us to work together and produce a product that will be a consensus product. I hope that after this hearing is over we can start fresh and we can produce a genuine bipartisan reform we all can support.

Madam Chair, I would like to yield the rest of my time and an additional 1 minute without any objection to Mr. Rush, who chaired this subcommittee in the last Congress and I think has an important statement to make.

Mrs. BONO MACK. Without objection, the gentleman is recognized.

OPENING STATEMENT OF HON. BOBBY L. RUSH, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Mr. RUSH. Thank you, Madam Chair, and I want to thank the ranking member for the full committee for yielding this time to me.

Madam Chair, consumer protection is one of the core functions of this subcommittee, and I want to commend you for convening this important hearing. However, I am surprised to see that instead of talking about improving safety for our children, making our new law's implementation possible, we are focusing on undoing one of the legislative achievements of this subcommittee historically. Demolition and destruction, not creative solution seems to be the policy agenda for our new Republican majority. I am still waiting to see when we will talk about real policy solutions, including the policy implementation issues as it relates to this bill for the American people.

Regulations are not a problem. It is the constant changes or the risk of changes that are difficult to manage for our manufacturers, our consumers, and for the American public. We need to agree once and for all and implement the laws that we have developed. We need regulatory predictability. There is a similar Product Safety

Improvement Act that the Republicans are attempting to revise today represents demolishing the most comprehensive overhaul of U.S. consumer protection oversight in a generation, one that established policies which repaired our Nation's broken product safety system.

And I must say, Madam Chairman, that I am very proud of what we did with bipartisan input, with input from all the stakeholders despite the political differences that we all shared. We were able to reinvigorate the CPSC with resources. We added additional commissioners. We authorized a shiny new testing lab. And Madam Chair, may I ask for an additional 30 seconds?

Mrs. BONO MACK. The clock——

Mr. RUSH. All right. Well, Madam Chair, I just want to conclude by saying that this hearing could be better spent if we were really trying to—maybe we could solve some of the problems——

Mrs. BONO MACK. All right——

Mr. RUSH [continuing]. That we have implementing the bill. Thank you.

Mrs. BONO MACK. All right. So the gentleman yields back. And now——

Mr. RUSH. I yield back the time I have.

Mrs. BONO MACK. Chairman Upton, in accordance with the committee rules, yielded me his 5 minutes, and as his designee, I would like to recognize the chairman emeritus of the full committee, Mr. Barton, for 2½ minutes.

Mr. BARTON. Well, Madam Chairman, I really can't do it in 2½ minutes. So you are going to have to give me at least 3 minutes or just go to somebody else.

Mrs. BONO MACK. Well, we were rather lenient with the other side, so that is not a problem. Go ahead.

Mrs. BLACKBURN. Madam Chairman, I will yield the chairman emeritus my time.

Mrs. BONO MACK. So the chairman emeritus is recognized for 3½ minutes.

OPENING STATEMENT OF HON. JOE BARTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BARTON. There is an old joke about somebody trying to get somebody to vote for him and the guy says I would never vote for you if you were running unopposed. And the man goes back and says well, how do we put that voter down? He says put him down undecided. That is kind of what we need to put Mr. Waxman down after what he said.

I participated as the ranking member when this bill was passed. I participated in the last Congress when there was an attempt to amend it. When Chairman Waxman said that the Republicans and the staff were consulted, that is a true statement, but we weren't listened to. In the last Congress, Chairman Waxman and his allies were almost totally inflexible in trying to come to some common ground on changes to the law that was passed under Chairman Dingell's chairmanship back in 2008.

This discussion draft does not take a wrecking ball to the law. It is a good-faith attempt to reconcile the law that, in its current state, is literally unenforceable. We have that in testimony from

the Consumer Product Safety Commission. They have basically—I wouldn't even use the term basically—they have no flexibility at all. The discussion draft that Chairwoman Bono Mack has crafted does give flexibility. I think that is a good thing. It does change some of the principles or modify some of the principles from the law that was passed 2 years ago, but it keeps the core of the law together and it does give the Commission the flexibility and the industry that has to live by it the ability to actually use a little common sense in implementation. I think that is a good thing. I think this discussion draft is a vehicle that can be a bipartisan compromise. But a compromise means both sides have to come together. And Chairman Waxman's statement indicates to me that it is the bill or nothing. And I don't think that is a position to take when we are trying to do something that should be everybody's best intentions to actually protect the children of America, but also gives those that provide the products for our children the ability to provide them in a safe and effective fashion.

I am the father of a 5-year-old and the grandfather of five grandchildren that are under the ages of 13. There is no way in this world that I want to do anything that would put my 5-year-old child or my grandchildren in harm's way. So Madam Chairwoman, I think the discussion draft is a good starting point. It is a starting point. It is not an end point. And if Mr. Waxman and Mr. Rush and our friends on the minority side wish to work with us, we can come up with something that improves the bill that is now the law and gives the flexibility that is necessary.

So with that, I want to thank the Chairwoman for giving me some extra time and thank the vice-chairwoman, Ms. Blackburn, for giving me some of her time. And I yield back.

Mrs. BONO MACK. I thank the gentleman for his statement and yield 1 minute to Ms. Blackburn.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TENNESSEE

Mrs. BLACKBURN. Thank you, Madam Chairman. I am only going to take about 30 seconds because there are several individuals that would like to speak on this issue. I want to thank the chairman for bringing forward a discussion draft that will encourage us all to listen to the science and to use some common sense. I am a mother. I am a grandmother. I am an aunt. I am a sister. There is no way I would want to have products in the marketplace that are going to be harmful to children and grandchildren, no way at all. And I think it is important that we listen to the science. I think that it is important that we apply some common sense. I have also listened to a lot of the crafters and the small producers in my area and have had good discussions with them. Also, Mr. Howell, when we get to you, I am going to want to talk about this database that I think is seriously flawed. And I thank the chairman and yield back.

Mrs. BONO MACK. I thank the gentlelady and recognize the gentleman from Florida, Mr. Stearns, for 1 minute.

OPENING STATEMENT OF HON. CLIFF STEARNS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF FLORIDA

Mr. STEARNS. Thank you, Madam Chairman. Let me echo what the emeritus chairman, Joe Barton, said. I was a conferee on this. We had lots of recommendations. We in fact specifically recommended what the CPSC did in January 2010 when they reported back to Congress and they identified some of the problems. There was no flexibility. And they recommended solutions. And we had these recommendations under Joe Barton's leadership to provide the CPSC with this kind of flexibility they need to grant exclusions to the lead limits but they didn't listen. So I think, Madam Chair, what you are doing here is the Lord's work. We need to have the flexibility. And we heard from Commissioner Northrup, who was a former Member of Congress. She also bought this out. And so I am pleased to be here and to support you and I appreciate what you are doing. Thank you.

Mrs. BONO MACK. I thank the gentleman. Last but not least, the gentleman from North Carolina, the ranking member of our subcommittee, Mr. Butterfield, is now recognized for his 5 minutes.

OPENING STATEMENT OF HON. G.K. BUTTERFIELD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NORTH CAROLINA

Mr. BUTTERFIELD. Let me thank you very much, Chairman Bono Mack, and especially thank you to all of the witnesses who have come forward today to give us your testimony.

You know, Madam Chairman, my recollection—and I was simply a rank and file member of the subcommittee in the last Congress—but my recollection of this is somewhat different from my good friend from Texas, Mr. Barton. My recollection is that CPSIA followed a long and well-considered road to passage that included many, many hearings and extensive conference with the Senate from introduction to enactment. I recall that this legislation at all times remained a bipartisan effort, and I am surprised to hear today that it was not. The vote tally speaks volumes about the bipartisanship nature of this law. Much of the law was taken word-for-word from some of Mr. Barton's language that he had authored. The House passed the conference report with a vote of 424 to 1. And while I don't know it for a fact, I suppose Mr. Barton may be the 1, but the vote was 424 to 1. And the Senate passed it——

Mr. BARTON. Could the gentleman yield?

Mr. BUTTERFIELD. Yes.

Mr. BARTON. I voted for the bill.

Mr. BUTTERFIELD. You did vote, right.

Mr. RUSH. He voted for it, yes.

Mr. BUTTERFIELD. All right. And the Senate vote was 89 to 3. Today, however, it is apparent some portions of the law need to be refined. The ranking member of the full committee has acknowledged that and I do as well. Unfortunately, the discussion draft does not seek to refine the law. Rather, it seeks to undo nearly 2 years of close consultation and careful compromise with Members of Congress, industry—many of whom are here today—and consumer groups, and potentially puts consumers and children at risk. The minority was not consulted to my knowledge in the prepara-

tion of the draft legislation. And I am confident the language would look very different had we been invited to the table and had an opportunity to participate. The draft language would redefine what is considered a children's product to a yet-to-be-determined age, possibly exposing both those who would be classified as children and those who would not to potentially dangerous products.

I ask my colleagues about households with multiple children, if a 9-year-old has a toy intended only for ages 9 and older, is it not reasonable to expect that 9-year-olds with a preschool-age sibling would also want to and will find a way to play with that toy? But perhaps most alarming is rolling back the current lead content limits in favor of risk assessment. This is similar to the model that proved to be inadequate prior to CPSIA but with the twist of creating additional burdens for the Commission.

Since the model and the draft will require premarket risk assessment, CPSC will have to determine for each and every children's product how manufacturers should measure the risk. I am troubled that the draft eliminates independent third-party testing for all children's products with a very narrow exception for five categories. I remind my friends of the millions of toys that were recalled in '07 due not only to high lead levels but design-related safety defects as well. It was clear that manufacturers of children's products and their suppliers had fallen asleep at the wheel and their in-house safeguards were inadequate.

Finally, and I am going to yield to the gentlelady from Illinois in just a minute—CPSIA required the CPSC to create a Public Product Safety Information Database so that consumers would have a convenient way to report and learn about dangerous products. The draft language marginalizes the efficacy of the database by limiting who can submit information, as well as establishing a drawn-out process by which the submitter, the Commission, and the manufacturer are required to have ongoing contact. The more burdensome it becomes to make a safety complaint, the less likely consumers are to use the database. At this time I will yield my remaining time, Madam Chairman, to the gentlelady from Illinois.

OPENING STATEMENT OF HON. JANICE D. SCHAKOWSKY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF ILLINOIS

Ms. SCHAKOWSKY. I thank the gentleman for yielding.

To say that I am concerned about the draft bill would be a vast understatement. Here we are in the Subcommittee on Commerce, Manufacturing, and Trade, and instead of looking at ways that we can create jobs, good jobs for the American people, we are examining a bill to undermine consumer protection, words that used to be part of the subcommittee's title. The draft bill is not a collection of small fixes. It would fundamentally gut key pieces of the CPSIA, including the provisions I authored to ensure that durable infant and toddler products are subject to rigorous testing requirements.

I want to read a letter I received from Danny Keysar's parents, which I hope to submit for the record, along with two other letters from parents who lost their children. Danny's mom wrote, "As parents who have paid the ultimate price for unsafe products, we know you don't want to see more children suffer as our son did."

Giving flexibility to the CPSC to enforce safety provisions is one thing, but this wholesale reversal of crucial safety provisions sends us back to a scenario we know leaves children at risk.

I yield back the balance of my time.

Mrs. BONO MACK. All right. And the chair inadvertently overlooked the last 30 seconds on our side, and I would like to recognize the gentleman from Texas, Mr. Olson, for 30 seconds.

OPENING STATEMENT OF HON. PETE OLSON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. OLSON. I will be brief. I am pleased to be here, and I thank the Chair for her leadership in bringing forward this important draft legislation to fix the unintended consequences of CPSIA.

As a parent, nothing is more important to me than the safety and health of my children. I think this draft provides us with a balanced way forward that protects my children from harmful products without devastating our country's small businesses. If my children are protected, your children are protected.

I thank the Chair and looking forward to helping her advance a commonsense fix to this law. I yield back.

Mrs. BONO MACK. I thank the gentleman. And now all opening statements are concluded. And we have three panels before us today. Each of the witnesses has prepared an opening statement that will be placed in the record. Each of you will have 5 minutes to summarize that statement in your remarks. On our first panel we have, in reverse order, but we have Robert Howell, Assistant Executive Director of Hazard Identification and Reduction at the U.S. Consumer Product Safety Commission. That is a mouthful. And then Dr. Barbara Beck, a widely respected expert in toxicology and a former EPA region chief and fellow at the Harvard School of Public Health; and Dr. Dana Best, who is presenting on behalf of the American Academy of Pediatrics.

Good morning. I would like to thank you all for coming. You will each be recognized for 5 minutes. To help you keep track of time, the little clock in front of you, when it turns yellow, please recognize that is the 1-minute mark if you could start wrapping up and when the light turns red, your time is up. I would also ask you to remember to turn the microphone on before you begin. And now I would like to start with Dr. Best for your 5 minutes. Good morning and welcome.

STATEMENTS OF DANA BEST, MD, MPH, FAAP, AMERICAN ACADEMY OF PEDIATRICS; BARBARA D. BECK, PH.D., DABT, FATS, PRINCIPAL, GRADIENT; AND ROBERT JAY HOWELL, ASSISTANT EXECUTIVE DIRECTOR, HAZARD IDENTIFICATION AND REDUCTION, U.S. CONSUMER PRODUCT SAFETY COMMISSION

STATEMENT OF DANA BEST

Ms. BEST. Good morning. Thank you for this opportunity to testify today. I am a pediatrician and pleased to represent the American Academy of Pediatrics. The AAP is deeply concerned that the subcommittee is considering legislation that would profoundly alter the CPSIA and could reverse the progress towards safer toys and

children's products. Today I will focus on four areas: the scope of children's products, lead limits in children's products, risk assessment, and the need for third-party testing.

First, the scope of children's products should protect children up to age 12. The AAP recommended that the CPSIA cover products for children up to age 12 years based on developmental and pragmatic concerns. With regard to developmental issues, the mouthing behaviors that cause the most concern for exposure to hazards like lead peak in the toddler years and taper off throughout school age, although it is not unusual for school-age children to place toys and other objects in their mouths or to mouth or suck on items like jewelry and pens. For some groups, such as children with developmental delays, mouthing behaviors may persist until adolescence or later.

Another concern is that toys are often shared. While most parents work hard to keep toys for older children away from younger children, they may not always be successful. It is therefore important to ensure that toys are as safe as possible for all children in the household.

Second, the CPSIA's limits on lead in children's products should not be relaxed. In the judgment of the AAP, there is no scientific basis for establishing a de minimis level for lead in children's products. To date, science has not identified a threshold below which lead ceases to damage a child's brain or body. There is no known safe level of lead. During the development of the CPSIA, the AAP was asked to recommend a limit for lead in children's products. Following a rigorous scientific review, the Academy recommended that lead in children's products be limited to 40 parts per million. The rationale behind this level is explained in my written testimony.

The AAP is also concerned that the discussion draft proposes to distinguish between lead exposure due to sucking on an item from lead exposure due to licking an item. From a scientific perspective, there is no basis for making this differentiation. Both actions defined as "mouthing" in the pediatric literature are associated with lead ingestion.

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

Third, risk assessment is not an appropriate method for limiting lead exposure in children's products. The draft before the subcommittee appears to shift from measurement of total lead in children's products to risk assessment frameworks. The AAP urges you to leave intact the straightforward, predictable total lead standard in the CPSIA. The fundamental premise of risk assessment is that some degree of risk is acceptable such as when the benefit of receiving a drug is compared to its side effects. In the case of lead, there is no benefit to exposure. While the harms are numerous and significant such as decreased IQ, if the CPSIA standard is altered, Congress would need to determine what level of IQ loss is considered acceptable.

In addition, standards should protect not only the average child, but also children at higher risk of lead exposure and its consequences. This is best accomplished using the lead limits currently in the CPSIA.

The AAP is deeply concerned that a risk assessment framework would require the CPSC to perform or confirm risk assessment on many different products. It is unclear who would bear the ultimate responsibility for determining risk or what the process would be for reconciling differences when risk assessments differ between the agency and the manufacturer.

Finally, third-party testing is necessary to ensure the safety of children's products. The discussion draft proposes significant changes to CPSIA's third-party testing requirements, dramatically reducing the number and types of products subject to independent testing. This would essentially return us to the pre-CPSIA state of affairs in which consumers were expected to guess which toys and children's products were really safe.

The AAP would like to make one more comment on another point made in the discussion draft and strongly recommend that non-compliant cribs not be permitted in childcare facilities.

In conclusion, the AAP urges you to not weaken the CPSIA's protections against lead and other hazards as you consider ways to improve the ability of manufacturers and businesses to comply with this important law. Thank you.

[The prepared statement of Dr. Best follows:]

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Summary of Testimony of Dana Best, MD, MPH, FAAP
on behalf of the American Academy of Pediatrics
Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade
Discussion Draft of a Bill That Would Revise the Consumer Product Safety Improvement Act of 2008
Thursday, April 7, 2011

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

- The scope of children's products should protect children up to age 12 years.
- The CPSIA's limits on lead should not be relaxed.
- Risk assessment is not an appropriate method for limiting lead exposure in children's products.
- Third-party testing is necessary to ensure the safety of children's products.
- Non-compliant cribs should not be permitted in child care facilities.

The AAP has serious concerns that many of the concepts in the Discussion Draft before the Subcommittee would roll back important child health safety protections. The CPSIA was passed in response to significant deficiencies in our nation's product safety system, which had allowed for the widespread sale and distribution of products dangerous to children's health. The AAP urges Congress not to weaken the CPSIA's protections against lead and other hazards as it considers ways to improve the ability of manufacturers and businesses to comply with this important law.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

Thursday, April 7, 2011

Testimony of
Dana Best, MD, MPH, FAAP

On behalf of the
American Academy of Pediatrics

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

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Dana Best, MD, MPH, FAAP
American Academy of Pediatrics
April 7, 2011

Thank you, Mr. Chairman, for this opportunity to testify today before the Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade about children's product safety. My name is Dana Best, MD, MPH, FAAP, and I am pleased to represent the American Academy of Pediatrics (AAP), a non-profit professional organization of 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. I am an Associate Professor of Pediatrics at George Washington University School of Medicine here in Washington, D.C. and served for six years on the AAP's Committee on Environmental Health, which is the primary body within the AAP that handles lead and other environmental health issues.

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

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

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

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

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

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

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Lead is a Potent Neurotoxin

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

Exposure to lead is amply documented to cause the loss of intellectual capacity. On average, children whose blood lead levels (BLLs) rise from 10 to 20 micrograms per deciliter (mcg/dL) lose two to three IQ points. More recent studies have shown an even greater impact on IQ of BLLs under 10 mcg/dL. Key studies reported a loss of 4 to 7 IQ points in children whose lead levels rose from 1 mcg/dL to 10 mcg/dL.[1,2] These studies suggest that "low" levels of exposure – meaning BLLs less than 10 mcg/dL – cause proportionately greater harm than higher levels.

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

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

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

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

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

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The CPSIA's Limits on Lead Should Not Be Relaxed

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

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

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

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

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

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

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

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

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

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

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

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

Dana Best, MD, MPH, FAAP
American Academy of Pediatrics
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Third-Party Testing Is Necessary to Ensure the Safety of Children's Products

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

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

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

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

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

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

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

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January 21, 2009

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

Dear Chairman Waxman:

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

Lead and Children's Health

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

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

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

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

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

Lead in Children's Products

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

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

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

Development of the AAP Lead Recommendation

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

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

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

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

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

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

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

Development of the CPSIA Standard and Exceptions Clause

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

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

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

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

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

Sincerely,

David T. Tayloe, Jr., MD FAAP
President

DTT:cp

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Mrs. BONO MACK. I thank the gentlelady and recognize Dr. Beck for 5 minutes. Can you make sure your microphone is on and close to your mouth, please?

Ms. BECK. Sorry.

Mrs. BONO MACK. Thank you.

STATEMENT OF BARBARA D. BECK

Ms. BECK. My name is Barbara Beck. I am a toxicologist risk assessor at Gradient, an environmental consulting company and I have worked on issues of lead exposure, toxicology, and risk for over 20 years, starting from my time at EPA Region 1 where I was involved in development of one of the first clean up levels for lead in soil that I am aware of. I have evaluated exposures, toxicology of lead in products, workplace, and in the environment.

In its present version, the CPSIA Act has established a concentration limit of 300 parts per million for lead, which will go in August to 100 parts per million unless it is not feasible. This is going to be problematic and is problematic at present, especially for metallic alloys that contain lead such as tire stem valves. My concern with the present approach is that it doesn't consider the actual exposure, the intake, the absorption, and the impact of lead releases from such products on blood lead levels. Blood lead levels are typically considered the appropriate metric for evaluating exposures to lead.

Risk-based approaches have been used to establish limits for lead for decades. It has been used to establish limits for lead in air, water, and soil. Such approaches have been beneficial. Blood lead levels of children in the U.S. have declined by over a factor of 10 over the past 20 years as lead has been removed or reduced from air, from food, and from paint.

The proposed changes represent a step in the right direction. Determination of a de minimis level of lead exposure is consistent with what has been conducted with other types of materials such as soil, air, and water, and it also proposes the use of a methodology to identify how much lead is released, what the actual exposure would be from a children's product. This approach is not only consistent with regulatory policy in other settings, but with fundamental principles of toxicology. The dose is what matters. The dose of a chemical—whatever the chemical is, how hazardous it is—is really critical in determining whether there would be a risk or no risk.

I am not here to propose a specific model or a specific de minimis limit, but I do note that the approaches should consider the age of the child: mouthing behavior peaks at age 2 to 3, absorption of lead from the gut peaks around that age, and choosing a value of, say, 7 years old would be protective of younger children. The method that is considered should consider how a child actually interacts with the product and risk-based methods are available to evaluate mouthing behavior, contact by hand with products, hand-to-mouth, as well as the potential swallowing of a product and the impact that contact on blood lead. That can be modeled.

My comments that are provided to the committee provide a hypothetical example of how such an analysis could be conducted. It is not meant to propose specific de minimis values or the specifics of

an approach but to demonstrate that there are methods. In my particular example, I demonstrate how a release of 1 microgram of lead from a product per day every day for a 2- to 3-year-old child would not have a discernible impact on blood lead. Some people may consider that de minimis.

In conclusion, I strongly encourage the committee to consider the use of such risk-based approaches in proposing amendments to the CPSIA. Such approaches will allow for health-protective risk-based limits that would be sound public health policy, as well as sound risk management policy. Thank you.

[The prepared statement of Ms. Beck follows:]

Testimony of Barbara D. Beck, Ph.D., DABT

Regarding "Discussion Draft of H.R.___, a Bill that would Revise the Consumer Product Safety Improvement Act"

Prepared for the
Subcommittee on Commerce, Manufacturing, and Trade Hearing
April 7, 2011
at the
Committee on Energy and Commerce
2125 Rayburn HOB/316 Ford HOB
Washington, DC 20515

Prepared by
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April 7, 2011

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Executive Summary

The lead limits stipulated by the Consumer Product Safety Improvement Act (CPSIA) of 2008 have forced many manufacturers to stop selling certain products, because the products contain components exceeding the current 300 ppm total lead standard of the Act. The difficulty with this approach to regulating lead in products is that it does not consider the *actual* exposure of children to lead. This is because the presence of lead in a product, as reflected by the concentration of lead, does not necessarily mean that there will be a significant exposure to lead. If the exposure to lead is very small, there will not be any health effects. Unfortunately, the present version of the CPSIA does not support consideration of exposure. Risk-based analyses that take into consideration age of child, exposure frequency and duration, exposure route, and dose represent a scientifically supportable approach to determine exclusions from the lead standard. In 2009, I recommended at a Congressional Briefing that that such risk-based analysis be allowed under the auspices of the Act. The "Discussion Draft H.R.____," dated March 29, 2011, proposed by the Subcommittee on Commerce, Manufacturing, and Trade to amend the Act, suggests just such an approach. Although details need to be worked out with respect to the testing method and specific criteria (*e.g.*, allowable lead exposure limits), conceptually the proposal, by focusing on *actual* exposure of young children to lead from a product, rather than concentration of lead in the product, represents an improvement over the present version of the CPSIA, while remaining health protective.

1 Introduction

Good morning and thank you for this opportunity to testify regarding the CPSIA and the need for a risk-based approach for lead in children's products. I am Barbara D. Beck, Ph.D., diplomate of the American Board of Toxicology (DABT), and fellow of the Academy of Toxicological Sciences. For 24 years I have been a toxicologist and Principal with Gradient, a firm specializing in human health exposure and risk assessment, and located in Cambridge, Massachusetts. Prior to Gradient, I held positions at the Harvard School of Public Health, US EPA Region I, and Tufts University School of Medicine. I am past president of the Academy of Toxicologists, and have been a DABT for 20 years.

Over my 30+ year career in toxicology and public health, I have worked extensively on projects involving lead. More than 20 years ago, while at US EPA Region I, I developed the first target action level for lead in soil. During my tenure at Gradient, I have worked for the private and the public sector on many projects involving lead exposure, toxicology and risk. These projects have included refinery and mining sites, children's toys, consumer products, and automotive vehicles. I was also significantly involved in providing regulatory comment for the lead National Air Quality Standard (NAAQS). On April 1, 2009, I testified at the CPSIA Rally and Congressional Briefing regarding lead and the CPSIA.

I would also like to emphasize that I am presenting my testimony this morning on my own behalf as an independent scientist. I am not being compensated for my travel expenses or any of the time I have spent preparing for today's testimony. In addition, I am not representing myself under any Federal contract or grant.

2 Consumer Product Safety Improvement Act (CPSIA) of 2008

The Consumer Product Safety Improvement Act (CPSIA) of 2008 stipulates that, as of August 14, 2009, children's products that contain more than 300 ppm (mg/kg) lead may no longer be sold in the United States (US Congress, 2008). The limit will be reduced to 100 ppm on August 14, 2011, unless the Commission determines that this lower limit is not technically feasible. Based on the current language, while manufacturers may petition for exclusion from these standards, exclusions are allowed only if the manufacturers can demonstrate that no lead can be absorbed by children.

The scientific community understands that, based on multiple lead-related recalls occurring in 2007, Congress was motivated to write the Act to be protective of our children's health, and, in the case of lead, to eliminate lead risk to children. However, there have been untoward consequences of the Act, as some manufacturers and businesses have suspended sales of their existing inventory. The act has been particularly burdensome for manufacturers of steel, copper, and aluminum alloys, as components made from these materials typically contain fairly high concentrations lead. The end result is that certain individual components in the products exceed the current lead standard – even though exposure to lead in those components is, because of the nature of the way children come into such components, unlikely, and would not result in health effects. Thus, the Subcommittee on Commerce, Manufacturing, and Trade has responded with a proposed bill that would amend the CPSIA to allow for a risk-based approach, that is protective of public health, and to relieve the burden to manufacturers.

As I explained during my testimony at the Congressional Briefing in 2009, a risk-based approach focuses on *actual* exposure and the health significance of that exposure. Such an approach can be extremely effective in protecting a child's health. Consider, for example, how average blood lead levels in children have been reduced by nearly 10-fold, from 15 μg/dL in 1976 to 1.5 μg/dL in 2007-2008 (CDC,

2011), an important public health success story. This was accomplished by focusing on *important* sources of lead exposure (*i.e.*, sources that had a significant impact on blood lead levels), specifically lead in air (from leaded gasoline), in food (primarily from lead solder in cans), and in paint, to the general population of children. Indeed, risk-based approaches are widely used and considered appropriate in other sectors, for example, in human health risk assessment for lead in soil performed for Superfund sites (US EPA, 1997).

3 Lead Standards and Permissible Intake

Regulatory agencies develop standards to prevent harmful health effects. In general, the agencies purposely over-estimate exposures to and the toxicity of chemicals in order to be certain that human health is protected. This means that standards have a margin of safety (*i.e.*, the permissible dose of a chemical is well below the dose that causes harmful health effects). This provides confidence that regulatory limits will be sufficiently protective for all individuals, even those who might especially sensitive to the chemicals of interest. In the case of lead, children are typically considered to be more susceptible than adults.

A permissible level of lead in a toy or another children's product must be based on an understanding of how lead is released from a toy, the amount of lead potentially ingested by a child, and the quantitative impact of that ingested lead on blood lead. Lead that cannot be released from a toy or other product because the lead is in an inaccessible location or bound in a matrix would not constitute a risk potential because the lead would not be ingested by the child. Thus, to be meaningful, a standard should be linked to the amount of lead released from the toy. A standard based on soluble lead [*e.g.*, the 90 ppm standard specified for soluble lead in ASTM F963-07e1 (ASTM, 2007)] would, in general, be

preferable to a standard based on total lead (unless a robust relationship between total lead and soluble lead has been determined).

Thus, a standard could be developed by setting a target blood lead increment and then calculating the amount of lead released from a toy or other product that would result in an impact at or below the target blood lead increment. Conceptually, health-based limits for lead in other media, such as air, water, or soil, have been developed in this manner, using exposure parameters specific to that medium (see, for example, CPSC, 1977; US EPA, 2001, 2002).

4 Proposed Change to the CPSIA: *De Minimis* Exemption

The new bill proposed by the Subcommittee on Manufacturing, Trade, and Commerce proposes a *de minimis* exemption for lead released from children's products, specifically stating that:

> The limits established under subsection (a) shall not apply to any component part of a children's product if, under reasonably foreseeable conditions of use and abuse, it is unlikely that a child who is exposed to the product would ingest more than a *de minimis* amount of lead. (Subcommittee on Manufacturing, Trade, and Commerce, 2011)

In terms of implementation, the proposed amendments state:

> The Commission shall, by regulation, establish a methodology for estimating the amount of lead a child would likely ingest from exposure to a component part. Such methodology shall distinguish, at a minimum, between parts that can be placed in the mouth and parts that cannot be placed in the mouth. (Subcommittee on Manufacturing, Trade, and Commerce, 2011)

Moreover, until such methodology is defined by the US Consumer Product Safety Commission (CPSC):

> [A] manufacturer may use any reasonable methodology to estimate the amount of lead a child would ingest from exposure to a component part. (Subcommittee on Manufacturing, Trade, and Commerce, 2011)

Although details on implementation (*e.g.*, testing method and definition of the *de minimis* lead exposure limit) need to be worked out, the proposal focuses on *actual* exposure of young children to lead from a product, and considers the impact of that exposure in terms of health. This is an important improvement over the present version of the CPSIA.

The following sections provide scientific support for the use of a risk-based approach, including a hypothetical example that describes an approach to assist in the definition of a *de minimis* level. The sections also contain information on application of such a risk-based approach to children's products, including a discussion of possible extraction methods for product testing and the use of blood lead modeling.

5 Consideration of Exposure: Risk-Based Approach

The mere presence of lead in a children's product or component does not mean that there is an exposure hazard to a child. Moreover, a component with a high concentration of lead does not necessarily mean that a child will subsequently be exposed to a high concentration of lead. Several exposure factors, described below, must be considered to determine whether the lead in a particular product constitutes a health risk to a child contacting that product.

5.1 Dose Response

The most fundamental concept in toxicology is the dose-response relationship, commonly summarized as "the dose makes the poison" (Eaton and Gilbert, 2008). All substances show a dose-response relationship. For example, small amounts of salt may be consumed without adverse effects, but ingestion of much larger quantities can result in adverse effects, such as elevated blood pressure (Braunwald *et al.*, 2001, p. 1415). As another example, at the recommended dose of two tablets,

aspirin yields pain relief from headaches or other minor aches, and even lower doses can be used to prevent and manage cardiovascular disease. However, taking more than the recommended dose can lead to increasing levels of toxicity, including death (Roberts and Morrow, 2001). Similarly, lead exhibits a dose-response relationship, with the likelihood and nature of effects being greater with increasing dose, typically expressed as blood lead levels.

5.2 Exposure Duration and Frequency

The dose of a chemical is affected by a number of factors. For example, how long and how often someone comes into contact with a chemical will affect the dose. In the case of a children's consumer product, it is important to know whether the child comes into contact with the product every day, or only occasionally. It is also important to know how many hours or minutes of each day a child contacts the product. For example, daily or infrequent contact with the product may be possible. With less time of contact, exposure will generally be less. One-time acute exposure (*i.e.*, accidential ingestion) is also possible; appropriate science-based assessments are available to account for such potential acute exposure, if that is a plausible exposure scenario.

5.3 Exposure Route

The manner in which a person comes into contact with the chemical (for example, through the skin *versus* taking the chemical in through the mouth) is also important. The chemical also must be accessible to the child in order for an exposure to occur. While some chemicals can be taken in through the skin, others are not taken in through the skin very well, if at all. In the case of children's products, a young child might possibly chip or bite paint off a painted product, or, if the paint is loose, take paint off by sucking on the children's product. If the paint contains lead, these activities could result in some lead taken into the body through the mouth; this is termed "ingestion." Because lead is not taken up through

the skin, just handling the children's product will not result in a dose of lead. Another possible exposure scenario is surface-to-hand transfer and subsequent transfer from hand to mouth. Considerations for this scenario include the surface area of the hand/fingers touching a component, the transfer of lead to the hand/fingers, the frequency and duration of the contact, the transfer of lead from hand/fingers to mouth, and subsequent intake of the lead into the body. Methods are available to quantify the transfer of metals, such as lead, from components to hands *via* use of wipe tests (see, for example, Dubé *et al.*, 2004).

5.4 Lead Intake *versus* Uptake

Intake is generally expressed as the amount of a chemical at the skin, lungs, gastro-intestinal tract that is available for absorption. Intake, while necessary to yield a "dose," is not equivalent to absorbed dose (uptake), the amount of a chemical absorbed into the blood stream. Lead intake (particularly from children's products) is primarily through ingestion (*e.g.*, through direct mouthing of a children's product or through hand-to-mouth contact).

How much lead a child actually absorbs, after lead is ingested, is an important consideration in a risk-based approach. Bioavailability (*i.e.*, the fraction of ingested lead that is solubilized in the gastro-intestinal tract) determines the amount of lead that can be absorbed into the body (uptake). Bioavailability <u>should</u> be considered when evaluating exposure using a risk-based approach. The bioavailability of lead in the digestive tract depends on the physical (*i.e.*, particle size) and chemical form of lead, and can vary by more than 10-fold. This is clearly an important determinant of the amount of lead uptake into the body.

5.5 Blood Lead Modeling

In order to evaluate the impact of lead exposure to the body, the amount of lead absorbed must be converted to a blood lead value. Models such as the *Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children* (US EPA, 1994), or the O'Flaherty model (1997) are widely accepted risk-based approaches that have been used in a number of circumstances to quantify the impact of lead uptake on blood lead. These models can be and have been applied in risk-based approaches to evaluate the impact on blood lead of different types of exposures of lead, from soil, air and products.

5.6 Consideration of Age of Child

The Act considers products manufactured for children up to age 12. However, it is important to note that there is a significant difference between a 2- to 3-year-old toddler and a 12-year-old, and how they will interact with a children's product. The 2- to 3-year-old will have much more frequent hand-to-mouth contact than the 12-year-old and will contact products in a different manner than a 12-year-old (US EPA, 2006; RIVM, 2008). The 2- to 3-year-old absorbs more ingested lead and is more susceptible to the developmental effects of lead than older children (US EPA, 2006; O'Flaherty, 1998). Recognition of the important behavioral and physiological differences between the young child and older children would represent a significant improvement in the CPSIA. Although the proposed amendment does not specify the age group under consideration, it appears to be reducing the target group to younger children (*versus* as old as 12 years).

6 Appropriate Extraction Methods

The new amendment is written in such a way that approaches beyond the testing procedures defined in ASTM Method F963-7e1 (ASTM, 2007) toy safety standard might be considered appropriate

for evaluating lead exposure. The use of extraction methods is one accepted approach to evaluating exposure of lead and other constituents from products. Some of the methods evaluate chemicals leaching in acidic solutions that mimic gastric fluid [*i.e.*, the solubility extraction procedures in ASTM Method F963-7e1 (ASTM, 2007)]. As another example, CPSC recently released an updated 24-hour acid extraction test procedure to address acute exposure and mimic accidental ingestion of metal jewelry; the method was designed to evaluate cadmium leaching from swallowable small parts (CPSC, 2011). These methods, while appropriate for the scenario where a small part is likely to be swallowed whole, would potentially overestimate exposure in certain cases, such as mouthing or sucking scenarios. However, protocols have also been developed and used to assess chemical leaching in saliva. For example, CPSC developed a method to assess migration of diisononyl phthalate (DINP) from polyvinyl chloride (PVC) children's products (CPSC, 1998), a method that has also been adapted by CPSC to assess lead leaching from objects due to contact with saliva. This method involves shaking the sample for 6 hours in a simulated saliva solution at a neutral pH of approximately 7.2 and at a temperature of 37°C. A similar method was adapted and used by Duke University to evaluate lead leaching from brass ball point pen tips (Baker, 2009). CPSC has used a saline extraction method to evaluate cadmium leaching from metal jewelry during a mouthing scenario (CPSC, 2010). Depending on the nature of the product and how young children interact with that product, a saline extraction method would be more appropriate than an acid extraction method in a number of cases.

7 Use of Blood Lead Modeling in Developing Permissible Lead Limits

Blood-lead modeling is an important tool used to calculate the impact of exposure on blood lead. It has been used to set permissible limits for lead in other media, such as air, water, and soil (for example, US EPA, 2008, 1988, 1998, respectively). Various blood lead targets may be considered for determination of the *de minimis* amount of lead extracted from a product. For example, in developing the

National Ambient Air Quality Standard for Lead, US EPA used a 1-2 μg/dL increment in blood lead as the target to establish a permissible air lead limit (US EPA, 2008). In the case of lead in soil, US EPA (1998) focuses on a modeled distribution of blood lead for a hypothetical child. Another consideration is whether the modeled impact of the extractable lead could have a detectable incremental impact on blood lead.[1]

While the proposed amendment does not define a *de minimis* daily intake of lead, I provide here a hypothetical example using a value of 1 μg/day intake of lead, every day for a 2- to 3-year-old. Using blood modeling, specifically US EPA's IEUBK model, this amount of ingested lead would result in a mean blood lead change of 3.0 μg/dL to 3.1 μg/dL. As presented graphically below, such an increment would be negligible.[2]

Specifically, Figure 1 compares the blood lead impact based on a 1 μg/day intake of lead. In this example, I assumed that a 2- to 3-year-old child would take in this amount of lead in a soluble form, every day for two years.[3] Alternate assumptions may, depending upon the product and the plausible ways in which a child might interact with that product, also be appropriate. In this calculation, it can be seen that the contribution of lead from 1 μg is indiscernible as the blood level remains the same.

[1] It should be emphasized that my description of these approaches is meant to be illustrative. I am not proposing a specific increment to blood lead as a target under the CPSIA, but rather describe approaches whereby a permissible limit may be developed.

[2] An impact of approximately 2 μg/dL or less of a lead release would not be reliably and routinely detectable in an individual child, For example, in a study by Chandramouli *et al.* (2009), the majority of quality control results were within a range of +/- 2 μg/dL. These findings are generally consistent with recommendations from the US Centers for Disease Control that, for investigative actions, laboratories set their internal quality control limits to +/-2 μg/dL or ±10%, whichever is greater (Parsons and Chisolm, 1997).

[3] I do not provide these exposure assumptions as ones that ought to be used under amendments to the CPSIA, but to illustrate a process.

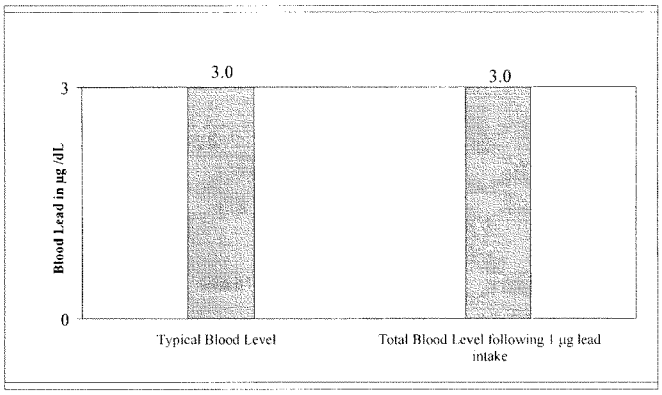

Figure 1. Comparison of Blood Lead Levels in µg/dL Before and After a 1 µg Intake by a 2- to 3-Year-Old Child

8 Recommendation

In conclusion, in order to appropriately evaluate exposure to lead in children's products, I recommend use of a risk-based approach that incorporates methods such as saliva extraction and blood lead modeling. This approach would reasonably mimic exposure scenarios relevant for a young child, while also emphasizing prevention of significant increases to blood lead. While many details remain to be worked out, I urge Congress and CPSC to seriously consider the new bill proposed by the Subcommittee on Manufacturing, Trade, and Commerce, which would amend the CPSIA to allow a health-protective risk-based approach.

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Mrs. BONO MACK. Thank you, Dr. Beck. Mr. Howell, you are recognized for 5 minutes.

STATEMENT OF ROBERT JAY HOWELL

Mr. HOWELL. Good morning, Chairman Bono Mack, Ranking Member Butterfield, and members of the subcommittee. My name is Robert Howell. I am the assistant executive director for the Office of Hazard Identification and Reduction at the Consumer Product Safety Commission. I appreciate the opportunity to testify before you this morning regarding certain technical aspects of the discussion draft of legislation that would revise the Consumer Product Safety Improvement Act. The testimony that I will give this morning represents my personal views and has not been reviewed or approved by the Commission and may not necessarily reflect the views of the Commission.

In my role at CPSC, I oversee the technical work of the Agency within the Office of Hazard Reduction's directorates for Engineering Sciences, Epidemiology, Economic Analysis, Health Sciences, and Laboratory Sciences. My office is responsible for the collection and analysis of death and injury data associated with consumer products, the evaluation of consumer products for potential safety hazards and regulatory compliance, and the development of technical solutions to product safety concerns.

Prior to joining CPSC in 2006, I served as vice-president of manufacturing and operations for a multinational corporation with responsibility for the management of global manufacturing and logistics.

On January 15, 2010, the five members of the CPSC issued a report to Congress regarding possible improvements to the CPSIA. In suggesting those improvements, the commissioners noted that the recommendations were focused on maintaining the "safety and welfare of consumers while minimizing administrative burdens on the Agency or significant market disruptions caused by the implementations of specific provisions of the CPSIA."

Specifically, the Commission listed the following recommendations for improvement of the statute: that the Commission "needs additional flexibility within Section 101 to grant exclusions from the lead content limits in order to address certain products, including those singled out by the conferees;" that "Congress may, with some limitations, choose to consider granting an exclusion for ordinary children's books and other children's paper-based printed materials; the Commission believes that a prospective application of the 100 parts per million lead limits would be helpful for our continued implementation of the law;" and that the "Commission remains committed to working with Congress to explore other ways to address the concerns of low-volume manufacturers" with regard to the testing and certification requirements in Section 102 of the CPSIA.

From my perspective, the CPSIA has improved the health and safety of consumers, particularly children. In additional, industry has made substantial progress over the past 2½ years adapting to the requirements of the law. For example, the children's product industry has made progress in reducing the levels of lead since the enactment of CPSIA. In a recent Commission hearing on the tech-

nological feasibility of reducing the lead limits to 100 parts per million, a representative of SGS—a global inspection, verification, testing, and certification company—presented a statistical analysis of lead content testing data with close to 90,000 data points collected primarily from its Shenzhen laboratory that specializes in the testing of children's toys and other children's products.

In its analysis, SGS found that 96.3 percent of metal components tested at or below 100 parts per million. The analysis also determined that just over 97 percent of glass and ceramic components tested at or below 100 parts per million. Concerning plastic components, SGS found that 99.4 percent of those components tested at or below 100 parts per million. However, there are certain provisions of the CPSIA such as the current exceptions to the Section 101 lead limits that can be improved in such a way as to reduce the burden on the regulated community while maintaining an appropriate level of safety for America's consumers. I personally believe this balance is necessary to ensure efficient and effective implementation of the CPSIA from the perspective of both the regulated community and the regulators.

There are several approaches that could allow the CPSC to address the unintended consequences of certain regulatory requirements in the CPSIA. For example, the Commission has heard from a number of Members of Congress that they did not intend to cover all-terrain vehicles under the provisions of Section 101. Accordingly, Congress could permit the Commission to exempt certain products like ATVs from the lead limits. This will allow the CPSC to weigh the risk of possible lead exposure to a child riding a youth-sized ATV against the risk to the child from riding a larger and more powerful adult ATV.

Assuming that the exceptions would be made on a notice-and-comment basis, the underlying analysis and support for any exceptions would be public, allowing for transparency and accountability for all stakeholders involved in the process.

Finally, allowing the Commission to regulate on a timetable influenced by the seriousness of the actual risk would allow for better priority-setting that will permit Commission resources to be put towards the most serious health risk.

Mrs. BONO MACK. If you could please sum up now.

Mr. HOWELL. Madam Chairman, thank you.

[The prepared statement of Mr. Howell follows:]

Statement of
Robert J. Howell
Assistant Executive Director
Office of Hazard Identification and Reduction
U.S. Consumer Product Safety Commission

Before the

House Energy and Commerce Committee

Subcommittee on Commerce, Manufacturing and Trade

Legislative Hearing: "Discussion Draft of H.R. _____, a bill that would revise the Consumer Product Safety Improvement Act."

April 7, 2011

Good morning, Chairman Bono Mack, Ranking Member Butterfield, and Members of the Subcommittee on Commerce, Manufacturing, and Trade. My name is Robert J. Howell, and I am the Assistant Executive Director for the Office of Hazard Identification and Reduction at the U.S. Consumer Product Safety Commission ("CPSC").

I appreciate the opportunity to testify before you this morning regarding certain technical aspects of the discussion draft of legislation that would revise the Consumer Product Safety Improvement Act (CPSIA). The testimony that I will give this morning represents my personal views.[1]

In my role at CPSC, I oversee the technical work of the agency within the Office of Hazard Reduction's directorates for Engineering Sciences, Epidemiology, Economic Analysis, Health Sciences and Laboratory Sciences. My office is responsible for the collection and analysis of death and injury data associated with consumer products, the evaluation of consumer products for potential safety hazards and regulatory compliance, and the development of technical solutions to product safety concerns.

In addition to these responsibilities, I served as Acting Director of CPSC's Office of Compliance and Field Operations from July 2010 through February 2011. Prior to joining CPSC in 2006, I served as Vice-President of Manufacturing and Operations for a multinational corporation, with responsibility for the management of global manufacturing and logistics.

I. Past Commission Statements on Possible CPSIA Changes

On January 15, 2010, the five members of the CPSC issued a Report to Congress regarding possible improvements to the CPSIA.[2] In suggesting those improvements, the Commissioners noted that the recommendations were focused on maintaining the "safety and welfare of consumers while minimizing administrative burdens on the agency, or significant market disruptions, caused by the implementations of specific provisions of the CPSIA."

Specifically, the Commission listed the following recommendations for improvement of the statute:

1) that the Commission "needs additional flexibility within [section 101(b)] to grant exclusions from the lead content limits in order to address certain products, including those singled out by the Conferees;"

[1] The testimony has not been reviewed or approved by the Commission and may not necessarily reflect the views of the Commission.

[2] A copy of the January 15, 2010, "U.S. Consumer Product Safety Commission Report to Congress Pursuant to the Statement of Managers Accompanying P.L. 111-117," is available at: http://www.cpsc.gov/ABOUT/Cpsia/cpsiareport01152010.pdf.

2) that "Congress may, with some limitations, choose to consider granting an exclusion for ordinary children's books and other children's paper-based printed materials;"

3) "the Commission believes that a prospective application of the 100 ppm lead limits would be helpful for our continued implementation of the law;" and

4) that the "Commission remains committed to working with Congress to explore other ways to address the concerns of low volume manufacturers" with regard to the testing and certification requirements in section 102 of the CPSIA.

II. Staff Comments on the Discussion Draft

In general, the CPSIA has improved the health and safety of consumers, particularly children. In addition, industry has made substantial progress over the past two and a half years adapting to the requirements of the law.

For example, the children's product industry has made significant progress in reducing the levels of lead since enactment of the CPSIA. In a recent Commission hearing on the technological feasibility of reducing the lead limits to 100 ppm, a representative of SGS, a global inspection, verification, testing, and certification company, presented a statistical analysis of lead content testing data (89,273 data points) collected primarily from its Shenzhen laboratory that specializes in the testing of children's toys and other children's products.[3]

In its analysis, SGS found that 96.29 percent of metal components tested at or below 100 ppm lead. Of those components exceeding 100 ppm, 2.22 percent tested greater than 600 ppm lead, 0.8 percent tested between 300 ppm and 600 ppm for lead, and 0.69 percent tested between 100 ppm and 300 ppm for lead. The analysis also determined that 97.46 percent of glass and ceramic components tested at or below 100 ppm lead. Of those components exceeding 100 ppm, 1.39 percent tested greater than 600 ppm lead, 0.81 percent tested between 300 ppm and 600 ppm for lead, and 0.34 percent tested between 100 ppm and 300 ppm for lead. Concerning plastic components, SGS found that 99.4 percent of plastic components tested at or below 100 ppm lead. Of those components exceeding 100 ppm, 0.37 percent tested greater than 600 ppm lead, 0.17 percent tested between 300 ppm and 600 ppm for lead, and 0.06 percent tested between 100 ppm and 300 ppm for lead.

However, there are certain provisions of the CPSIA, such as the current exceptions to the section 101 lead limits, that can be improved in such a way as to reduce the burden on the regulated community while maintaining an appropriate level of safety for America's consumers. I personally believe this balance is necessary to ensure efficient and effective

[3] A copy of the presentations and written comments from the February 16, 2011, Public Hearing, including the SGS presentation, can be found at http://www.cpsc.gov/library/foia/foia11/pubcom/lead100pres.pdf.

implementation of the CPSIA from the perspective of both the regulated community and the regulators.

There are several approaches that could allow the CPSC to address the unintended consequences of certain regulatory requirements in the CPSIA. For example, the Commission has heard from a number of Members of Congress that they did not intend to cover all-terrain vehicles (ATVs) under the provisions in section 101. Accordingly, Congress could permit the Commission to exempt certain products, like ATVs, from the lead limits. This would allow the CPSC to weigh the risk of possible lead exposure to a child riding a youth-sized ATV against the risk to the child from riding a larger and more powerful adult ATV.

Assuming that the exceptions would be made on a notice and comment basis, the underlying analysis and support for any exceptions would be public, allowing for transparency and accountability for all stakeholders involved in the process. Finally, allowing the Commission to regulate on a timetable influenced by the seriousness of the actual risks will allow for better priority setting that will permit Commission resources to be put towards the most serious health risks.

* * * * *

Madame Chairman, thank you again for the opportunity to testify regarding certain technical aspects of the discussion draft.

I would be happy to answer any questions at this time.

Mrs. BONO MACK. Thank you. Oh, perfect. Thank you. That worked out just well. I want to thank our panel of experts. And now the chair will recognize herself for the first 5 minutes of questioning.

And Mr. Howell, the first question to you. How does the CPSC staff go about deciding whether a substance or a product poses a risk to children? And briefly, what factors are important?

Mr. HOWELL. As CPSC staff evaluates potential risk to children, it involves several different teams within CPSC. We have a human factors team that will actually age-grade the product and determine what particular product characteristics are important in age-grading to ensure that the product is targeted to the correct group of children. If, for example, we are evaluating that product with regards to lead, for example, a complete risk assessment would be conducted taking into account not only the intended consumer but any other children that may be attracted to that particular toy based on characteristics of the toy.

Mrs. BONO MACK. Thank you. Does the Commission have information on the cost of third-party testing? For example, do you know how much it would cost to have a bicycle tested by a third-party laboratory to all the applicable standards?

Mr. HOWELL. We have heard from the bicycle industry that the cost to test a $50 bicycle for all the applicable standards would run somewhere in excess of $10,000.

Mrs. BONO MACK. Wow. Thank you. And the focus of a lot of our attention, especially on this side of the aisle and again, Mr. Howell, is the database. I actually think the database is helpful and useful, but I think it has problems and we should talk about it a great deal. My thinking is that it is 100 percent negative derogator and that if the manufacturer can respond that they are seen as defensive. There must be a way—if you buy anything anywhere on the internet now, Amazon, I mean even Zappos.com, you know, there are comments on both sides. People can give the good and the bad of a product. Yet this database is 100 percent negative. Can it not be refined so that there is a more accurate depiction of a product?

For example, if I complain about something potentially hurting my child but this is one example out of 10,000—but nobody else would have any way of knowing that—can't the database be refined to be a more accurate depiction about a product in society?

Mr. HOWELL. Chairman Bono Mack, I am quite certain that either Congress or the Commission could—within CPSIA as written—make modifications. But that is certainly more of a policy matter and is beyond my responsibilities at CPSC.

Mrs. BONO MACK. Well, thank you. I think I made my thoughts pretty clear there in my questions. So also, to you Dr. Best, you state from a scientific perspective that there is no basis for differentiating between a child licking versus sucking on an object. In CPSIA however, Congress drew that very distinction for purposes of phthalate limits. Do you see a reason why this is changed? And I always do that on that word. Do you see a reason why this distinction makes sense for phthalates but not for lead?

Ms. BEST. We didn't actually work on the phthalates issue, and so I can do some research and perhaps offer you a response. But again, I am an expert on lead, not on phthalates.

Mrs. BONO MACK. All right. Thank you. And you mentioned also that older children sometimes put ballpoint pens or jewelry in their mouths. You also mentioned that toys may be shared among multiple children in the same household. But aren't there many other items which older children do not mouth and to which younger children rarely, if ever, have access?

Ms. BEST. Of course. But we are talking about the harms to children from lead-containing objects. And so, you know, our focus is on those lead-containing objects that may be dangerous to younger children.

Mrs. BONO MACK. But common sense would say, as a parent—my kids are now 23 and 20 and my step-kids are 8 and 11—common sense would say to a parent their children don't only come in contact with children's products whether it is a 2-year-old toy, a 10-year-old toy or an adult, say, electronic component of some sort. Is that not a problem as well? Is it common sense that we are trying to say that a—from what I understand—a Hannah Montana DVD is under one category and a Miley Cyrus DVD is on another category and then a DVD player is entirely exempt? So parents ask themselves these questions all the time. It is one of these things, what are they thinking in Washington? Because it makes no sense at all. As a pediatrician, how do you address that?

Ms. BEST. I am having trouble understanding the question. So yes, there are products in the house that are not intended for children that do not come under the CPSC's purview in this context. And while there are other safety groups that may work with those products, we are focusing on the safety of children's toys here and products intended for children. And that is our focus.

Mrs. BONO MACK. We are out of time. Just to make a little more clear that it is common sense, sometimes, that you can't protect from everything here. And that is the question. Is the Commission focused on its highest priorities? So I am sorry, but I need to yield now to Mr. Butterfield for his 5 minutes of questioning.

Mr. BUTTERFIELD. Thank you, Chairman. Prior to the enactment of this legislation, the Consumer Product Safety Commission assessed the risk posed by children's products containing lead by estimating the amount of lead intake from the product and the subsequent effects of exposure on blood lead level. For the most part, this was what I call an after-the-fact assessment. That is the Commission mostly looked at products for exposure to and risks from lead after products had entered the marketplace and been put into the hands of children. The discussion draft seems to create a de minimis exception that makes the total lead content limits in CPSIA more meaningless. Basically, any component part that cannot be swallowed can contain any amount of lead so long as a child isn't expected to ingest more than some amount to be determined amount of lead. So rather than determining the total amount of lead contained in a product, the discussion draft would call on manufacturers to estimate the amount likely to be ingested and takes it as a given that it is oK for kids to take in some amount of lead from their toys.

Ms. Best, the de minimis exception in the discussion draft is essentially a return to the approach that the commission used prior to the legislation. As I read it, any component part of a toy or other

children's product such as a crib would be allowed to release a de minimis amount of lead, say 6 micrograms per day. Can you please explain what would happen if a child played with more than one toy in one day? Even a child who has one special toy plays with dozens of toys in a day. Could that child be exposed to 6 micrograms per day per toy? I do not read the de minimis standard as requiring the consideration of other exposures to lead in a given day. Can you help me with this?

Ms. BEST. Well, the Academy is very much against the de minimis standard for many of the points you raised. Lead exposure doesn't come just from one individual product. It comes from the environment. It can be found in our food, in our air, certainly on paints, certainly in the water in Washington, D.C., in the past. And so we are very concerned about the bioaccumulation of lead through all these different sources. Because lead doesn't immediately get passed out through your body, you can actually store it. Some of these stores persist for years, if not decades. And that is one of the things we are very much concerned about.

Mr. BUTTERFIELD. Thank you. Many of us agree that there are specific products that can't meet the lead content limits and can't be made without lead—we acknowledge that—and that some form of relief should be provided for the narrow universe of products. We agree, some of us, that this relief should be as simple to understand and apply as possible while remaining protective of children's health and safety. So far as I can tell, the proposed de minimis exception in the draft fails on all of these counts. Implementing the de minimis exception will require taking into account very product-specific considerations, and on a good number of instances, it will require applying varying lead requirements for differing parts of the same product.

For example, say I manufacture a toy truck that contains plastic and metal, some large enough not to be swallowed and others that can be swallowed. For each plastic component, I would have to ask is this small enough to be swallowed? If the answer is no, then I would have to ask how do I expect a child to interact with this component? Is lead likely to be ingested from the interaction? How much lead can I expect to be ingested from the interaction? What age is the child doing the interacting? For the metal components, the manufacturer would then have to ask, can I meet the alternative 600 parts per million total lead count standard in the draft? If the answer is no, the manufacturer would again have to run through the analysis as I described. Can it be swallowed? So forth and so on.

Mr. Howell, let me ask you this yes or no, sir, and I am going to be out of time momentarily. Would the Commission have to develop multiple methodologies given that children interact differently with different products?

Mr. HOWELL. Yes.

Mr. BUTTERFIELD. Would requiring the Commission to develop multiple methodologies to account for the different ways children can interact with different products and parts require substantial investment of the Commission's limited resources?

Mr. HOWELL. No.

Mr. BUTTERFIELD. In your experience, sir, do retailers and manufacturers prefer clear lines for compliance over estimating the likelihood that their product might behave in a certain way?

Mr. HOWELL. Many do.

Mr. BUTTERFIELD. Under current law, sir, enforcement is simply the product meets the standard or doesn't meet the standard. Under the draft that we have in front of us, the Commission's enforcement seems to be more complicated. For each product at the border where there might be a problem, the Commission will have to do complicated testing. Couldn't this slow down products and have them retain longer at some of our ports?

Mr. HOWELL. Yes.

Mr. BUTTERFIELD. All right. Thank you very much. My time is out.

Mrs. BONO MACK. All right. The chair recognizes the vice chair of the subcommittee, Ms. Blackburn, for 5 minutes.

Mrs. BLACKBURN. Thank you, Chairman, and thank you to our witnesses.

Mr. Howell, I would like to start with you if I may, please. As I mentioned in my opening statement, the database—as we hold our initial hearing on this issue, we are very much aware that the database is incomplete; it has problems. The chairman mentioned some of the problems that are there with how information is recorded. And I want to know two things from you if you would, please, sir. Number one, would we be better off to take that thing down until the problems are worked out? And number two, what needs to be done to correct the problems that are around the database? Very quickly, please. I have got other questions.

Mr. HOWELL. Ms. Blackburn, because the problems that you cite are not clearly defined, I am going to respond to your question clearly in a very broad way. Certainly the decision whether to keep the database up or down becomes a policy decision. It is not one that my technical staff necessarily are the appropriate ones to make. The challenges of implementing anything that is new certainly will require the attention of staff in order to get it right. Many of the things that we see in the database, regardless of the nature of the reports of harm, would require resources to get a handle on the appropriate way to respond.

Mrs. BLACKBURN. OK. And I will help you with that definition. The prior hearing that we had we heard from the commissioners that if there is a complaint against, say, Graco cribs, then all Graco cribs are—you know, you don't define between that. So I would ask you to submit to us in writing with a little bit more detail what you think needs to be done. Because I think we need to take the thing down and bring it offline, work out the kinks, and then bring it back so that it is understandable to consumers so they know exactly what the product is and so there is a method for them to evaluate what actually is the problem and then if they do or do not want to purchase that product. At this point right now, people can just rail against a brand and not necessarily a specific product or a part. And there is that problem of definition within that use.

I want to come to Dr. Beck. Mr. Vitrano, who is going to testify on the next panel, submitted testimony. And thank you all for submitting your testimony in advance. And in there he talks about the

lead intake from children's interaction with ATVs is less than the intake from drinking a glass of water. And I would like to know in your opinion do you agree with that? Do you find that to be an accurate statement and a little bit of definition around that and see if—what I am looking at is if the metal parts on an ATV contain higher lead than are permitted by the EPA for drinking water standards, I am sure you can understand our confusion with that issue.

Ms. BECK. Yes. His statement is correct. It is based on analysis that we did in which we had wipe samples. Because the question is how does a child interact, say, with the valve stem? We had samples of wipes that rubbed the valve stem, and that was to mimic a child touching a valve stem when they fill their——

Mrs. BLACKBURN. OK. So Dr. Beck, it would be true that a child gets more lead content in drinking a glass of water than from playing with an ATV?

Ms. BECK. They would get more lead from what is commonly found in drinking water but is permissible under EPA than they would get from contacting their hands with the valve stem on an ATV or from touching the handles.

Mrs. BLACKBURN. OK, now, let me ask you this. Do you find this with other products? Have you found this same association in other products that you have tested, maybe with the wipe test?

Ms. BECK. We have also done wipe tests on scooters and we had similar results, that what came off in a wipe was relatively small, less than what a child might typically get from drinking water.

Mrs. BLACKBURN. OK. Thank you very much. I appreciate that. And I will go ahead and yield back.

Mrs. BONO MACK. I thank the gentlelady. The chair recognizes Ms. Schakowsky for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Madam Chairman. Mr. Howell, in your testimony you note that an independent testing lab, SGS, has found that almost 90 percent of toys tested by it recently comply with the 100 parts per million lead limit. While I realize this is data from only one entity, it seems to provide at least some evidence that the children's product marketplace has largely adapted already to the 100-parts-per-million limit. Would you say that is true?

Mr. HOWELL. Yes, I would. I would also add to that, though, that it may also indicate that we are rapidly approaching a point of diminishing returns in that the effort to achieve the final reduction in lead may be much more costly than the incremental cost of getting to where we are today.

Ms. SCHAKOWSKY. Certain members of industry have been very critical of fixed parts-per-million limits for lead in children's products and have advocated a move back—as we heard from Dr. Beck today—to risk-based standard. However, the American Society of Testing and Materials, ASTM's F–963 toy standard, which has been drafted through a consensus process and is now a mandatory rule under the CPSIA, contains fixed parts-per-million limits for certain toxic metals and surface coatings of toys like cadmium—is it antimony?—and barium and in those areas—well, so I am asking why not lead? If they could go to a PPM for other things, why not

lead? And let me pose the same question to Dr. Best. But Mr. Howell?

Mr. HOWELL. Certainly you can regulate lead either on a fixed-content limit or on the extractable amount. That becomes, basically, not only a policy choice but a choice of economics and ease of test, if you will, that would facilitate compliance.

Ms. SCHAKOWSKY. So would you say that it is easier to administer for many companies and for the Commission to go on a parts-per-million basis?

Mr. HOWELL. Certainly, there are advantages to testing by content in the fact that it is that time is much faster. It certainly doesn't generate the level of hazardous waste than what chemistry does. But at the same time I believe another way to look at the problem, perhaps, would be a balance between both the parts-per-million content at some prescribed level and then a risk-assessment approach at levels above that to deal with, perhaps, products such as ATVs and bicycles where the exposure is, perhaps, much, much less of a concern than you might have in something that is mouthable or swallowable.

Ms. SCHAKOWSKY. Thank you. Dr. Best, I wonder if you would comment on these issues.

Ms. BEST. One of the big differentiations between the CPSIA and the ATSM—or MS, whatever—their levels is that the ATSM's levels are soluble lead. And we are concerned not only about the surface coating but as the product wears, the surface coating may be worn off and so then you are getting deep into the content of whatever product we are talking about, and again, the swallowing question comes into play.

Ms. SCHAKOWSKY. Right. But my question is if the toy manufacturers could go to a parts per million for these other things, why not with lead?

Ms. BEST. Well, we believe that they can go to a total lead content level and achieve that reasonably. And as some of these data have shown, many manufacturers——

Ms. SCHAKOWSKY. OK. One other question on lead content. You had mentioned that children with disabilities sometimes continue mouthing, you know, well past a little kid and yet products designated as—I am looking what it is called—special products for the disabled are not in the category that would require a mandatory third-party testing for almost all children's products. Do you think that is a mistake?

Ms. BEST. I can't say I know all of the definitions of special products for the disabled. Certainly, you know, I wonder if some of them are more adapted products such as adaptive listening devices and adaptive hearing devices, so they are not toys. And so we have been very focused on the toys and so that is where, you know, all of our evidence has been based.

Ms. SCHAKOWSKY. Thank you.

Mrs. BONO MACK. All right. The chair recognizes Mr. Barton for 5 minutes.

Mr. BARTON. Thank you. Mr. Howell, my recollection is that in the Congress and the hearing in this Congress that the commissioners who testified, testified that the current law doesn't give

them the flexibility that they need to implement the law. Is my recollection correct?

Mr. HOWELL. I recall the same thing.

Mr. BARTON. You recall the same thing? So that is a yes?

Mr. HOWELL. That is a yes.

Mr. BARTON. OK. Dr. Best, what is wrong with giving the CPSC some flexibility to implement the law?

Ms. BEST. It is my understanding that they already have some flexibility to——

Mr. BARTON. That is not their understanding.

Ms. BEST. Well——

Mr. BARTON. I mean they testified at least twice——

Ms. BEST. Right.

Mr. BARTON [continuing]. That they need more flexibility. So let us stipulate that they don't have flexibility. Why, then, would it not be prudent for Congress to give them some flexibility?

Ms. BEST. Well, the stipulation I would have to look at. But the concern we have is that children's health is not something that should be negotiated based on manufacturers' profit.

Mr. BARTON. Well, nobody is saying that the stipulation should be based on profit. That is a fairly obnoxious comment to make in reply to my question.

Ms. BEST. When we do a risk-based assessment or we allow great freedom in terms of how safe toys are, we go back to the days where children——

Mr. BARTON. OK, well, look, I don't have time for a 5-minute longwinded non-statement. Do you support any flexibility at all for the Commission? Yes or no?

Ms. BEST. I will support some——

Mr. BARTON. So that is a——

Ms. BEST [continuing]. Very defined, limited——

Mr. BARTON. Thank you.

Ms. BEST. [continuing]. Carefully protective flexibility.

Mr. BARTON. You do support some flexibility. That is a good thing. Let me go back to Mr. Howell. The House bill, when we actually passed the bill under Chairman Dingell's leadership, had a 12-year-and-under standard. The Senate bill had a 6-year-and-under standard for children. The Senate receded to the House to the 12-year. That is one of the changes in the draft before us is that we leave the age as undefined. If you split the difference between the Senate and the House, obviously it would be 9 and under. Is that a reasonable compromise or is that unfeasible in your opinion?

Mr. HOWELL. To some degree it depends on the risks that you are trying to manage. I will say in that some work done several years ago in establishing lead limits for children's jewelry, which the work was terminated because of the CPSIA, staff had determined that 9 and under would be an appropriate age based on how children interact with a product such as jewelry.

Mr. BARTON. Let me ask that same question to Dr. Best. Is there some middle ground between 6 and 12?

Ms. BEST. We carefully reviewed this in 2007 and we believe 12 is the right age.

Mr. BARTON. OK. What about Dr. Beck?

Ms. BECK. I think that it is somewhat of a science policy decision that there really is no bright line. I do think what Mr. Howell has proposed, 7, 9, that they are reasonable compromises. Obviously, a young child might play with toys of an older child, but it will be less frequent. But as I said, ultimately, I think that there is need for some judgment in determining what the actual age should be.

Mr. BARTON. OK. Mr. Howell, on third-party testing, the draft preserves third-party testing for certain priority standards and priority products and it gives the Commission the flexibility to require third-party testing for other standards. Is that something you think the Commission would support in this draft, the third-party testing amendments?

Mr. HOWELL. Sir, I am unable to speak for the Commission.

Mr. BARTON. You work for the Commission. You are the only Commission representative we have.

Mr. HOWELL. I work for the Commission but the question was do I believe the Commission would buy into this proposal,and I cannot predict what the Commission might accept or not accept.

Mr. BARTON. So you just walk around in a daze when you are at the Commission even though you are the——

Mr. HOWELL. No, sir, but I do not control the votes of the commissioners.

Mr. BARTON. Well, but you can have an opinion about what their position might be. You have got a better opinion than I do.

Mrs. BONO MACK. The chair would recognize that we are out of time and, with all due respect to my dear colleague, but recognize now for 5 minutes Mr. Towns.

Mr. TOWNS. Thank you very much, Madam Chair. Let me ask discretion, first of all, I guess to you Dr. Best. Can you explain how lead buildup in bones throughout a lifetime can impact pregnant women and developing fetuses and why children are born with lead in their blood?

Ms. BEST. Yes. Lead is similar to calcium in that our bodies see lead as if it was a calcium molecule and then absorb it into our bones throughout our lives. And so if you are exposed to more levels of lead as you are developing bones or remodeling bones, which goes on throughout life, you are likely to absorb and store lead in your bones to a greater extent.

During pregnancy, there is a very high calcium demand on the mother's body and the fetus actually steals calcium from the mother. And if the mother doesn't have enough daily dietary intake from calcium, the bones will be resorbed and calcium from the bones will then be used to help the fetus develop. And so if there is calcium being released from the bones and there is also lead in the bone, the lead is released at the same time and then transferred to the fetus.

Mr. TOWNS. Thank you very much. Let me ask you this, Mr. Howell. When can a product that has shown consistent compliance, you know, through a third-party testing be relieved from testing? How many years?

Mr. HOWELL. If the objective is to establish a prevention-based program, the answer to that would be that while the frequency of testing could certainly be extended, I would suggest that perhaps it could never be terminated if you will but just longer periods of

time between third-party testing. In the industry that would be a skip-lot quality approach.

Mr. TOWNS. Even if you test it and there is consistency and you still feel that you can't say 2 years, 10 years, 20 years? You just would have to continue?

Mr. HOWELL. Well, the assumption there is that things never change in the manufacturing process. And, for example, the lead in paint that some say was the beginning of the CPSIA discussion was a total surprise to the manufacturer. They thought they had their process totally under control and they had a supplier who brought material into their factory, they assumed it was correct—and, in fact, it was loaded with lead. So if indeed the goal is to measure compliance to assure the American public that the product is safe, I would suggest that while you could increase the time between testing that you might be accepting some risk if you chose to terminate the testing until such time as you determine there was another problem and then reinstitute the testing.

Mr. TOWNS. Right. Thank you. Is there sufficient flexibility for the Commission to allow for—I am trying to see if there is anything on this side that we need to do.

Mr. HOWELL. In my opinion and, of course, as has been stated many times by the Commission itself, there is certainly a need for additional flexibility for the Commission to act appropriately to implement the law and safeguard consumers.

Mr. TOWNS. Dr. Best, is there anything that we need to do on this side as Members of Congress? Let us switch roles for a minute.

Ms. BEST. Besides pass a budget? Sorry. I think we need to remember that toys are not a requirement for life and we want children to have the best opportunity that they can possibly have. And, you know, the option is not between a drug that has side effects for a child. The option is between a toy that is safe and a toy that may not be safe. And so we need to remember that, you know, every toy is not a required product to help a child grow. They need toys but they need to know that those toys are safe. And we need to continue to remember that lead is dangerous at small levels. Even very small levels it causes IQ loss and the more we find out about the low levels of lead, the more harms we discover.

Mr. TOWNS. Thank you. I see my time has expired, Madam Chair. Thank you very much.

Mrs. BONO MACK. I thank the gentleman and recognize the gentleman from New Hampshire, Mr. Bass, for 5 minutes.

Mr. BASS. Thank you very much, Madam Chairman, and I appreciate your holding this important hearing to discuss a piece of legislation which corrects a response to a problem which was clear and understandable and necessary which occurred during the period of time that I was not serving in the Congress. And I was thinking of saying I am not surprised that the response that was passed by Congress essentially endeavors to use a Howitzer to kill a mosquito and so here we are trying to make this necessary new law work better.

However, my questions are for Mr. Howell, and they don't deal with the central controversy of the bill but rather with some equipment that the CPSC is using and whether or not its use should be expanded. I understand that the Consumer Product Safety Com-

mission uses several dozen handheld x-ray fluorescence analyzers and they are used both in the laboratory and also in ports of entry. They quickly, effectively, non-intrusively, and accurately determine whether and how much lead is in a product. Can you give us a brief description of your experiences using this equipment and enforcing limits on lead?

Mr. HOWELL. Certainly. The XRF scanners have certainly helped the efficiency and effectiveness of implementing the law. There initially were some limitations. The XRF is a good tool for detecting lead and other potentially toxic heavy metals in homogenous materials like plastics. However, there were some limitations early on in checking for lead in surface coatings, as in paint.

Mr. BASS. Um-hum.

Mr. HOWELL. However, just recently CPSC issued a Notice of Requirements recognizing that HD XRF technology had been developed, a testing protocol had been developed under ASTM and that is now an approved method to test for lead in paint. So it certainly is an efficient technology.

Mr. BASS. As the lead individual for hazard reduction's support expanded use of these XRF devices by manufacturers, retailers, and porters as a means to ensure compliance with lead limits?

Mr. HOWELL. I believe the cost savings, in my experience, has been motivation enough. Certainly, most manufacturers who can afford a unit, to my knowledge, have acquired one.

Mr. BASS. So the expanded use of this equipment would, in your opinion, improve the safety and quality of the products on the market today?

Mr. HOWELL. It certainly is an effective way for a manufacturer to monitor his incoming materials and his outbound materials.

Mr. BASS. OK. And lastly, as you may know, the EPA and HUD have used handheld XRF for decades to test for lead in homes and they are obviously protecting children. CPSIA includes a limit for lead in small painted areas on children's products. I think it is 2 micrograms per square centimeter of paint. Do you support making this limit applicable to larger painted areas as well?

Mr. HOWELL. If you would allow me to respond to that question in writing, I would like to get with our chemist and give you an appropriate response.

Mr. BASS. OK. Fair enough. Thank you very much. And I thank the chairlady. I yield back.

Mrs. BONO MACK. I thank the gentleman. And the chair recognizes we have a series of votes on the floor so it is my intention to have Mr. Dingell as his 5 minutes of questioning and then we will break and return to resume questioning after the series of votes. So Mr. Dingell, you are recognized for 5 minutes.

Mr. DINGELL. Thank you, Madam Chairman. To the witnesses, these questions will require a yes or no answer only because of time.

The draft legislation requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given child's product. However, while the Commission establishes such procedures, the draft legislation would permit the manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component

part." Question: Is there any such reasonable methodology in use by manufacturers today for testing children's products? Starting with Dr. Best.

Ms. BEST. I am not familiar with what manufacturers can do.

Mr. DINGELL. Ms. Beck?

Ms. BEST. Oh, I am sorry.

Mr. DINGELL. Yes or——

Ms. BECK. There is methodologies. I don't know if the manufacturers know about them.

Mr. DINGELL. Thank you. And if you please, Mr. Howell, yes or no?

Mr. HOWELL. I am not aware.

Mr. DINGELL. Now, starting again, Dr. Best, is it possible the ambiguity of the term "reasonable methodology" would lead to a wide variance in test results across the manufacturers of similar products? Yes or no?

Ms. BEST. Yes.

Mr. DINGELL. OK. Dr. Beck?

Ms. BECK. I don't know.

Mr. DINGELL. Mr. Howell?

Mr. HOWELL. I do not know.

Mr. DINGELL. Could this—well, I will just defer on that particular question. Now, Mr. Howell, the draft legislation would allow CPSC, subject to conditions, to require a third-party testing of children's products. Under the draft bill, CPSC would require a third-party testing only if the Commission first verifies the testing capacity of "accredited third-party conformity assessment bodies," as well as establishes and publishes Notice of Requirements for such accreditation of such assessment bodies. Does this include both national and international or domestic and international bodies? Yes or no?

Mr. HOWELL. I believe it does, yes.

Mr. DINGELL. OK. Now, if so, how many such assessment bodies are there worldwide?

Mr. HOWELL. CPSC recognized conformity assessment bodies are currently in excess of 300 I believe.

Mr. DINGELL. OK. Now, further, does the Commission have the resources with which to verify the testing capacity of all third-party conformity assessment bodies? Yes or no?

Mr. HOWELL. I can't answer that question yes or no.

Mr. DINGELL. It means that you do not know they do have such capacity. Now, moreover, is it your understanding the draft legislation, the Commission would have to accredit all third-party conformity assessment bodies? Yes or no?

Mr. HOWELL. No.

Mr. DINGELL. If so, do you believe the Commission has the resources with which to accomplish this purpose? Yes or no?

Mr. HOWELL. Yes.

Mr. DINGELL. In summary, do you believe the practical effect of these requirements would be that the Commission would seldom, if ever, require third-party testing of children's products? Yes or no?

Mr. HOWELL. No.

Mr. DINGELL. Now, Mr. Howell, CPSIA defines a children's product as one "primarily intended for a child 12 years of age or younger." The discussion draft would change this definition to "intended for use by a child," then it leaves a gap, "age to be determined—years younger." Would these words "for use by" limit the number and type of products covered by this definition? Yes or no?

Mr. HOWELL. Yes.

Mr. DINGELL. Now, to Drs. Beck and Dr. Best. Would you care to comment briefly on Mr. Howell's response to the last questions? Starting with Dr. Best.

Ms. BEST. No.

Mr. DINGELL. You can if you wish. Ms. Beck?

Ms. BECK. If the age decreases from 12 to some number less than 12, then the number of products to be tested, of course, would diminish because the products are defined for different age groups.

Mr. DINGELL. Ladies and gentleman of the panel, thank you. Madam Chairman, I thank you for your courtesy.

Mrs. BONO MACK. I thank the distinguished gentleman. And it is my intention that we recess now for this series of votes and we return at high noon. So we will see you all at high noon if we are quick on the floor with votes. If not, a little wiggle room. See you guys at noon. Thanks.

[Recess.]

Mrs. BONO MACK. All right. The chair will recognize Mr. Pompeo for 5 minutes.

Mr. POMPEO. Great. Thank you, Madam Chairman. Thank you, panelists, for hanging with us through the vote.

You know, I heard Mr. Waxman say this was a wrecking ball and I heard somebody say we were comprehensively demolishing the CPSIA. I think there is lots more to do. I think this is a very good first step, but there is a lot more work to do.

I wanted to ask you, Mr. Howell, just a couple questions about the database. We have been live now for almost a month, right? How many reports have we received since March 11 under the database rule?

Mr. HOWELL. The number is approximately 1,500 at this point.

Mr. POMPEO. And other than those—so there is a 5-day period before it goes out to the manufacturer. How many of those have been sent on to the manufacturer of those 1,500?

Mr. HOWELL. I would like to respond in writing with precise numbers. But at this point of those that we have received, I think approximately 50 percent at this point have been sent to manufacturers.

Mr. POMPEO. And so how many of those are past the required time period to send on to the manufacturer approximately?

Mr. HOWELL. Actually, once they pass the CPSIA check, which is the eight requirements to be considered, at that point they would be passed to the manufacturer and we are not late in sending the initial notice to the manufacturer. Those are happening on time.

Mr. POMPEO. So everything is on time. Everything is good. You have got the resources to respond at the level of the reports that have come in so far and you are making all of the deadlines that were imposed by the rules that CPSC put in place?

Mr. HOWELL. I believe for the most part, yes.

Mr. POMPEO. And how is this being conducted? How do these come in? Who is reviewing them? Are you reviewing them along with staff and a committee? What kind of resources are being dedicated to that project?

Mr. HOWELL. At this point in time, there are several different staff members involved in the review, part of that because it is a brand new process and we are trying to understand what we are getting in, making the appropriate decisions regarding reports of harm to ensure that they do, indeed, meet the qualifications. It is roughly a team of 10 to 12 with representatives of technical staff, legal staff, and IT.

Mr. POMPEO. Wow. 10 to 12 people. Wow, for 1,500 across 30 days. So what do you have? 35 a business day, 50 a business day, something like that?

Mr. HOWELL. Probably somewhere in the neighborhood of 50 a business day.

Mr. POMPEO. Yes. Can you keep up with it?

Mr. HOWELL. At this point yes, but we are in a learning curve and we understand that as we get a better handle of the nature of these incoming reports, we expect efficiencies to increase.

Mr. POMPEO. Why would you go through a learning curve when you have had this database running without it being public for such a long time? Why wouldn't we have done the learning curve before we went live?

Mr. HOWELL. When we were in the soft launch, not every manufacturer necessarily felt compelled to respond knowing that those reports would not necessarily go live. Now that we are live, we are getting many more responses from manufacturers.

Mr. POMPEO. My first question focused on the process internal to CPSC before forwarding on. Tell me how the process is going in getting a response from manufacturers to date that have had the deadline arrive for their response to be due?

Mr. HOWELL. You know, the manufacturers receive notification that there has been a report of harm. Manufacturers can file a claim of material inaccuracy.

Mr. POMPEO. How many have done that so far?

Mr. HOWELL. I believe there has been less than 10 percent have filed claims for material inaccuracy. They can also file claims for confidentiality, which is extremely rare at this point in time. And they are certainly free to file a comment without necessarily filing a claim of inaccuracy or confidentiality.

Mr. POMPEO. How many have said "not me, not my stuff?"

Mr. HOWELL. The vast majority of the material inaccuracy claims tend to be just that nature. "It is not my product."

Mr. POMPEO. And are those still online readily accessible to the public? So you all send it to the manufacturer and they say it is not my stuff, are you then putting it online?

Mr. HOWELL. No, if they claim that it is not their product, that is a valid claim of material inaccuracy. And until such time as that is resolved and the problem clearly identified, it does not get posted.

Mr. POMPEO. Thank you, Mr. Howell. Ms. Best, you talked about—she is not here. Let me ask you one more question, Mr. Howell. How many items from the punch list that Commissioner

Tenenbaum gave me on the database have you all been able to work through since she was here? That is what is still left to fix?

Mr. HOWELL. I am not familiar with that punch list. I will certainly respond to that in writing.

Mr. POMPEO. Thank you. Madam Chairman, I yield back the balance of my time.

Mrs. BONO MACK. I thank the gentleman and recognize Mr. Butterfield to explain the absence of the witness.

Mr. BUTTERFIELD. Thank you, Madam Chairman. You will notice that Dr. Best is absent this afternoon. I want the record to show that she had prior obligations this afternoon and had to leave. I am told that she is seeing patients today and has scheduled those appointments with the understanding that we would convene this morning at 9:00 a.m. instead of 10:00 a.m. But please be assured that she will be available to answer any questions that any of the members may have. Thank you.

Mrs. BONO MACK. I thank the gentleman and would remind the committee that we did delay the starting point of today's hearing to accommodate the Democrats. And it is unfortunate that the witness had to leave but remind members, too, you can submit further questions to her in writing later. And at that point, we will be happy to recognize Mr. Harper for 5 minutes.

Mr. HARPER. Thank you, Madam Chair. Mr. Howell and Dr. Beck, thank you for being here today. I am sure you can come up with a list of a dozen things you would rather be doing or maybe 100 things, but we welcome your attendance and appreciate what you are sharing with us.

And Mr. Howell, just a couple of questions on some issues involving this. And I know that when we are talking about the common toy box theory applying, of course, to toys, it seems like there are a lot of other products that it really makes no sense at all. For example, infants and toddlers are not going to have access to motorized products like ATVs or at least we hope they are not. What is the situation with, say, ATVs and other things like that when it comes to these regs?

Mr. HOWELL. One would certainly not expect that small children would have frequent access with those type of outdoor products, certainly.

Mr. HARPER. OK. When we talk about, say, electronics, you know, the Commission set much higher lead limits for certain metal alloys. When the Commission granted a stay of the lead content limits for ATVs and bicycles, it set temporary limits at the same or very low or similar levels I mean. Why does the CPSC consider them to be safe or at least safe enough for now? What is the rationale for that?

Mr. HOWELL. When the Stay of Enforcement was issued, it was simply a stay from the testing and certification requirements. There was not a stay of the requirement to conform to the law as written. So the limits that are established are the limits that were prescribed in law.

Mr. HARPER. Got you. Now, I will ask if the Commission is aware of any deaths in fixed-side cribs in daycares?

Mr. HOWELL. Would you repeat that, please?

Mr. HARPER. Sure. Yes, sir. Is the Commission aware of any deaths involving fixed-side cribs in daycares?

Mr. HOWELL. I am not aware of any but I will certainly take that question back and have our epidemiologist do a data-pull.

Mr. HARPER. In your testimony, Mr. Howell, you have suggested the Commission be allowed to regulate on a timetable influenced by the seriousness of the actual risk to allow for better priority-setting. Do you have specific suggestions that you can share on how you can do this or how we can do this?

Mr. HOWELL. I believe any organization that has finite resources needs to ensure that they are allocating those resources to the highest priorities. You know, certainly there are various ways to rank those within the Commission. One might suggest that frequency and severity at-risk populations are all criteria that would help identify higher-priority projects versus those that might fall lower on the list. And it is really all about managing finite resources in a way that provides the greatest return on those efforts.

Mr. HARPER. OK. Dr. Beck, Mr. Vitrano, who will testify on the next panel, submitted testimony that says you estimated the lead intake from children's interaction with ATVs is less than the intake from drinking a glass of water and I ask if that is true or any info on that statement.

Ms. BECK. Yes, we did an analysis in which we used wipe tests from ATVs so we had actual data and we compared how much children would get from that scenario versus what a child might drink in a typical glass of drinking water, which may contain small amounts of lead. So that is a correct conclusion from our analysis.

Mr. HARPER. And when was that analysis done? How recently?

Ms. BECK. It was, I believe, either 2008 or 2009.

Mr. HARPER. All right. But wouldn't it be true, though, that the metal parts of the ATVs contain much higher lead than permitted by EPA drinking water standards?

Ms. BECK. It is a little bit apples and oranges because the drinking water standards based on what is in the water——

Mr. HARPER. Right.

Ms. BECK [continuing]. That is a very low concentration in the water. And then if you were to say what does that mean in terms of—you could compare it to PPMs in a valve and, of course, that would be much, much higher. But it is a little bit of an apples-and-orange comparison.

Mr. HARPER. But based on that analysis, your concern about ATVs as it concerns infants and toddlers, you would not be overly concerned with that at all, would you?

Ms. BECK. No, because it is really not a plausible scenario.

Mr. HARPER. Sure. OK. I yield back.

Mrs. BONO MACK. I thank the gentleman and recognize Dr. Cassidy for 5 minutes.

Mr. CASSIDY. I really enjoyed this panel. All of you attempted to be very fact-based and referenced-based. So let me just first compliment you. And my compliments to Dr. Best, who is no longer here.

First you, Mr. Howell. Clearly it is common sense that a kid is not going to chew on an ATV and probably not on the stem of a bicycle. On the other hand, I can understand that if there was

some other product that the varnish wore off that the child could gnaw down to and actually have some lead exposure. So I guess my question to you is are we able to come up with a definition that which is absurd that the kid would ever chew on is moved over here and that which it is plausible is moved over there? Is that something within the Commission's ability to accomplish?

Mr. HOWELL. Certainly in the Commission's traditional risk-based evaluation of consumer products, that would be an evaluation that would be conducted. How a child interacts with the product is important in determining the level of risk that that child may be subjected to from that certain product. In the case of ATVs, we would find it less likely the child would swallow or mouth an ATV. Certainly you would expect that there could be some migration of lead from contact with the hand on an ATV.

Mr. CASSIDY. Now, I gather from Dr. Best—and I am sorry she is not here because I just wanted to explore this because all three of you know so much more about this issue than I. That is why you are the panel members and I am not—that there was some dissatisfaction from the risk-based assessment. So now I am sure there are many aspects of risk-based assessments, but was one of the areas that folks were unhappy with, did that include your ability to differentiate lead paint peeling off a wall from an ATV, one is a great risk, one is a minimal risk for lead exposure?

Mr. HOWELL. I have certainly heard the arguments against risk-based but I am not fully aware of all the underlying rationale behind that criticism.

Mr. CASSIDY. So it sounds like you feel like risk-based is a practical thing for the Commission to implement?

Mr. HOWELL. The Commission has been using a risk-based approach for decades now.

Mr. CASSIDY. Now, you mentioned in response to Mr. Harper, the last line of your testimony to "effectively prioritizing Commission resources towards those of the most serious health risk." Now, I have learned in life that if you attempt to monitor everything, you end up monitoring nothing. But on the other hand, if you monitor a few things, you often can monitor them well. And I have also learned that there is oftentimes, you know, 99.9 percent risk with this subset of activities and .1 percent with this subset. Is that so clearly broken out in lead exposure? Can you say, listen, this is really high-risk stuff. We need to focus our resources even more so than now if we were so allowed, as opposed to this, which is incredible low-risk. We are kind of killing our time over here.

Mr. HOWELL. Certainly, the Agency is extremely concerned with those lead-bearing items that can be swallowed. Acute exposure to lead is certainly a very serious, serious thing. One would expect that the risk decreases as you move from swallowing to mouthing, from mouthing to touching. And the management of that risk at that point then becomes a decision on how the child interacts with the product and what you——

Mr. CASSIDY. So you mean by risk-based would make some differentiation between high- and low-risk and it would all be upon how the child interacts and the relative amount, et cetera, et cetera?

Mr. HOWELL. Yes, that is a basis of——

Mr. CASSIDY. Now, the other thing occurs to me is that we have heard last time from a previous panel about the craft-makers and you know, somebody in Oregon who makes these nice little airplanes that apparently needs a—I shouldn't laugh—but you know, it would make probably 100 planes a year, sells them out of their shop and now has to get a third-party assessment as to the lead content of the paint. Now, in your risk assessment, do you also say listen, if it is below a certain production value or quantity per year—I mean the ability of something that is produced on the scale of 100 a year, as one example, is really unlikely to have a significant impact, do you have any such sort of evaluation like that?

Mr. HOWELL. Our evaluation is from a risk approach is a product evaluation and the consideration of the volume of the product produced is not relevant to the assessment of the risk that that particular product may present to the consumer who is using that product.

Mr. CASSIDY. Yes, it wouldn't be for the particular consumer, but it would be for the epidemiology of it in terms of a population issue, correct?

Mr. HOWELL. Absolutely. And when it comes to prioritizing the Agency's work, that is where the frequency severity factors come into play.

Mr. CASSIDY. So you do incorporate the population aspect to it. OK. Well, thank you. Ms. Beck, I am sorry, no questions for you. It was just mine were more oriented to Mr. Howell. Thank you.

Mrs. BONO MACK. The chair recognizes Mr. Kinzinger for 5 minutes.

Mr. KINZINGER. Let me see if I can get this to work here. Well, maybe. Well, how are you doing today? Hopefully well. I don't need to take a lot of time because I think you guys have been very good at answering the questions. I appreciate your time and I appreciate the chairwoman for organizing the hearing.

You know, one of my concerns when we get to government involvement in areas is something that I affectionately refer to—as many other do—as the law of unintended consequences. You know, it is obviously when somebody does something that looks great on paper and then in actuality has a completely different effect.

So Mr. Howell, my question, speaking in terms of the law of unintended consequences to you, do you agree with the past-acting Chairman Nord's statement of April 3, 2009, that the "application of the lead content mandates of this act may have actually the perverse effect of actually endangering children by forcing youth-sized vehicles off of the market" and in a result actually children riding vehicles that are bigger or, in essence, too big for them, adult-sized ATVs if you will.

Mr. HOWELL. I agree with that statement.

Mr. KINZINGER. OK. So you do agree with that. Madam Chairwoman, I would like to ask unanimous consent to insert two documents into the record.

Mrs. BONO MACK. Without objection.

Mr. KINZINGER. The first, a statement from acting Chairman Nancy Nord of the CPSC from April 2009 requesting exclusions from the lead-content limits of the Consumer Protection Safety Improvement Act of '08. The other is a letter from Edward Moreland,

Senior Vice President of the American Motorcyclists Association to Chairwoman Bono Mack and Ranking Member Butterfield regarding the discussion draft.

[The information follows:]

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

STATEMENT OF ACTING CHAIRMAN NANCY NORD
ON THE REQUEST FOR EXCLUSIONS FROM THE LEAD CONTENT LIMITS OF THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008
April 3, 2009

In considering exclusions, consumer safety must direct the outcome of our deliberations. Therefore, it is with extreme reluctance that I am voting today to deny the petition, filed by companies and associations representing the ATV and motorized bike industries, for an exclusion from the lead content limits found in Section 101 of the Consumer Product Safety Improvements Act (CPSIA). I do this because the clear language of the law requires this result, not because it advances consumer safety. To the contrary, application of the lead content mandates of the CPSIA to the products made by the petitioners may have the perverse effect of actually endangering children by forcing youth-sized vehicles off the market and resulting in children riding the far more dangerous adult-sized ATV's.

For this reason, in my capacity as chairman, I am directing compliance staff to stay enforcement of Section 101 and related provisions of the CPSIA to this category of products for twelve months and hope my colleague, Commissioner Moore, will join me in making this a unanimous decision by the Commission. During this time-out, it is my hope that Congress will consider how the law needs to be fine-tuned to address this serious child safety dilemma. This enforcement hiatus will also give industry the opportunity to examine what reasonable changes can be made in their products to bring them closer to the requirements Congress set out in the CPSIA. Staff will meet with industry to do more testing to determine how their products can meet the 300 ppm threshold Congress set and determine what is possible. I will expect periodic status reports on progress to this plan.

It is clear that the law does not give the Commission the flexibility to grant an exclusion for petitioners' products. Congress wrote Section 101(b) in such a way as to leave little discretionary power with the agency to grant common sense exclusions. This lack of flexibility was brought to the attention of Congressional staff working on the legislation during the conference process and it was confirmed this is what was intended. As our career staff has discussed on many occasions and as we now have been formally advised by staff, we do not have the statutory authority to grant the exclusion requested in this case.

Even though the career staff of the agency has concluded that we cannot grant the exclusion, they have NOT concluded that petitioners products present a health risk to children because of exposure to lead. To the contrary, staff states "a bigger safety concern than lead exposure is that the elimination of youth ATV sales will most likely increase the number of adult ATV's purchased to be used by younger children; therefore increasing their risk of injury and death."

The issues presented to us in the petition are much more complex than just ordering petitioners to "get the lead out" of their products by a certain date. Petitioners have presented persuasive evidence that lead serves

a purpose in the structural integrity of the metals used in the products and that suitable substitutes are not available. They point out the impracticality of using virgin materials for these products, including issues dealing with the recycling of metals. They point out that the approach in the CPSIA is contrary to the approach taken in the rest of the world, e.g. the European Union which has looked at these issues rather extensively and made allowances. These are all issues that the Commission should have the authority to consider but under the rigid language of the CPSIA, we cannot.

The effect of denying the petition is to make Section 101(e) of the CPSIA, which limits the Commission's authority to stay enforcement during rulemaking, no longer applicable. Therefore, during the pendency of a stay of enforcement, ATV's and motorized bikes appropriately sized for children twelve and younger can again be available and the Commission will not seek penalties for violation of Section 101 and related provisions of the CPSIA against those who sell them. I hope that the state attorneys general will follow the lead of the agency on this matter.

All stakeholders—industry, users, Congress, and the Commission—need to come together to fix the statutory problems that have become so apparent, in a common sense approach that does not unnecessarily burden those regulated, yet provides safety for American families.

AmericanMotorcyclist.com

April 6, 2011

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce,
Manufacturing & Trade
House Committee on Energy & Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable G.K. Butterfield
Ranking Member
Subcommittee on Commerce,
Manufacturing & Trade
House Committee on Energy & Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Bono Mack and Ranking Member Butterfield:

Thank you on behalf of the American Motorcyclist Association (AMA) and the All-Terrain Vehicle Association (ATVA) for holding the hearing on April 7, 2011 regarding a discussion draft of a bill to revise the Consumer Product Safety Improvement Act (CPSIA) of 2008.

Founded in 1924, the AMA is the premier individual rider-based advocate of the motorcycling community. Along with our sister organization, the ATVA, the Associations represent the interests of millions of on- and off-highway motorcyclists and ATV riders nationwide.

Please act to provide a categorical exclusion for youth-model motorcycles and all-terrain vehicles (ATVs) from the deleterious effects of the CPSIA. A permanent exemption for youth-model off-highway vehicles (OHVs) is the only solution that will remove the burden of economic strain from the powersports industry, create jobs and, above all else, preserve the safety of young riders. For all of these reasons, the AMA and ATVA urge the Subcommittee to consider and pass H.R. 412, the "Kids Just Want to Ride Act."

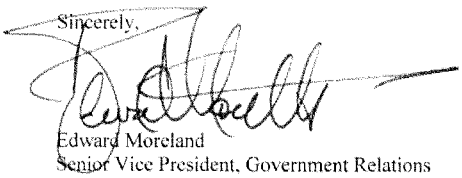
Authored by Representative Denny Rehberg and supported by 61 bipartisan cosponsors, H.R. 412 is the most promising and viable legislative remedy available to permanently exclude youth-model OHVs from the perilous and unintended consequences of the CPSIA. H.R. 412 would provide relief to families that wish to participate in responsible youth-motorized recreation by continuing to make right-sized vehicles available to all young riders.

In a statement on April 3, 2009, then-Acting Consumer Product Safety Commission (CPSC) Chairman Nancy Nord commented that the "application of the lead content mandates of the CPSIA … may have the perverse effect of actually endangering children by forcing youth-sized vehicles off the market and resulting in children riding the far more dangerous adult-sized ATVs." Nord again underscored this notion on May 1, 2009, in her statement on *The Stay of Enforcement for Youth Recreational Off-Highway Vehicles* by writing that, "We have heard from the Members of Congress that they did not mean for the law to impact youth ATVs in this way."

For these reasons, the AMA and ATVA urge the Subcommittee to consider and pass H.R. 412, "the Kids Just Want to Ride Act," which provides the necessary categorical exclusion for youth-model motorcycles and ATVs from the CPSIA.

Again, thank you for the opportunity to provide comment on this important issue.

Sincerely,



Edward Moreland
Senior Vice President, Government Relations

CC: Chairman Fred Upton
Ranking Member Henry Waxman
Members of the U.S. House of Representatives Committee on Energy & Commerce

Mr. KINZINGER. The next question I have, common sense seems to support the notion that youth model OHV should not be subjected to the lead content provisions of this act. Would one of the solutions to this conundrum be an outright categorical exemption, like the one provided in H.R. 412? It is called the Kids Just Want to Ride Act. It is one I am a co-sponsor on.

Mr. HOWELL. As a policy decision, that certainly would be an option.

Mr. KINZINGER. OK. Well, like I said, those are basically my two big questions I had. You all have done a great job here in front of us today. I appreciate your time. And I would yield back my time.

Mrs. BONO MACK. I thank the gentleman. And at that point I am happy to thank our panelists for staying and for your expert testimony. We appreciate everything you have had to offer today and hopefully we will craft some great legislation. So thank you for your time and we will spend a quick 30 seconds or a minute seating the new panel and get started right away. Thank you again.

All right. Thank you. Our second panel is comprised of four witnesses. Welcome. And thank you for staying with us this morning. Our first witness, again, but not in the order of recognition, but to introduce Erika Jones. She is a partner at Mayer Brown here representing the Bicycle Product Suppliers Association. Welcome. Our second witness is Paul Vitrano, General Counsel for the Motorcycle Industry Council. Also testifying today is Sheila Millar, a partner at Keller and Heckman, LLP. And our fourth witness on this panel is Caroline Cox, Research Director for the Center for Environmental Health. Welcome to each of you.

You all know the drill now, the 5 minutes and the clocks and how they work. So if you could just pay attention to those, we appreciate it. We will have some floor votes again eventually, so if we can move it along, that would be terrific.

So now we are going to begin with our first witness and recognize Ms. Cox for 5 minutes.

STATEMENTS OF CAROLINE COX, RESEARCH DIRECTOR, CENTER FOR ENVIRONMENTAL HEALTH; SHEILA A. MILLAR, PARTNER, KELLER AND HECKMAN, LLP; PAUL C. VITRANO, GENERAL COUNSEL, MOTORCYCLE INDUSTRY COUNCIL; AND ERIKA Z. JONES, PARTNER, MAYER BROWN, ON BEHALF OF THE BICYCLE PRODUCT SUPPLIERS ASSOCIATION

STATEMENT OF CAROLINE COX

Ms. COX. Thank you very much for the opportunity to testify today. My message is that CPSIA, as written, has been an enormous success and I am really privileged today to be able to provide research data to document that success.

You heard earlier that health professionals agree that there is no safe level of exposure to lead for children. So I am discouraged to see the proposed revisions in the CPSIA that would weaken a law that has worked so well to protect American children from unnecessary lead.

For the last 15 years, my organization, the Center for Environmental Health, has worked to protect children and families from harmful chemical exposures. Our experience before and after pas-

sage of the CPSIA demonstrates that the law has been highly successful. Prior to adoption of the law, we found high lead levels in dozens of children's products sold to millions of American families by major retailers. At that time there was no federal law to protect children from lead so we relied on California State Law. Since the lead limits under CPSIA went into effect, our experience shows a dramatic change in the marketplace for children's products.

In the last year and a half, we purchased over 1,200 children's products from major national retailers and screened them for lead. These were stuffed animals, toys, games, lunch boxes, backpacks, jewelry, toy sporting equipment, lots of other things. As far as we know, it is the largest independent monitoring of compliance with CPSIA to date.

Out of these 1,200 products, we found only 46 that did not comply with CPSIA lead standards based on tests by a CPSIA-certified lab. In other words, more than 96 percent were in compliance. And because we intentionally purchased products that were likely to have lead problems, we believe overall compliance is even higher.

This data contrasts with what we found in 2007 and 2008. Our results show that over the 4-year interval, the prevalence of lead hazards in children's products was reduced by a factor of about 3. Given the immense size of the U.S. market for children's products, this is a major accomplishment.

We do understand that CPSIA requirements can be a hardship for small business and we would support amendments to help with that. We believe that the CPSIA has been effective because one, the lead standards are comprehensive. They cover virtually all children's products and all accessible parts of those products. And that has created a huge market for complaint materials and components.

The standards are straightforward, and because they are based on a total content standard, testing is accessible, consistent, and affordable. Lead content standards are the only kind of standards that allow materials and components to be tested upstream in a supply chain. When you have exposure-based standards or risk-based standards, the testing can only be done on finished products after it is already made.

And the third point I would like to make is that the lead standards apply to a really meaningful definition of "children," up to age 12. Because lead is a cumulative and persistent toxicant, it is particularly important to maintain this requirement. Protect children as they move into their teenage years and girls move into childbearing years.

I wanted to just give a quick visual demonstration of the success of the CPSIA. Here is Curious George from 2007. His face contains lead at a level 20 times the current CPSIA standard. Don't kiss this George. And I think most kids probably wanted to. Here is the current post-CPSIA George. George is lead-free and sold at the same price. I think this really shows how successful the law has been.

We respectfully recommend that this committee support the public health success that the CPSIA has been. Crucial support includes the lead content standards, as well as the definition of a child as 12 years old and younger. Thank you so much.

[The prepared statement of Ms. Cox follows:]

CEH

Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
Thursday, April 7, 2011
"Demonstration of CPSIA Success"
Summary of Testimony from Caroline Cox
Research Director, Center for Environmental Health

My fundamental message today is that the CPSIA as written, has been an enormous success. I am privileged today to be able to provide research data to document that success. As you heard earlier today, health professionals agree that there is no safe level of exposure to lead for children. So it is discouraging to see proposed revisions in the CPSIA that would significantly weaken a law that has worked so well to protect American children from unnecessary lead exposures.

CEH's experience before and since passage of the CPSIA demonstrates that the law has been highly successful in promoting safer products for American children. Prior to adoption of the law, CEH found high lead levels in dozens of children's products sold to millions of American families by Wal-Mart, Target, Kmart, and other major retailers. But at that time, we were unable to point to any federal law to protect children from the lead hazards posed by these products

Since the lead limits under CPSIA went into effect, our experience shows a dramatic change in the marketplace for children's products. Between September 2009 and December 2010, we purchased over 1200 children's products from major national retailers, and screened them for lead. We purchased stuffed animals, toys, games, lunch boxes, backpacks, jewelry, toy sporting equipment, and other products. We believe that this is the largest independent monitoring of compliance with the CPSIA to date.

Out of these 1200 plus products, we found only 46 that did not comply with CPSIA lead standards, based on independent tests by a CPSIA-certified laboratory. In other words, more than 96% of the products tested were in compliance with the law. Because we intentionally purchased products made with materials that were previously known to have had lead problems, this suggests that overall compliance with CPSIA is likely even higher.

This data also contrasts with testing we conducted in 2007, before the law was developed, and in 2008, before its lead limits were in effect. Our results show that over the four-year interval, the prevalence of lead hazards in the children's products was reduced by a factor of approximately three, suggesting a similar decrease in children's products in general. Given the immense size of the U.S. market for children's products, this is a major accomplishment.

We understand that CPSIA requirements can be a hardship for small business and would support amendments to help small business meet the testing and certification requirements in the law. But based on our compliance monitoring, we believe the CPSIA has been effective because:

- The lead standards are comprehensive and cover virtually all children's products;
- The standards are straightforward, and the total content basis means that testing is accessible, consistent, and affordable.
- The lead standards apply to a meaningful definition of "children," up to age 12. Since lead is a cumulative and persistent toxicant, it's especially important to maintain the 12 and under age requirement of the law, as this is the best way to prevent exposures as children move into their teenage years, and as girls move into their child bearing years.

When a law is working well, the basic successful characteristics of the law should continue. We respectfully recommend that this committee support the public health success that the CPSIA has been since 2008. Crucial support includes continued support for the lead content standards passed in 2008, as well as support for the definition of a child as a person 12 years old and younger.

CEH

Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
Thursday, April 7, 2011
"Demonstration of CPSIA Success"
Testimony of Caroline Cox
Research Director, Center for Environmental Health

The U.S. Public Health Service states, "No safe blood lead level in children has been determined." According to the U.S. Environmental Protection Agency, lead can affect children "at blood lead levels so low as to be essentially without a threshold." The Centers for Disease Control and Prevention has concluded that "no level of lead in a child's blood can be specified as safe."

So it is discouraging to see proposed revisions that would significantly weaken a law that has worked so well to protect American children from unnecessary lead exposures.

For more than fifteen years, the Center for Environmental Health has worked to protect children and families from harmful chemical exposures. We work collaboratively with major corporations, helping them identify ways they can reduce their use of toxic chemicals, often resulting in economic savings while protecting public health. In some cases, we use litigation to reduce the use of and exposure to toxic chemicals. For example, in a landmark 1997 study, CEH investigated the use of lead-containing brass pipes in home water filtration systems. By 2000, we reached legal agreements with major producers of home water filters, ending the industry's use of materials that were leaching lead into "filtered" water.

Use of a total content standard is more appropriate for lead limits than a limit based on presumed exposures. Total content standards are inexpensive, easily replicable, and not subject to interpretation. By contrast, exposure assessment testing is a subjective process open to interpretation and manipulation. Witness the case of lead-containing vinyl in children's lunchboxes. When CEH found high lead levels in many vinyl children's lunchboxes, the FDA initiated an investigation. FDA used the lead test data from CPSC's testing of lunchboxes, and based on this testing FDA warned lunchbox makers about their use of lead-containing vinyl, concluding that "some migration of lead to food as a result of such use may reasonably be expected." But CPSC interpreted their test data differently: explaining the agency's inaction on lunchboxes, an agency spokesperson stated, "The food that you put in the lunch box may have an outer wrapping, a baggie, so there isn't direct exposure."

Because its lead standards are content based, under the CPSIA, producers, consumers, and regulators all know and understand the standards. Reverting to subjective standards now would be a setback for American families, who expect Congress to take the most protective approach when it comes to our children's health.

Changing the law from a total lead content standard to a standard based on exposure would be detrimental to public health, regulatory and industry needs. Total content testing of materials used in children's products is consistent and objective; screening devices for total content are available and inexpensive; total content

standards allow companies to specify materials to meet the standard. The latter is one of the most important characteristics of a total content standard: with today's complex supply chains, retailers, distributors, and manufacturers need an objective way to specify the quality of products or materials when they commit to a contract. Measuring lead content is the only efficient way for the complete supply chain to document compliance.

By contrast, exposure assessment is inconsistent and subjective; there is no way for companies to screen products for any of the typical exposure assessment tests, so testing costs will increase; and it is not possible to specify standards for components or materials.

CEH's experience before and since passage of the CPSIA demonstrates that the law has been highly successful in promoting safer products for American children. Prior to adoption of the law, CEH found high lead levels in dozens of children's products sold to millions of American families by Wal-Mart, Target, Kmart, and other major retailers. Examples of some of the lead-tainted children's products we found before advent of the law include:

- Imported candies;
- Diaper rash creams;
- Children's anti-diarrheal medicines;
- Baby bibs and lunchboxes;
- Toys; and
- Dozens of items of children's jewelry, including many with components containing 90% or more lead.

In each case, we were unable to point to any federal law to protect children from the lead hazards posed by these products, and thus we relied on California law to address the problems.

Since the lead limits under CPSIA went into effect, our experience shows a dramatic change in the marketplace for children's products. Between September 2009 and December 2010, we conducted what we believe is the largest independent monitoring of children's products for compliance with the CPSIA lead standards. We purchased and screened over 1200 children's products for lead. We bought the products in California primarily from major national retail chains. Because our charge (under a grant from the California attorney general) was to identify non-compliant products, we did not purchase products at random, but rather selected products that were similar to, or made from similar materials as ones identified in the past with lead problems. We purchased stuffed animals, toys, games, lunch boxes, backpacks, jewelry, toy sporting equipment, and other products.

Out of more than 1200 products tested, we found only 46 products that did not comply with CPSIA lead standards, based on independent tests by a CPSIA-certified laboratory. This suggests that at least 96% of children's products are compliant with the CPSIA lead standards. Because we intentionally purchased products that were made from materials known to have had lead problems in the past, our results suggest that overall compliance with CPSIA lead standards is likely even higher.

We also have data from 2007 and 2008, and have used it to demonstrate the downward trend in lead-tainted children's products since the law took effect. Our results show that lead hazards are less prevalent post-CPSIA than either before the law was passed or just prior to implementation of the law. Of the 100 products we tested in 2007, 9 (9%) had components whose lead content exceeded 600 parts per million (ppm), the level that became the first CPSIA standard. Of the 400 products we tested in 2008, 20 (5%) had components whose lead content exceeded 600 ppm. These results show that over the four-year interval, the prevalence of lead hazards in the children's products we tested was reduced by a factor of approximately three, suggesting a similar decrease in children's products in general. Given the immense size of the U.S. market for children's products, this is a major accomplishment.

Based on our experience with monitoring CPSIA compliance, we suggest that the following characteristics of the CPSIA lead standards helped make them successful:

- The lead standards are comprehensive. They cover virtually all children's products, virtually all retailers, suppliers, and manufacturers, and virtually all accessible parts of those products. We believe that this provided assurances to manufacturers that compliant products would find a market.

- The way that the numerical standards are expressed is straightforward. With the exception of paint (90 ppm standards), all materials must currently meet the same standard (300 ppm). In addition, the standards are expressed in terms of lead content, a characteristic that can be measured at any point in the chain of commerce. This made it possible for retailers, vendors, and manufacturers to specify lead content in contracts with their suppliers and to be able to determine if those specifications were being met.

- CPSIA lead standards apply to a meaningful definition of "children," up to age 12. Based on the most recent research, doctors and scientists now say that pregnant women and therefore young women who intend to become pregnant may be the most important subpopulation to protect from lead exposure. Since lead is a cumulative toxicant that is stored in the body for years, lead exposure of 12 year olds is a serious concern.

  At this point I'd also like to speak briefly as a parent rather than as a researcher. Most parents have seen the strong attraction that their children have for toys and other items designed and used by older children. In order to protect young children we need to make sure that products designed for somewhat older children are made of safe materials.

- The lead standards, as written in CPSIA, apply to businesses of all sizes. We believe that the wide scope of the standards has been one of the important factors in making the law a success. However, we would support amendments that recognize the special needs of small businesses.

In conclusion, we respectfully recommend that this committee support the public health success that the CPSIA has been since 2008. Crucial support includes continued support for the lead content standards passed in 2008, as well as support for the definition of a child as a person 12 years old and younger.

Mrs. BONO MACK. Thank you, Ms. Cox. Ms. Millar?

STATEMENT OF SHEILA A. MILLAR

Ms. MILLAR. Thank you, Chairman Bono Mack and Ranking Member Butterfield, members of the subcommittee. I appreciate the invitation to appear here today.

As a longtime consumer protection attorney—and I think all of the members of the panel here and everybody in this room share the same view. We need and want a strong and effective CPSC that has both the authority and the resources necessary to adopt and enforce national consumer product safety standards. Where we differ is that some of us favor revisions to CPSC's arbitrary one-size-fits-all limits that apply irrespective of the type of product, material, age of the user, or actual risk of exposure, its illusory or nonexistent exemption scheme, its retroactive effect and burdensome testing requirements, which have cost money and jobs.

Based on my experience with many different federal agencies, if I have learned one thing over the years, it is that sound public policy should be based on facts and science and risk. So I want to focus on a few key points from my written testimony.

First, the lead and substrate limits were derived from the unfounded assumption that presence equals risk. It doesn't. And I think Dr. Beck illustrated that point carefully this morning. The CPSC's own research has demonstrated that materials that are high in lead may sometimes yield less migratable lead or about the same amount of migratable lead as products that comply with 600 or 300 parts per mission. Exposure is the key to risk. And so we do believe that revisions that are more targeted to exposure keying off of proven things that the CPSC has done for years makes a lot of sense.

In terms of the lead exemption process, the proposal here offers a good step forward but remains unnecessarily complex. In addition, the limited exemption scheme is coupled with a general provision that gives the CPSC new authority to adopt 600 ppm limits on older children's or even adult products. Because I support a risk-based approach, I favor neither the current exemption process as drafted, nor giving CPSC general authority to simply adopt the 600 ppm limit on any product, irrespective of risk.

In contrast, the phthalates provision offers an elegantly simple view that could be applied more generally. It tracks the CPSIA exemption for inaccessible component parts but gives the Commission authority to adopt health-based exemptions, exemptions from the prohibition that are not necessary to protect children's health. Why not adopt a consistent science-based exemption process for both lead and phthalates predicated on the simple basic rule: that the government should not be in the business of banning safe products.

I do want to spend a couple minutes talking about testing. Let me be clear. Testing has an important role in compliance. And as Mr. Howell referenced this morning, there may be ways to look at how to dovetail testing regimes with supplier assurances, self-certifications, and other proven techniques that help confirm safety.

Let us also be clear that the prospect of $15 million penalties offer very powerful incentives to comply to say nothing of the prospect that your products will simply be rejected by your customers.

From the standpoint of total content testing, I differ with Ms. Cox in that we have seen over and over again the total content lead tests are not so uniform as you might expect. There is considerable variability and the absence of any definitive inter-laboratory variability factor is a key problem, particularly as levels drop lower and lower. So when we look at these differences in terms of inter-laboratory variability, a material—which may have residual lead content, let us say, a plated piece of metal where you are building on a piece of tin coupled with a nickel-plating, a copper-plating, a silver-plating—at the end of the day, the addition of those added metals, each of which could have residually low total content, could put you above 100 ppm. And I think we have seen the need for exemptions to perhaps look at a broader array of material to address that naturally occurring problem.

I would also caution against assuming that component testing is the solution to all ills with certification testing here. I represent many raw materials suppliers of plastics, chemicals, and other materials, and they are simply not willing to subject themselves to the jurisdiction of the CPSC to provide component-test certifications in the rigid scheme required by CPSIA.

I strongly support a national safety net for consumers. I also strongly support reducing unnecessary burdens on the regulated community by restoring the CPSC its authority to make sound risk-based decisions. Thank you again for the invitation and I look forward to responding to any questions.

[The prepared statement of Ms. Millar follows:]

STATEMENT OF

SHEILA A. MILLAR

PARTNER

KELLER AND HECKMAN LLP

BEFORE THE SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

DISCUSSION DRAFT OF H.R. ____, A BILL THAT WOULD REVISE THE CONSUMER PRODUCT SAFETY IMPROVEMENT ACT OF 2008

April 7, 2011

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SUMMARY

The Consumer Product Safety Improvement Act of 2008 (CPSIA) includes some important updates to the Consumer Product Safety Commission's (CPSC) authority that generated considerable support from businesses and consumer groups alike. However, other provisions were and remain controversial because they depart from sensible risk-based decision-making designed to be protective of public health. CPSIA adopted an unduly proscriptive scheme of absolute limits on total lead and phthalates, setting standards inconsistent with risk-based measures commonly adopted by other regulatory agencies and indeed by CPSC itself. Those limits were coupled with 1) an exemption process that has proven to be meaningless, in the case of the lead limits, or non-existent, in the case of phthalates limits, 2) arbitrary reduction schedules for lead content, 3) retroactive effect, and 4) a confusing, burdensome testing scheme. The result is legislation that bars the CPSC from making common sense decisions about protecting the public, and thus results in bans on safe products, costing both money and jobs since the law went into effect. We need and want a strong and effective CPSC with both the authority and the resources necessary to adopt and enforce national consumer product safety standards based on science and risk. The draft legislation offers some positive steps towards this goal, but further revisions should be considered to advance a consistent public policy framework that assures that children are protected and that responsible businesses can continue to produce safe, affordable compliant products for children.

Chairman Bono-Mack and members of the Subcommittee, my name is Sheila Millar. I am a partner with the law firm of Keller and Heckman LLP. Thank you for the opportunity to appear before you today to discuss reform of the Consumer Product Safety Improvement Act of 2008 (CPSIA). I have represented manufacturers, importers, retailers, and trade associations who make consumer products, packaging, medical devices, and other products, as well as suppliers of raw materials used in these products, for over 30 years. My practice involves issues before many different regulatory agencies, often involving the intersection of law and science, so I will focus principally on the provisions relevant to children's products. My comments reflect my personal views, drawn from my years of regulatory experience, on how to advance a strong, national, uniform consumer product safety law that achieves the goal of protecting children without eliminating products that, by any reasonable and accepted objective health measure, are safe. The draft CPSIA reform bill offers some modest steps towards this goal.

1. **Defining a "child."** CPSIA defines "children" to be those 12 and younger. Children are not "little adults." Nor, however, should all children in this age group be treated identically. "Children under 12" have physical and developmental differences and interact with consumer products differently. This is reflected in current law, which establishes different requirements for particular hazards based on the age of a child. Adopting a risk-based policy framework will allow for the development of health-protective standards for children's products keyed to the actual intended user.
2. **Lead substrate limits.** The cornerstone of a sound health and safety public policy is risk-based regulation. This is reflected in laws administered by health and safety agencies such as the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and the Consumer Product Safety

Commission (CPSC) pursuant to the Federal Hazardous Substances Act (FHSA). It is a well-acknowledged law of science that hazard is a function of toxicity plus exposure. Risk is the potential hazard posed by the exposure, which in turn requires an assessment of the type of material, the type of product, foreseeable handling and use, and age of the intended user. In enacting CPSIA's arbitrary total content limits on lead in substrate, Congress departed from well-established health risk management concepts. It first adopted a 600 ppm limit, then dropped to 300 ppm, with an impending 100 ppm limit coming up this summer unless modified. These limits are not related to actual risk, since the presence, existence or content of a substance in a product or component does not automatically result in potential harm to health. As a result, CPSIA imposes burdens beyond those needed to address the potential risk of harm through reasonably foreseeable handling and use, obsoleting products that are "safe" one day and banned the next. Although the revisions in the draft legislation are a positive step, they do not restore a risk-based framework. Consequently, the likelihood remains that safe products will be banned by the legislation even as revised. Other agencies, like FDA and EPA, have developed health-protective risk-based approaches to managing potential lead exposure which may offer useful alternatives to the current framework.

3. **The lead exemption process should be modified.** If CPSIA is not modified to establish a more sensible basic policy framework in regulating lead in children's products, the exemption process in Section 101(b) should be modified to allow for exemptions for materials or products that will not pose a potential health risk based on reasonably foreseeable use and abuse. The proposed legislation is an improvement to the current exemption process, which has resulted in no exemptions despite demonstrated *de minimis* risk of exposure. However, the new exemption process remains unnecessarily complex and restrictive. It establishes two

approaches for exemptions, one for certain specific metals (steel, copper and aluminum alloys), and one for materials that pose a *de minimis* risk, provided, in each case, that they are not small parts. The scientific rationale for this limited two-step exemption process is not apparent. Any product or material that does not result in anticipated adverse health effects based on appropriate science relevant to the reasonable worst-case anticipated exposure route should be exempt. In some cases that may be hand to mouth contact. In others it may be mouthing, and in still others it may be accidental ingestion. If a product or material is demonstrated to be reasonably safe, utilizing appropriate scientific methodology to assess exposure via the anticipated potential route of exposure, there is simply no health or policy reason to ban it. In contrast, the suggested phthalates exemption process in Section 6 of the draft bill authorizes the Commission to exempt from the phthalates limits products or materials where the Commission determines that compliance with the prohibition is not necessary to protect children's health. This is a more sensible way to address the issue, and we believe that you should create a consistent and scientifically appropriate path for all health-based exemptions.

4. **Phthalates provisions.** The proposed bill includes a much-needed exception for inaccessible component parts that contain phthalates, similar to the inaccessible component parts exemption from the lead limits, and allows the Commission to grant an exclusion when it determines that compliance with the limits is not necessary to protect children's health. This is a sound risk-based approach that could easily substitute for the more complex and restrictive lead exemption options offered in the draft bill. Inclusion of an accessibility requirement will also assure that the phthalates limits apply only to products that will result in direct exposure through interaction of a child. Again, the risk of actual exposure to children

in the age range of concern is key. Products like breast pumps and bottle warmers, among others, should obviously be exempt from the phthalates limits, as should toys or child care articles that realistically would not likely involve health risks to children.

5. **Lead and phthalates standards should be prospective.** We support clarifications to CPSIA to assure that limits apply prospectively to products manufactured after the effective date. The lost businesses and lost jobs that were the result of the earlier implementation schedule of CPSIA cannot be restored, but further adverse impact to businesses whose products comply one day but not the next, or are otherwise safe, can be avoided.
6. **Modify unduly burdensome testing requirements.** Manufacturers have an obligation to meet applicable standards and to take appropriate measures to assure that they do. Otherwise, they face recalls and possible penalties for non-compliance. Testing has an important and ongoing role in compliance. However, micromanaging the test process by statute is not the best way to achieve the most cost-effective compliance, nor does it allow companies to rely on other compliance strategies or to leverage existing federal and other regulatory requirements to assure compliance. The draft bill offers important modifications to the current burdensome CPSIA testing scheme, recognizing that a system of compliance must be predicated on the specifics of the product category and supply chain. A few additional suggestions include:
    a. **Allow for supplier self-certifications, including as a mechanism to establish a reasonable basis of compliance with chemical content limits for components and raw materials.** Manufacturer certifications are a proven legal method to establish compliance under many laws, including the Flammable Fabrics Act, for example. CPSC's proposed final testing rule suggests that component testing will

be a solution to the costs and burden of mandatory third party testing of children's products. However, to take advantage of component testing, the raw material supplier must agree to subject itself to the jurisdiction of the CPSC and meet the requirements of a "reasonable test program." Raw material producers often do not themselves produce a consumer product, and may not be willing to subject themselves to the jurisdiction of CPSC for this purpose, particularly the burdensome production testing approach. However, they can often offer assurances of compliance. For example, many consumer product companies specify FDA-compliant raw materials for use in children's products, sourcing materials from reputable third parties who can provide written supplier assurances of compliance with FDA requirements adequate to assure that the material meets lead limits. A company that is willing and able to offer low lead materials safe for use in contact with food surely offers adequate assurances of safety for use in a consumer product.

b. **If production testing is retained, refer to "representative samples" rather than "random samples" in Section 102(b).** The draft bill now allows the CPSC to prescribe reasonable testing programs to be used as the basis for certification for test requirements not yet in effect. However, further guidance on the parameters of a reasonable testing program in general may be needed. For example, with regard to production testing, the CPSC's proposed definition of the term "random samples" requires manufacturers to adopt a complicated statistical approach to the selection of samples. A better term to substitute for "random samples" is "representative samples," meaning samples that are selected in a

manner intended to assure that they are representative of actual production, avoiding preselected or "golden" samples, not implementation of a complicated and expensive statistical selection process.

c. **Direct the CPSC to issue public guidance on inter-laboratory variability in total lead and phthalate test results.** Many reports have been submitted to CPSC documenting inconsistent results from laboratory to laboratory on total lead and phthalate content when the same product or component is tested. Products that meet lead or phthalates limits based on tests by one laboratory may fail when the same product is tested by another laboratory. Many companies require that tests be conducted by "their" laboratory so that they have consistent results for just that reason. This adds cost to the process, defeating one of the purposes behind third party testing. Products tested by any party that do not meet the applicable lead or phthalates limits by even a small margin cannot be sold and will not be accepted by customers. By virtue of failing a test these products are treated as banned hazardous products, subject to reporting and recall, irrespective of any actual potential risk of harm to a child. The problem is exacerbated as small differences in inter-laboratory results can have an enormous impact as regulatory limits drop, even as manufacturers operate on tighter and tighter tolerances in an effort to assure compliance. Adoption of an inter-laboratory uncertainty factor is a much-needed step in addition to adopting a risk-based framework of regulation.

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The revisions in the draft bill are a good start towards ameliorating some of the adverse impacts of CPSIA, but further changes along the lines I have outlined here will help maintain a strong national safety net for consumers and reduce unnecessary burdens on the regulated community by restoring to the CPSC its authority to make sound risk-based determinations. The result will be an improved CPSIA, grounded in a public policy framework that draws on proven health-protective approaches to risk. I appreciate the opportunity to appear here today and would be happy to respond to questions.

Mrs. BONO MACK. Thank you very much. Mr. Vitrano, 5 minutes.

STATEMENT OF PAUL C. VITRANO

Mr. VITRANO. Chair Bono Mack, Ranking Member Butterfield, and distinguished members of the subcommittee, thank you for the opportunity to testify. I am Paul Vitrano of the Motorcycle Industry Council, which represents nearly 300 manufacturers of motorcycles and ATVs, aftermarket companies, and allied trades. We appreciate the subcommittee's efforts to address the unintended consequence of the CPSIA, which has effectively banned the sale of youth ATVs, motorcycles, and snowmobiles. The act has actually created unsafe situations for young riders by reducing the unavailability of appropriately-sized speed-restricted youth models.

As you noted during the last hearing, Chair Bono Mack, the CPSC has made the judgment that the risk of lead exposure to children is outweighed by the risk that children face if youth ATVs are not available. The act also has cost manufacturing and dealership jobs.

We urge Congress to fix this unintended ban and appreciate the subcommittee has offered an initial draft reform bill. Within the framework of the draft bill, the only way to fix the ban on youth vehicles with certainty and without imposing further needless costs and burdens on our industry and its customers is to amend the range of children's products at least for these vehicles to age 6 and under.

Alternatively, we ask you to consider adding a categorical exemption to the bill. There already is widespread support for this approach. Representative Rehberg has authored the Kids Just Want to Ride Act, H.R. 412, which currently has 61 bipartisan cosponsors. And just last week, Senators Klobuchar and Tester offered a categorical exemption as an amendment to the small business bill currently before the Senate.

ATVs and motorcycles do not present any lead-related health risk to young riders and Congress has made it clear that it never intended the lead content restrictions for toys to apply to these vehicles. We ask that you keep in mind the following points as you work to provide young riders in our industry with much-needed relief.

First, the lead content in metal parts of ATVs and motorcycles poses no risk to kids, as Dr. Barbara Beck testified earlier this morning. The estimated lead intake from kids touching metal parts is less than the lead intake from drinking a glass of water.

Second, everyone agrees that the key to youth safety on ATVs and motorcycles is ensuring they ride the right size vehicles. By reducing the availability of these vehicles, the CPSIA has created—in the CPSC's own words—a "more serious and immediate risk of injury or death" than any risk from lead exposure.

Third, in 2009 MIC estimated that a complete ban on youth-model vehicles would result in about 1 billion in lost economic value in the retail marketplace every year.

Fourth, motorcycles and ATVs are motor-powered machines, not toys or other articles kids wear or play with. So the extent and nature of the children's interaction with our vehicles is materially different. As you know, kids do not mouth tailpipes or swallow bat-

tery terminals. Young riders typically only touch a few parts of the vehicles like handlebars and clutch levers and often with gloved hands.

Finally, ATVs and dirt bikes are stored outside the house, usually in garages, sheds, or barns and thus are much less likely than household items to be touched by young children. In addition to being remotely located, the vehicles have keys and use is controlled and supervised by parents.

There are two commonsense ways to fix this problem once and for all and without imposing further unnecessary testing and certification costs and burdens on our industry and customers. We urge you to exclude these youth vehicles from the lead content provisions by lowering the age range to primarily intended age 6 and under or adding a categorical exemption.

We also support the recommended changes to the CPSIA database provisions. One of our members recently received a report of harm where a rider who had been drinking prior to riding rode off a cliff at night in the dark. Nothing in the report indicated any problem with the ATV, but because the CPSIA database on its face only accepts reports of "unsafe" products, the inclusion of this report will result in the ATV implicitly being classified as an unsafe product. Unless Congress acts, the database will become a repository of inaccurate information that defames manufacturers and misleads customers. We believe the modest changes proposed in the draft legislation will result in a more useful database with accurate and relevant information for consumers. Thank you. I am happy to answer any questions.

[The prepared statement of Mr. Vitrano follows:]

SUMMARY OF TESTIMONY OF PAUL C. VITRANO
Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
United States House of Representatives
April 7, 2011

The CPSIA was intended to protect children from ingesting lead from toys. However, the lead provision has had unintended consequences and I am here to testify about what many believe is one of the most absurd of those consequences. The CPSIA has effectively banned the sale of age-appropriate youth ATVs, motorcycles and snowmobiles because of the tiny amount of lead content in certain components. As a result, the Act has actually created unsafe situations for youth off-highway vehicle riders by reducing the availability of appropriately-sized, speed-restricted youth models. As you noted during the last hearing Chair Bono Mack, "the CPSC has made the judgment that the risk of lead exposure to children is outweighed by the risks that children face if youth ATVs are not available and they ride adult-sized ATVs instead." The Act also has crippled key parts of our industry, costing manufacturing and dealership jobs across the country.

On behalf of our members, their thousands of dealers, youth off-highway enthusiasts and their families, the Motorcycle Industry Council urges Congress to fix this unintended ban. We appreciate that the Subcommittee has offered an initial draft reform bill and is holding this hearing to discuss it. Within the framework of the draft bill, the only way to fix the ban on youth ATVs, motorcycles and snowmobiles with certainty – and without imposing further needless costs and burdens on our industry and its customers – is to amend the range of "children's products" – at least for these vehicles – to age 6 and under.

In the alternative, we ask you to consider adding a categorical exemption to the bill. There already is widespread bi-partisan support for a categorical exemption for youth motorcycles and ATVs. Rep. Rehberg has authored The Kids Just Want to Ride Act, H.R. 412, which currently has 60 bi-partisan co-sponsors. And just last week, Sens. Klobuchar and Tester offered a categorical exemption as an amendment to the small business bill which was on the Senate floor.

ATVs and motorcycles do not present any lead-related health risk to young riders, and Congress has made it clear that it never intended the lead content restrictions for toys to apply to these vehicles. It is time to correct this untenable situation by either lowering the age to 6 and under or adding a categorical exemption in the bill. The industry also strongly supports the Committee's recommended changes to the CPSIA database provisions.

TESTIMONY OF PAUL C. VITRANO
Subcommittee on Commerce, Manufacturing and Trade
Committee on Energy and Commerce
United States House of Representatives
April 7, 2011

Chair Bono Mack, Ranking Member Butterfield and distinguished Members of the Subcommittee on Commerce, Manufacturing and Trade, thank you for the opportunity to testify on the urgent need for amendments to the Consumer Product Safety Improvement Act. I am Paul Vitrano, General Counsel of the Motorcycle Industry Council. MIC is a not-for-profit, national industry association representing nearly 300 manufacturers and distributors of motorcycles and all-terrain vehicles; motorcycle, ATV and recreational off-highway vehicle parts and accessories; and members of allied trades such as insurance, finance and investment companies, media companies and consultants.

The CPSIA was intended to protect children from ingesting lead from toys. However, the lead provision has had unintended consequences and I am here to testify about what many believe is one of the most absurd of those consequences. The CPSIA has effectively banned the sale of age-appropriate youth ATVs, motorcycles and snowmobiles because of the tiny amount of lead content in certain components. As a result, the Act has actually created unsafe situations for youth off-highway vehicle riders by reducing the availability of appropriately-sized, speed-restricted youth models. As you noted during the last hearing Chair Bono Mack, "the CPSC has made the judgment that the risk of lead exposure to children is outweighed by the risks that children face if youth ATVs are not available and they ride adult-sized ATVs instead." The Act also has crippled key parts of our industry, costing manufacturing and dealership jobs across the country.

On behalf of our members, their thousands of dealers, youth off-highway enthusiasts and their families, the MIC urges Congress to fix this unintended ban. We appreciate that the Subcommittee has offered an initial draft reform bill and is holding this hearing to discuss it. Within the framework of the draft bill, the only way to fix the ban on youth ATVs, motorcycles and snowmobiles with certainty – and without imposing further needless costs and burdens on our industry and its customers – is to amend the range of "children's products" – at least for these vehicles – to age 6 and under.

In the alternative, we ask you to consider adding a categorical exemption to the bill. There already is widespread bi-partisan support for a categorical exemption for youth motorcycles and ATVs. Representative Rehberg has authored The Kids Just Want to Ride Act, H.R. 412, which currently has 60 bi-partisan co-sponsors. And just last week, Senators Klobuchar and Tester offered a categorical exemption as an amendment to the small business bill which was on the Senate floor.

ATVs and motorcycles do not present any lead-related health risk to young riders, and Congress has made it clear that it never intended the lead content restrictions for toys to apply to these vehicles. It is time to correct this untenable situation by either lowering the age to 6 and under or adding a categorical exemption in the bill.

It is estimated that over 13 million Americans enjoy riding off-highway motorcycles and over 30 million enjoy riding ATVs. Safety of our riders – particularly our youngest riders – is a top

priority of the powersports industry. Vehicles, helmets and other gear and accessories are specially designed for youth riders to allow them to safely enjoy this family-friendly form of outdoor recreation.

In February 2009, however, ATVs and motorcycles designed and primarily intended for youth riders aged 6 to 12 became banned hazardous substances under the CPSIA because small amounts of lead – that pose no risk to youth – are imbedded in metal parts of those vehicles to enhance the functionality of those components.

As you know, the CPSC concluded that the language of the CPSIA prevented it from making common-sense decisions and resulted in the CPSC denying the powersports industry's petitions for exclusion from the lead content provision. The exclusion was denied despite the fact that the CPSC's own staff acknowledged that there was no measurable risk to children resulting from lead exposure from these products.

As a temporary stop-gap measure, the CPSC issued a stay of enforcement of the CPSIA's lead content limits in May 2009. Unfortunately, this stay of enforcement has proven unworkable. Due to the risks, uncertainties and burdens of the law, many manufacturers and dealers are no longer selling youth model off-highway vehicles. Over half of the major ATV manufacturers are no longer selling the smallest youth models despite the stay, significantly reducing the availability of these vehicles for children.

The CPSC has acknowledged that the ban on youth off-highway vehicles creates a significant safety issue because it likely will result in children 12 years of age and younger riding larger and faster adult-size vehicles. CPSC studies show that almost 90% of youth injuries and fatalities occur on adult-size ATVs. In contrast, the CPSC's staff scientists acknowledge that the presence of lead in metal alloys in these youth models does not present a health hazard to children. The Commission also acknowledges that children riding these vehicles only interact with a limited number of metal component parts that might contain small amounts of lead, like brake and clutch levers, throttle controls, and tire valve stems.

We appreciate the Subcommittee's efforts to address the unintended consequences of the CPSIA. We ask that you keep in mind the following points as you work to provide young riders, their families and our industry with much-needed, long overdue relief.

First, the lead content in metal parts of ATVs and motorcycles poses no risk to kids. In 2009, Dr. Barbara Beck estimated that the lead intake from kids' interaction with metal parts is less than the lead intake from drinking a glass of water.

Second, everyone agrees that the key to keeping children safe on ATVs and motorcycles is by ensuring they ride the right-sized vehicles. The CPSIA has put kids at significant risk by reducing the availability of youth model vehicles. The CPSC has described this unintended consequence of the Act as a "more serious and immediate risk of injury or death" than any risk from lead exposure from these products.

Third, the CPSIA is needlessly harming the economy and costing jobs when everyone is trying to grow the economy and create jobs. In 2009, MIC estimated that a complete ban on youth model vehicles would result in about $1 billion in lost economic value in the retail marketplace every year.

Fourth, motorcycles and ATVs are motor-powered machines, not toys or other articles kids wear or play with or, so the extent and nature of children's interaction with our vehicles is materially different. Young riders typically only touch a few parts of the vehicles, like handlebars and brake and clutch levers, and often with gloved hands.

Finally, ATVs and dirt bikes are stored outside the house, usually in garages, sheds or barns, and thus are much less likely than household items to be touched by young children. In addition to being remotely located, the vehicles have keys and use is controlled and supervised by parents.

As Representative Rehberg stated when introducing his bill to exclude youth ATVs and motorcycles from the Act's lead content restrictions, "the original legislation Congress passed was meant to keep kids safe from lead content in toys. Ironically, the overreaching enforcement wound up putting kids at risk by forcing them to use larger more dangerous machines that are intended only for adults."

Everyone agrees that the lead content restrictions for toys were never meant to apply to youth model motorized recreational vehicles. There are two obvious, common sense ways to fix this problem once and for all, without imposing further unnecessary regulatory costs and burdens on

our industry and customers. We urge you to exclude youth ATVs and motorcycles from the lead content provisions of the CPSIA by lowering the age range to age 6 and under or adding a categorical exemption in the bill.

I also would like to express the powersports industry's support for the Committee's recommended changes to the CPSIA database provisions. Industry has already experieneed requests for misleading reports of harm to be posted on the government-run database. Indeed, one manufacturer recently received a database entry where a rider, who had been drinking prior to riding his ATV, rode off a cliff at night in the dark. Nothing in the report indicated any problem with the ATV. But nevertheless, because the death was "related to use of [a] consumer product," the CPSC has indicated that the ATV should be classified as being "unsafe" in the database. With the Commission having implemented the database the way it did, the database likely will become a repository of inaccurate information that defames manufacturers and misleads consumers. A guiding principle before anything is posted should be accuracy, and we believe the modest changes proposed in the draft legislation would result in a more useful database with accurate and relevant information for consumers.

Thank you. I would be happy to answer any questions.

Mrs. BONO MACK. Thank you, Mr. Vitrano. Ms. Jones, you are recognized for your 5 minutes.

STATEMENT OF ERIKA Z. JONES

Ms. JONES. Good afternoon, and thank you for inviting me to be with you this afternoon. I am Erika Jones, and I am counsel to the Bicycle Products Suppliers Association, which represents most of the manufacturers and importers of children's bicycles and adult bicycles offered for sale in the United States.

The bicycle industry has taken very seriously the expectations of Congress when the CPSIA was enacted. The bicycle industry has made substantial progress toward reducing lead in children's bicycle products or making the lead inaccessible to children and appreciated the Stay of Enforcement that was enacted by the Commission and used that time productively to make these design changes and material substitutions in their products.

Nevertheless, the industry is facing another brink of uncertainty as later this year a new standard of 100 parts per million looms on the horizon and presents a number of feasibility and practicability challenges for the industry. The industry presented data to the Commission in February of this year and again last month in written comments providing data from testing of a bicycle that was specced by its manufacturer to be below 100 parts per million because retailers are beginning to demand that level of achievement. And despite this effort to reach that goal, over 38 of the over 100 parts that were tested by the laboratory exceeded 100 parts per million, and that is attributable to the variability that is present, inherent, and we think at this point, can no longer be worked out of the system. These were metal parts. The bicycle industry has solved the issue with respect to plastic and other non-metallic parts but continues to have a problem with those components on bicycles that are made from metal alloys.

A witness at the CPSC regulatory hearing last month, who was retained by the bicycle industry and who runs a CPSC-certified lab, testified that he has in his experience seen a shrinkage in the number of children's bicycle models that are offered for sale and the number of manufacturers willing to engage in this sector, which means a loss of choice for consumers. And this, we believe, is attributed to the cost of testing for the over 100 parts of a bicycle that are accessible and therefore have to be tested.

Bicycles provide safe, affordable, and environmentally friendly transportation. They provide children with an enjoyable means of outdoor exercise, which we think is far more important for the health of children than protecting them from the theoretical risks from touching metal bicycle components with their hands. If lead testing costs make children's bicycles too expensive for average families to afford or if affordable used bicycles are difficult to obtain, the health of America's children could be affected far more than from the presence of lead in a tire valve stem that they may touch only on occasion.

I would like to address a comment made by the previous panel, by Dr. Best, who made a comment that there is no benefit to lead and therefore it should be inherently unnecessary. We disagree with that. Lead in the quantities that we see it in metal alloys that

are used in bicycles provide a tremendous benefit. They provide corrosion resistance. Lead alloys provide strength and durability that is needed for appropriate performance of a bicycle. And it would not be socially useful or desirable to produce a bicycle that may meet a lead-free standard but which falls apart or which cannot be operated in an outdoor environment where it is intended to be used.

The industry applauds your subcommittee for convening this hearing today. We believe there is a need to reform the CPSIA to reverse these unintended consequences and eliminate the unnecessary regulatory requirements that are driving up the cost of children's bicycles making them less available and we urge prompt action on sensible reforms of the CPSIA. Thank you.

[The prepared statement of Ms. Jones follows:]

BEFORE THE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES
APRIL 7, 2011

TESTIMONY OF
ERIKA Z. JONES
ON BEHALF OF
BICYCLE PRODUCT SUPPLIERS ASSOCIATION

SUMMARY OF TESTIMONY

- The Bicycle Product Suppliers Association supports reforming the CPSIA and believes that sensible reforms are needed to address practical problems in the market.
- BPSA supports revising the age threshold for the definition of "children's product" to a lower age, and recommends establishing the threshold at age six.
- BPSA agrees that any new lead substrate standard should be prospective only.
- BPSA supports the establishment of an alternative lead substrate standard for components manufactured of certain specified metal alloys.
- BPSA welcomes provisions that recognize that component parts not likely to result in the ingestion of more than a de minimis amount of lead should not be subject to the standard and the testing requirements.
- BPSA supports an exclusion for the resale of used and refurbished children's products by charitable organizations.
- BPSA supports the proposed changes to the public database to make the data submissions more useful and accurate.
- BPSA does not support conferring authority on CPSC to extend the 100 ppm lead substrate limit to adult products.
- BPSA urges prompt action on sensible reforms of the CPSIA.

BEFORE THE
SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES
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TESTIMONY OF
ERIKA Z. JONES
ON BEHALF OF
BICYCLE PRODUCT SUPPLIERS ASSOCIATION

Chair Bono Mack, Ranking Member Butterfield, and members of the Subcommittee, I appreciate the opportunity to testify before you this morning on the important matter of the need for amendments to reform the Consumer Product Safety Improvement Act of 2008 ("CPSIA").

I am Erika Jones, counsel to the Bicycle Product Suppliers Association, an association of suppliers of bicycles, parts, accessories and services who serve the specialty bicycle retailer. BPSA has engaged actively and constructively with the U.S. Consumer Product Safety Commission since the enactment of the CPSIA. BPSA's efforts to work with the CPSC staff to find solutions to CPSIA implementation issues have included the following:

- BPSA met in the fall of 2008 with the staff to discuss issues related to the bicycle standard (Part 1512) and challenges that were presented by the requirement for certification to all provisions of that standard, in light of the fact that the standard had not been revised in many years and contained some provisions which were not applicable to some modern bicycle designs. Since that time, BPSA has worked with the staff to identify the bicycle standard provisions requiring clarification or modification.
- In early 2009, BPSA petitioned the CPSC for limited relief from the lead standard for children's bicycles on the grounds that the lead in the metal materials used for children's bicycles would not result in the absorption of any measurable lead in a child's body. The

BPSA petition was supported by the best available scientific evidence, including specifically the expert report of Dr. Barbara Beck of Gradient, who analyzed worst-case scenarios of exposure to BPSA's members' products and concluded that no measurable increase in the blood levels of children could be expected to result from their exposure to, and contact with, the metal materials for which the BPSA sought relief. As the Committee knows, the CPSC concluded that it was unable to provide the relief sought under the terms of the statute, but provided a limited stay of enforcement for the lead requirements.

- BPSA presented data at a public Commission meeting earlier this year regarding the imminent change in the lead substrate standard, which is scheduled to change from 300 ppm to 100 ppm in August of this year. BPSA advised the Commission that its test data documented the significant variability that exists in components manufactured of certain metal alloys, making it infeasible to certify compliance with a 100 ppm standard with any reasonable degree of confidence.
- BPSA also advised the Commission at that hearing that its members had been successful in identifying substitute materials for high lead-content metals and/or alternative designs that resulted in making the high lead-content materials inaccessible to children, but that these efforts came at high costs, and despite substantial investment, the industry has still not been able to identify suitable metal materials that can consistently meet a 100 ppm standard. Yet, the prospects for obtaining administrative relief from the Commission are unclear, particularly with respect to products that will be on retail shelves as of August 2011.

In short, BPSA members have taken seriously the expectations of the Congress in enacting the CPSIA, and have made substantial progress toward achieving the goal of reducing unnecessary lead in children's bicycle products. Nevertheless, despite these substantial efforts, BPSA members are facing yet another brink of uncertainty as the date for implementation of the 100 ppm standard looms on the horizon.

With respect to the requirements for third-party laboratory testing of children's products, BPSA has worked constructively with the CPSC staff to address issues related to laboratory capacity; however, some issues remain, particularly with respect to the costs of testing. BPSA presented information to the Commission at the recent public meeting on the feasibility of the 100 ppm standard about the shrinkage of the market in terms of the number of companies willing to market children's bicycles. While the total volume of children's bicycles sold annually has not diminished, the number of children's bicycle models in the market is reduced from the number that were offered for sale before CPSIA's enactment, and the number of manufacturers willing to participate in the children's bicycle market sector has diminished, according to BPSA's expert who participated in the recent public meeting at the CPSC regarding the technological feasibility of a 100 ppm lead substrate standard. We believe that these market impacts are directly traceable to the onerous requirements of the CPSIA, including specifically the testing costs that are required to certify compliance with the CPSC's regulations.

For all of these reasons, BPSA strongly supports the efforts of this Subcommittee to bring some sorely needed reform to the CPSIA.

BPSA is particularly supportive of the following proposals in the discussion draft:

- Reducing the age threshold for definition of a "children's product." BPSA supports lowering the age threshold for the definition of a "children's product," and recommends

that the appropriate age threshold for determining whether a bicycle is a "children's product" should be whether the bicycle is intended primarily for use by a child six years of age or younger. This change alone would relieve BPSA members of the need to expend scarce resources on lead substrate testing on those bicycles intended for use by pre-teens, for whom there is no reasonable prospect of being injured from exposure to lead, as documented in Dr. Beck's analysis supporting the 2009 BPSA petition.

- Specifying that any new lead substrate standard would be prospective only, and not apply to products on retail shelves. BPSA has provided the Commission with information as to why a 100 ppm standard is not technologically feasible for metal components on children's bicycle products, and urges this Committee to report legislation that will provide complete relief from this requirement for bicycles. Although BPSA members are not seeking relief from a 100 ppm lead substrate standard for non-metal components, such as vinyl handgrips, it is unfair and extremely disruptive to apply that standard, or any new performance standard for that matter, to products that were manufactured before the effective date of the new standard. Except in the rarest of circumstances, new government standards should apply prospectively to products that are manufactured after the effective date of the new standard.
- Establishing an alternative lead substrate standard for metal components made of steel, copper or aluminum alloys. BPSA supports this provision, and believes its enactment would be directly responsive to some of the practical concerns that BPSA members have identified, and documented in prior presentations to the CPSC; however, it is unclear whether this provision would provide any relief from the testing burdens associated with the requirement to certify compliance. BPSA suggests that one additional step that might

be helpful to small businesses that are struggling with the testing costs would be to direct the CPSC to establish a roster of those metal alloys (perhaps identified by grade or other recognized identifier) that would be identified as presumptively compliant with the alternative standard, thereby relieving the manufacturer of the obligation to test separately for lead substrate compliance if the manufacturer chooses to use one of the alloy grades specified on the roster. (Of course, a manufacturer would remain free to specify a different material and test components made of that different material for compliance with the lead substrate standard.)

- Establishing a de minimis exception for component parts that are not likely to result in ingestion of more than a de minimis amount of lead. BPSA welcomes any provision that acknowledges the fact that the mere presence of lead in certain components does not necessarily present a health or safety risk to children. BPSA believes that product regulations that effectively ban the use of certain materials should be based on scientific risk assessments and a thorough understanding of the societal trade-offs that arise from such effective bans.
- Creating an exclusion for the resale of used or refurbished children's products by charitable resellers. BPSA strongly supports the intention of this provision, which is to permit the distribution of used or refurbished children's products by charitable organizations. Particularly given the scientific evidence strongly supporting the conclusion that children's bicycles do not present a health or safety risk to children based on the presence of lead in certain components, there is no good public policy reason to deprive families of the option of obtaining affordable, second-hand bicycles.

- Revising the public database provisions to make the submissions more useful by ensuring that submitters have actually experienced harm or risk of harm and by requiring more verification of disputed reports.

* * *

BPSA does not support conferring authority on the CPSC to extend the 100 ppm lead substrate limit to adult products. No justification has been offered for the need for any such requirement for adult products. In the short time since this draft legislation has been made available for review, BPSA members have been unable to evaluate whether the materials substitutions and redesigns for inaccessibility that were done for children's bicycles are feasible or practicable for adult bicycles. Before conferring any such authority on CPSC, BPSA urges this Committee to allow more time to evaluate the need for, and consequences of, any such new authority to impose a new mandate.

Our collective experience with the CPSIA has reminded us all of the need for regulators to consider unintended consequences before moving to ban a product or a material. The CPSIA was enacted with the best of intentions, but has proven in practice to present some practical challenges for manufacturers. BPSA believes that the CPSC should maintain its traditional method of regulating potentially harmful products and substances on the basis of a scientific risk-based assessment of potential harm balanced against the costs and other consequences associated with the ban or other regulation.

BPSA members are very proud to serve the needs of American bicycle consumers of all ages. Bicycles provide safe, affordable and environmentally friendly transportation. Bicycles provide children with an enjoyable means of outdoor exercise, which is far more important for the health of America's children than protecting them from the theoretical risks from touching

metal bicycle components with low lead levels. If lead testing costs make children's bicycles too expensive for average families to afford, and if affordable, used bicycles are difficult to obtain, the health of America's children could be affected far more than from the presence of lead in tire valve stems.

BPSA applauds this Subcommittee for convening this hearing today to consider the need to reform the CPSIA to reverse the unintended consequences of that law and to eliminate unnecessary regulatory requirements that are driving up the costs of children's bicycles. BPSA urges prompt action on sensible reforms of the CPSIA.

Mrs. BONO MACK. Thank you, Ms. Jones. You get the record for coming in 45 seconds short, so I am going to recognize myself for the first 5 minutes of questioning and direct my question to you.

You made reference several times in your written testimony to the August time frame. What happens in August that this time frame is of such concern that we need to do something about it in this amendment that we are looking at?

Ms. JONES. On August 11 of this year the lead standard for substrate will drop to 100 parts per million, and under the current interpretation of the statute that will have immediate effect at the retail level, meaning it will really be retroactively applied to products that are on the retail shelves that are being built right now as we speak. And that has a devastating effect on product planning and as I testified a few minutes ago and as we have submitted data to the CPSC, the 100-parts-per-million standard is technically not feasible right now for the bicycle industry to meet.

Mrs. BONO MACK. Thank you. And you also state that "except in the rarest of circumstances, new government standards should apply prospectively to products that are manufactured after the effective date of the standard." Can you give us examples of circumstances in which new standards have been applied immediately and retroactively? And how do those examples differ from the instance we have before us?

Ms. JONES. Well, the best example is the one we were just discussion of the 100 parts per million, which will apply immediately on August 11, not to products built after that date but to products on retail shelves as of that date, the same process applied when the 300 parts per million standard took effect in 2009. And it had the same effect and disruptive effect at the retail level.

This is not the norm for product regulation in other government agencies where normally—even at the CPSC as well—normally, manufacturers are given lead time to plan for the new regulation, to redesign their products, to absorb the costs in a more orderly fashion, and to work out their inventory so that products sold after the effective date reach retail shelves in a compliant fashion. That is the proper, orderly way to regulate products for safety improvement, not to disrupt the market with these very abrupt changes that do not permit that kind of orderly transition.

Mrs. BONO MACK. Thank you. Ms. Cox——

Ms. COX. Could I make a brief comment there?

Mrs. BONO MACK. No, I would like to move on. I have limited time and I do have a question for you, though. And you do mention that the FDA's warning about lunchboxes containing lead claiming that FDA interpreted CPSC's data differently than CPSC itself. How many lunchbox recalls did FDA order after it reviewed CPSC's data?

Ms. COX. This happened a long time ago but my recollection is there were not recalls but just a warning letter sent to lunchbox manufacturers telling them to fix the problem.

Mrs. BONO MACK. I guess you mentioned this in your testimony that your discussion of lunchboxes suggests that FDA would disapprove of a risk-based lead standard and insist on a total lead content standard, but in fact they don't have any total content standard for lead, do they?

Ms. COX. I actually think the example of the lunchboxes shows that, you know, one of the big advantages of the total content standard, it provides a clear, consistent number which manufacturers, retailers, regulators, everybody knows what the threshold is. I mean one of the issues with the lunchboxes was that it occurred pre-CPSIA, and so different agencies interpreted the results of the risk-based testing in different ways. And what we have now with CPSIA is a clear standard and lunchboxes all across the country—I have tested a lot of them over the last couple of years, and they are great.

Mrs. BONO MACK. All right——

Ms. COX. They comply with the standards.

Mrs. BONO MACK. Thank you. Ms. Millar, why isn't a total lead standard as health-protective as an exposure-based standard?

Ms. MILLAR. The risk to a child or to any consumer is based on actual handling and use. One of the assumptions that is incorrect that is underlying CPSIA is the notion that 100 percent of lead and substrate will migrate out of the product. That is actually not true and the CPSC's own data demonstrates that actual migration rates are generally very low, even in worst-case, 24-hour acid ingestion test conditions. That is why we think that total content—and I think Mr. Howell expressed it this morning—can be useful as a benchmark screen, but absolute limits that ban products that actually don't result in exposure of the sort that Mr. Vitrano and Ms. Jones talked about this morning do serve to essentially ban products that are objectively safe because they don't result in significant harmful exposure to the consumer who is handling the product.

Mrs. BONO MACK. Thank you. Mr. Butterfield, you are recognized for 5 minutes.

Mr. BUTTERFIELD. Thank you very much. Let me go to you if I can, Ms. Cox. In your testimony you state that exposure assessment testing is a subjective process, open to interpretation and manipulation. Is that a fair characterization of your statement, that it is subjective as opposed to objective?

Ms. COX. It is definitely subjective, yes.

Mr. BUTTERFIELD. All right. And the gentlelady on the first panel, Dr. Beck, testified and supports the risk assessment, seems to provide support for your view as well. Her written testimony that she submitted indicates that assessing risk is highly contextual and hinges on a number of factors.

Dr. Beck testified that you would want to know a lot of different things. You would want to know what the product is, how frequently a child interacts with the product, the duration of the interaction, will the child likely bite or suck on the product, will the child touch the component, how large an area the child will touch, and so forth and so on. That is about seven separate pieces of information that Dr. Beck identified. And I can add a couple more. How old is the child and in what stage of development is that particular child? What is the nutritional status of the child? Does the child have certain genetic traits that will lead to greater absorption? And so forth. It seems to me that perhaps the only person who could know all of these things and come up with that type of risk assessment would be someone who is superhuman.

Let me start with one simple question. Is it correct that with a lead content limit, a manufacturer or a retailer only has to know the answer to one simple question, how much total lead is in the component?

Ms. COX. Yes, that is correct. And just to reinforce what I said earlier. That allows the manufacturer or anyone in the supply chain to specify to their suppliers the type of material that they need.

Mr. BUTTERFIELD. Dr. Beck also in her testimony asserted that a standard based on soluble lead is generally preferable to a standard based on total lead. And as I understand it, total lead is a measure of how much lead is in a component, period. This is the measure required by the legislation. Solubility, on the other hand, refers to the amount of lead released from a component under certain specified conditions. Is it correct, Ms. Cox, that the conditions for measuring solubility are not consistent? That is they could choose to vary the time, temperature, and the solution that is used, whether to agitate the solution and so on. Would you elaborate on that, please?

Ms. COX. I think I could just say that I have actually heard people in the laboratory and testing industry say that if something complicated like a solubility test or other exposure-based testing was required that there actually wouldn't be lab capacity enough to be able to do these tests because they are so much more complicated and time consuming than a simple test for lead content.

Mr. BUTTERFIELD. Will changing even one of these conditions affect the amount of lead that will be released during the test?

Ms. COX. I think—yes, I am not a lab specialist but that is my understanding, yes.

Mr. BUTTERFIELD. All right. My next question is—I guess I have time to do it. Let me try this. In your testimony, Ms. Cox, you point out that a total lead content limit allows companies to specify materials that meet the standards when contracting with suppliers. If I understand you correctly, a manufacturer can tell his or her metal supplier, I want to buy metal from you but only metal that contains no more than 300 parts per million and a supplier would be able to easily fill that order as specified. Could you respond?

Ms. COX. Correct. In the exposure-based testing you can't do until the product is completed, so that would happen at the very end of the manufacturing process, whereas with the total content, you can specify the content of all the materials and components that are used in a product. So it allows you to do it sort of premanufacture rather than having to potentially reject a product after it is already made.

Mr. BUTTERFIELD. All right. All right, Madam Chairman, I yield back.

Mrs. BONO MACK. Thank you, Mr. Butterfield. And now I would like to recognize Ms. Blackburn for her 5 minutes.

Mrs. BLACKBURN. Thank you so much. And thank you all for your patience today.

Ms. Cox, I enjoyed listening to your testimony and especially that you used Curious George. I have got a 3-year-old and a 2-year-old grandchild and that is one of their favorites. Let me ask you some-

thing. Do you find more lead in products that we import or products that are domestically manufactured?

Ms. COX. I think probably everybody here is aware that virtually all the products on the shelves of major national retailers are products that are not made in this country. So, you know, when we find products that exceed CPSIA limits, it is not surprising that that is also true.

Mrs. BLACKBURN. OK. In listening to your testimony and the testimony of others, it has been kind of curious—and Mr. Vitrano and Ms. Jones, I will ask you. With motorcycles and bicycles, do you all find more lead in those that we import or those that are domestically produced?

Mr. VITRANO. All the major manufacturers of ATVs actually produce many of the models in the U.S. itself.

Mrs. BLACKBURN. OK.

Mr. VITRANO. Some models are made by those companies from outside the U.S. and——

Mrs. BLACKBURN. Well, maybe that they are domestically produced is one of the reasons we have less lead in a wipe test than in a glass of water. Ms. Jones, bicycles?

Ms. JONES. Most children's bicycles are not made in this country any longer.

Mrs. BLACKBURN. OK. And so you don't see that as being pertinent to what you all do?

Ms. JONES. We do not see that as being pertinent.

Mrs. BLACKBURN. OK. That is fine. You know, I have wondered if maybe since we have driven manufacturing out of this country is one of the reasons we are here having this hearing today and talking about the amount of metals that are there and some of the environmental litigation that has been brought forward and has driven manufacturing away from our shores. Maybe that is one of the reasons that we are here.

And I know, Ms. Cox, that the Center for Environmental Health uses litigation quite frequently under California's Prop 65 warning requirements. And I know that you all do some work and wanted to ask you, do you all get a bounty for identifying violations under Prop 65 labeling laws?

Ms. COX. Proposition 65, for those of you who don't know, was a ballot initiative in California in 1986——

Mrs. BLACKBURN. Yes, but you identify violations under that, so do you all get a bounty?

Ms. COX. The statute, as passed by the voters, provides for if the statute is violated, there are civil penalties that are paid to the State——

Mrs. BLACKBURN. Yes, I have got some of them in front of me——

Ms. COX [continuing]. And the plaintiffs who identify the violation is entitled to 25 percent of those civil penalties.

Mrs. BLACKBURN. OK. So I have got an exhibit in front of me that identifies some of these. So if one type of fashion accessory listed above is checked, it would be $45,000 in that identification. So you all would get 25 percent of that if you identified those.

Ms. COX. 25 percent of the civil penalties.

Mrs. BLACKBURN. OK. All right. So 25 of the 45,000. So, OK, is this a funding revenue stream for your organization?

Ms. COX. My organization has a diverse source of revenue. Like most nonprofit organizations, we receive grants from foundations. We also have a strong committed group of individual supporters who support us financially. And then we do get some money from our litigation as well.

Mrs. BLACKBURN. Is that with the Lexington Law Group? Is that under a consent decree?

Ms. COX. Could you repeat the question? Sorry.

Mrs. BLACKBURN. I said is that with the Lexington Law Group, your litigation? OK. Let us move on. So then you get some money that comes to you through identifying these violations and most of the product, I guess, that you are looking at is things that are imported and they are on the shelves of major retailers, is that correct?

Ms. COX. Yes.

Mrs. BLACKBURN. And how many lawsuits have you partnered with the Lexington Law Group?

Ms. COX. Let us see. There were a lot of questions there.

Mrs. BLACKBURN. Yes, let me help you out with this. My time is nearly out. What I would like to know—and you can submit in writing—I would like to know what percentage of your funding relates to litigation. I would like to know how many lawsuits you have partnered with the Lexington Law Group. And I would like to know how much money you have made, what your revenue stream is from Prop 65 lawsuits in violations since the passage of CPSIA. And with that, Madam Chairman, I yield back the balance of my time.

Ms. COX. Yes, I think it probably would be best for me to provide that information in writing since it is a lot of numbers.

Mrs. BLACKBURN. Yes, ma'am, I was asking for it in writing.

Ms. COX. I would be happy to do that.

Mrs. BLACKBURN. For the record.

Mrs. BONO MACK. Thank you. The chair is happy to recognize Mr. Pompeo for 5 minutes.

Mr. POMPEO. Thank you, Madam Chairman. Following up on Ms. Blackburn, would you submit all of the sources of funding for your organization when you put that in writing to us, not only that that you get for Prop 65 but other sources for funding for the center, the CEH?

Ms. COX. Yes, I would be happy to.

Mr. POMPEO. Thank you.

Ms. COX. And just to clarify, the work that I talked about in my testimony, monitoring for CPSIA compliance, that money came from the California Department of Justice, California Attorney General.

Mr. POMPEO. So governmentally funded, is that right?

Ms. COX. Sorry?

Mr. POMPEO. Government funding from the State of California?

Ms. COX. It went through a private foundation but the source of the money was the attorney general's office.

Mr. POMPEO. Thank you. Ms. Millar, this is fascinating to me. I am new here. This is all very fascinating. You, on the other hand,

you get paid by your clients and you are here today trying to avoid them paying you by reducing the regulatory burden. I find that fascinating to see the charitable effort you are making here today. Yes, no, I truly meant it that way. I meant it as a compliment.

Ms. Jones, you said that you have a problem with metal alloys in the bicycle industry?

Ms. JONES. Yes, sir.

Mr. POMPEO. Why do you use metal? Just why don't you stop using it?

Ms. JONES. Metal alloys add a great deal of important value to bicycles. They help the bicycle be corrosion-resistant, they help them be strong and durable, and we really couldn't make bicycles without them.

Mr. POMPEO. So there is no substitute?

Ms. JONES. Well, no, that is not true. There are substitutes, for example, carbon fiber. Some very high-end racing bikes for adults are made of carbon fiber but they would be way too expensive——

Mr. POMPEO. But I am not going to buy that for my son?

Ms. JONES. You are not going to buy that. It would be too expensive.

Mr. POMPEO. Yes. Yes, my son might like it but I am not going to buy it.

Ms. JONES. There is no affordable, practical substitute.

Mr. POMPEO. Thank you. That is what I figured. We were talking before about these different tests. Mr. Butterfield, Ms. Cox, asked you about some different tests and you said boy, the testing would just be really hard. He was describing these testing would be very difficult, soluble, non-soluble, it would be really hard and inconsistent. Is that right? And so you then said yes, that would be hard, so let us just take a simpler test that probably doesn't really accomplish what we are trying to do. So it is a proxy at best. The perfect testing would be hard and difficult so what everybody defaults to is this simple test that really doesn't get to the true risk of exposure to a consumer of a product. Did I understand your response correctly?

Ms. COX. I would prefer to phrase it as——

Mr. POMPEO. I am sure you would.

Ms. COX [continuing]. The goal——

Mr. POMPEO. I would prefer if you would not rephrase it but simply answer my question.

Ms. COX. The goal of CPSIA was to remove a toxic metal from children's products. And there had been a long history prior to CPSIA of risk-based approaches not being successful, and the lead content standard has been very successful at changing the marketplace and getting lead out of these products.

Mr. POMPEO. I have no doubt. And banning lots of things would make them successful, too. We can always create a test that is over-inclusive and solve a problem. But as you can see from Ms. Jones' comment earlier, we create another one. My son doesn't get to exercise on his bicycle. Ms. Millar, do you have a view on the testing that Mr. Butterfield asked Ms. Cox about?

Ms. MILLAR. Yes. As I said earlier—and I think Mr. Howell alluded to this as well this morning in his testimony—the ability to use total content as screening is an important tool. There is no

question about it. And I think it is true that people do try to target where they can meet a certain limit. It does help in the supply chain. It is not true that total lead tests are always uniform and never varied. We see a lot of different variability in total content test. And I think the problem becomes that when you establish an absolute ban, what we have seen for bikes, for ATVs, for certain, you know, pearlized buttons, for example, have agents in them that are metallic, you can have violations of total content limits where objectively applying standard accepted procedures that the CPSC uses, whether it is a wipe test, a saline test to mimic mouthing, which is a 6-hour-test procedure—they have an established procedure—or their updated 24-hour acid exposure test, you can establish whether or not that product is going to pose a risk. And so the manufacturers are going to always target to some objective limit where they can. The problem is that you are going to ban them where they exceed it where there is not a risk.

Mr. POMPEO. It makes sense. I have got one more question, just 20 seconds. Mr. Vitrano, Ms. Jones, have any of you had any experience responding to a CPS database complaint at this point? There has only been a month. Have any of you had experience responding to——

Ms. JONES. Yes.

Mr. POMPEO. How did it go?

Ms. JONES. We still have a couple in process but, you know, it is certainly something that people pay attention to. They take it seriously. In no case, however, has a client to date had a materially inaccurate incident report submitted to them.

Mr. POMPEO. But they have had to spend a bunch of money talking to you? Thank you. I yield back my time.

Mrs. BONO MACK. I thank the gentleman and recognize the distinguished chairman emeritus, Mr. Dingell, for 5 minutes.

Mr. DINGELL. Madam Chairman, thank you. The questions are to all witnesses and I would very much appreciate it if they would be answered yes or no.

First of all, beginning with Ms. Cox, are you aware of a uniform reasonable methodology in use by manufacturers of children's products to find what is the amount of lead in a product? Yes or no?

Ms. COX. Yes.

Mr. DINGELL. Ma'am, Ms. Millar?

Ms. MILLAR. Yes.

Mr. DINGELL. And you, sir?

Mr. VITRANO. Yes.

Mr. DINGELL. Ma'am?

Ms. JONES. Yes.

Mr. DINGELL. OK. Now, is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products? Yes or no? Ms. Cox?

Ms. COX. Yes.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. No.

Mr. DINGELL. Sir?

Mr. VITRANO. I don't know.

Mr. DINGELL. Ma'am?

Ms. JONES. No, we are not seeing that.

Mr. DINGELL. The next question, if it wouldn't lead to a variance, do you believe that this could pose a risk to the health of the children who use such products? Yes or no? In other words——

Ms. COX. I don't think I am able to answer that question.

Mr. DINGELL [continuing]. Is that variance going to put the children at risk? Well——

Ms. COX. Well, certainly, we need consistent testing.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. I don't see the variability, so my answer is no.

Mr. DINGELL. And you, sir?

Mr. VITRANO. It would depend on the variability.

Mr. DINGELL. Ma'am?

Ms. JONES. And we are not seeing the variability.

Mr. DINGELL. Ms. Cox, do you want to take another shot at it? All right. We will go to the next set of questions because time is very limited here.

We have the term "accredited third-party conformity assessment bodies." I assume that this includes both domestic and international bodies that would do this kind of testing? Am I correct? Yes or no, Ms. Cox?

Ms. COX. Yes.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. Yes.

Mr. DINGELL. Sir, if you please?

Mr. VITRANO. Yes.

Mr. DINGELL. Ma'am?

Ms. JONES. Yes.

Mr. DINGELL. All right. Now, if so, how many such assessment bodies are there worldwide? I don't expect you to know but give me a shot in the dark, the best count you can give. How many do you think there are? Ms. Cox?

Ms. COX. I don't know.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. A couple of hundred, I believe.

Mr. DINGELL. Sir?

Mr. VITRANO. For youth model ATVs there currently is 1.

Mr. DINGELL. Ma'am?

Ms. JONES. For bicycles there are only two in the U.S. and about a half-dozen outside of the U.S.

Mr. DINGELL. Thank you, my friends. Does the Commission have the resources with which to verify the testing capacity of all of these third-party conformity assessment bodies? Yes or no? Ms. Cox?

Ms. COX. I don't know.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. I don't know.

Mr. DINGELL. Sir?

Mr. VITRANO. I don't know.

Mr. DINGELL. Ma'am?

Ms. JONES. I don't know.

Mr. DINGELL. Now, is it your understanding of the draft legislation that the Commission would have to accredit all third-party conformity assessment bodies? Yes or no?

Ms. COX. I don't know.

Mr. DINGELL. In other words, would they have discretion under the legislation to decide who they would accredit and how and why they would accredit? Yes or no?

Ms. COX. I don't know.

Mr. DINGELL. Ma'am?

Ms. MILLAR. I don't know.

Mr. DINGELL. Sir?

Mr. VITRANO. I don't know.

Mr. DINGELL. Ma'am?

Ms. JONES. I don't know.

Mr. DINGELL. All right. Now, in summary, do you believe that the effect of these requirements would be that the Commission would seldom, if ever, require third-party testing of children's products? Yes or no?

Ms. COX. I don't know.

Mr. DINGELL. Ma'am?

Ms. MILLAR. I don't know.

Mr. DINGELL. Sir?

Mr. VITRANO. No.

Mr. DINGELL. Ma'am?

Ms. JONES. No.

Mr. DINGELL. Now, here are some questions about the database which are troubling us. And everybody, I think, is troubled. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of the accuracy of the information? Yes or no? Ms. Cox?

Ms. COX. I don't know.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. Yes.

Mr. VITRANO. Yes.

Ms. JONES. Generally, yes.

Mr. DINGELL. Thank you. Now, should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published? Yes or no? Ms. Cox, please? What is your opinion, just your best judgment on the matter, please?

Ms. COX. These questions are outside my expertise.

Mr. DINGELL. All right. Then I will not press you on it, ma'am. Ms. Millar?

Ms. MILLAR. Yes.

Mr. DINGELL. Mr. Vitrano?

Mr. VITRANO. Yes.

Mr. DINGELL. Ms. Jones?

Ms. JONES. Yes.

Mr. DINGELL. All right. Now, if a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should the dispute be resolved and by whom? If you please, Ms. Cox?

Ms. COX. I don't know.

Mr. DINGELL. Ms. Millar?

Ms. MILLAR. I think the CPSC should resolve the inaccuracy before posting the complaint to the database.

Mr. DINGELL. Mr. Vitrano?

Mr. VITRANO. CPSC should resolve it before posting.

Mr. DINGELL. Ms. Jones?

Ms. JONES. CPSC should resolve it before posting.

Mrs. BONO MACK. The gentleman's time has expired.

Mr. DINGELL. I thank you, Madam Chairman. I have one more great question. Could I ask unanimous consent to ask it, please?

Mrs. BONO MACK. Yes, without objection.

Mr. DINGELL. Thank you. The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe that the draft legislation's narrowing of eligibility to submit the complaints is necessary? Yes or no?

Ms. COX. Not necessary.

Mr. DINGELL. OK. Ms. Millar.

Ms. MILLAR. Necessary.

Mr. DINGELL. Mr. Vitrano?

Mr. VITRANO. Yes, it is necessary.

Mr. DINGELL. Ms. Jones?

Ms. JONES. Yes, it is necessary.

Mr. DINGELL. Madam Chairman, you have been most courteous. May I have an additional unanimous consent request? I have a splendid statement that I have labored long and hard on.

Mrs. BONO MACK. I have nothing but fondness and admiration for the distinguished chairman, but we still have another member and another panel to go and votes on the floor. So I will——

Mr. DINGELL. I am not delaying——

Mr. BUTTERFIELD. Madam Chair——

Mr. DINGELL [continuing]. Madam, I have a statement I would like to put in the record.

Mr. BUTTERFIELD. Whenever the chairman emeritus talks like that, he has a pleasant surprise for us. I would ask unanimous consent to yield to the chairman emeritus.

Mr. DINGELL. Thank you very much. No, it is just a statement that I want to put in the record, Madam.

Mrs. BONO MACK. Of course. Without objection.

[The information follows:]

Statement of
Representative John D. Dingell
Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
Hearing on "H.R. __, a bill to revise the Consumer Product Safety Improvement Act of 2008"

April 7, 2011

Thank you, Madam Chairman, for holding this important hearing. My concerns about the impracticability of certain provisions in the Consumer Product Safety Improvement Act (CPSIA) are a matter of public record and need not be revisited here. I commend you, Madam Chairman, for circulating draft legislation meant to remedy these concerns. I hope the Committee's deliberations on this matter will yield bi-partisan legislation that maintains the tenor of CPSIA's landmark consumer protections, yet at the same time grants the Consumer Product Safety Commission greater administrative flexibility and facilitates compliance with the Act.

I wish to stress that my support of legislation to amend CPSIA is contingent to a great extent on such legislation's having bi-partisan support. Further, my interest with respect to this Act has always been to avoid intractability in the face of common-sense ways to make CPSIA workable. To that end, I urge my colleagues on both sides of the aisle to cooperate on this matter, engage stakeholders, and produce a bill – much like the House's Consumer Product Safety Modernization Act – that the Committee and House will unanimously approve.

I look forward to hearing our witnesses' thoughts about the legislation pending our consideration today, as well as their general advice for addressing what some consider CPSIA's apparent shortcomings.

Thank you for your courtesy, Madam Chairman, and I yield back the balance of my time.

Mr. DINGELL. And I do thank my good friend for his kindness to me. Thank you, Madam Chairman.

Mrs. BONO MACK. Thank you. And reminder, I am new at this chairmanship, so I appreciate the kindness of the distinguished chairman emeritus but will recognize Dr. Cassidy for 5 minutes.

Mr. CASSIDY. I don't know. I am sorry. I was out when you all were making testimony so I don't know if anyone can address what I am about to ask. As I look at the epidemiology of lead poisoning, it seems to be not generally distributed, but it seems to be in certain populations. Those which are recent immigrants, for example, appear to have a disproportionate amount of lead toxicity. And in fact I was looking at something from a hospital in Los Angeles that found even within the Hispanic community there, there was three ZIP codes which were particularly impoverished ZIP codes in which there was even more. Now, assuming that toys are generally distributed but that the people who have problems with lead toxicity are concentrated in certain areas, it suggested to me that the culprit for those children who have increased lead, it may be geographic or related to how recently they came from another country without standards than it is almost anything else.

I toss that out not knowing if anyone can answer that or if these are just musings. Anybody want to take a crack at that?

Ms. COX. I will take a crack at it. Exposure to old lead-based paint in homes is the primary source of lead exposure to children, and that has been the case for several decades. Current statistics are about 70 percent of elevated blood lead levels in children are caused by exposure to paint. The other 30 percent are not. Further——

Mr. CASSIDY. Now, wait. I am sorry. Just so I understand, so if you have a blood level of 100, just to pick a number, does that mean that 70 percent of that 100 is related to paint exposure and 30 percent to another environmental factor or does it mean that 70 percent of the children that have elevated lead levels have it due to paint?

Ms. COX. 70 percent of the children with elevated blood lead levels, they are able to trace back that exposure to paint.

Mr. CASSIDY. So the 30 percent, is that those for whom no point source can be identified or those for whom another point source is identified?

Ms. COX. In general, when there is a child with an elevated blood lead level, there is a huge effort to identify the source. So the number of unidentified ones is really small.

Mr. CASSIDY. And so again, as I look at this concentration among recent immigrants, it suggests to me that recent immigrant status is a separate factor. I did my medical residency in Los Angeles and we used to see all these diseases from other countries in Los Angeles, very odd diseases that we wouldn't see in Washington, D.C., for example, even though this is also a place of immigrants. So I guess to what is the impact of immigrant status? Is there exposure to lead that is occurring south of the border that we are importing?

Ms. COX. I am not aware of any statistics about immigrant status and lead exposure. I do know that because the deteriorating paint is a factor, you know, living in older housing or housing——

Mr. CASSIDY. OK, I got that.

Ms. COX [continuing]. That is not well-maintained——

Mr. CASSIDY. The 30 percent of folks for whom paint is not a factor—and I should know this but I have been trying to track it down and I apologize—what percent of those have a point source identified and what are those point sources?

Ms. COX. The point sources tend to be lead in soil, lead in water, and then lead in various kinds of consumer products.

Mr. CASSIDY. What, for example?

Ms. COX. Examples of consumer products?

Mr. CASSIDY. With lead that have been identified as a risk for children.

Ms. COX. Jewelry, toys, there is some lead-containing makeup that has been a problem. There is lead-containing foodware that has been a problem——

Mr. CASSIDY. I assume that some of this, though, must be older stuff. I mean I can remember playing with lead when I was a kid. Obviously, my mother didn't care for me. I am assuming that much of what is now available with or without these regulations that lead is gone. Is that a fair statement? I am looking at all of you all now because I can only imagine that my pencil that I used to chew on in third grade probably had lead in it.

Ms. COX. The regulation of lead over the last 40 years has been, you know, one of the country's greatest public health successes. So removing lead from paint, removing lead from gasoline, and then removing lead from other consumer products has had a dramatic reduction in the number of children with elevated blood lead levels. The goal of CDC was to get that level to 0 by 2010. It hasn't quite happened but——

Mr. CASSIDY. And if it is true that immigrants are the cause of a lot of this, it will never happen. I just say that because our tuberculosis problem will never go to 0 as long as we have people immigrating from Mexico because it is just endemic there. I am just trying to understand to what degree can we attribute products, you know, toys for this as opposed to everything else? Thank you for your time. Thank you.

Mrs. BONO MACK. I thank the gentleman and that concludes the panel. And I would like to thank Ms. Cox and Ms. Millar, Mr. Vitrano, and Ms. Jones for your time and testimony today. And I am sure we will be working together in the future on refining this legislation.

Mr. BUTTERFIELD. Madam Chairman, may I be recognized before the panel leaves?

Mrs. BONO MACK. Yes.

Mr. BUTTERFIELD. Earlier Ms. Blackburn requested Ms. Cox, if she would furnish financial information for her nonprofit organization, and at first I had a little heartburn about that, but after I thought about it, it is an appropriate request. It goes to her credibility as a witness today. As a former judge I guess I should know that. But I was wondering if it would be appropriate to ask the other three witnesses if they would similarly furnish the sources of their revenue for their organizations that they represent.

Mrs. BONO MACK. Well, I will remind the gentleman that you can submit any question you would like to any witness and that you have 10 days to do so and remind the gentleman also that

Members of Congress are allowed to ask any question that they would like of any witness and again remind you that you have that prerogative to do that in writing to the witnesses. And with that, again, if the gentleman will yield back.

Mr. BUTTERFIELD. He will. Thank you.

Mrs. BONO MACK. I thank the panelists again and would call for the third panel if we can get seated. We are going to have votes shortly on the floor so we would love to get started and see how much progress we can make. So a short break and then we will roll into the third panel.

Thank you. That was a quick transition. Thank you, staff. So now the third panel, I would like to thank you all very much for being here. We have the final four witnesses. First up, we have Frederick Locker of Locker, Greenberg, and Brainin, P.C. Our next witness is Charles Samuels of Mintz, Levin, Cohn, Ferris, Glovsky, and Popeo, P.C. Also testifying will be Dan Marshall, Vice President of the Handmade Toy Alliance. And our fourth panelist today is Rachel Weintraub, Director of Product Safety and Senior Counsel for the Consumer Federation of America. Welcome everybody. You know the drill, 5 minutes, and you know where the lights are so we are going to begin, Mr. Samuels, with your 5 minutes. Thank you and welcome.

STATEMENTS OF CHARLES A. SAMUELS, MEMBER, MINTZ, LEVIN, COHN, FERRIS, GLOVSKY, AND POPEO, P.C.; FREDERICK LOCKER, LOCKER, GREENBERG, AND BRAININ, P.C.; DAN MARSHALL, VICE PRESIDENT, HANDMADE TOY ALLIANCE, AND CO–OWNER, PEAPODS NATURAL TOYS AND BABY CARE; AND RACHEL WEINTRAUB, DIRECTOR OF PRODUCT SAFETY AND SENIOR COUNSEL, CONSUMER FEDERATION OF AMERICA

STATEMENT OF CHARLES A. SAMUELS

Mr. SAMUELS. Thank you, Chair Bono Mack, and members of the subcommittee. Thank you for the opportunity to testify. I have the privilege of serving as general counsel of the Association of Home Appliance Manufacturers, as well as representing companies on product safety matters.

I support a fully resourced, focused, and effective Commission with the tools to protect Americans from unsafe products. I supported the revamping of the federal product safety laws and I respect the hardworking and dedicated officials at the Commission. Unfortunately, parts of the law are overreaching, over-prescription, and distort the Agency's mission to the detriment of consumers and industry. The discussion draft makes great strides towards remedying the imbalances and deficiencies in the current law without doing violence to the core public policies.

I will focus on the database provision. Technology should be used to disseminate good and easily accessible information to consumers about product safety. It makes no sense, however, for so much of the resources of the Commission to be invested in this effort unless it provides useful and accurate information to the extent feasible. We cannot expect perfection, but we now have a database that can

be manipulated for purposes other than that intended. Vague, useless, and incorrect information can be placed online. This not only harms manufacturers, retailers, and importers, but harms consumers who receive bad information and cannot focus on truly unsafe products. Discrete changes can be made to the law, which will greatly improve the operation, utility, and fairness of the program.

First, the intent of the law is that posted reports of harm will come from those who suffer the harm, their family and legal and medical representatives. The database should not be a platform for manufacturers, trade associations, trial lawyers, or consumer groups who are trying to make policy points or enhance their economic status.

I support the tighter definition of "consumers" to restrict it to the persons who actually suffer the harm related to the use of the product and their representatives. I also support revising the term "public safety entities" that make clear that you are referring to public safety officials.

The requirement that the Commission ascertain the location and availability of a product is important for the manufacturer to evaluate the complaint or for the Commission to look further at the allegations. The Commission also should know the identity of the person who allegedly was harmed.

A major deficiency of the database is the agency decision to publish the report regardless of whether a good faith, substantial claim of material inaccuracy has been submitted but has not been resolved within 10 days. This is unfair, a lack of due process and absolutely not what we should be expecting from our Federal Government. We have great freedom in this country to blog and publicly report bout almost anything without much legal restriction, but the government should show more prudence and responsibility.

The draft properly provides that if a manufacturer claims a material inaccuracy and the Commission determines that the claim is "potentially valid," the Commission must resolve that inaccuracy before posting by communicating with the reporter, investigating the incident, or providing the manufacturer a reasonable period of time to investigate. This does not need to be a lengthy process. It is likely the vast majority of database reports will receive little or no response and, at most, there will be a response suitable to be placed on the database along with the consumer report. But in those cases where a company has gone to the trouble to evaluate and provide proof that a report is materially inaccurate, that ought to be resolved before the report is posted. Once it is posted, pulling it from the database later is of very limited utility and great harm can be done.

The existing database also is deficient in that it allows reports which are so unspecific as to a particular model that the information is useless, even deceptive. I support the language in the discussion draft that a manufacturer may respond that the report is insufficient for determining which of its products are the basis of the complaint and that that must be determined before the complaint is posted.

The present 10-day limitation for companies to evaluate and respond to a report and the Commission to resolve any issues is extraordinarily short and unreasonable. Even well-organized compa-

nies will have difficulty dealing with this time frame. Therefore, I recommend that the 10 days be increased to at least 15 days, which will have no material impact on the timing of postings or the value of the database.

Also, there is an indication that the Commission may be limiting its review of material inaccuracy only to those situations where there has been a misidentification of the product. That is definitely not the extent of material inaccuracy. The Commission's regulations state that material inaccuracy includes all relevant facts which significantly impact a consumer's decision on whether to purchase a product and that includes causation.

Congress should make clear to the Commission that second- and third-hand reports do not constitute reports of harm eligible for the database. And simple consumer complaints of dissatisfaction about the quality or performance of the product which are not safety-related should not be posted.

I hope that these comments are helpful. I would be pleased to answer your questions. Thank you.

[The prepared statement of Mr. Samuels follows:]

Testimony of

Charles A. Samuels

Before the House Energy and Commerce Committee,

Subcommittee on Commerce, Manufacturing and Trade

Hearing on Draft Bill to Revise the

Consumer Product Safety Improvement Act

April 7, 2011

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April 7, 2011

Summary

The CPSIA is an important contribution to consumer product safety. It has a number of defects, however, in that it is over-prescriptive, unduly restricts Commission discretion and lacks proportion and balance in dealing with safety risks. The draft legislation goes far in remedying these deficiencies while maintaining the strengthened and new authorities.

The concept of a publicly available database makes sense in the internet age as a tool for consumers. Unfortunately, this database, as prescribed by Congress and developed by the Commission, is not well designed to provide useful, accurate information to consumers or manufacturers. The existing database procedures do not comport with the original intent of the CPSIA which is that reports should only be posted from those who are harmed, their family or representatives or actual public safety agencies. Nor do the CPSC procedures require resolution of well-founded claims of material inaccuracy before reports are posted or require sufficient information such that manufacturers can respond to and evaluate the reports. The draft legislation resolution goes a long way to resolve these issues.

The legislation's tightening of the definitions of who may report on the database will improve and focus the database while retaining the important roles of consumer groups, trial attorneys, and industry representatives on CPSC matters. The legislation's requirements for resolution of claims of material inaccuracy before posting on the internet will add quality and fairness to the database, and the procedure for ascertaining specific models will enhance the value of the program to consumers, manufacturers and CPSC.

April 7, 2011

Testimony of
Charles A. Samuels
Before the House Energy and Commerce Committee,
Subcommittee on Commerce, Manufacturing and Trade
Hearing on Draft Bill to Revise the
Consumer Product Safety Improvement Act

Dear Chair Bono Mack and Members of the Subcommittee:

Thank you for the opportunity to testify on this important matter. Product safety regulation has been at the center of my professional interest for 25 years. I have the privilege of serving as General Counsel for the Association of Home Appliance Manufacturers and have represented many individual companies – manufacturers, retailers and importers -- before the CPSC and in Canada, Europe and elsewhere on product safety matters. Like my colleagues on this panel, I am a strong supporter of a fully resourced, focused and effective Commission which has the tools to protect Americans from unsafe products.

That is why I supported the revamping of the federal product safety laws which led to the Consumer Product Safety Improvement Act, and I believe that many of the provisions in the law were necessary and appropriate. The hard working and dedicated career and political officials at the Commission have been laboring to interpret and implement the new requirements.

Unfortunately, as well intentioned as it was, the legislation contains elements of over-reaching, over-prescription and distortion of the Agency's mission and obligations in ways that do not well serve consumers and are a great burden on regulated industry. There was a lack of appreciation that many of the issues that arose during the so-called "year of the recall" were mostly violations of existing law which simply needed full implementation and compliance.

The March 29, 2011 discussion draft makes great strides towards remedying the imbalances and deficiencies in the current law. Yet, the draft also does not do violence to the

core provisions of the law and, in my view, in some respects does not go far enough. Obviously, compromises and moderation are necessary to reach agreement and this draft is an excellent start. All the essential provisions of CPSIA would be intact and would be implemented as contemplated but in a more reasonable fashion. Like much legislation, 90 percent of the benefits of CPSIA are achieved with reasonable application of the core provisions and the more extreme or unreasonable provisions or interpretations of those provisions create great problems with little consumer benefit. This bill goes far to remedy that imbalance.

The Commission must remain capable of carrying out its mission and, where necessary, added authority and resources are appropriate. I support the expanded subpoena powers in Section 9 of the draft. Also, I support strengthening the provisions that make it unlawful for anyone, including industry, trial lawyers, consumers, or consumer groups, to make misrepresentations to the Commission regarding, but not limited to, the database. Our federal product safety system relies extensively on honesty and good faith reporting and where there are breaches of that obligation they should be penalized.

I will focus on the database provision. I support the policy that modern technology should be used to disseminate good and easily accessible information to consumers about product safety. Even under the law prior to CPSIA that type of database could have been created. In CPSIA, you instructed CPSC to build such a platform.

It makes no sense, however, for so much of the resources of this Commission to be invested in this effort unless it provides useful and quality information to the extent feasible. The database will never be perfect and it is unreasonable and not necessary that every piece of information placed on it be fully vetted beforehand by the CPSC. But, due to the over prescription in the legislation and some unfortunate interpretations by the Commission, we have

a database that can be manipulated for purposes other than that intended. Also, vague, useless and incorrect information can be placed on the database. This not only harms manufacturers, retailers and importers whose products are impugned but harms consumers who receive bad information and are not able to focus on those products where there are real safety problems.

Fortunately, discrete but significant changes can be made to the current law, as exemplified in this draft, which will greatly improve the operation, utility and fairness of the program while maintaining its essential characteristics to provide quick, useful information to consumers.

First, the spirit and even the letter of Section 6A(b) of the Consumer Product Safety Act requires that posted reports of harm should come from those who suffer harm or risk of harm, their family members, legal representatives and those in a position to directly know about the incident. Although they play huge roles in the activities of the CPSC, the database should not be a platform for the submissions of manufacturers, trade associations, trial lawyers or consumer groups who are trying to make policy or regulatory points, enhance their economic or competitive opportunities or advantages or simply provide third or fourth hand information. All of these folks, including myself, have important roles to play with the CPSC but not as reporters.

Therefore, in Section 8(a)(1)(A) of the draft bill, I support the tighter definition of "consumers" to restrict it to the persons who actually suffer harm or risk of harm related to the use of the product, their next of kin or members of their household, legal representatives or another person expressly authorized by any such person. The latter could be an advocacy group or anyone else.

I also support striking the term "public safety entities" which, unfortunately, the Commission has misconstrued, and making clear that you are restricting the reports to police,

fire, ambulance, emergency services, law enforcement and related public safety officials. Section 8(a)(1)(B) of the draft bill. Many of us consider ourselves to be representatives and advocates of public safety but this provision ought to be focused on governmental and health authorities and the like.

These revisions do not mean that the interest and information of competitors, trial lawyers and consumer groups are or should be irrelevant to the Commission. Certainly, those are sources of information that the Commission should gather and evaluate when considering whether there should be regulatory action or if there has been a violation of the law, a substantial product hazard or a defect, but such information, which is often indirect and biased, should not be presented to the public through the database. It, of course, may be disclosable through FOIA. Trial lawyers and consumer groups have sufficient means to present their views and do not need a government platform.

The requirement that the Commission attempt to ascertain from the reporter the location and availability of the product is an important requirement. Section 8(a)(2)(A) of the draft bill. For a manufacturer or retailer to attempt to respond and evaluate the complaint, or for the Commission to look further at the alleged incident, such information can be critical. We should all want the database to be used by manufacturers and retailers to consider whether there is a situation that needs to be remedied. Similarly, if the report is made by someone other than the victim, then the CPSC should know who the actual person harmed is. This is critical for follow up by the Commission and, where the identification is released, for follow up by retailers and manufacturers.

One of the major but unnecessary deficiencies of the database, as it has been implemented by the Commission, is the erroneous agency decision to publish the report

regardless of whether a good faith, substantial claim of material inaccuracy has been submitted but it has not been resolved within 10 days. This is unfair, a lack of due process and absolutely not what we should be expecting from our federal government. We have great freedom in this country to blog and publicly report about almost anything without much legal restriction, but the government should show more prudence and responsibility.

The draft properly provides that if a manufacturer notifies the Commission of a material inaccuracy in a report and the Commission determines that the claim is "potentially valid," the Commission must resolve that inaccuracy before posting. Section 8(b)(2)(B)(ii) of the draft bill. The Commission may communicate with the reporter, investigate the incident or provide the manufacturer a reasonable period of time to investigate and resolve the material inaccuracy claim. This should not be and does not need to be an endless process. It is highly likely, as was reported during the soft launch/pilot, that the vast majority of database reports will receive little or no response from the manufacturer and at most there will be a response suitable to be placed on the database along with the consumer report. But, in those cases where a company has gone to the effort to evaluate and provide positive proof that a report is materially inaccurate, that ought to be resolved before the report is posted. Once a posting is made, pulling it from the database later is of limited value given the realities of how the internet works and how it may already have affected consumers.

The database as now implemented also is significantly deficient in that it allows consumers to report allegations about products which do not specify a particular model of a product such that the information is useless, even deceptive, to the public and impossible for companies to evaluate. Under their corporate names and brands, many manufacturers and retailers have multiple -- dozens -- of models, which can be quite different, often manufactured

in different places. A database report that Brand A caused harm, when there may be many models and types of Brand A, makes meaningful response by the manufacturers, even putting explanatory material on the database, and internal evaluation often impossible. Therefore, I support the language in the discussion draft that a manufacturer may respond that the report is insufficient for determining which of the manufacturer's products are the basis of the complaint. Section 8(b)(1)(i) of the draft bill. But, a company must provide information to assist the person submitting the report to sufficiently identify or provide an adequate description of the report. If manufacturers sufficiently document this issue then the Commission should be able to work with the consumer to provide that information before the posting is made. Submitters should be required to provide a serial or model number where available and tracking label information for children's products.

I am confident that under these provisions a very high percentage of the reports still will go on the database very quickly, some with explanatory information from the companies. A small percentage -- where the product has been misidentified or where there is proof that the product did not or could not have caused the harm -- should be resolved in an expeditious way by the Commission which is experienced to do so. There should be a high but not impossible hurdle for companies to demonstrate why material should not be posted.

In this regard, the present 10-day limitation for companies to evaluate and respond to a report and for the Commission to resolve any issues is extraordinarily short and unreasonable. Even well-organized companies will have difficulty dealing with some of these reports, particularly where they are fragmentary and where no consumer identification is provided. I recommend that the ten days be increased to 15 days which will have no material impact on the

timing of postings or value of the database to consumers but provide some means or opportunity for companies to consider the information.

Also, there is an unfortunate and inappropriate indication from some at the Commission that, as a practical matter, the Commission is limiting its review of material inaccuracy in a narrow and cramped way to cover only those cases where there has been a misidentification of the product -- i.e., the Company does not make the type of product or the product related to the incident was another brand. Those cases are very important and will be often the simplest to resolve but that is definitely not the limit of material inaccuracy. The Commission's own regulations indicate an understanding that material inaccuracy includes all relevant facts that might significantly impact a consumer's decision on whether to purchase a product and therefore go to issues of causation. According to the CPSC, "materially inaccurate information is a report of harm" with "information that is false or misleading, and which is so substantial and important as to affect a reasonable consumer's decision making about the product."16 C.F.R. §1102.26(a).

It will often be impossible for the Commission to resolve causation issues and make a determination whether there is a material inaccuracy, but sometimes it will be clear and there will be sufficient proof that the product could not have caused the incident or the risk of harm. In those cases, inaccurate information should not be placed on a public database. Again, even if not in the public database, the report will be in the CPSC database for internal evaluative purposes which can lead to an investigation.

It does not require an amendment of the law, but Congress should make clear to the Commission that second and third hand reports do not constitute reports of harm eligible for the database. Also, consumer complaints of dissatisfaction about the quality or performance of the

product which do not relate to a report of harm should not be posted. These are concerning indications in these regards from the early database activities.

I hope that these comments are helpful, and I would be pleased to answer your questions. This important corrective legislation will rebalance the law while fully maintaining the benefits and protections to consumers.

Mrs. BONO MACK. Thank you. Briefly, we are going to go through Mr. Locker and then we are going to run to vote. So 5 minutes, Mr. Locker, please.

STATEMENT OF FREDERICK LOCKER

Mr. LOCKER. OK. Thank you. And I will try to make sure you don't waggle the gavel.

Chairman Bono Mack, Vice Chairman Butterfield, members of the subcommittee, thank you for the opportunity to appear before you on this important subject matter of practical, commonsense solutions—and I emphasize "solutions"—to unintended consequences involved in the implementation of the Consumer Product Safety Improvement Act of 2008, or as it has been come to be known as CPSIA.

Now, our firm works as safety counsel to the Craft and Hobby Association, Toy Industry Association, Juvenile Product Manufacturers Association, Halloween Industry Association, apparel makers, publishers and retailers. And for better and for worse, we have had a lot of experience in the last 2½ years with the problems with implementation of the law.

Now, we have been involved in developing product safety standards over many decades and we have also worked in collaboration with many foundations and consumer organizations to advocate the need for uniform product safety standards and initiatives, both in the United States and globally. We keenly recognize that sometimes in this rush to regulate, attention may be focused on relatively small risks associated with products while some very big risks remain unappreciated and unaddressed. In a world where perception is reality, where misinformation often drives perception, and where new, scary, and uncertain hazards can receive enormous amounts of attention very quickly, it is important to understand context for managing children's risks and for regulating them.

We understand, however, that there is no more important theme than protecting our population of consumers and in particular our children. As much work as we all do, there is always room for improvement in this regard. We may not always agree with everyone appearing before you today on how to achieve our common goals, but we always stand willing, ready, and able to work with everyone for the betterment of children's lives.

Now, in the past appearances before this committee, we have supported the legislative initiatives, including the concepts embodied in CPSIA. However, to the extent that implementation of provisions have resulted in regulations that depart from sensible risk-based decision-making, it has become clear to all involved on both sides of the aisle that Congress needs to act to restore a commonsense regulatory framework. The CPSC has strained under the burden, but despite admonitions from Congress that the agency was empowered with discretion to implement practical commonsense regulations on at least five or six separate occasions in the past, the Commission in a bipartisan fashion has readily acknowledged, as it has today, that its discretion has been limited without statutory changes.

CPSIA adopted an unduly prescriptive regime and as often happens, Congress can act with a sledgehammer instead of a scalpel

when trying to deal with issues. CPSIA adopted a set of absolute total limits on lead and phthalates. This House body, I note, didn't even consider the phthalate legislation that was grafted in the Senate and in conference. These wholesale limits were coupled with an exemption process that we all had hoped would work better but had proved to be impractical for lead and phthalates regulation.

In effect as a result and direct result of that, the stream of commerce and business suffered significantly as the imposition of these requirements was further deemed to apply in a retroactive manner to any previously produced goods entered into commerce when the laws and step-down levels went into effect. These confusing and burdensome testing schemes—which have yet to be fully and clearly enunciated as we sit here today—have resulted in additional marketplace confusion and cost.

So let me share just a few of the comments and proposals on the law that is before us today. Our comments are for the record—but in terms of the budget, it is clear that an era of restrained budgets and limited resources, the CPSC will need to allocate funds based upon risk/hazard analysis and sound scientific principles. In terms of lead, Congress recognized this approach when they adopted as a regulatory requirement, for example, the toy safety standard ASTM F–963 to which Congressman Schakowsky referenced. That standard, by the way, is a soluble migratable standard. It is not a total limits standard and has proved to be remarkably effective both in the United States—which is why Congress adopted it—Europe, and the rest of the world.

Exemptions for certain materials have been adopted by the CPSC but they have not gone far enough. So we favor the types of processes that have been adopted and proposed in the draft resolution in phthalates. In terms of phthalates, they need to have an inaccessibility recognized. There needs to be action on the Chronic Hazard Advisory Panel when they come to conclusions that action has to be quick.

[The prepared statement of Mr. Locker follows:]

STATEMENT OF

FREDERICK LOCKER

BEFORE THE SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

PROTECTING CONSUMERS: CURRENT ISSUES RELATED TO COMMON SENSE PRACTICAL PRODUCT SAFETY REGULATIONS & CPSIA REFORM

April 7, 2011

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Chairman Bono Mack, Vice Chairman Butterfield and members of the Subcommittee, thank you for the opportunity to provide comments about the important subject of practical common sense solutions to unintended consequences involved in the implementation of the Consumer Product Safety Improvement Act of 2008 (CPSIA) (Pub. L. No. 110-314). Our firm works as product safety counsel to the Craft& Hobby Association (CHA), Toy Industry Association (TIA), Juvenile Product Manufacturers Association (JPMA), Halloween Industry Association (HIA), Apparel makers, Publishers and Retailers of an array of children's products. I have been involved with developing product safety standards over many decades through relationships with the National Safety Council (NSC), National Bureau of Standards (NBS), American National Standards Institute (ANSI), ASTM International and International Organization for Standardization (ISO). We have also worked in collaboration with many foundations and consumer organizations and others to advocate the need for uniform product safety initiatives in the U.S. and internationally.

We keenly recognize that sometimes in the rush to regulate attention may be focused on relatively small risks associated with children's products while some very big risks remain underappreciated and unaddressed. In a world where perception is reality, where misinformation often drives perception, and where new, scary and uncertain hazards receive widespread attention, it is no wonder that policy makers can lack context for understanding and managing children's risks. Unfortunately, the net result is that we often collectively waste scarce financial resources at the expense of allocating them efficiently to make children's lives measurably safer. Further, this perpetuates a lack of coordination between groups that are all arguably committed

to helping children; focuses on individual issues and agendas instead of children themselves; and competition rather than cooperation for the resources to truly protect children. There is no more important theme than protecting our children. As much work as we all do, there is always room for improvement. We may not always agree with everyone appearing before you today on how to achieve our common goals, but we always stand willing and committed to work for the betterment of children's lives.

SUMMARY

In past appearances before this committee we have supported important legislative initiatives to expand the authority of the Consumer Product Safety Commission (CPSC) to effectively pursue it's mission of consumer protection. Along these lines, we believe that there are ways to make the Commission more effective and at the same time more efficient. Allow me to share a few proposals on ways the Commission can increase its effectiveness in protecting consumers while minimizing burdens on the manufacturing sector of this country.

CPSC's mission is to protect children and families against an unreasonable risk of injury and death from more than 15,000 types of consumer products from a wide range of product hazards. Their work is vital in that it addresses consumer product hazards through a framework of mandatory product safety standards; engagement in the voluntary or consensus standard-setting process; compilation of consumer injury data; issuance of safety guidelines; implementation of information and education programs in an effort to proactively avoid injuries; and product recalls and corrective actions when necessary. The agency is operating with a vastly improved budget as a result of the CPSIA. However, in an era of restrained budgets and limited resources CPSC will need to allocate funds based upon better risk hazard analysis and sound

scientific principles. Allowing them the same discretion afforded other agencies to do so, based upon real world public health risks, would be a step in the right direction. Statutory changes that permit the agency greater discretion as regards regulation of lead and phthalate exposure would allow the Commission to address unintended consequences of mandates imposed under the CPSIA. Adoption of consensus standards and deferral to existing ASTM product safety standard setting processes can efficiently result in flexible regulatory requirements that can more readily be adjusted based upon hazard data than historically stagnant standalone mandatory federal regulations. Congress should clearly provide for only prospective application of new rules and regulations under CPSIA.To assure that American Brands have access to foreign markets there will continue to be a need to support of increased coordination with other countries regarding alignment of standards with better inspection and enforcement coordination. In a global economy we can ill afford disparate requirements without reasonable basis or foundation. Similarly Congress should assure uniform standards apply nationwide. U.S. manufacturers in the consumer product industry presently face increasing global competition that is more intense than ever before. In such an economic environment, U.S. manufacturers (small and large) should not be disadvantaged by an unnecessarily intrusive and inefficient domestic and international regulatory regime.[1]

We supported many of the concepts reflected in the CPSIA to the extent effective good manufacturing standards and practices are recognized. However, to the extent that a myopic

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[1] Congress intended this when it established a requirement that only identical standards uniformly apply to the same product risks regulated under the Sec. 18 of the Federal Hazardous Substances Act ("FHSA" 15 U.S.C. § 1261n) and Sec. 26 of the Consumer Product safety Act ("CPSA" 15 U.S.C. § 2075). Even the European Union proposed that trade between EU countries would be boosted by making it more difficult for member states to block imports of specific products on the basis that they do not meet a national product safety standard. *Procedures Relating to the Application of Certain National Technical Rules to Products Lawfully Marketed in Another Member State and Repealing Decision 3052/95/EC.*

implementation of provisions have resulted in regulations that depart from sensible risk-based decision-making Congress needs to act to restore a common sense regulatory framework. CPSC has strained under the burden of unrealistic timelines for implementation of imposed regulations.

Despite admonitions from Congress that the agency was empowered with discretion to implement practical regulations, the Commission in a bi-partisan fashion has determined that it's discretion is limited without statutory changes[2]. CPSIA adopted an unduly prescriptive scheme of absolute limits on total lead and phthalates resulting in standards inconsistent with risk-based measures commonly adopted by regulatory agencies. These wholesale limits were coupled with an exemption process that has proven to be impracical for lead and phthalates regulation. The stream of commerce suffered significantly as the imposition of such requirements was deemed to apply in a retroactive manner to any previously produced goods entered into commerce. Confusing, burdensome testing schemes (yet to be fully and clearly established as we sit here today) have resulted in additional marketplace confusion and cost. Notwithstanding a dedicated effort the Commission, continues to strain under the requirements imposed upon it. An efficient U.S. marketplace favors clear regulations and test methods and abhors chaos. Unfortunately, two and half years after passage legislation that bars the CPSC from making common sense decisions about protecting the public has had the unintended effect of banning safe products while imposing needless, costly burdens on small businesses. We appreciate that this Committee has elected to respond by drafting legislation that affords the agency the discretion that it requires to implement regulations that provide children protection from actual harm but that accords

[2] For example see STATEMENT OF COMMISSIONER NANCY NORDON THE PROPOSED AMENDMENT ENTITLED*CONSUMER PRODUCT SAFETY ENHANCEMENT ACT OF 2010*
March 18, 2010; STATEMENT ON LEAD REGULATION UNDER THE CPSIA COMMISSIONER ROBERT ADLER January 22, 2010. Both statements make it clear that Congressional action is required to adjust the CPSIA.

responsible businesses the opportunity to distribute safe products without being unreasonably overburdened.

Prospective Requirements. We support clarifications to CPSIA to assure that limits apply only prospectively to products manufactured after the effective date of any regulation implemented. In the absence of a clear and unmistakable congressional intent to apply provisions of the CPSIA retroactively to products previously manufactured and placed in the stream of commerce, there is a strong presumption that "retroactivity is not favored in the law," and that, as a result, "congressional enactments and administrative rules will not be construed to have retroactive effect unless their language requires this result.[3]" Unfortunately, due to imposition of requirements on *any* products in commerce, regardless of when produced or imported, the provisions have been applied in a retroactive fashion that forced the destruction of hundreds of millions of dollars of safe goods, as they were swept off shelves, nothwithstanding the Commission's issuance of repeated stays of enforcement. This approach could also provide badly needed relief for charitable organizations and thrift stores.

We respectfully request that new standards developed under CPSIA apply *"only to product manufactured and introduced into interstate commerce after their effective date"*. In recent testimony before this committee the CPSC Chairman noted that all five Commissioners support changes to ensure prospective application of rules and regulations promulgated under CPSIA.We hope Congress will heed their call.

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[3] *Chevron, U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-45 (1984); *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988); *Landgraf v. USI Film Products*, 511 U.S. 244 (1994); *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 237 (1995); *INS v. St. Cyr*, 533 U.S. 289, 316 (2001); and *Martin v. Hadix*, 527 U.S. 343 (1999). Compare: National Resources Defense Council, Inc. v. CPSC,. 597 F.Supp.2d 370 (S.D.N.Y. 2009), requiring Congressional clarification OF CPSIA to assure prospective application.

Lead Limits. We have always favored risk-based regulation of potential hazard posed by real world exposure to a substance. Congress recognized this approach under CPSIA Section 106 when it it adopted as a regulatory requirement *ASTM F-963 Standard Consumer Safety Specification for Toy Safety*, which in turn regulates toxic heavy metals in toys from paints and similar surface coating based upon soluble extractable limits. This approach is currently embodied in the regulatory approaches under the Commissions administered FHSA and by other agencies, such as FDA and EPA. These are based upon risk-based approaches to managing potential hazardous lead exposure in an alternative fashion from CPSIA's Section 101 banning approach and duly consider reasonably foreseeable handling, use, and routes of exposure from products. With imposition of total content limits on lead in substrate, Congress departed from well-established scientific based models related to actual risk of exposure. Exacerbating this approach, CPSIA language failed to provide the safety valve needed to assure the Commission with reasonable discretion to provide for exceptions to rigid requirements[4]. This resulted in positions that seem removed from common sense, when products which do not result in an appreciable risk of exposure are never-the-less banned. Although the CPSIA purported to allow for exemptions the contraining language used in CPSIA Section 101(b)(1)[5] created a legal nullity as an exception based upon such requirement became impossible to obtain in practice when reasonably likely exposure with adverse health consequences was not a qualifier for exemption.

[4] In relation to "safety valves" for example brass tire valves which are intended to be durable and corrosion resistant can't be used on children's products, even though there is no risk of hazardous lead exposure to a child.

[5] 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.

Proposed legislation under consideration by this committee is a needed improvement, by providing time prior to further reduction limits and exemptions for certain metal materials certain metals (steel, copper and aluminum alloys) and materials that pose a *de minimis* risk, provided they are not small parts (as defined by widely used criteria under *16 CFR 1501, et seq*). Any product or material that does not result in anticipated adverse health effects based upon a reasonably likely exposure route should be exempt (as applicable under FHSA protocols already administered by the agency). The CPSC can establish a methodology to estimate the amount of lead a child would likely ingest, distinguishing between parts and substabnces that are reasonably likely to be placed in the mouth and those that cannot. A reasonable expansion in the amount of discretion granted to the Commission to provide exemptions from the lead bans in the CPSIA and allowance of time to *get it right* is justified.

We have long supported the limitations on lead in pain and note that the marketplace has met with great success in being able to achieve conformance to reduced limits tp 90 ppm under 16 CFR 1303, et seq.

Phthalates. The Commission should be directed and permitted to exempt from the phthalates limits under Section 108 of the CPSIA products or materials that are not reasonably likely to result in hazardous exposure. The proposed bill includes a much-needed exception for inaccessible component parts that contain phthalates, similar to the inaccessible component parts exemption from the lead limits, and allows the Commission to grant an exclusion when it determines that compliance with the limits is not necessary to protect children's health. We believe they have this authority, but clarification is needed to assure that they excercise it in a manner that reduces unreasonable test burdens on manufacturers. In practice the failure to make such requiremnet clear has resulted in needless costly phthalate testing of materials and parts to

which there exists no reasonble liklihood of exposure. The ban should be limited ban to accessible, ingestible parts and CPSC sholud be provided explicit authority to exempt certain products and materials from burdensome testing when it determines determines that compliance with the limit is simply not necessary to protect children's health. The definition of toys under the Section should be aligned with Section 106 requirements and scope definitions. Finally after requiring CPSC to expend funds to convene another Chronic Hazards Advisory Panel to assess health risks from exposure to restricted phthalates, the Commission should be required to act upon recommendations in a finite time or the bans should be subject to recission.

ASTM Standards. Adoption of consensus standards and deferral to existing ASTM product safety standard setting processes can efficiently result in flexible regulatory requirements that can more readily be adjusted based upon hazard data than historically stagnant standalone mandatory federal regulations. These standards are the bulwark of our national and even international safety system, and the Commission plays an important role in providing comments and proposals.[6] We believe the Commission can better manage staff input to standards organizations to prevent proposals which lack technical merit or otherwise cannot be justified as federal standards from incorporation in ASTM standards. We support greater deferral and adoption of effective ASTM standards for durable infant products in a manner similar to Section 106 of the act[7]. We also support updates to CPSIA Section 104 durable nursery product

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[6] CPSC has worked with stakeholders to develop effective consensus standards completing approximately 10 times as many voluntary standards as mandatory standards.

[7] An excellent example is their work with industry to revise the ASTM consensus baby walker safety standard to address injuries from stair falls. There has been a decrease in walker injuries of over 84 percent since 1995, likely due in large part to the effectiveness of such standard requirements. The commission projected societal costs decreased by about $600 million annually from this one action. Similarly, there was an 89 percent reduction in crib-related deaths from an estimated 200 in 1973 and an 82 percent reduction in poisoning deaths of children younger than 5 from drugs and household chemicals from 216 in 1972. Recent collaborative efforts have also resulted in further enhanced crib safety regulations.

standards to provide relief for licensed daycare centers that meet appropriate rules related to inspection and operation of their facilities. In general we support the existing definitions that limit the definition of consumer products under the CPSA, so as not to require the Commission to expend scarce resources regulating products subject to the jurisdiction of other agencies such as the FDA and NHTSA.

Reduce burdensome testing requirements. In our experience manufacturer and importers take their obligation obligation to meet applicable standards seriously. The consequences of failure to do so have greatly increased since passage of the CPSIA. Most U.S. based businesses take extraordinary measures to assure compliance of they face recalls, reputational risk, harm to their brands and relationships with customers and possible penalties for non-compliance. We have often noted that testing plays an important and ongoing role in assuring compliance compliance. However, good manufacturing and procurement practices, adherence to quality assurance procedure in production and viglence in qualification of material sourcing play an even greater role in assuring the safety and integrity of consumer products. Manufacturers producing products test them in production and then sample production lots continuously prior to shipping them. Major retailers duplicate this process on product orders. Most U.S based manufacturers and brand owners have a vested interest in developing and maintaining reputations as "safety conscious" companies.

We agree with other witnesses that micromanaging the test process by statute is not the best way to achieve the most cost-effective compliance, nor does it allow companies to rely on other compliance strategies to assure compliance. The draft bill offers important modifications to the reduce burdensome CPSIA testing scheme, recognizing that a system of compliance must

be predicated on the specifics of the product category and supply chain. CPSC should determine that accredited third party laboratory testing provides sufficient added safety benefits to justify the cost in lieu of materials that could be subject to certifications of complaince based upon independent testing. Additional criteria related to other test burdens when impracticable based upon laboratory capacity and logistics involving material availability within supply chains should be a consideration in establishing product or material specific test requirements or alternate test regimes. Alternate test rules as contenmplated under CPSIA should be permitted as optional for products and must be flexible based upon product categories and should permit representative sample and composite testing when appropriate. Additional efforts should be required to recognize and "safe harbor" best parctices already used in the supply chain.
We have filed extensive comments with CPSC in support of permissable reliance on supplier certifications as a mechanism to establish a reasonable basis of compliance with substance content limits for both sub-components and raw materials. Manufacturer certifications are a proven legal method to establish compliance under many laws, including but not limited to use of FDA complaint materials, the toxicological certification under the Labeling of Hazardous Art Materials Act (LHAMA), and continuing guarantees under the Flammable Fabrics Act (FFA) already administered by the agency.

Database Accuracy. Other witnesses may provided more extensive comments on database issues. However in order to assure the integrity of it's Database CPSC should continue to assure that only authorized reports are filed, duplicative reports eliminated and reports unrelated to actual or potential injury are duly eliminated , as required. Congress should assure that the CPSC maintain, and not disclaims, it's responsibility to assure that potentially valid claims of

"materially inaccuracy" are investigated and resolved in a reasonable time prior to posting in the database. As was noted at this committees recent hearing improvements should be required as to the sufficiency of data (ie. make, model number, mandated tracking identifiers already required by law on children's products), in order to provide more meaningful data. Finally, CPSC should act to clarify that brand licensors to the extent they are niot manufacturers, importers orf record or private labelers of products distributed by them are not misclassified as such in the database. .

CPSC Needs To Allocate Resources Based Upon Hazard Data In spite of remarkable progress that dramatically improved the length and quality of children's lives in the U.S. over the past century, today's children still face significant, real risks. For example, often-avoidable unintentional injuries take the lives of more than 1 out of every 10,000 children in the U.S. annually. That may not sound like much, but this includes over 150 infants that die before their first birthday in motor vehicle accidents and nearly 50 who drown in bathrooms[8]. This is why we would support dynamic new partnerships between stakeholders and the Commission to promote safety and safe consumer practices. Consumer information and education does not substitute for the essential responsibility of manufacturers to provide safe products, but it can help with a large percentage of accidents due to improper or irresponsible conduct or lack of supervision of minors. The Commission is fully authorized to embark on such programs, but encouragement from Congress should be provided

[8] Kimberly Thompson, M.S. SCP, Assoc. Professor of Risk Analysis and Decision Science, Children's Hospital Boston, Harvard Medical School Co-Founder/Director of Research Center on Media and Child Health; Director HSPH Kids Risk Project.

Thank you again for the opportunity to provide these comments. We appreciate the efforts of this committee to improve the CPSIA and expand the discretion afforded the Commission as it seeks to develop practical efficient and effective regulations to enhance children's product safety.

Mrs. BONO MACK. That is the red light and we have to run to the floor for a vote. And we will recess and reconvene immediately following the last vote in the series.

Mr. LOCKER. OK. Sorry.

Mrs. BONO MACK. I don't have the time. I tried last time and I was off by 20 minutes. So immediately following the last vote, we will return. We have a five-vote series.

Mr. LOCKER. Thank you.

[Recess.]

Mrs. BONO MACK. We are ready to begin. So we left off with Mr. Marshall and so we will recognize you for your 5 minutes.

STATEMENT OF DAN MARSHALL

Mr. MARSHALL. Thank you very much. Hello. My name is Dan Marshall. I am the founder and vice president of the Handmade Toy Alliance. The HTA represents 644 small businesses affected by the unintended consequences of the Consumer Product Safety Improvement Act. I would like to mention also that we receive no outside funding whatsoever. We are funded entirely by our members and some small donations that folks have made along the way. We are kind of a shoestring operation.

My wife and I own Peapods Natural Toy Store in St. Paul, Minnesota. I am here today with my daughter Abigail and fellow HTA Board members Rob Wilson of Challenge and Fun in Massachusetts and Randy Hertzler of euroSource in Pennsylvania.

The HTA began in November of 2008 after I began to understand how the newly passed CPSIA will decimate the small-batch manufacturers who supply our store. Since then, I have been working with hundreds of other small business owners to save small-batch manufacturers from regulatory burdens of the CPSIA, the greatest of which is the cost of mandated third-party testing. These fixed costs, which are easily bourn by mass-market manufacturers, who make tens of thousands of units at a time, are simply impossible for small businesses that make toys, children's clothing and accessories in batches of a few dozen at a time, often in home-based studios.

These required tests are not limited to lead testing. Toys, for example, will be subject to mandatory ASTM F–963 testing, which requires the destruction of multiple units of each toy. The CPSC's current schedule would mandate ASTM testing as soon as this October. Unless the CPSIA is reformed, hundreds of small American toymakers will not survive that date.

Unlike similar product safety legislation such as the Food Safety Modernization Act, FDA food labeling rules, or California's Proposition 65, the CPSIA makes no allowances whatsoever for small businesses, nor does it allow the CPSC any discretion in how it applies third-party testing requirements to various types of products. Bicycles, books, hand-knit sweaters, and wooden toy cars are all tested the same.

As a result, the CPSIA, as it stands now, is basically unenforceable. Key provisions have been stayed numerous times. The CPSC is slowly being transformed from a public safety guardian into an enforcer of procedures and technicalities dictated by Congress at huge cost. Congressional action has dramatically undermined the

CPSC, an agency which has effectively protected the American public for almost 40 years.

Meanwhile, we have watched numerous trustworthy businesses fold because of the CPSIA. Untold others have decided not to pursue their dreams as toymakers or crafters. We have even begun to see secondary effects such as the end of Mothering Magazine, which closed this February after 35 years, citing reduced ad revenues due to the CPSIA's impact on their advertisers. If the CPSIA is not amended, hundreds more small family businesses will perish for no good reason.

Thanks to the work of this committee, we have a way forward. Our alliance endorses the draft amendment because of the relief it provides to our members. This bill requires either an exemption from third-party testing or alternate testing procedures, such as XRF screening for lead in substrates, for products that are produced in small quantities. This is exactly what we have been asking for since the formation of our organization. Small-batch manufacturers would be given a safety valve which was originally left out of the CPSIA.

We desire a thoughtful and measured reform worthy of meaningful bipartisan discussions. These issues deserve a full hearing to ensure that a high degree of consumer protection is maintained. We do not wish to create loopholes that would benefit the types of irresponsible companies that created the toy safety scare in the first place.

We urge you to reach out to your colleagues in the Senate to reach a bipartisan agreement. The CPSIA was the product of a strong bipartisan effort in 2008 and its reform requires the same effort. We believe this discussion draft is a suitable foundation for that discussion. We urge both Houses of Congress to set aside differences and find a way to see this reform process through. Our family businesses are watching the process closely and we are depending on you.

In conclusion, on behalf of our members, I would like to thank this committee for addressing this important issue and urge you to quickly pass meaningful reform of the CPSIA. Thank you.

[The prepared statement of Mr. Marshall follows:]

Hello. My name is Dan Marshall. I am the Founder and Vice President of the Handmade Toy Alliance. The HTA represents 644 small businesses affected by the unintended consequences of the Consumer Product Safety Improvement Act (CPSIA) of 2008.

My wife Millie and I own Peapods Natural Toy Store in St. Paul, Minnesota. I am here today with my daughter Abigail and fellow HTA Board members Rob Wilson of Challenge and Fun in Massachusetts and Randy Hertzler of euroSource in Pennsylvania.

The HTA began in November of 2008, after I began to understand how the newly-passed CPSIA would decimate the small batch manufacturers who supply our store. Since then, I've been working with hundreds of other small business owners to save small batch manufacturers from regulatory burdens of the CPSIA, the greatest of which is the cost of mandated third party testing. These fixed costs, which are easily bourn by mass market manufacturers who make tens of thousands of units at a time, are simply impossible for small businesses that make toys, children's clothing and accessories in batches of a few dozen at a time, often in home-based studios.

These required tests are not limited to lead content testing. Toys, for example, will be subject to mandatory ASTM F963 testing, which requires the destruction of multiple units of each toy. The CPSC's current schedule would mandate ASTM testing as soon as this October. Unless the CPSIA is reformed, hundreds of small American toymakers will not survive that date.

Unlike similar product safety legislation such as The Food Safety Modernization Act, FDA food labeling rules, or California's Proposition 65, the CPSIA makes no allowances whatsoever for small businesses. Nor does it allow the CPSC any discretion in how it applies third party testing requirements to various types of products. Bicycles, books, hand-knit sweaters, and wooden toy cars are all treated the same.

As a result, the CPSIA as it stands is basically unenforceable. Key provisions have been stayed numerous times. The CPSC is slowly being transformed from public safety guardian into an enforcer of procedures and technicalities dictated by Congress at huge cost. Congressional action has dramatically undermined the CPSC, an agency which has effectively protected the American public for almost 40 years.

Meanwhile, we've watched numerous trustworthy businesses fold because of the CPSIA. Untold others have decided not to pursue their dreams as toymakers or crafters. We've even begun to see secondary effects such as the end of Mothering Magazine, which closed in February after 35 years, citing reduced ad revenues due to the CPSIA's impact on their advertisers.

If the CPSIA is not amended, hundreds more small family businesses will perish for no good reason.

Thanks to the work of this committee, we have a way forward. Our alliance endorses the draft amendment because of the relief it provides for our members. This bill requires either an exemption from third party testing or alternate testing procedures, such as XRF screening for lead in substrates, for products that are produced in small quantities. This is exactly what we have been asking for since the formation of our organization. Small batch manufacturers would be given a safety valve which was originally left out of the CPSIA.

We desire a thoughtful and measured reform worthy of meaningful bipartisan discussions. These issues deserve a full hearing to ensure that a high degree of consumer protection is maintained. We do not wish to create loopholes that would benefit the types of irresponsible companies that created the toy safety scare in the first place.

We urge you to reach out to your colleagues in the Senate to reach a bipartisan agreement. The CPSIA was the product of a strong bipartisan effort in 2008 and its reform requires the same effort. We believe this discussion draft is a suitable foundation for that discussion. We urge both houses of congress to set aside differences and find a way to see this reform process through. Our family businesses are watching the process closely. We're depending on you.

In conclusion, on behalf of our members, I would like to thank this committee for addressing this important issue and urge you to quickly pass meaningful reform of the CPSIA. Thank you.

Mrs. BONO MACK. Thank you very much. Ms. Weintraub, your 5 minutes.

STATEMENT OF RACHEL WEINTRAUB

Ms. WEINTRAUB. Chairman Bono Mack, Ranking Member Butterfield, Representative Schakowsky, I am Rachel Weintraub, Director of Product Safety and Senior Counsel for Consumer Federation of America. I offer this testimony on behalf of CFA as well as Consumers Union, Kids In Danger, National Research Center for Women and Families, Union of Concerned Scientists, and the U.S. Public Interest Research Group. I thank you for inviting me to testify today.

The CPSIA institutes the most significant improvements to the Consumer Product Safety Commission since the Agency was established. The millions of recalls of toys for excessive lead and tiny powerful magnets, children's jewelry because of high lead levels, and cribs because of durability problems cause consumers to question the effectiveness of our Nation's safety net. The CPSIA has restored consumer confidence by requiring children's products to be tested for safety by banning lead and certain phthalates and toys and by creating a publicly accessible consumer complaint database and authorizing necessary resources to CPSC.

The consumer community has stated previously that any changes made to the CPSIA must not weaken product safety standards and must not weaken public health protections. The current discussion draft fails this litmus test unfortunately. This discussion draft is not narrowly tailored, but rather carves gaping loopholes in the consumer protections created by the CPSIA. It covers fewer children's products, undermines the lead and phthalate standards, substantially weakens the third-party testing requirements, and makes the consumer complaint database vastly less useful for consumers. I will highlight some of the most critical provisions of the discussion draft in my testimony.

We oppose an effort to weaken the scope of the protections of the CPSIA. The discussion draft implies that only those products for children of some younger age, we presume, should be afforded protections by the CPSIA. Congress embraced the belief that there is a shared toy box, which we know reflects the reality of what is true in many homes across this country. School-age children are at risk from lead exposure and from hazards posed by powerful magnets in toys, for example. If those toys are not required to meet any lead limit or meet the standard for magnetic toys, the potential for harm is large. Further, the voluntary standard for toys, ASTM F–963, covers toys intended for children under age 14 years of age.

The third-party testing provision of the CPSIA will be eliminated almost entirely by the discussion draft. Third-party testing is necessary to confirm compliance with safety rules and prevents hazards before they enter the marketplace. While the discussion draft preserves third-party testing for lead in paint, full-size cribs, non-full-size cribs, pacifiers, small parts, and children's metal jewelry, the fact that all infant durable products other than cribs will not be subject to third-party testing is untenable. And there is even ambiguity about the crib standard.

The provision makes it very difficult for CPSC to require third-party testing for other products. The rule-makings required in this section require a cost analysis while ignoring the benefits of lives saved, injuries avoided, or healthcare costs reduced as a result of the testing requirement. And no time frame is established for these rule-makings. This section lists products that can never be required to undergo third-party testing but fails to define them. While we understand that a narrowly-targeted exemption for third-party testing provisions may be the only solution for small-batch manufacturers, the lack of definition and an alternative testing mechanism to ensure safety makes it impossible to determine the appropriateness of this relief.

The discussion draft puts babies at risk in childcare facilities by allowing fixed-side cribs to remain in use if there is required supervision. Slowly removing the drop-side cribs misses numerous other hazards that the new crib standard addresses such as hardware failures, material integrity problems, mattress support failures, slat hazards, and corner posts. This provision drastically weakens the consumer protections of the CPSIA and will keep babies in known unsafe cribs.

The consumer complaint database will give consumers access to lifesaving information and will help CPSC to more nimbly identify and act upon safety hazards. CPSC's rule is responsive to the public interest needs for disclosure and protective of a manufacturer's effort to protect their brand and confidential business information. The database includes more checks on the information and more opportunities for a manufacturer to comment than other similar government agency databases.

The discussion draft tips the balance that the database rule has achieved by limiting who can report to the database, unnecessarily increasing the types of information consumers must report before their complaint can be considered for posting, requires consumers to unwittingly engage in a dialogue with a manufacturer about the reported harm rather than simply reporting the incident to the CPSC, stays the reporting of information until final decisions about the sufficiency and accuracy of the information are made, and will substantially increase the time it will take for information to be posted publicly. This will discourage reporting by consumers to the database and decrease the utility of this important consumer protection.

I thank you for your consideration and am happy to take questions.

[The statement of Ms. Weintraub follows:]

Consumer Federation of America

Testimony of

Rachel Weintraub

Director of Product Safety and Senior Counsel

Consumer Federation of America

Before the

Subcommittee on Commerce, Manufacturing and Trade

of the

House Committee on Energy and Commerce

Legislative Hearing – Discussion Draft CPSIA Amendments

Rayburn House Office Building 2123

April 7, 2011

Summary of Testimony

I. Introduction

II. CPSIA's passage was a significant step forward for consumer protection.

III. CPSC and CPSIA Successes

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2. The consumer incident database will provide transparency and provide useful information about products.
3. Product Registration cards will inform consumers about recalls.

IV. Proposed Revisions in Discussion Draft

1. Definition of a Children's Product- Protections Must Remain for Children 12 and Younger.
2. Application of Lead Limit
   a. Alternative Limit and De Minimis Exception
      i. Alternative Limits will weaken current lead standards
      ii. The de minimis standard will require time consuming risk analysis for a known toxin.
   b. Lead limit exemption for used children's products is too broad.
3. Third party testing requirements are undermined significantly.
4. Cribs in child care facilities will be permitted to violate strong crib standard.
5. Phthalate standard is weakened considerably.
6. Exemption authority for tracking labels is too broad.
7. Database provision is significantly narrowed limiting its effectiveness.
8. We object to the provision making this Discussion Draft entirely retroactive.

V. Conclusion

Chairman Bono Mack, Ranking Member Butterfield, and members of the Subcommittee on Commerce, Manufacturing, and Trade. I am Rachel Weintraub, Director of Product Safety and Senior Counsel at Consumer Federation of America (CFA). The Consumer Federation of America is an association of nearly 300 nonprofit consumer organizations that was established in 1968 to advance the consumer interest through research, advocacy, and education. I offer this testimony on behalf of Consumer Federation of America as well as Consumers Union, Kids In Danger, National Research Center for Women & Families, Union of Concerned Scientists, and the U.S. Public Interest Research Group.

As organizations dedicated to working to protect consumers from unsafe products, I offer testimony today to articulate our serious concerns about the Discussion Draft that amends the Consumer Product Safety Improvement Act of 2008 (CPSIA).

I. Introduction

The bi-partisan CPSIA passed overwhelmingly in the House on July 30, 2008 by a vote of 424-1, in the Senate on July 31, 2008 by a vote of 89-3 and was signed into law by President Bush on August 14, 2008. Before this law passed, Congress undertook a year-long deliberative process to consider the implications of this act: there were approximately 15 hearings and markups in the House and Senate covering issues and products related to the CPSIA, and once each chamber passed its version of the bill, there was a conference in regular order between both Houses of Congress. This law institutes the most significant improvements to the Consumer Product Safety Commission (CPSC) since the agency was established in the 1970's.

II. CPSIA's Significance, New Requirements and Implementation

The CPSIA's passage followed a period of record numbers of recalls of hazardous products that injured, sickened, or killed children. Consumers had lost faith in the safety of consumer products, particularly children's products. The approximately 25 million toys recalled for excessive levels of lead paint, tiny powerful magnets, and other hazardous chemicals, the recalls of children's jewelry because of high lead levels, and the recalls of millions of cribs because of durability issues caused consumers to question whether our safety net was working to protect them.

The bill's passage was also in response to a weakened federal oversight agency, one without enough resources, which failed in its meager efforts to protect the public's health and safety.

In response to this dismal picture, Congress infused the CPSC with new authority and more resources. It has been almost three years since the CPSIA was passed. This law has already made products safer and when fully implemented will increase safety dramatically by requiring that toys and infant products be tested for safety before they are sold, and by banning lead and certain phthalates in toys (although implementation of the testing requirement has been delayed by the CPSC). The law also created a publicly accessible consumer complaint database and authorizes resources CPSC needs to protect the public, such as enabling it to hire additional staff.

III. CPSC and CPSIA Successes

1. Mandatory Crib Standard

There have already been important successes as a result of the CPSIA. One of the most notable examples is the mandatory crib standard that is required by section 104 of the CPSIA. Pervasive design flaws have lead to the recall of more than 10 million cribs over the past three and a half

years. It was essential that the CPSC place safe sleep environments at the top of their mandatory standards-setting list.

Recalls and corrective actions for cribs have been issued for non-compliance with safety standards; strangulation hazards; risk of head entrapment when side rails, spindles, and slats in side rails become loose or break; risk of suffocation; choking hazards; risk of falling; and danger of laceration when fingers become trapped in folding drop gates.[1]

While the previous voluntary crib standards effectively banned the drop-side design in new cribs, only since passage of the CPSIA has there been an effort made to strengthen the voluntary and mandatory standards and require testing and verification of new cribs. The final CPSC crib standard incorporates many provisions that consumer advocates have been supporting for years that replicate the real world use of cribs, such as durability tests, mattress support tests, and tests for the effectiveness of hardware. The resulting CPSC standard, that passed CPSC unanimously, is a strong one and is a successful outcome of the CPSIA. Section 104(c) of the CPSIA seeks to address hazards posed by older model cribs by removing them from the market. This section applies to cribs sold new and used, cribs used in child care facilities, and cribs used in public accommodations such as hotels and motels. The application of this provision means that older cribs that pose significant risks to children will be taken out of the stream of commerce. This provision is based upon laws already in existence in numerous states including Arizona, Arkansas, California, Colorado, Illinois, Louisiana, Michigan, Minnesota, Oregon, Pennsylvania, Vermont and Washington. This provision extends the protections previously offered in just these states to the entire nation to ensure that children sleep in cribs that meet the most recent and most protective crib safety standards.

[1] Kids in Danger, http://www.kidsindanger.org/prodhazards/recalls/cribs.asp

2. Consumer Incident Database

Another success of the CPSIA is the implementation of the consumer product safety information database. CPSC was required by Section 212 of the CPSIA to establish the database. As a result of the CPSC staff's leadership and commitment to the effectiveness of the database, consumers will have access to lifesaving information and the agency will more nimbly be able to identify and act upon safety hazards. CPSC staff worked hard to formulate CPSC's final rule in a manner that is consistent with Congress' intent, responsive to the public interest need for disclosure, and protective of a manufacturer's effort to protect their brand and confidential business information. The database includes more checks on the information and more opportunities for a manufacturer to comment than other similar government agency databases.

Consumers have been in the dark about the dangers of products regulated by CPSC. CPSC has collected incident data from consumers in a manner similar to how it is collected as part of the new database. However, the difference is that prior to the launch of the database, when consumers went to CPSC's web site to look for information, it was hidden. All that they could find typically related to a previous recall. If the Commission had been alerted to the dangers of a product but has yet to conduct a recall, the product's hazard might never have been known to the public.

The database changed that. Public access to information is vital to safety. Simply allowing consumers access to the safety record of products will increase safety and encourage the speedy removal or redesign of unsafe products. Making it simple for consumers to report into a single database the problems they encounter with products also helps the Commission to do its job of

protecting the public from unsafe products more efficiently, which can help save government resources. Launched on March 11, 2011, the first reports were posted last week in the database.

3. Product Registration

The CPSIA requires that infant durable products, such as cribs, strollers and high chairs, include a product registration card in their packaging and provide an opportunity to register online. This will give manufacturers information necessary to directly contact consumers in the event of a recall or other product safety issue.

The requirements for the product registration cards and an online registration program are contained in Section 104 of the CPSIA, which incorporates the Danny Keysar Child Safety Notification Act. Danny, whose parents founded Kids In Danger, died in 1998 when the portable crib he slept in at a child care center collapsed and strangled him. The crib had been recalled five years earlier, but no one at the child care center, including the mom who donated the crib, had heard of the recall. Too many consumers never hear about a recall of a product that they have in their home. In fact, only 10 to 30 percent of product recalls receive a consumer response. This leaves most consumers in contact with recalled products. Registering products is an important step that will increase the number of consumers who hear about a recall.

IV. Proposed Revisions in Discussion Draft

We understand that the Discussion Draft was written in response to requests for flexibility and exceptions from many CPSIA provisions raised by various manufacturer and retailer entities, including micro businesses, large corporations and trade associations. The CPSC itself has requested additional discretion to implement certain CPSIA provisions, particularly regarding the lead requirements. We are open to discussions about finding ways to address the precise needs of

micro-businesses while also protecting public health. However, this Discussion Draft goes well beyond additional discretion and weakens, eliminates or alters significant provisions of the CPSIA, rendering them vastly less protective of the public health and consumers. The most significant successes of the CPSIA are weakened significantly by this Discussion Draft. This Discussion Draft is not narrowly tailored but rather carves gaping loopholes in the consumer protections created by the CPSIA. I will discuss our concerns with the Discussion Draft section by section.

1. **Definition of a Children's Product- Protections Must Remain for Children 12 and Younger**

We oppose an effort to weaken the scope of the protections in the CPSIA. The Discussion Draft rejects the current scope of CPSIA and instead implies that only those products for children of some younger age, we presume, should be afforded protections by the CPSIA. This approach of covering fewer children was rejected by Congress when it passed the CPSIA. Congress embraced the belief that there is a "shared toy box" in many families' homes. We agree with this view, as it reflects the reality of what we know to be true in many homes across the United States. Children of younger ages play with the toys of their older siblings. Younger children mouth their older siblings' toys. The implications of this change are significant. No matter how conscientious a parent, or how well educated the family is about segregating toys for each child, it is inevitable that younger children will obtain access to older children's toys. School aged children are at risk from lead exposure and from hazards posed by powerful magnets in toys. If those toys are not required to meet any lead limit, or meet the standard for magnetic toys, the potential for harm is large and the potential for consumer concern is also considerable.

Further, the voluntary standard for toys – ASTM F 963 – includes an even broader scope to cover toys intended for children under 14. This means that many companies are already complying with voluntary safety standards that encompass toys intended for children under age 14. Thus, the reality that children's toys and products are often shared by children within a family, plus the fact that many within the industry are already complying with a higher age standard, requires the scope of the CPSIA to remain as it is.

2. Application of Lead Limit

Section 2(a) of the Discussion Draft extends the limit for compliance with the 100 ppm lead limit and technological feasibility analysis for an additional year. We oppose this provision. At a recent CPSC hearing on this issue, many organizations testifying stated that testing to 100 ppm was technologically feasible and that companies were already complying with that standard. Companies have also had almost 3 years to prepare for compliance with the 100 ppm standard. There is no justifiable reason to delay this standard.

Section 2(b) of the Discussion Draft reverses the CPSIA's requirement that all children's products meet the new lead limits, and then requires only certain categories of products, established by CPSC at their discretion, to be subject to any lead limit. Rather than applying the lead limits to all children's products and excluding only a select few, this provision would establish a new, less protective standard for many categories of children's products. Except for the few categories that have to meet the current CPSIA lead limits, the rest would only have to meet a higher allowable lead limit of 600 ppm lead only if CPSC holds a hearing and makes a determination that lead in that product or class presents an unreasonable risk to children's health.

We oppose this provision for numerous reasons. First, the lead limit of 600 ppm is too high and children's products are already easily meeting the current 300 ppm standard; second, "unreasonable risk to children's health" is not defined; and third, CPSC has so much discretion as to what to cover in this section that it is unclear what in fact would be covered and in what time-frame. This approach gives neither adequate protection to public health nor assurance to parents and caregivers that they can trust the products they bring into their homes – a problem that helped spur passage of the CPSIA in the first place.

Section 2(c) of the Discussion Draft changes the current language to apply the lead limits to the date of manufacture (as opposed to the date of sale). Unfortunately, because this provision modifies section 101(a), it means that manufacturers are allowed to sell their stock of products that do not even meet the 600 ppm limit if their products were manufactured before February 2009. This provision goes too far in allowing products with dangerously high lead limits to be sold to consumers. Any gains that were made in re-establishing trust in the safety of children's products would be diminished. Consumers may have no way of knowing what lead limit a product on the shelf would meet, if any, further confusing consumers trying to protect their children from lead exposure.

a. Alternative Limit and De Minimis Exception

Section 2(d) rejects the previous bright line test for lead and eliminates section 101(b)(1) of the CPSIA by establishing new alternative limits for metal products and establishing a "de minimis" exception for all other materials.

i. Alternative Limits

The alternative limit for children's products made of steel, copper, or aluminum alloys would be some level yet to be determined that is measured in parts per million unless the product or part is a small part or can break and create a small part. For these small parts made of metal, the limit would be 100 ppm if found to be technologically feasible. Unfortunately, this language is problematic. While the 100 ppm standard is consistent with CPSIA and thus does not weaken current law, it is important to know what the lead limit is for non-small part metal products. Raising the amount of allowable lead in metal items that are not "small parts" is a concern, because children mouth larger products. In addition, this language would expose children to higher levels of lead and not seek to minimize exposure from other parts of that same product even if these products involve common hand-to-mouth interaction by children.

For all non-metal products, if the product is a small part or can break and create a small part, it would have to meet the 100 ppm standard if it is technologically feasible. This section does not change the current 100 ppm limit, but it only applies to small parts and not to other non-metal children's products such as vinyl books or bibs that are often mouthed by children.

The Discussion Draft also makes an unsupportable distinction between choking hazards and non-choking hazards. Under long-standing law, all products intended for babies, toddlers and young children cannot contain small parts, a provision that was not altered by this Discussion Draft. Thus, products designed to be mouthed by babies such as teething rings, baby spoons and sippy cups would fall outside of the 100 ppm test and fall under the "de minimis" standard unless they contained metal, which could expose children to higher lead levels. To protect children from

lead in such non-small-part containing products, the Discussion Draft requires CPSC to undertake extensive review—all for a well known, well documented neuro-toxin.

ii. De Minimis Standard

The definition of "de minimis" is not defined other than being measured in micrograms per day and requires a rulemaking by the CPSC to be revised. This would require a complex risk assessment to determine the exposure level and would require many assumptions to be made that could be incorrect. The testing for this type of exposure limit is time consuming, expensive and subject to inaccuracies, poor repeatability and reproducibility making compliance a challenge unwelcome by the CPSC, retailers, and industry alike. It puts CPSC in the position it was in before CPSIA passed—unable to direct its resources to protect consumers from known and significant hazards. The current requirement for measuring total lead content is a clearer, less expensive, and quicker method for determining compliance with lead limits.

Section 2 of the Discussion Draft also requires the CPSC, by rule, to establish a methodology for estimating lead ingestion. We see at least two problems with this approach: CPSC is not required to do this in a certain time period, which leaves rulemaking open to long-term delays; and CPSC is directed only to distinguish between parts that can be placed in the mouth and parts that cannot be placed in the mouth. In the absence of a methodology promulgated by CPSC, any reasonable methodology that is documented is acceptable to estimate lead ingestion. As a result, unless and until the CPSC establishes a new lead-ingestion limit, a manufacturer can use almost any test, no matter how weak, to assess the danger posed to a child who ingests lead in a component part. The lack of a time frame and the lack of a standard provided to estimate lead ingestion is not protective of the public health.

Finally, the "de minimis" provision also reverses the presumption for the safety of products and allows products to be sold and be exempt from testing for lead unless the CPSC finds otherwise. This would mean that the CPSC would not have to act until a child had been harmed by a lead-laden product or until an entity tested the product and brought it to the attention of the CPSC. This is a profoundly misguided approach because almost all lead exposure except for acute lead toxicity silently impacts victims - decreasing IQ points and affecting behavior. As we witnessed in the years before the CPSIA, the record number of lead-laden products that were sold and later recalled from the market proves that this approach resulted in an unreasonable risk of injury to consumers. The approach to lead-laden children's products proposed in this Discussion Draft will amount to a waste of Commission resources, has been rejected by Congress previously as not being sufficiently protective of public health, creates uncertainty for consumers and for manufacturers, and far exceeds the flexibility that the CPSC requested.

b. Lead Limit Application to Used Children's Products

This provision further weakens the lead standard by establishing that the lead limits do not apply to certain used children's products. While this provision is based upon language in the Consumer Product Safety Enhancement Act, (CPSEA) a bill introduced last year by Representative Waxman to narrowly address concerns raised by certain product safety stakeholders, it limits the consumer protections in the original language that exempted vinyl products from this provision and removes CPSC's discretion to add other products to this list.

3. Section 3- Application of Third Party Testing Requirements

The third party testing provision of the CPSIA will be eliminated almost entirely by the Discussion Draft. The Discussion Draft does preserve third party testing for lead in paint; full

size cribs; non full size cribs; pacifiers; small parts; and children's metal jewelry.[2] This provision makes it very difficult for CPSC to require third party testing for other products beyond this limited list of products. CPSC is permitted to issue a rule to require third party testing for a product, but that rule can only move forward if CPSC has completed an accreditation of conformity assessment bodies and determined the adequacy of the testing capacity of the accreditation bodies. Further, the rulemaking must consider the costs of the regulation and be limited by imposing the "least possible burden" of the costs of regulations while ignoring the benefits of lives saved, injuries avoided or health care costs reduced as a result of the testing requirement. Further, no time-frame is established for these rulemakings.

This section also enumerates those products that can never be required to undergo third party testing: works of art and one of a kind products; specialty products for the disabled (all are not defined); and products that are produced in such small quantities that the cost of testing by an independent third party is not "economically practicable." The definition of a small quantity is yet to be determined. This provision no longer requires CPSC to promulgate the "15 Month Rule." This so-called "15-month rule" is important because it ensures that manufacturers are continually testing their products to the most up-to-date standards, and that safety is not slipping through the cracks in later batches of product runs.

Independent third party testing is proactive, and is better for both consumers and manufacturers: it builds safety into the supply chain early on, with the intent of avoiding the need for expensive recalls *after* children have been injured or killed. We understand that a narrowly targeted exception to the third party testing provision may be the only solution for small batch

[2] Unfortunately, even within this small list there is ambiguity: for cribs, a robust standard was promulgated by CPSC in December 2010—a significant success of the CPSIA. This Discussion draft, however, at the end of this section, prohibits CPSC from enforcing standards that became effective after August 14th 2009 and further references a portion of the Code of Federal Regulations that has since been moved, rendering the status of the standard to which cribs would be tested in question.

manufacturers who make few products and cannot absorb costs of testing, and we are willing to have a discussion about this issue. However, with the definition of small batch manufacturer still undefined it is impossible to determine the appropriateness of this relief for truly small manufacturers. Further, it is unreasonable to provide exemptions for an undefined class of products, called "specialty products for the disabled." Children in the disability community are more likely to mouth products at older ages. Products for this community should be tested to prove compliance.

Further, this provision overreaches by eliminating third party testing for all but a few product categories. In particular, the fact that all infant durable products other than cribs will not be subject to third party testing is untenable.

Finally, third party testing is not a new concept. Many retailers rely upon third party testing results before stocking their store shelves. Some toy manufacturers have used third party conformity assessment laboratories for compliance testing for many years. The CPSIA appropriately applied a testing requirement to all children's products subject to mandatory standards, and created minimum testing criteria.

4. **Section 4- Application of and Process for Updating Durable Nursery Products Standards**

This provision requires cribs in licensed child care facilities to comply with the new crib standard but does not require these child care facilities to comply with revisions to this standard in the future. While we understand that the cost of replacing cribs can be a significant challenge, CPSC has already recognized this and has given child care facilities until late 2012 to comply

with this standard. CPSC should be given discretion to require compliance with future revisions to the crib standard in case there are significant changes that address emerging hazards.

Even more critical is the concern that fixed-side cribs in child care facilities will not be required to meet the new crib standard if certain state or local laws are in place. These laws that are purported to make up for crib dangers include: that a child cannot be in crib for substantial periods if awake; a child over 12 months of age cannot be in the crib; and a requirement that adults are present when an infant is in the crib. Unfortunately, the supervision required by state laws cannot prevent the often silent deaths and injuries when babies are in hazardous cribs. In addition, these state laws frequently vary for center-based versus family-based child care. Further, focusing solely on removing drop-side cribs misses many other hazards that the new crib rule addressed such as hardware failures, material integrity problems, mattress support failures, slat distance hazards and corner posts. This provision drastically weakens the consumer protections in the CPSIA and will put babies at risk.

The Discussion Draft includes a provision for updating infant durable safety standards. While it relies on the text of the CPSEA, it differs by eliminating a provision allowing CPSC to issue a standard that is more stringent and more protective of the public health than the revised voluntary crib standard. CPSC must be able to revise a standard in a way that best protects the public health. Tying the agency's hands in this way is not in the public interest.

5. **Section 6-Application of Phthalate Standard**

Section 6 amends the CPSIA's phthalate provision in a variety of ways. Most significantly, it creates large exemptions where, by rule, CPSC can carve out toys or child care articles from both the prohibition and interim bans where the Commission finds "compliance with the prohibition is

not necessary to protect children's health," and makes the provision prospective, allowing manufacturers to sell their non-compliant products. In contrast to every other rulemaking this Discussion Draft requires, this provision includes a very tight timeline, including a time by which a rulemaking must be started that makes a rule almost impossible to complete.

The phthalate provision in CPSIA protects our children from the cumulative risks of hormonal chemicals that affect genital development and have been associated with testicular cancer and other fatal diseases and serious conditions. Narrowing the definition of the scope of the products covered by the phthalate provision, creating large opportunities to exempt products from coverage and making a rulemaking difficult to accomplish successfully will undermine the health protection of the original phthalate provision of the CPSIA.

6. **Section 7- Exemption Authority for Tracking Labels Requirement**

Section 7 gives CPSC the ability to exclude products or classes of products from tracking label requirements if CPSC determines that it is not "economically practicable" to have tracking labels, and allows CPSC to establish alternatives for those products exempted. When a product poses a hazard to a consumer, a consumer needs information to notify CPSC and the manufacturer of the hazard and CPSC must be able to identify products. In fact, it is this type of information that manufacturers argue is necessary for filing "complete" reports to the database. When Liam Johns died in 2005, his crib, made by Simplicity, but labeled "Graco" went uninvestigated for two years because of confusion resulting from a lack of information on the product. At least two other babies died during this time. Especially because of the high rate of licensing in children's products, tracking labels are imperative, both to adequately identify a product involved in a hazard and to accurately report to the database or manufacturers. Tracking

labels provide critical information and this Discussion Draft creates a mechanism through which manufacturers may not have to comply with this provision.

7. **Section 8- Database**

The consumer incident database is a significant success of the CPSC. Yet this Discussion Draft goes far in limiting the utility and the benefit of the database. The flaws in this section are many: it limits who can report, unnecessarily increases the types of information consumers must report before their complaint can be considered for posting, requires consumers to unwittingly engage in a dialogue with the manufacturer about the reported harm rather than simply reporting the incident to the CPSC; stays the reporting of information until final decisions about the sufficiency and accuracy of the information are made; and will substantially increase the time it will take for information to be posted publicly. This goes much too far and will act to discourage reporting by consumers to the database.

Like other efforts to minimize the effectiveness of the database, this Discussion Draft narrows the definition of who can successfully report to the database, permitting essentially only those related to the person who suffered harm or else requiring authorization by that person, as well as changing the definition of a public safety entity to exclude consumer groups, among others. Among many other new confounding requirements, the provision now allows for another claim of "insufficiency of information," that is not defined and not necessary. This claim of "insufficiency" is ripe for abuse by manufacturers seeking to suppress information about their product. This provision fails to take into account a consumer's limited time to report such harm and a consumer's desire, especially one who suffered a loss as a result of a product hazard, to not want to engage in a conversation, which may or may not be respectful, with a manufacturer.

Finally, this provision makes it a prohibited act for a consumer to misrepresent information submitted in the database. This provision is unnecessary, given that the database already requires verification of the accuracy report by the submitter. This Discussion Draft clearly rejects the need for transparency and seeks to maintain the status quo by rendering the database imbalanced in favor of maintaining the secrecy of harms resulting from use of consumer products.

8. Section 11- Effective Date

The final provision of the Discussion Draft makes this entire bill retroactive to August 2008. We oppose this provision due to its vitiation of critical consumer protections that have already taken effect and rules already promulgated.

V. Conclusion

This Discussion Draft is a broad attack on the most important provisions of the CPSIA: it narrows the scope of products covered by the CPSIA; weakens the lead standard; drastically limits third party testing requirements; allows unsafe cribs to be used in child care facilities, limits the phthalate provision; preserves the secrecy of harms caused by consumer products by making the database less useful and more difficult for consumers; requires rulemakings while not requiring timelines except in one instance that makes compliance untenable and renders the entire Discussion Draft retroactive. Unfortunately, this moves back the clock on safety and puts children at risk.

Mrs. BONO MACK. Thank you very much. All right. The chair recognizes herself for 5 minutes for the first round of questions.

And I would like to ask Mr. Marshall, please, would you be willing to register with the Commission in order to qualify for this small-batch exemption to the third-party testing requirements?

Mr. MARSHALL. I think that would be a fair tradeoff so that the CPSC would know who the small-batch manufacturers are and it would be consistent with how the FDA approaches food labeling laws. So yes.

Mrs. BONO MACK. Thank you. And you also mentioned the other laws that have provisions to accommodate the different circumstances of small-batch manufacturers. Can you say more about the approaches that you believe are the best?

Mr. MARSHALL. Well, the issue with third-party testing is cost, so I think it makes sense to create exemptions based on the number of units produced per year. That seems like the most logical way to us to get at the cost versus the output of a particular manufacturer.

Mrs. BONO MACK. Thank you. Ms. Weintraub, first of all, your testimony—you and I have not read the legislation at all in the same way—but you testified that the CPSIA became law as a result of "a period of record numbers of recalls of hazardous products that injured, sickened, or killed children." What I remember most are the lead-in-paint recalls and no one here will ever argue that lead-in-paint restrictions should ever be loosened. "However, the most significant problems with this bill relate to lead in substrate." Putting aside metal jewelry, again, restrictions for which we do not intend to loosen, were there any children injured, sickened, or killed by lead in substrate, and if so, how many and can you provide verified statistics of those injuries?

Ms. WEINTRAUB. I can't provide verified statistics of those injuries because many of those injuries are silent. They could cause—and likely have caused but we just don't know—neurological impairments, decreases in IQ——

Mrs. BONO MACK. You are saying they are all speculative injuries that you——

Ms. WEINTRAUB. No, I wouldn't say that they are speculative——

Mrs. BONO MACK. But they are speculative?

Ms. WEINTRAUB [continuing]. But they are very difficult to document.

Mrs. BONO MACK. All right. And—again, you and I read the legislation entirely differently—contrary to what you said in your testimony, the discussion draft does not deprive consumers of third-party testing. It gives the Commission authority to decide what should be third-party tested. You know, what I have heard from the commissioners is that they need a little bit more common sense, the ability to apply common sense. You completely disagree with that notion and what I see in the legislation and what you see are entirely different?

Ms. WEINTRAUB. Well, I am not entirely sure what you see, but what I see is a system where there is a list of products that are subject to third-party testing, a list of products that can never be subject to third-party testing, and then a very rigorous rule-making

without any timelines that is required in order for other products to be third-party tested.

Mrs. BONO MACK. You are saying that there are products that can never be tested?

Ms. WEINTRAUB. My understanding was that there is a list in this discussion draft that includes——

Mrs. BONO MACK. Have you seen the discussion draft?

Ms. WEINTRAUB. Yes, I have seen it.

Mrs. BONO MACK. OK, but your understanding—I am sorry. You confused me right there. You said your understanding is that——

Ms. WEINTRAUB. Well, you are disagreeing with my interpretation so——

Mrs. BONO MACK. Well, and you disagreed with mine so I——

Ms. WEINTRAUB. Well, the way that I read the discussion draft is that there are a list of products which are undefined, products for children with disability, one-of-a-kind products, works of art, and products manufactured by small-batch manufacturers that would never be subject to——

Mrs. BONO MACK. Well, nothing is excluded from testing and the Commission can decide to impose the testing. But just moving on a little bit to Mr. Samuels.

You state that the Commission has made some unfortunate interpretations in implementing the database. What interpretations are you referring to and are they corrected by this legislation?

Mr. SAMUELS. Thank you very much. Two very troublesome interpretations is their unnecessary—in fact, I think really improper—increase of the number of parties that can make reports of harm. So that includes trial lawyers; it includes consumer groups that may not be direct representatives of someone that is harmed. It is totally improper and your draft limits it to those people really harmed and their representatives, which is what the database is supposed to be all about.

The second thing is a very unfortunate interpretation that even if a manufacturer has claimed a material inaccuracy in a report that it isn't even their product, that if the 20-day clock runs out, they are going to post it anyway, even if they have failed to resolve it. That is unfair and unnecessary and your draft does a very good job on dealing with that.

Mrs. BONO MACK. Thank you. I just want to finish my last 9 seconds by saying that I believe the database has room for improvement and we can do all of these things. But I also want to go on the record that I support the database. I think there is some consternation from the other side that I don't. But I think it is very flawed and we should make sure that it serves both the public and make sure that we continue to make "made in America" matter again. So with that I am happy to recognize Mr. Butterfield for his 5 minutes.

Mr. BUTTERFIELD. Thank you, Madam Chairman. Ms. Weintraub, well, you are probably well aware that the existing law that we passed a couple of years ago sets clear lines on total lead content that becomes increasingly stringent over time. The purpose of decreasing the amount of lead allowed in children's products over time was to gradually get these products closer to a total lead level that would not result in at least one form of neurological dam-

age, and that is the loss of IQ. Some manufacturers, however, have been complaining ever since the law went into effect, many of whom were at the table when the law was being written, that there is no way they can make their products without certain components that exceed the limits and that those components don't put children's health at risk.

The discussion draft that we have seen and that you acknowledge that you have seen attempts to give these manufacturers relief from the lead content limits. However, it does so in a very broad and far-reaching way that not only lets those who claim they need lead for their products to function properly to exceed the limits, but lets anyone who wants to continue using lead to do so as long as they are willing to play a game of risk with children's health.

The de minimis ingestion-based standard in the draft is available for any component part so long as it isn't a small part. And there is no consideration of whether lead needs to be in that particular component.

My question to you is to the extent there is bipartisan sentiment that Congress should grant manufacturers some form of relief from the lead content limits, do you agree or disagree that any such exception must, as a fundamental matter, consider whether that product needs to have lead in it to function properly?

Ms. WEINTRAUB. I agree.

Mr. BUTTERFIELD. Let me skip over a couple of questions. I will stay with you if you will. Tucked away at the very end of the Republican discussion draft is a one-sentence section regarding the effective date of the amendments in the draft. Although that section is at the very end and only one sentence long, what this section says is actually quite important. As I understand it from my staff, what this sentence says is that anyone who is currently in compliance with any part of CPSIA gets a free pass. Would you agree or disagree with that and would you elaborate for me, please?

Ms. WEINTRAUB. I do agree. I think that provision that you are referencing is truly retroactive provision of this law. I think the term "retroactivity" as it applies to other lead standards I think is legally not accurate. But in this case I think this is true retroactivity. The one sentence actually states that this draft will go back to the time that the CPSIA was passed in August of 2008.

Mr. BUTTERFIELD. OK. I want to get to the database in the few seconds that I have left and this is a rather long question. This is going to be too lengthy for me to complete in the time allotted, but would you speak to the database that we rolled out a few weeks ago and tell us your conclusions on it?

Ms. WEINTRAUB. Sure. The consumer complaint database is a very important consumer protection. It is so important because consumers have been in the dark about product safety. There is many incidents that we know about and obviously others that we couldn't possibly know where consumers were just completely in the dark, that manufacturers had information about a safety problem with the product. CPSC may or may not have known and consumers continued to use the product. They were in the dark. They were under a veil of ignorance and weren't able to make the right choices for their families because they just didn't know about inci-

dents that sometimes were pervasive and affected many, many people.

So what the database seeks to do is equal this playing field a little bit. It still requires CPSC to go to manufacturers outside of the database before they can release information about particular products. But it requires a very specific number of fields of information that really narrow the information so that information has to be very targeted to the type of harm, a description of the product, and really provide useful information to consumers.

And unlike other government databases, it provides a place where manufacturers can comment simultaneously. If you go on the database today, you will see a consumer filed a comment and then in the same page the manufacturer files a comment, which is significant.

Mr. BUTTERFIELD. Thank you. I yield back.

Mrs. BONO MACK. I thank the gentleman. And the chair now recognizes Mr. Olson for 5 minutes.

Mr. OLSON. I thank the Chair, and I thank the witnesses for your knowledge, for your patience, and your persistence.

And my first question is going to be for you, Ms. Weintraub. What is more dangerous, a product of 10,000 parts per million lead that does not leach enough lead to result in a measurable increase in a child's blood lead level, or a product that contains 100 parts per million lead that leaches enough lead to result in a measurable increase in a child's blood lead level?

Ms. WEINTRAUB. I think it depends on a number of scenarios, so I am not sure. I could get back to you.

Mr. OLSON. OK. So you can't tell me between 10,000 parts per million or 100 parts per million?

Ms. WEINTRAUB. I think, you know, there is many factors that go into that sort of analysis. So I would like to review the information and get back to you if I could.

Mr. OLSON. OK. Thank you. I would appreciate that. Is there a mechanism to aid CPSIA to prevent these safe products to be sold to children under age 12?

Ms. WEINTRAUB. I am sorry. Can you repeat that?

Mr. OLSON. I can, yes, ma'am. Is there a mechanism to aid CPSIA to prevent these safe products to be sold for children under age 12—safe lead products?

Ms. WEINTRAUB. Well, I am not sure that I agree with underlying assumption of the question, but products intended for children 12 and under have to meet the current lead standards, as well as the other mandatory standards that are relevant to those products.

Mr. OLSON. OK. Thank you for that answer. A couple more questions. You testified that Congress took over a year in a deliberate process to consider the implications of this law. Unfortunately, as much as we would like to think we are, we are not immune to error. We are not omniscient. I would bet the vast majority, if not all the Members of Congress, had no idea we would be essentially banning bicycles, jungle gyms, and golf equipment—in a time of a child obesity crisis—banning science equipment, like microscopes and organic geology sets—again, in a time when students are falling behind in the sciences—or banning musical instruments in a

time when our students are also falling behind in the arts. Did you know this law would ban those products?

Ms. WEINTRAUB. I think what is important to note is that lead is not necessary to be in products. And if it is in fact necessary, I think that should be part of any analysis that would give flexibility for any type of exemption, because the important thing to focus on from the consumer perspective is that when consumers are purchasing a product for their child, a toy, they don't expect that they will be exposing them to risk. And especially when it comes to lead, it is impossible for a consumer to identify whether there is lead in that product. So the consumer is really relying on the manufacturer and also relying upon Congress and the CPSC to make choices that will protect consumers.

Mr. OLSON. And we are doing that, ma'am, with all due respect. And one final question. You testified that CPSIA became law as a result of "a period of record numbers of recalls of hazardous products that injured, sickened, or killed children." What I remember most are the lead-in-paint recalls. And no one here will argue that lead-in-paint restrictions should be loosened. No one. However, the most significant problems with this bill relate to lead in substrate. Putting aside metal jewelry, again, restrictions for which we do not intend to loosen, were there any children injured, sickened, or killed by lead in substrate? How many and can you provide verified statistics of those injuries?

Ms. WEINTRAUB. I believe I answered a similar question previously and I will answer the same information that, unfortunately, I am sure that there were injuries, there were harms to public health, but it is very difficult to document because these harms and these injuries occur as neurological impacts to effects of behavior and decreases in IQ. So it is very hard to document. But to say that there has been no harm from lead in substrate I think is not accurate.

Mr. OLSON. I appreciate those answers again. I would submit to you that it is important we know those answers before we take action. We should be able to document it. I yield back my time.

Mrs. BONO MACK. Would the gentleman yield, actually, for your final minutes? I would like to ask a follow-up question if might to Mr. Locker and take the final minute. So you state the regulations have departed from sensible risk-based decision-making at the Commission and the law does not grant them the ability to make commonsense decisions—there are those words "common sense" again—but commonsense decisions that has resulted in banning safe products. How do you know the products are safe?

Mr. LOCKER. That comment related to the ability of the Commission to grant exceptions based upon data that was available to them. I mean the Commission is not going to act to grant exceptions if there was exposure—as Mr. Howell testified under the Federal Hazardous Substances Act—to any hazardous substance. So in that situation the problem is not that the Commission can't make that determination. The problem has been that the language in the statute, which you now seek to correct, provides the Commission cannot make the decision if there is any lead that comes from the product. And that creates a Catch-22. So what we are saying is that when the Commission can determine that there is no extract-

able lead from the product that presents a hazard, the examples of the ATV fender, the bicycle fender, brass latches on safety devices maybe in car seats and strollers, when there is no actual human health risk, they should be able to say that these are exempt or excluded products. So far they can't and the way, you know, many of our clients know they are safe is they do do testing. They do do extraction testing. They do do formulations. They avoid hazardous substances where possible because under the Federal Hazardous Substances Act for children's products, they have to.

Mrs. BONO MACK. Thank you. All right. The balance of the time has expired. I will recognize Ms. Schakowsky for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Madam Chairman. I wanted to make it clear particularly to Mr. Marshall that Mr. Waxman, who at the time in April of 2010, who was chairman of the full committee, released a discussion draft that gave targeted relief to industry while maintaining important protections, which I am sure you agree are important for the health and safety of children brought about by this legislation. I was very involved in it. At the time Mr. Rush wasn't here for health reasons and I helped negotiate the bill and I worked with Chairman Barton and afterwards, you know, things happened. And you see some problems and so Mr. Waxman introduced this draft that would make some changes.

And at the time the draft was supported by the National Association of Manufacturers, the Retail Industry Leaders Association, the Motorcycle Industry Council, the Handmade Toy Alliance, and Goodwill Industries. And Chairman Tenenbaum wrote that the Waxman discussion draft would provide CPSC with the flexibility needed to implement the law. And then at that time the Republican minority refused to support the legislation and it didn't move forward in the 111th Congress. So I want to make the point that we understand that there are some things that need to be tweaked. We want to do it but we don't want to blow up the bill.

This has been an issue so dear to my heart, and I did want to ask Ms. Weintraub an important question. The draft bill exempts most children's products, including durable nursery goods—which I have been working on for many sessions—from third-party testing but then says that cribs will be tested. However, the current language remains ambiguous on cribs. Can you talk about this ambiguity? If the bill were to become law, could parents be assured that the crib they are using is safe?

Ms. WEINTRAUB. Sure. Yes, I agree that there is ambiguity. On the one hand, in the list of products that clarifies that there is third-party testing, cribs and non-full-size cribs are included, but yet there is a reference to a C.F.R. that seems to have moved. So it is a little bit confusing. But then further confusing there is another provision later on—I believe it is in the third-party section—which says that this would stay all standards having to do with third-party testing that were passed since some date in 2009. So there is definitely confusion about whether cribs would be required to be tested to the new robust crib standard.

Ms. SCHAKOWSKY. There is another part. The bill would eliminate the requirement that daycares and hotels in certain states use newer, safer cribs. And I have subsequently become friends with Linda Ginzel, mother of Danny Keysar, whose son died a really

tragic accident. And I had in my hand the letter from her that I wanted to read just one paragraph.

"We founded Kids In Danger in 1998 after the death of our beloved son Danny in a poorly-designed inadequately-tested and recalled portable crib. Danny was 16 months old when the top rails of the Playskool Travel-Lite crib he slept in at his licensed childcare home collapsed around his neck, strangling him. He was the 12th child to die in cribs of this design."

So, you know, is it necessary to eliminate that requirement?

Ms. WEINTRAUB. No, it is incredibly problematic. In terms of what the draft bill does for childcare facilities, it seems to be allowing all fixed-side cribs and the new robust crib standard does much more than eliminate drop-sides. It adds many important provisions that ensure the durability of the crib so that cribs can actually wear, reflecting how children use cribs has to do with slat integrity, has to do with mattress support, and the integrity of the hardware. So by just saying that all fixed-side cribs can be used in daycares, it unfortunately isn't capturing the universe of those cribs that we have reason to be concerned about.

Ms. SCHAKOWSKY. Let me just say in the seconds I have left, Madam Chairman, that I know that you care very much about the safety issues and just I for one would love to be able to work with you to address some of the problems that we are hearing and to work to come up with some kind of a compromise.

Mrs. BONO MACK. The gentlelady yields. I thank her very much for the spirit and I look forward to working with you and I acknowledge your expertise and your passion over the years in this and I can say, I think, just in listening to these past few seconds, I think there is some misinterpretation of this. But this is a draft discussion. Sometimes I feel it is almost like a Mad Libs when we were kids. There are blanks in here for this very reason. And I would never dream of doing this without working with you. So I thank you very much for your comment. And now the chair recognizes Mr. McKinley for his 5 minutes.

Mr. MCKINLEY. Thank you, Madam Chairman. Ms. Weintraub, I have got a couple questions for you. Apparently, the chairman and others on the committee, they asked you about substantiating the claims that children have been "injured, sickened, or killed" by toys with lead in its substrate. And you have responded that these injuries are, by and large, silent and undocumented. How do we know they exist if they are silent and undocumented? And could you provide us some documentation that supports this, how many people have and with names or circumstances?

Ms. WEINTRAUB. We know that lead exposure to children causes a range of neurological——

Mr. MCKINLEY. I am looking for some specifics because you made the statement. That is why I am just trying to——

Ms. WEINTRAUB. Yes, so first, the——

Mr. MCKINLEY. I don't want the generalities. That is what happens around here. I am new at this game and everyone likes to talk in the abstract. I am an engineer. I want to deal in details. So when you make that statement, I want you to prove it.

Ms. WEINTRAUB. Sure. Well, first, the statement that I made applied to a full range of products. And when I talked about the inju-

ries and deaths, I was also talking about magnet-toy deaths, as well as injuries from other toxic chemicals.

Mr. MCKINLEY. Can you document it?

Ms. WEINTRAUB. It is very difficult to document if a child——

Mr. MCKINLEY. Well, then you shouldn't be making that statement.

Ms. WEINTRAUB. I can provide you with scientific studies that will——

Mr. MCKINLEY. Let me go on my second question for you. Last week we had at the request, perhaps, or insistence of the administration and the Congressman from California, we included language in a broadband oversight bill to take care of the false and erroneous claims against people for waste, fraud, abuse, and precisely to protect these companies' reputations. We used Congressman Waxman's own language that he had inserted in a radio spectrum bill that he had produced last year. So we were using specifics. And then last year there was a data security bill that the Republicans were trying to put in to a consumers' right bill to protect access to databases, protect it for security for people's reputations. I have got a company in my area that has cried out on this. He has already had legal advice that is suggesting that he could be accused anonymously by people using false names put up there against him and he won't be able to clear his company name.

Shouldn't companies who manufacture consumer products not be provided the same ability to protect their reputations from erroneous or false claims as the companies who receive broadband like we just did?

Ms. WEINTRAUB. I think there are very similar protection that is not identical. But first of all, on the consumer complaint database, complaints cannot be anonymous.

Mr. MCKINLEY. Would you work with us on that? Is that something that you think we should be doing? Shouldn't we be protecting everyone and not just certain people?

Ms. WEINTRAUB. I think there are adequate protections already. And already in order for a claim to be filed and posted on the database, a consumer needs to verify that what they are saying is true.

Mr. MCKINLEY. Their counsel doesn't agree with you on that. That is why we need to do this language. We need to have something in there to be able to take care of that because we are looking for something that is consistent with it. But the last question I have——

Ms. WEINTRAUB. Well, I am happy to take a look at——

Mr. MCKINLEY [continuing]. Is, Mr. Marshall, if I could—back to you. You know, one of the things we were looking for in this hearing were some data because there are a lot of blanks. And you heard the chairman talk about it.

And on page 11 it says the term "produced in small quantities means not more than 'blank' number of units of the same product." What would you recommend is a number that we should use in that?

Mr. MARSHALL. I think that could be a range of numbers. I think on an outside I think 10,000 units per year would be the highest we would like to see.

Mr. MCKINLEY. One thousand?

Mr. MARSHALL. Ten thousand is the highest.

Mr. MCKINLEY. Ten thousand?

Mr. MARSHALL. Yes. But it has to do with——

Mr. MCKINLEY. And that maybe I am dealing more with your company, what you all produce.

Mr. MARSHALL. Well, I own a toy store and my wife and I, we buy from small-batch manufacturers.

Mr. MCKINLEY. OK.

Mr. MARSHALL. But that is a number that we are willing to discuss.

Mr. MCKINLEY. Ten thousand.

Mr. MARSHALL. As a high number. That would be the highest that we would want to see that number. It could be a range of numbers below that as well.

Mr. MCKINLEY. OK. I yield back my time.

Mrs. BONO MACK. I thank the gentleman. And seeing no other members present, I believe that we are now ready to wrap it up. I ask unanimous consent that these 16 letters be made a part of the record, all of which have been vetted previously by the minority. Without objection.

[The information follows:]

Statement on behalf of
American Apparel & Footwear Association

Congressional Hearing on Discussion Draft of H.R. ____,
a bill that would revise the Consumer Product Safety
Improvement Act
April 7, 2011

Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
Unite States House of Representatives

The following comments are submitted on behalf of the American Apparel & Footwear Association (AAFA) – the national trade association of the apparel and footwear industries, and their suppliers – regarding the House Subcommittee on Commerce, Manufacturing and Trade's draft legislation to amend the Consumer Product Safety Improvement Act (CPSIA) of 2008.

AAFA and its members strongly support a product safety system that effectively ensures that safe and compliant products are designed, produced, marketed, and sold. Even before the passage of the CPSIA, AAFA has worked to educate the apparel and footwear industry on important product safety compliance initiatives. For example, for several years, we have published a Restricted Substances List (RSL), that is now translated into several languages, that helps companies understand international product safety standards and implement a chemical management program. The RSL is published on a semi-annual basis and is available to anyone without cost.

Furthermore, well before the CPSIA was conceived, AAFA staff and member companies have been active participants in many of the Consumer Product Safety Commission (CPSC) regulatory activities and have worked closely with the Commission's staff to ensure that the regulations were crafted in such a way that they address specific safety risks while not hindering the ability of companies to make safe and compliant products. As a result of this on-going partnership, some of the critical CPSIA implementation issues faced by textile, apparel, and footwear businesses have been addressed. Unfortunately, many problems remain, many of which cannot be fixed through the regulatory process.

The proposed amendment to the CPSIA is a significant step forward in the process to fix many of the unintended consequences of the CPSIA. These unintended consequences have caused considerable disruption to businesses over the past few years. Furthermore, the amendment preserves many of the CPSIA's much needed improvements to consumer product safety regulation and enforcement. The draft language, which we strongly support, represents a thoughtful balance that protects consumers without unduly burdening industry with unnecessary regulations and requirements. Below are specific comments on several provisions in the draft amendment and additional comments on areas of improvement not addressed by the amendment.

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Section 1: Definition of Children's Product

By expanding the definition of a "children's product" to products intended primarily for children 12 years of age or younger, the CPSIA created a lot of confusion for products that were marketed to "tweens." Manufacturers are still unclear whether these products are children's products or not. Moreover, this expansive definition of children's product meant that regulations like the lead standard would be applied equally to all age groups even if the behavioral characteristics of the age groups are vastly different. For example, the lead standard applies equally to the sole of a baby's shoe as it does to the sole of a 10 year old's shoe – even though 10 year olds will not likely be putting their shoes in their mouths. AAFA therefore strongly supports the amendment's intentions to drop the age limit down to where the Senate had proposed during the drafting of the CPSIA – age 7 and under.

Section 2: Application of Lead Limit

Section 2 of the amendment addresses several key issues with the lead standard that have been extremely problematic for the apparel and footwear industries. Overall, the amendment helps tailor the lead standard to appropriately take into account risk. AAFA supports several key components including the extension of the deadline for lead limit, changing to a prospective application of the lead limit and the inclusion of an alternative limit and *de minimis* exception. These aspects are a good start in relieving the crushing burden on companies, while still ensuring consumer product safety but there are other concerns that must be addressed.

Changing the lead limit to be a prospective application is a change that AAFA and other industry groups have been requesting for many years. A retroactively applied lead limit has resulted in safe and compliant products that have been deemed safe one day and "banned hazardous substances" the next. Companies had to remove millions of dollars worth of inventory from shelves for minor problems such as non-compliant zipper stoppers on the bottom of the fly on children's pants. The result has been a huge unnecessary financial loss for companies that have diligently complied with CPSC regulations and have taken additional steps beyond regulatory requirements to ensure the safety of their products. As stated by CPSC Commissioner Adler, "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. In fact, the Consumer Product Safety Act expressly bars the agency from imposing safety standards retroactively."[1]

We further support language that postpones the application of the 100ppm lead content standard for a year to give the CPSC time to finish technological feasibility determinations. As the CPSC has not yet issued any determinations on whether products can or cannot meet the 100ppm lead content limit, manufacturers do not know whether they will need to comply with the standard. Consequently, manufacturers are destroying safe inventory even if tests have come back only slightly above 100ppm. As a general rule, regulations should be applied in a transparent, timely manner to be fair to businesses. Furthermore, we believe the amendment should apply the 100ppm lead content standard to specific products or materials *only if* the CPSC makes a determination that meeting 100ppm is technologically feasible and is necessary for public health and safety.

Making the 100ppm lead content limit applicable only if the CPSC determines that it is technologically feasible and necessary to protect public health and safety will provide significant relief to manufacturers whose products are not meeting 100ppm due to testing variances. Lead testing is *never* exact, a single product that is sent to three different laboratories will likely return with three different results. Moreover, companies are struggling with test results that come back just slightly above the 100ppm lead standard. Including a standard error that takes into account statistical error would save a company from having to destroy an entire product line because one test reached 101 ppm. It is our understanding that no test will ever give you a standard deviation of zero so including room for testing error is the only way to make "reasonable testing" just that, reasonable.

[1] http://www.cpsc.gov/pr/adler01222010.pdf

We are also very supportive of both the *de minimis* exception and the alternative limit for steel, copper and aluminum alloys. In particular, the apparel and footwear industries have been struggling with several issues that would be solved by a *de minimis* exception, from crystals to fabric being used as a barrier for inaccessible components. Under the *de minimis* exemption many items that ***do not*** pose a risk to children, like the soles of children's shoes, would be exempt due to the absorption of lead falling below any *de minimis* limit that is introduced.

In addition, the *de minimis* standard could solve some regulatory issues that the apparel and footwear industry has been facing. For example, the CPSC came out with a methodology for determining components inaccessible and therefore not covered by the lead standard. This methodology included language saying that fabric could act as a barrier for inaccessible components provided that the inaccessible component is not less than five centimeters in any one dimension. While the intent was to cover components that could be swallowed (like fabric covered buttons), the language of the regulation ended up making the fabric inaccessibility exception useless for the apparel and footwear industry as no component in the apparel and footwear industry is greater than five centimeters in all dimensions. Therefore, components like the shanks in children's shoes and the zipper stopper in children's pants (even if the fly has been bartacked over so a child could not touch the zipper stopper) are still covered by the lead standard even if a child could not touch let alone mouth the inaccessible component.

In addition to the *de minimis* exemption, we recommend the accompanying conference report address state regulations such as California Proposition 65. Proposition 65 has been a particular burden on industry. In the last few years alone, the apparel and footwear industry has been ensnared in costly and time consuming litigation brought by private litigants pursuant to Proposition 65. While industry is struggling to do the right thing and comply with Proposition 65, simply stated, there is no clear guidance on how to comply with the safe harbor limits (which are measured in micrograms per day) contained within Proposition 65. Instead, there has been regulation through litigation resulting in companies spending tens of thousands of dollars to buy into legal settlements that provide little to no improvement to public safety. Report language should clarify that any methodology that comes out of the CPSC to determine the *de minimis* standard should be applicable for state standard compliance as well. This will provide manufacturers a clear path to Proposition 65 compliance.

Section 3: Application of Third Party Testing Requirements

We are extremely supportive of the changes provided in Section 3 of the proposed amendment. AAFA and its members believe that testing is a crucial element of an effective quality control program and we strongly support provisions within the amendment that provide manufacturers with flexibility to implement their own testing programs. Prior to the implementation of the CPSIA, apparel and footwear manufacturers had in place long-standing quality control programs that have developed over time based on the unique circumstances of the product, production of the product and the manufacturer. These programs were effective and did not need to be changed. To demonstrate, in 2007 (the so-called "year of the recall") only 0.0424% of all apparel and footwear sold in the United States were involved in a recall.[2] Moreover, most apparel and footwear recalls were, and continue to be, drawstring violations – a compliance issue that results from lack of information and not a lack of testing.

While the amendment provides much-needed flexibility for third party testing requirements, it does not address any of the issues that non-children's product manufacturers are facing. Prior to the implementation of the CPSIA, all apparel was subject to the Flammable Fabrics Act (FFA) and FFA testing. 16 C.F.R. Part 1610 laid out testing and certification requirements for manufacturers. These rules were promulgated through significant discussion among industry, consumer product safety advocates, the CPSC, flammability experts and testing facilities who worked together to determine what test methods are appropriate to assess fabric compliance with flammability standards. Now, Section 14(a) paragraph (1) of the CPSA requires non-children's product manufacturers to issue a General Conformity Certification based on a "reasonable testing program" that certifies compliance with the applicable product safety standards. As the CPSC has issued two rulemaking that define what a "reasonable testing program"

[2] CPSC recall data, AAFA statistics http://www.apparelandfootwear.org/statistics.asp

entails, manufactures now have to comply with *three* different regulations.[3] Not only is this unnecessary as there was significant compliance with the testing requirements for FFA prior to the CPSIA, but this is extremely burdensome and an inefficient use of manufacturer resources.

Requiring compliance with multiple rulemakings will not make products safer. Instead, it diverts resources that could be more effectively spent on other quality control operations that may not be required by the proposed rulemakings. Therefore, we propose that Section 3(b)'s title (page 9 line 5) be amended to, "Testing Requirements" (as the amended Section 14(b) of the CPSA affects more than just third party testing, it impacts general testing requirements as well). In addition, we propose that the "Rulemaking Considerations" such as the cost-benefit analysis proposed in Section 3(b)(3)(D) (page 11, line 16) be applied to Section 3(b)(1) (page 9, line 9). Additional testing requirements should only be applied to consumer product safety standards if they are necessary. We therefore suggest that the "Rulemaking Considerations" proposed in Section 3(b)(3)(D) include the following, "that, on the basis of investigations or research, any testing requirements pursuant to this paragraph are needed to protect the public against unreasonable risk of injury."

Including this language will also prevent the CPSC from imposing the proposed "Testing and Labeling Pertaining to Product Certification" and requirements laid out in the "Condition and Requirements for Testing Component Parts of Consumer Products" to other long-established testing standards like the children's sleepwear standard and to children's products subject to FFA. As with adult apparel subject to FFA requirements, children's products subject to the children's sleepwear standard and the FFA have had testing requirements in place for many years – testing requirements that are effective because they are functional and appropriately tailored to the standards.

Requiring childrenswear manufacturers to comply with all three regulations simply to demonstrate compliance with the underlying safety standard is not only overly burdensome, but sometimes, the regulations can be contradictory and extremely confusing. For example, in the proposed "Testing and Labeling Pertaining to Product Certification" rulemaking, §1107.22 requires manufacturers to submit random samples for periodic testing so that, "each sample in the production population [has] an equal probability of being selected." However, according to the "Laboratory Test Manual for 16 CFR Parts 1615 and 1616: Standards for the Flammability of Children's Sleepwear," the normal sampling plan for fabric production unit testing requires the manufacturer to "take one sample from the beginning of the first fabric piece in the unit and the other sample from the end of the last fabric piece in the unit."

In another example, the CPSC Small Business Ombudsman's office issued a guidance document titled, "Lifting the Stay of Enforcement of Certification Requirements for Non-Children's Clothing Textiles, Carpets and Rugs, and Vinyl Plastic Film." The document sought to clarify how "continuing guaranties" (certifications of compliance allowed by the FFA which are similar to supplier-issued General Conformity Certifications) relate to General Conformity Certification. The document states, "For non-children's clothing textiles, carpets and rugs, and vinyl plastic film, manufacturers may rely on their suppliers' guarantees if furnished in good faith and with written assurances from the supplier that the product has been subjected to a reasonable testing program." Industry is still yet unclear as to whether continuing guarantees can be used for children's products. Furthermore, according to the CPSC FAQ on continuing guaranties, "The issuance of a guaranty must be based on reasonable and representative tests conducted in accordance with applicable flammability standards..." Therefore, a manufacturer has to certify that the continuing guaranty is based on a reasonable testing program when, in fact, a continuing guaranty can only be issued if it is based on reasonable and representative tests. As a result, in an effort to help clarify two conflicting standards, the FAQ created an additional compliance layer, an additional paperwork requirement and more confusion.

[3] Manufacturers will need to comply with 1) 16 C.F.R. part 1610, "Standard for the Flammability of Clothing Textiles," 2) proposed 16 C.F.R. part 1107, "Testing and Labeling Pertaining to Product Certification," and, for those suppliers who are using supplier certification, 3) proposed 16 C.F.R. part 1109 "Testing and Labeling Pertaining to Product Certification."

Finally, many consumer groups are concerned that without third party testing, manufacturers will not undertake the necessary steps to ensure compliance with such standards as the lead standard or the phthalate standard. We strongly disagree with these concerns. To start, the CPSC has not issued any recalls of children's apparel or footwear for violations the lead substrate standard since the passage of the CPSIA. Thus, industry has effectively ensured that only products compliant with the lead standard reach the marketplace. This is despite the fact that currently, third party testing and certification requirements for the lead substrate and phthalate standards have been stayed. However, during this stay of testing and certification, companies have implemented robust, efficient and effective testing programs throughout their supply chains to check production and ensure product compliance. Members use both third party testing facilities as well as various technologies at the production line to immediately test for a problem and, if they happen to encounter one, deal with it right away. We believe that implementing strict, one-size-fits-all testing requirements for thousands of types of consumer products and supply chains is an ineffective regulatory burden on companies. Companies know their supply chains best and know the most effective way to ensure product compliance. The stay of testing and certification has shown that regulatory flexibility is important so that companies can utilize the most effective and efficient testing methods available.

Section 6: Application of Phthalates Standard

In relation to Section 6, Application of Phthalates Standard, AAFA strongly supports the language in Section 6(c)(1) limiting the application of the phthalate regulation to accessible plasticized component parts in children's toys and child care articles. Unlike chemicals like lead, which is a naturally occurring element, phthalates are intentionally added to products. Therefore, as the CPSC recognized in the "Statement of Policy: Testing of Component Parts with respect to Section 108 of the CPSIA,"[4] testing should be limited to materials and components that could contain phthalates. Requiring testing for components that do not risk phthalate contamination is a wasteful and inefficient use of quality control resources. We also suggest the section be strengthened with either bill or report language that exempts manufacturers from the phthalate standard who have strong supply chain control and chemical management processes in place and know that phthalates will not be used in the production of their products.

In addition, the definition of a "child care article" and "children's toys" as it pertains to phthalate standards should be clarified in either bill or conference report language. The CPSC general counsel has declared that that footwear and most apparel are not covered by the definition of a "children's toy" or "child care articles" and therefore not subject to the CPSIA phthalate ban. Congress should include language to clarify that products such as footwear, apparel and fashion accessories are not considered children's toys and child care articles to strengthen this guidance.

Furthermore, report or bill language should be included to harmonize the definition of a child care article with pre-existing phthalate regulations such as the European Union Phthalate Directive which states, "The main purpose of pyjamas is to dress children when sleeping and **not to facilitate sleep.** Pyjamas should therefore be regarded as textiles and, like other textiles, do not fall under the scope of the Directive" (emphasis added).[5] Not only is harmonization of product safety standards important for businesses to be able to effectively conduct business, but quite simply pajamas are not child care articles. Children do not interact with pajamas in the same way as they interact with other child care articles such as teethers, pacifiers or bottles. Child care articles are actively handled and mouthed. While children may wear pajamas when asleep, pajamas are not likely to be mouthed – especially when the child is asleep. Therefore, pajamas do not pose a risk to children and should not be covered in the definition of child care articles.

[4] http://www.cpsc.gov/about/cpsia/sect108.html#test

[5] Guidance Document on the interpretation of the concept "which can be placed in the mouth" as laid down in the Annex to the 22nd amendment of Council Directive 76/769/EEC: http://ec.europa.eu/enterprise/chemicals/legislation/markrestr/guidance_document_final.pdf

Section 7: Exemption Authority for Tracking Labels Requirement

Overall, we are supportive of giving the CPSC the authority to create exemptions or alternative requirements to the tracking label requirement "if the Commission determines that it is not economically practicable for such product or class of products to bear the marks." We believe that in addition, the Commission should have the authority to make exceptions or alternative requirements if the CPSC believes sufficient information is already available on the consumer product. The predominant purpose of the tracking label requirement is to help consumers, retailers and manufacturers identify a product in the event of a recall. Prior to the CPSIA, in most, if not all cases a picture would sufficiently identify the product being recalled. In fact, most apparel and footwear recalls are drawstrings in children's upper outerwear – a hazard easily identifiable even without a picture. Therefore, requiring additional tracking information serves no purpose other than requiring manufacturers to comply with yet another regulation.

Section 8: Requirements for Public Database

The consumer database has the potential to provide consumers with meaningful information about the products that they purchase as long as this information is accurate and based on first hand reports and proper investigation. However, as it is currently implemented, the database does not have sufficient checks in place to ensure the accuracy of the information posted. Materially inaccurate information serves no one, is detrimental to businesses and can ultimately do more harm than good to public safety. We are strongly supportive of provisions of the amendment that we believe will improve the database for all stakeholders.

To start, we strongly support narrowing the definition of "consumers" and requiring verification that the submitter is "the consumer who used the product that gave rise to the harm, the user's next of kin, a member of the user's household, the legal representative of the user, or another person expressly authorized by any such person." Individuals posting to the database should have as much information as possible to ensure the accuracy of the information posted. Those who have not actually purchased the product, third parties and casual observers are much less likely to have specific information about the product or the incident itself. This information is also important so that consumers can easily identify products involved in the incident. Moreover, limiting the scope of submitters will help deter individuals who do not have a personal, vested interest in product safety and consumer protection and who may have improper motives.

To that end, we also support the inclusion of Section 8(c), "Misrepresentation Prohibited." Honest reporting is a vital element of the success of the database. Furthermore, a submitter who intentionally posts false information can cause a business irreparable damage. The amendment is necessary to discourage maliciously false information from being reported on the database.

In addition, the amendment's provisions to ensure the adequacy and accuracy of information posted takes significant steps to make the database a credible, useful and reliable resource for consumers. It is important for consumers using the database and for manufacturers to be able to specifically identify the consumer product referred to in the report of harm. Without this specificity, consumers may not be able to determine whether their product or a product they are considering purchasing is the same as the product named in the incident report. Moreover, the current strict timeline between when a manufacturer receives the report of harm and when the report of harm must be posted to the database does not give manufacturers and the CPSC sufficient time to review for material inaccuracies. The amendment gives all parties more time to collect necessary information to ensure the database entries are both accurate and complete.

The amendment should also remove "...***or any risk*** of injury, illness, or death as determined by the Commission, relating to the use of a consumer product" (emphasis added) from the definition of "harm." AAFA and its members strongly believe that "risk of harm" should be strictly determined by the CPSC. For example, reports of "risk of harm" could include reports of products "violating" inapplicable product safety standards. Someone could observe a child using a general use product, like a computer, test the computer for lead content, and make an unfounded determination that the computer's lead content presents a risk of injury – even if the computer is not subject to the lead standard. The Commission is in

charge of determining what is "safe" and "unsafe" – *not* the general public and any reports of risk of harm on the ".gov" database should come ***only*** from the Commission (through voluntary recall notices or other official Commission statements). However, the CPSC should be encouraged to collect reports of risk of harm for their own regulatory and investigation purposes and post the information to the database if they make a determination that there is an actual "risk of harm." Reports of risk of harm from other sources will likely result in additional burden on the CPSC, overpopulation of reports that are not in the public interest, and cause damage to both the database's and the Commission's credibility.

Preemption

The amendment does not address preemption issues and we strongly believe that the amendment should include language clarifying that the CPSIA fully preempts state and local product safety rules. Companies find it increasingly difficult to manage the conflicting and ever growing number of state regulations that are being promulgated. Companies labor to comply with the CPSIA only to find out – often after the fact – that they are not in compliance with a little known state standard. To comply with drawstring limitations, companies must meet conflicting standards established at the federal level and in the states of New York and Wisconsin. And this is just the tip of the iceberg, with new rules coming online in Washington State, Illinois, Connecticut, Maine, and elsewhere. With regard to CPSIA, California Proposition 65, in particular, has created significant difficulties because it relies upon different standards and product coverage, even though it purports to address product safety as well. We believe Congress made a mistake when it exempted out Proposition 65 from the CPSIA. We urge you to make federal preemption stronger so that it clearly preempts all state and local product safety related measures so we can achieve a single, harmonized national product safety standard.

Conclusion

Thank you for holding this extremely important hearing to discuss the much needed and well thought out amendment to the CPSIA. While it was absolutely necessary for Congress to reform consumer product safety regulations in 2008, many of the new requirements have caused a devastating economic impact to the apparel and footwear industry. We are pleased that Congress has recognized the need to amend the legislation to address implementation concerns and establish a strong, risk-based regulatory regime that protects public safety but does not unduly burden compliant companies.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

April 6, 2011

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Henry A. Waxman
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce,
Manufacturing and Trade
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable G.K. Butterfield
Ranking Member
Subcommittee on Commerce,
Manufacturing and Trade
Committee on Energy and Commerce
U.S. House of Representatives
2322A Rayburn House Office Building
Washington, DC 20515

Dear Chairman Upton, Ranking Member Waxman, Chairman Bono Mack, and Ranking Member Butterfield:

As the majority of Commissioners of the U.S. Consumer Product Safety Commission (CPSC), we write to express our serious concerns with significant portions of the discussion draft circulated by the staff of the U.S. House Energy and Commerce Subcommittee on Commerce, Manufacturing and Trade (the Subcommittee), which would revoke key protections in the Consumer Product Safety Improvement Act of 2008 (CPSIA) and endanger the health and safety of American consumers, especially children.

Almost three years have passed since Congress nearly unanimously passed (424-1 in the House and 89-3 in the Senate), and President George W. Bush signed into law, the landmark CPSIA legislation. This legislation reinvigorated the CPSC and established a strong consumer product safety net that the American public demanded after the "Year of the Recall" in 2007, when millions of violative toys were recalled from American consumers. The Subcommittee draft bill seeks to reverse some of the significant steps made toward providing for a safer marketplace and would turn back the clock to the pre-CPSIA era when harmful products made their way into the stream of commerce and into the hands of innocent children.

Under the new protections established by the CPSIA, mothers and fathers now have more peace of mind knowing that during the day their young children play with toys that should no longer carry the same risks of harm. At night, those same boys and girls are likely to be in a much safer sleep environment. Moreover, on March 11, 2011, we ushered American consumers into a new era of government transparency and empowerment with the launch of the CPSIA-mandated publicly searchable consumer product database. Under this provision of the CPSIA, consumers can go online and search a centralized database for reports of actual harm or for reports of potential harm involving the consumer products they own or are considering purchasing.

We understand that Congress must be mindful of the effect of regulations on the business sector. However, the reversal of several of the core provisions of the CPSIA would likely diminish the health and safety of our nation's consumers. We cannot support such a reversal. Moreover, many responsible companies, especially here in the United States, have already taken the steps necessary to meet the law's requirements, built safety into their products, and proven that manufacturers and retailers can thrive under this new and improved consumer product safety framework. It would be unfortunate, indeed, at this time to penalize those who have come into compliance with the law and to reward those less conscientious by undoing these safety features of the CPSIA.

We recognize that some provisions within the CPSIA can be improved. In the past, the Commission has unanimously requested that Congress grant us flexibility to ease some of the administrative burdens the CPSIA has placed on manufacturers, particularly smaller businesses, without sacrificing safety. We continue to support those requested changes. The Subcommittee's draft bill, however, is not consistent with this approach. More specifically, although by no means an exhaustive list, certain provisions in the draft bill cause us great concern:

- Reducing Safety for Primary School Children: We believe that as children grow and age, the idea that they should continue to have access to safe products is—and should be—a noncontroversial one. Congress, through the CPSIA, made the policy judgment that all of our children ages twelve years and younger should be afforded greater protections. We agree with that policy judgment.

- Lead: The CPSIA set one of the most protective lead limits for children's products in the world. The public health community continues to hold its overwhelming consensus: There is no known safe level of lead. We oppose any change to the law that would lead to an increase in the doses of lead to which our children are exposed on a daily basis, particularly when the marketplace has for the most part already adjusted to lower lead levels and is well on its way to getting the lead out of children's products.

- Third Party Testing: The CPSIA requires that some objective oversight and safeguards be established for assuring that children's products meet all applicable safety standards. We have previously acknowledged the need for some targeted relief for small crafters and similar small businesses from some testing requirements and, where product safety would not be compromised, provided relief where we have been able to do so. Nevertheless, one simple fact remains: Parents should have some independent assurance that all products, whether made abroad or in the United States, are safe for their children to use.

- Cribs: The Commission spoke with one voice in 2010, when it unanimously approved the most pro-safety crib standard in the world and decided that whether an infant or toddler is at home or in a child care center, a crib should always be the safest place for a child to sleep. We cannot support a measure that places any child in a potentially life-threatening situation by allowing cribs that are decades past needing to be replaced to be used in many child care centers throughout the country.

- Database: For 38 years, the American public was kept in the dark with respect to crucial consumer product safety data that the CPSC possessed. The veil on this information was lifted on March 11, 2011, when the CPSC launched the public consumer product safety database (SaferProducts.gov). Saferproducts.gov serves as a resource for consumers to learn what other consumers already know about dangerous or potentially dangerous products and emerging hazards. We believe that consumers will be informed by the information in the database and empowered to make their own decisions to help keep their families safe. We are against any proposal that would shut the door on the open and transparent approach currently available through SaferProducts.gov and hide this vital consumer product safety information from the public once again.

We remain open to working with the Congress on adjusting aspects of the CPSIA. Nevertheless, while it is true that no one, including us, wishes to over-regulate, we similarly cannot support under-protecting the American consumer, particularly our nation's children.

Very truly yours,

Inez M. Tenenbaum
Chairman

Thomas H. Moore
Commissioner

Robert S. Adler
Commissioner

cc: The Honorable Marsha Blackburn (*Vice Chair*)
The Honorable Cliff Stearns
The Honorable Charlie Bass
The Honorable Gregg Harper
The Honorable Leonard Lance
The Honorable Bill Cassidy
The Honorable Brett Guthrie
The Honorable Pete Olson
The Honorable David McKinley
The Honorable Mike Pompeo
The Honorable Adam Kinzinger
The Honorable Joe Barton
The Honorable Charles A. Gonzalez
The Honorable Jim Matheson
The Honorable John D. Dingell
The Honorable Edolphus Towns
The Honorable Bobby L. Rush
The Honorable Jan Schakowsky
The Honorable Mike Ross

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The Honorable Mary Bono Mack, Chair
House Committee on Energy and Commerce
Commerce, Manufacturing and Trade Subcommittee
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable G.K. Butterfield, Ranking
House Committee on Energy and Commerce
Commerce, Manufacturing and Trade Subcommittee
2322A Rayburn House Office Building
Washington, D.C. 20515

April 6, 2011

Dear Madam Chair Ranking Member;

On behalf of Goodwill Industries International and its network of local Goodwill agencies throughout the United States, I am writing today to thank you and your staff for sharing recent discussion drafts of legislation that seeks to amend the Consumer Product Safety Improvement Act (CPSIA) and includes provisions that would address Goodwill's concerns about retroactively applying the CPSIA's sales ban on children's products manufactured before the law's implementation. Goodwill believes that the provisions pertaining to the selling of used children's products included in the most recent discussion draft (attached) would allow Goodwill stores to sell used children's apparel within the letter of the law and in good conscience.

Goodwill's first priority is the safety of its customers and the people it serves. Goodwill has a long history of working in good faith with the Consumer Product Safety Commission (CPSC) to prevent unsafe products from being sold in its stores. This commitment to protecting our customers is further demonstrated by Goodwill's continued partnership with the CPSC to educate the public, and inform and train our retail professionals to comply with CPSIA. Goodwill believes that this collaborative public awareness campaign has been extremely helpful in educating shoppers and employees about the hazards of certain products and proper recall procedures.

Goodwill looks forward to our continued work with the subcommittee and the full House Energy and Commerce Committee. Please feel free to contact me at (202) 333-5501 or Seth Turner, Goodwill's Senior Director of Government Affairs and Public Policy at seth.turner@goodwill.org or (240) 333-5508.

Again, thank you for your efforts to craft a solution.

Sincerely,

Jim Gibbons
President and CEO

CC:
The Hon. Fred Upton, Chair of the House Energy and Commerce Subcommittee
The Hon. Henry Waxman, Ranking Member of the House Energy and Commerce Subcommittee
The Hon. John D. Rockefeller, Chair of the Senate Commerce Science and Transportation Committee
The Hon. Kay Bailey Hutchison, Ranking Member of the Senate Commerce Science and Transportation Committee
The Hon. Mark Pryor, Chair of the Senate Consumer Protection, Product Safety, and Insurance Subcommittee
The Hon. Roger Wicker, Ranking Member of the Senate Consumer Protection, Product Safety, and Insurance Subcommittee

(attachment)

Attachment

EXCLUSION OF CERTAIN USED CHILDREN'S PRODUCTS.—

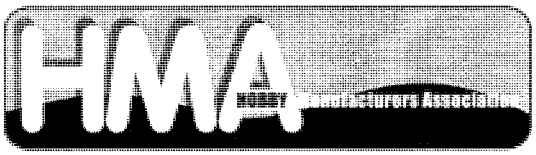
''(A) GENERAL EXCLUSION.—The lead limits established under subsection (a) shall not apply to a used children's product.

''(B) DEFINITION.—The term 'used children's product' means a children's product that was obtained by the seller for use and not for the purpose of resale or was obtained by the seller, either directly or indirectly, from a person who obtained such children's product for use and not for the purpose of resale. Such term also includes a children's product that was donated to the seller for charitable distribution or resale to support charitable purposes. Such term shall not include—

(i) children's metal jewelry; or

'(ii) any children's product for which the donating party or the seller has actual knowledge that the product is in violation of the lead limits in this section;

For purposes of this definition, the term 'seller' includes a person who lends or donates a used children's product.''.



April 1, 2011

Mr John "Gib" Mullan
2125 Rayburn House Office Building
Washington, DC 20515

Dear Mr. Mullan:

As President of the Hobby Manufacturers Association (HMA), I would like to personally thank the Republican Party for undertaking the clarification and re-definition of segments of the CPSIA as it relates to toy products. While not directly involved in the toy industry, hobby manufacturers must often operate under similar guidelines as those who manufacture toys, and therefore the clarification and re-defining of certain points of the CPSIA are of critical importance to the HMA and the hobby industry in general.

I have read the "discussion draft" suggesting proposed amendments to the CPSIA as written by the 1st session of the 112th Congress on Mareh 29, 2011 and, on behalf of HMA member manufacturers, I wish to provide some commentary and input to some of the proposed amendments contained in the draft.

1) The draft contains language concerning lowering the age as to what is eonsidered to be a toy used by children. The HMA proposes to amend from age 12 to age 7 based on the fact that by age 7 children are generally no longer chewing on or placing toys into their mouths. In addition, by age 7, many youngsters are already building snap-together model kits, flying model rockets at school or camp, and enjoying basic radio control cars and airplanes.

2) The HMA supports the proposed amendment to exempt products produced in small quantities from much of the testing which the original CPSIA required. It is apparent that the definition of "small quantities" is not yet defined in the draft. The HMA proposes that quantity be 7,500. The hobby industry is considerably smaller than the toy industry and our products are manufactured in low thousands, and not in hundreds of thousands or millions. In fact, a large part of the hobby industry consists of small manufacturers in small workshops or minimal manufacturing facilities producing short runs of products for modelers and collectors, often by hand or with basic tools and/or machines. The vast majority of these products are targeted to the adult modeler; however, under the original CPSIA guidelines, they could still fall within the "toy" category. One of the major concerns the HMA has regarding the CPSIA is that the required level of testing would be burdensome to the majority of small hobby product manufacturers and the costs of compliance would outweigh any potential profit to be made by producing the products. Revising this part of the CPSIA would enable those smaller companies to remain in business while still ensuring that the products are safely produced.

3) While the HMA agrees that tracking labels are of utmost importance in order to determine the origin of products, we maintain that in certain instances affixing tracking information directly on to products may not be practicable. A large percentage of hobby products are scale miniatures of real-life items such as houses and vehicles for model railroads, small collector cars and planes, and model kits. We are in favor of placing tracking information on the packages for these items if placing them on the product itself becomes unreasonable and impractical due to their smaller sizes.

On behalf of the HMA as well as the hobby industry as a whole, I offer my sincere thanks for your undertaking of the amendment of the CPSIA in order to make it more practical for hobby industry manufacturers to fully comply with the new regulations. I look forward to obtaining a copy of the final amendment so that members of the HMA may become aware of the changes and support them.

If you have any questions or if I may be of further assistance, please call me at (856) 435-1555.

Sincerely,

Michael S Bass
President – Stevens International
President – Hobby Manufacturers Association

cc: Patricia Koziol, Executive Director - HMA
Adam Tager, Member Model Railroad Division, HMA

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April 5, 2011

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

Subject: Improvements to the Consumer Product Safety Improvement Act on Lead Testing

Dear Chairman Upton:

I am writing this letter to address a technical and scientific matter that can help protect children and increase the reliability and feasibility of testing under the Consumer Product Safety Improvement Act. As you are considering changes to the Act, the protections in this law should be fully preserved and implemented on schedule, because it has been a success in helping to prevent childhood lead poisoning.

For over 20 years, I have led scientific research on childhood lead poisoning prevention. From 1995-2004, I served as the Director of the HUD office that led the nation's efforts to address childhood lead poisoning from paint in housing. I was the principal author of the lead poisoning report from the President's Task Force on Environmental Health and Safety Risks to Children and the HUD Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing (the seminal technical document in the field). I was also responsible for creating the quality control system to ensure that portable lead-based paint X-Ray Fluorescence (XRF) Analyzers can be used in a valid and scientifically defensible manner to enable residents and owners to have confidence in residential lead paint testing results.

The current CPSIA legislation seems to allow only laboratory-based destructive testing, making it practically impossible for parents to test their children's toys and other children's products in a non-destructive manner. It also unnecessarily limits the ability of manufacturers and others to conduct the large number of tests needed to protect children.

Years ago, HUD wrestled with a problem similar to that now facing the Consumer Product Safety Commission: how to test a massive number of items for lead in a way that effectively ensures child safety. Millions of homes, each one containing a hundred or more painted surfaces, needed to be tested to determine if lead-based paint hazards were present. Title X of the 1992 Housing and Community Development Act (also known as the Residential Lead Hazard Reduction Act) provided a lead-based paint

standard in two units of measure: loading (milligrams of lead per square centimeter of surface area - mg/cm^2) and concentration (parts per million by weight - ppm). While loading is the preferred measure, Title X (which I helped to craft) allowed both measures. Loading is independent of the number of non-leaded paint layers, avoiding a dilution problem. In other words, a layer of lead based paint covered by many layers of non-lead-based paint might not be detected using a laboratory test that reports only ppm, because the weight of the non-leaded layers would mask (dilute) the presence of lead paint. Loading does not suffer from this problem, because the amount of lead within a measured surface area does not change, regardless of how many layers of non-leaded paint there are. But loading does require accurate measurement of the surface area. As a practical matter, for some surfaces for which the surface area cannot be measured, ppm is the only reliable measure that can be used. Therefore, both units of measure are used.

When I was at HUD, we settled on a solution: portable X-Ray Fluorescence (XRF) technology and a quality control system that published the tolerance limits for each commercially available brand of XRF instrument on the market, combined with a laboratory quality control system. We tested the XRF instruments on hundreds of real-world paint samples on a variety of substrates and determined how well they worked. We published the results in "Performance Characteristics Sheets," for each type of XRF on the market. These are now in active use by thousands of licensed or certified lead-based paint inspectors and risk assessors across the country. It also stimulated the development of a new generation of instruments because we were able to create a level playing field in which instrument manufacturers could compete. Today, XRFs are widely understood to be reliable ways of determining the presence of lead-based paint in housing. They are typically used in conjunction with laboratory paint chip testing, for which EPA has established the National Lead Laboratory Accreditation Program. Both XRF and laboratory methods have their uses. Together, these actions have produced valid, reliable testing methods in which parents, building owners, inspectors and others have confidence.

As the CPSC looks for a way to test many thousands of products for lead content, the current law is unnecessarily limiting. While the CPSIA sets a standard of 2 micrograms of lead per square centimeter (2 $\mu g/cm^2$) for small painted areas that are less than 1 square centimeter, it does not allow this standard for larger areas. There is no scientifically valid reason to limit the size of the area for this standard. The important question is whether measurements (either by XRF or laboratory-based technologies), are reliable and supported by a good quality control/quality assurance system, such as that in place for lead-based paint testing.

Therefore, I suggest two actions for your consideration:

First, delete the current language requiring that 2 $\mu g/cm^2$ be used only for small surface areas and replace it with language that permits use of either the 90 ppm or 2 $\mu g/cm^2$ standard, regardless of the size of the surface being tested. If the materials being tested have lead at levels less than 90 ppm or 2 $\mu g/cm^2$, they would be deemed to be in compliance, regardless of the size of the area being tested. Second, CPSC (or possibly EPA and HUD) should be required to establish a quality control system to ensure that both laboratory testing and XRF testing for consumer products for children are both

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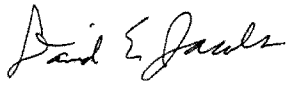
www.centerforhealthyhousing.org

accurate and precise for coatings, substrates and other components of children's products. Both laboratory and XRF technologies have their respective strengths and weaknesses that can be controlled. Such a quality control system would help to ensure that sampling and analytical error for both methodologies is minimized, increasing consumer and manufacturer confidence in testing results.

It is vital that this Act not be weakened. The current provisions and testing requirements can be implemented on schedule. I believe this technical improvement can help make the law even more effective in protecting children. While the nation has made considerable progress in childhood lead poisoning prevention, there are still far too many children poisoned each year and there are still far too many sources of lead exposure that can and should be eliminated.

Please feel free to contact me if I can be of additional assistance. I can be reached at 202-607-0938 or djacobs@nchh.org. I am happy to work with the committee on this language, as well as provide additional background on the reasoning behind it. Thank you for your consideration.

Sincerely,



David E. Jacobs, PhD, CIH
Research Director, National Center for Healthy Housing

Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy & Commerce
U.S. House of Representatives
Washington, D.C. 20515

April 6, 2011

Re: Hearing on Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act

Dear Chairman Bono Mack, Ranking Member Butterfield, and Members of the Subcommittee:

Our undersigned groups write to you regarding our serious concerns about the Discussion Draft amending the Consumer Product Safety Improvement Act (CPSIA), which is the subject of a hearing before your Subcommittee tomorrow, April 7th. We have concerns that the approach in this Discussion Draft will undermine the critical public health protections provided by the CPSIA.

The CPSIA was passed with an overwhelming bipartisan majority in 2008. It was crafted over the course of a year of deliberations, and was the congressional response to the recalls of millions of toys and other children's products for excessive lead levels, ingestion hazards, and other health risks. The CPSIA created, for the first time, a requirement that children's products be tested for safety *before* they get to store shelves. It set into place limits on lead in children's products, set safety standards for infant durable products, banned certain phthalates, and created a public database where consumers could report product safety hazards they have experienced. The law revived the Consumer Product Safety Commission (CPSC), an agency that had neither the resources nor the authorities to adequately protect children from the hazardous products.

Since passage of the CPSIA, there have been calls for a modification of some of the law's provisions to address the needs of makers of handmade children's products. The Discussion Draft, however, goes far beyond that and reverses several key components of the CPSIA. Below are just some of the serious concerns that we have about this draft:

1) **Undermines safety testing for children's products:** It would reverse the requirement that all children's products be tested for safety, and would confine the requirement of pre-market testing to only a few select categories of products. Other products – such as strollers, high chairs, bath seats, and all toys – would be safety-tested only if the CPSC undertook an extensive series of steps, including a cost benefit analysis that emphasizes the costs of testing while minimizing the benefits to public health and safety. Requiring independent third-party testing of all children's products builds safety into the supply chain early, and prevents costly recalls and unnecessary injury.

2) **Undermines lead protections:** It would dramatically weaken the lead limits of the CPSIA by only applying the law's current lead limits to paint on children's products and small parts that could be ingested. It would set a different, subjective standard (risk analysis) for all other children's products, including those that could be mouthed, such as vinyl bibs. We know that even small amounts of lead can cause a drop in children's IQ.

Lead is a known toxin, and we should have a single, strong standard that aims to keep it out of children's products.

3) **Undermines which children get the law's protection:** It would presumably lower the age scope of the CPSIA from its current protections for all children's products primarily intended for children age 12 and younger. This is inconsistent with the current ASTM toy safety standard, which covers toys intended for children under age 14, and it ignores the reality of the "shared toy box" – that young kids will, even with close parental supervision – play with the products that belong to their older siblings.

4) **Undermines the effectiveness of the new crib safety standard:** It would indefinitely delay, or possibly prevent, the implementation of the bipartisan, strong crib safety testing standards passed by the CPSC in December 2010 for cribs in child care facilities, and makes testing to that new standard uncertain.

5) **Undermines the phthalates ban:** It would allow large, undefined exemptions to both the prohibition and interim bans on phthalates in toys and child care articles. It would also, contrary to all other rulemakings in the Discussion Draft, require the CPSC to act within a very tight timeframe if the recommendations of the body assessing the safety of phthalates (the Chronic Health Advisory Panel, or CHAP) are to become law. This requirement is needless since the CPSIA already requires the CPSC to quickly act on a rulemaking; its only effect would be to make it difficult to permanently ban additional phthalates in toys and child care articles.

6) **Undermines life-saving tracking information:** It creates potentially large exemptions from the requirement that children's products have tracking labels, which will limit a consumer's ability to know whether their product is the subject of a recall, and to report vital product information to the CPSC database and manufacturers. Tracking labels can help save lives: When Liam Johns died in 2005, his crib, made by Simplicity, but labeled "Graco" went uninvestigated for two years because of confusion resulting from a lack of information on the product. At least two other babies died during this time.

7) **Undermines the new, public safety product hazard database:** The brand-new CPSC database for the first time allows consumer complaints about product safety problems to be posted publicly, after a screening process, while also giving manufacturers and private labelers ample opportunity to view and comment upon these reports before they are posted. This database will help consumers research products they are considering purchasing, will help the CPSC more efficiently identify emerging hazard trends, and can help prevent unnecessary deaths and injuries. However, the provisions in this Discussion Draft would place onerous burdens on the person making the complaint, thereby discouraging parties with valuable safety information from reporting. It would also remove the ability of consumer groups to report to the database. These changes would in turn keep valuable safety information out of the hands of parents and caregivers.

We urge you to reject the approach proposed by the Discussion Draft. It goes too far and will not adequately protect children from product safety hazards.

Sincerely,

Breast Cancer Fund

Center for Health Environment and Justice

Citizens' Environmental Coalition

Consumer Federation of America

Consumers Union

Demos

Illinois Public Interest Research Group

Indiana Toxics Action

Kids in Danger

Maryland Public Interest Research Group

National Research Center for Women and Families

Natural Resources Defense Counsel

Partnership for Working Families

Public Citizen

U.S. Public Interest Research Group

Union of Concerned Scientists

Vermont Public Interest Research Group

Women's Voices for the Earth

Linda E. Ginzel, PhD
Baaz Keysar, PhD
Co-Founders

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Karen Bertoli
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Geoffrey Phillips
Julius E. Rhodes, SPHR
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Karen Sheehan, MD, MPH
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Lisa Turano Solano, Esq
Board of Directors

Kristine Anderson
Sonny Garg
Howard Haas
Advisory Board

Sarah Chusid
Program Director

Nancy A. Cowles
Executive Director

April 5, 2011

The Honorable Fred Upton, Chairman, House Committee on Energy and Commerce
The Honorable Mary Bono Mack, Chairman, Subcommittee on Commerce, Manufacturing and Trade
The Honorable Henry Waxman, Ranking Member, House Committee on Energy and Commerce
The Honorable G.K. Butterfield, Ranking Member, Subcommittee on Commerce, Manufacturing and Trade

The Honorable Marsha Blackburn
The Honorable Cliff Stearns
The Honorable Charlie Bass
The Honorable Gregg Harper
The Honorable Leonard Lance
The Honorable Bill Cassidy
The Honorable Brett Guthrie
The Honorable Pete Olson
The Honorable David McKinley
The Honorable Mike Pompeo
The Honorable Adam Kinzinger
The Honorable Joe Barton
The Honorable Charles A. Gonzalez
The Honorable Jim Matheson
The Honorable John D. Dingell
The Honorable Edolphus Towns
The Honorable Bobby L. Rush
The Honorable Janice Schakowsky
The Honorable Mike Ross

Dear Chairman Bono Mack, Ranking Member Butterfield and members of the House Subcommittee on Commerce, Manufacturing and Trade,

We founded Kids In Danger in 1998 after the death of our beloved son Danny in a poorly designed, inadequately tested and recalled portable crib. Danny was 16 months old when the top rails of the Playskool Travel-Lite crib he slept in at his licensed child care home collapsed around his neck, strangling him. He was the 12th child to die in cribs of this design.

We have worked tirelessly from that time to improve our broken children's product safety system. This was a system where untested and dangerous children's products make it easily into the marketplace, their flaws tragically discovered by our children. After years of effort, we rejoiced in 2008 when the **Danny Keysar Child Product Safety Notification Act** was included in the **Consumer Product Safety Improvement Act** and signed into law.

This portion of the CPSIA assured parents that for the first time, cribs, strollers, high chairs and other juvenile products had to be independently tested for safety before we brought them into our homes to use with our

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children. Strong new standards would be adopted for juvenile products that would assure that the required testing would find potential flaws and make sure the products were safe for use. Very dear to our hearts were the provisions that ensured that child care facilities and other public accommodations could only offer children safe cribs that met federal standards. Danny died in a licensed child care home that had just been inspected by the state days before. And finally, parents would be given the opportunity to register their products with the manufacturer either through a postage paid card or online – making sure they would learn of recalls.

We are so disheartened to learn that this committee is considering erasing many of these gains.

In addition to many other onerous changes that reduce the safety of all products our children use, we ask you to reconsider this assault on the Danny Keysar Act.

This proposal strips the requirement for independent testing from all infant and toddler products, except for testing cribs to the old standards that eliminated gaps between slats, but little else. But for strollers, high chairs, play yards and more, our children will again be the test dummies for safety. Companies may say they employ their own testing, but we saw where that got us with the 10 million cribs recalled in the last four years and dozens of deaths each year in nursery products.

We are not opposed to allowing child care facilities that replace their older cribs to meet the mandatory standard passed in December, to avoid replacing those cribs every time a change is made to the standard. But combined with a requirement that allows many child care facilities to continue to use older model, possibly unsafe fixed sided cribs, these provisions erase the safety we so hoped the Danny Keysar Act would provide. First, a state requirement of supervision doesn't always equal optimum supervision in the field, and secondly, we all know supervision is no match for dangerous cribs. Danny died in a loving, licensed child care – not from lack of supervision, but because his crib was deadly. When a baby suffocates or strangles, it is usually with little or no noise. Babies have died when parents have been in the same room.

Will you take our concerns into consideration as you look to roll back these safety provisions? We feel strongly that all products in section 104 of the CPSIA (infant and toddler durable products – cribs, strollers, high chairs, etc) should be subject to third party testing with no exceptions. These are products parents and caregivers buy to keep their children safe. They involve many parts and hardware and can be very dangerous if defective. Let's not go back to the days of baby test dummies – let's make sure the products are safe before we use them for our children.

While it may not be reasonable to ask child care providers to replace all cribs every time there is a minor change to the crib standards, there should be a means by which CPSC can require that if necessary. If another flaw in cribs erupts as the drop-side issue did

over the past few years, CPSC should have the ability to require safe cribs in child care settings.

The new mandatory crib standard does so much more than ban drop-sides. In fact, it is unlikely that the drop-side cribs on the market over the past decade that led to millions of products being recalled and dozens of deaths could meet this standard – thereby eliminating the need to even officially ban them. The new standards will make sure crib hardware is sturdy, mattress supports and slats can stand up to real world use and that cribs, used to protect an unattended child, can keep a child safe. Allowing all matter of cribs, safe and unsafe, to remain in child care – just because they don't have a drop-side is a clear attempt to gut the safety improvements of the past few years. Child care is varied and diverse. It is unreasonable to have an exemption for fixed sided cribs without knowing the condition of the crib, when it was made and what standards it does meet.

Please, don't retreat on safety. As parents who have paid the ultimate price for unsafe products, we know you don't want to see more children suffer as our son did. Giving flexibility to CPSC to enforce safety provisions is one thing, but this wholesale reversal of crucial safety provisions sends us back to a scenario we know leaves children at risk.

Sincerely,

Linda Ginzel and Boaz Keysar
Co-founders, Kids In Danger

Linda.ginzel@chicagobooth.edu
Boaz@uchicago.edu

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

NANCY A. NORD
COMMISSIONER

TEL: (301) 504-7901
FAX: (301) 504-0057

April 7, 2011

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing and Trade
U.S. House of Representatives
104 Cannon House Office Building
Washington, DC 20515

Dear Chairman Bono Mack:

This letter is to provide comments for the record on the discussion draft amending the Consumer Product Safety Improvements Act (CPSIA). I believe that the draft legislation would solve many of the problems with the CPSIA that have become so evident, including what are clearly unintended consequences of the law. It is time to get our agency back on track and focusing on real safety issues, not imagined ones.

While the CPSIA gave the agency important tools for protecting the public, it also took away flexibility the agency needs to do its job in a sensible and rational way. For example, the lead provisions, the definition of "children's products" and the testing and certification provisions of the new law, working together, have directed the agency to results that impose unwarranted regulatory burdens while not resulting in an appreciable safety payback. In addition, we are aware of products that do not present a safety issue which have now been driven off the market because of this law. Consumers are not benefited by such a result.

I recommend that any final legislation include the following necessary changes to the current law:

- The lead exclusions need to be amended to give agency more flexibility to address unintended consequences.
    - The "Functional Purpose" language, suggested by some, does not provide adequate relief because it is subjective, costly, and favors big companies. It is also very resource-intensive for the agency.

- The amendment needs to recognize the expertise of the agency to define what is an unacceptable risk based on whether the child's interaction with the product results in measurable increase in blood lead levels.
- Migration of lead limit from 300 ppm to 100 ppm (effective in August, 2011) should be repealed. The Agency can set an appropriate lower level if dictated by safety.
- The scope of the lead provisions is too broad. The law treats all children – from infants to preteens – the same even though their product interaction is quite different and risks are different. The scope should be narrowed to apply to products intended for younger children (recognizing that the agency has inherent authority to deal with risks, regardless of source, to older children).

- The lead and phthalates provisions need to be amended so that the law applies prospectively, rather than retroactively. The retroactive provisions of the law have resulted in forcing billions of dollars worth of safe products off the market.

- The existing mandatory third party testing requirements for all children's products impose a significant burden especially on small businesses. Testing and labeling provisions need to be amended to minimize the damaging impact on product makers while protecting consumers. Rather than requiring third party testing in every instance, agency should be able to set reasonable and appropriate testing and labeling requirements that provide reasonable assurance of compliance with underlying safety standards.

- Regulations should be subject to cost/benefit analysis. Although historically the agency has followed the direction of the President in doing cost/benefit analysis, the current commission has chosen not to do this. Regulators need information on both the costs and benefits of proposed regulations to make sensible decisions. The quality of our regulations has suffered because we have not done the hard work to understand the impact of our actions.

- The Public Database provisions should be amended to include only complaints from consumers who bought or used the product or relevant public health or other public agencies; enhance the ability of businesses to respond to complaints; and include the duty of the agency to assure accuracy of any information made public.

The discussion draft would go a long way to solving the obvious problems with the CPSIA. Claims that the draft reverses progress are both wrong and deliberately misleading. The facts are that it brings some rationality back into the process. I hope that Congress will move swiftly to pass constructive legislation.

Sincerely,

Nancy A. Nord
Commissioner

April 5, 2011

G. K. Butterfield, Jr.
House Subcommittee on Commerce, Trade, and Manufacturing
Washington, D.C.

Dear Representative Butterfield,

On December 19, 2002, my 13-month-old daughter, Elizabeth (Ellie), died in a poorly and dangerously designed play yard. Recently, I wrote to committees, representatives, and senators in an effort to protect a database, required by the CPSIA, that plays an imperative role in keeping children safe by notifying parents of products that pose dangerous risks to children. Now, I am to learn that efforts to keep children safe are again threatened, this time by eliminating essential, deserved ***requirements*** that protect our children.

Specifically, I am referring to the committee's attempts to 1) eliminate the requirement for independent testing of children's products and 2) a measure that will weaken standards for cribs in daycare provider facilities. **Ladies and gentlemen of the committee, I am outraged at these propositions and you do a severe injustice to Danny Keysar's memory, as well as Ellie's and all other children whose lives were lost or bodies injured due to unsafe products, if you strip these imperative portions of the Danny Keysar Child Product Safety Notification Act.**

Eliminating the need for independent testing is in itself a death trap for children. Allowing companies to provide their own testing is erroneous and ineffectual. If a manufacturer's self testing and evaluation were adequate, we wouldn't have the thousands of recalls and warnings issued because their products failed to comply with standards or failed to keep a child out of harm's way. A manufacturer, whose goals are purely profit driven, cannot be trusted to efficiently and appropriately evaluate their own product safety without the risk of severe bias.

Had independent testing requirements been implemented prior to Ellie's death, I firmly believe Ellie would be bubbly, beautiful, nine-year-old girl, today because the product that took her life would never have made it to the store shelves without necessary modifications, like a locking mechanism and a less hazardous design. The manufacturer did not "find" the flaw, but several independent investors after the fact, certainly did. In fact, after her death, I was shocked to learn that this testing standard was never required!

Ask the parents of those children who died in cribs that were expected to be safe because cribs have required standards whether they feel that manufactures self analysis is a sufficient safe guard for product safety. The recent massive recall of drop-side cribs proves this to be otherwise. As parents, and as consumers we expect that all possible flaws have been researched and tested adequately. When we

buy a product, we have a right to expect that the particular product complies with a high quality of standards, given the products is designed and made for our precious child.

When we place our child in the trust of childcare providers, we maintain that same expectation. Daycare facilities require sufficiently trained and certified personnel as should the products they use in their facilities should require the same standard of safely and quality. The current threat to weaken requirements for cribs in use at childcare facilities is a dangerous risk that poses too many hazards. Only requiring drop side cribs to be eliminated from use in provider facilitates, implies that there aren't other dangerously designed cribs in use, and that is too risky an implication, allowing for too many dangerously gray areas. The cost childcare providers pay to replace unsafe products doesn't come close to the cost they will pay if a child dies in their care, due to an unsafe product they provided. The Danny Kesyar Child Product Safety Act not only provides protection for children, it protects the livelihood of child care providers by keeping them up to date with standards that parents expect of them.

There are too many of us parents whose children were injured or killed due to manufacturer carelessness and inadequate testing of their products. A child is priceless, beyond what any definition might attach itself to profit. Companies who make children's products should be held to the highest standards and accept accountability for their product at every moment. I can't ever escape from the pain of my grief, replace the permanent hole in my life that once was my toddling, smiling child. Manufacturers shouldn't escape the requirements of such instrumental standards.

I don't know whether Ellie was destined to be a ballerina or a professional race car driver. I also don't know what she might have looked like on her 9th birthday this past November, or what her laughter might sound like. What I do know is that Elizabeth's death lies in the hands manufacturers whose inadequate testing and attempts to cut costs resulted in the death of my little girl. Allowing these cuts to pass will then put the death of more children in your hands.

Sincerely,

Lisa L. Olney (f.k.a. Davis)
14 Bellmore Dr.
Orford, NH 03777

In Memory of
Elizabeth Morgan Davis
November 4, 2001 – December 19, 2002

April 5, 2011

Mary Bono Mack, Chair
House Subcommittee on Commerce, Trade, and Manufacturing
Washington, D.C.

Dear Representative Bono Mack,

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buy a product, we have a right to expect that the particular product complies with a high quality of standards, given the products is designed and made for our precious child.

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Sincerely,

Lisa L. Olney (f.k.a. Davis)
14 Bellmore Dr.
Orford, NH 03777

In Memory of
Elizabeth Morgan Davis
November 4, 2001 – December 19, 2002

Department of Environmental Health
Division of Environmental and Industrial Hygiene
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April 5, 2011

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

By E-mail: Attention John Gibson Mullan gib.mullan@mail.house.gov

Dear Chairman Upton:

The Consumer Product Safety Commission Improvement Act was a major public health legislative accomplishment and has done much to protect the health of children and others. Our research was among the first to document the presence of lead in currently produced paints in a number of developing countries and to warn of the threat they represented as painted products were imported into the United States. We and others are continuing this research and have now found lead paint available in each of the twenty countries whose paints have been tested.

As you consider changes to strengthen the Consumer Product Safety Improvement Act, I would like to respectfully suggest a provision that has the potential to greatly expand the nation's capability to monitor compliance and thereby increase protection of the health of children and others.

For many years, colleagues and I have engaged in research to develop lead exposure assessment procedures using a variety of portable X-Ray Fluorescence (XRF) analyzers and other technologies and to develop and evaluate lead-based paint hazard reduction programs. The research with XRF use laid the groundwork for the development of an official method for the measurement of airborne lead by field portable XRF analysis. Other research demonstrated that analysis of soil by XRF produced results comparable to those by laboratory methods. Our current research on analysis of new paint indicates that modern XRF analyzers are capable of measuring lead at the two micrograms of lead per square centimeter level (2 $\mu g/cm^2$) as permitted in the current law for small areas. XRF analysis can measure lead in these units at this level for surfaces of any size, not just small areas where that standard is allowed by the current law.

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Page two

The CPSC could help achieve its goal of expanding the testing of painted products in a major way if the current law was modified to permit the use of a standard of 2 micrograms per square centimeter (2 $\mu g/cm^2$) for areas of any size.

The current CPSIA legislative and regulatory structure seems to allow only laboratory-based destructive testing for other than small areas, making it practically impossible for parents to test their children's toys and other children's products in a non-destructive manner. It also unnecessarily limits the ability of manufacturers, health departments and others to conduct the large number of tests needed to protect children. Many health departments, importers, consumer goods wholesale and retail establishments and others could use trained individuals to screen for compliance using hand held portable XRF technology if this change was made. This would greatly expand the protection offered to children and others by the CPSCIA.

I would be happy to assist the Committee in any way possible to make some improvements in this excellent legislation.

Thank you for your consideration.

Sincerely,

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Thermo Fisher
SCIENTIFIC

The world leader
in serving science

April 6, 2011

The Honorable Fred Upton
Chairman
Committee on Energy & Commerce
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Upton:

On behalf of Thermo Fisher Scientific Inc., thank you for taking a leadership role in considering changes to the Consumer Product Safety Improvement Act (CPSIA). I would like to respectfully suggest a way to improve manufacturers', retailers' and importers' ability to inspect consumer goods for lead content, while providing a level of protection for children that we all seek. Handheld X-Ray Fluorescence (XRF) is portable, cost-effective, non-destructive, accurate and widely accepted as a tool to test for lead in both substrate and paint. **Allowing broader use of XRF by industry will ensure that more children's products are tested and proven to be compliant.**

Thermo Fisher is the world leader in serving science. The company enables its customers to make the world healthier, cleaner and safer by providing analytical instruments, equipment, reagents and consumables, software and services for research, analysis, discovery and diagnostics. Our analytical products include instruments that use XRF technology to analyze and detect the elemental composition of materials.

Lessons from EPA & HUD's Effort to Make Homes Safe from Lead Paint

The original ban on lead in paint became U.S. law in 1978, setting a limit for lead in units of "ppm" (parts per million). This is a common unit of measure for laboratory-based analytical methods. But lab-based techniques are not portable and, therefore, not well suited to inspect homes, schools, offices and public buildings. Recognizing this, EPA and HUD partnered with the scientific instrument industry in the early 1990's to develop the first handheld XRF spectrometer for the inspection of lead paint in the field.

In order to truly enable field-deployable XRF technology, **EPA and HUD wrote enforcement regulations for lead in paint that allowed an alternate standard of lead**: 1 milligram per square centimeter. Nearly 20 years ago, EPA and HUD recognized that they could drive far more testing for lead paint by setting this *parallel – and equally protective – standard* and thus enabling use of portable, cost-effective, accurate and non-destructive XRF testing in buildings nationwide.

The core technical hurdle behind the CPSIA's lead limit for painted surfaces on children's products is similar to that faced by EPA and HUD decades ago. Today, Congress and the CPSC want to encourage extensive testing to ensure that lead is not present in products given to children. In order to solve the testing conundrum, **Congress can take a simple, small step to allow a parallel – and equally protective – standard for lead that is as safe as the parts per million limits.**

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ThermoFisher
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CPSC Experience with Handheld XRF for CPSIA Compliance

The CPSC and Customs and Border Protection (CBP) are using handheld XRF for inspection of goods at the CPSC's lab and U.S. ports of entry. They understand that the technology is capable of quickly testing products – including painted products – for lead, allowing scientifically accurate yet quick decisions about whether to clear a shipment.

It is my firm belief that virtually every children's product found to violate lead limits over the past several years would have been – or in fact was – caught by a handheld XRF scan in less than one minute. This is the kind of technology required to protect children from lead exposure in the millions of consumer products that must be inspected each year.

CPSIA XRF-related Language

In considering original passage of CPSIA, Congress understood the lessons from EPA and HUD's efforts many years before. And, as such, the CPSIA sets a limit for lead in small painted areas of 2 micrograms per square centimeter (2 ug/cm2). However, limiting this standard to "small" areas is unnecessary, arbitrary and without scientific basis. And, the limitation creates an opening for problematic products to reach the marketplace. As such, **I encourage you now to apply this same 2 ug/cm2 standard to any painted surface.**

Taking this simple, practical step will enable a significant increase in testing and result in more safer products. This additional testing can be performed by handheld XRF, which has already gained wide acceptance as an integral part of reasonable testing programs across industry. **Manufacturers, retailers and importers seek a practical, cost-effective and defensible method to test their products accurately and efficiently. Handheld XRF provides that answer.**

With over 15 years of experience in applying XRF technology for the testing of environmental toxins, I want to assure the committee and the Congress of the efficacy and validity of what is proposed, namely allowing broad use of a lead standard in micrograms per square centimeter. Additionally, please consider the experience of the EPA and HUD and the success the U.S. government has had by enabling maximum testing of homes and other buildings to reduce lead hazards.

In closing, I appreciate your consideration and would be pleased to discuss this issue directly with you, the committee, your staff and others who are interested in protecting children from the hazards of lead and other heavy metals.

Sincerely,

Bob Wopperer
Senior Director, Marketing and Business Development
bob.wopperer@thermofisher.com

Michele Witte
129 Commonwealth Avenue, Merrick, New York 11566
michelewitte@gmail.com

April 3, 2011

RE: Independent testing on infant and toddler products

Dear Chairman Bono-Mack and Ranking Member Butterfield:

All products in section 104 of the CPSIA (infant and toddler durable products – cribs, strollers, high chairs, etc) should be subject to independent, third-party testing with no exceptions. If a simple, independent "shake" test was done before the distribution of the Child Craft crib I bought for my children, the flaw within the crib design that is responsible for the death of my first born son would have been detected and corrected. When I woke up on the morning of December 12th 1997, I found my son, Tyler Jonathan, with his neck caught between the side rail and headboard of his drop side crib. Sometime after his one am bottle, a single screw became loose creating a gap wide enough to entrap his neck. When this happened, the side of his crib became a spring-loaded vice, strangling him to death instantly. The very last image I have of my precious son is that of him trapped and killed by a crib that I thought was his one and only safe haven.

Tyler's crib was purchased new, meeting CPSC standards, and had the JPMA seal of approval. This enrages me. When my mother first announced that she wanted to buy a crib for her first grandchild I was so excited. We went from store to store searching for the perfect crib. My mother spent hundreds of dollars on a very pretty crib that matched the paint in my nursery and had the convenience of a side that lowered. I am not very tall. When we decided on that particular crib I falsely believed that I was making an informed decision to purchase a safe crib that looked pretty and was convenient. If I knew that the crib I purchased was built with hardware that a ten month old could shake loose, suffocating and strangling babies in the middle of the night, I would NOT have purchased the death trap that is responsible for the death of my Tyler. Tyler's crib was not tested for safety and I, as a consumer, assumed it was because of that JPMA seal and the fact that the crib was falsely advertised as "#1 in safety."

My family and I went to Washington, DC this past December near the anniversary of my son's death. We were there to celebrate. The CPSC was to announce the fact that it unanimously voted YES to new crib regulations that would ban the distribution of cribs like my son's: cribs that are unsafe for our littlest consumers. Finally, standards will be in place that will force manufacturers to sell child products that meet and exceed new and improved safety standards. To think that if these standards were in place in the 1990s my son would be alive today, arguing with his siblings about who gets the last portion of mashed potatoes. Our lives were torn apart when Tyler died. It is horrific that simple testing and stronger hardware could have saved him. I urge this subcommittee to protect children like Tyler and allow the CPSIA regulations to assure child product safety.

Sincerely,

Michele Witte

FULFILLING CPSIA'S MISSION – YKK'S STATEMENT IN SUPPORT FOR A MORE EFFICIENT STATUTORY SCHEME

APRIL 6, 2011

INTRODUCTION

My name is Jim Reed, and I am the Chief Legal Counsel for YKK Corporation of America. YKK Corporation is a leading manufacturer of zippers, buttons, snaps, webbing and other fastening components. YKK has supplied these components to the apparel industry for more than 50 years. YKK is a family owned business that has grown into a global operation through its commitment to quality, innovation and customer service.

YKK'S COMMITMENT TO THE U.S.

We opened our first U.S. office in New York in 1960, and opened our first U.S. manufacturing facility in Georgia in 1973. YKK now employs over 1,800 people in the U.S. in its plants and offices in Alabama, California, Florida, Georgia, Illinois, Kentucky, Maryland, Massachusetts, Michigan, New Jersey, New York, Ohio, Texas and Washington.

YKK'S FAMILIES IN THE U.S.

"YKK" is best known as those three initials on zipper pulls, but we are much more than that. We are American workers, and, more importantly, we are parents, as fiercely protective of our children as other parents.

YKK's Tape Craft Corporation has 180 employees in Oxford, Alabama, making webbing of all kinds since 1946. They have struggled over the last several years due to the recession, but through the incredible effort of the employees in the plant, they are returning to profitability.

YKK Snap Fasteners America Inc., formerly known as Universal Fasteners, has been making buttons for over 100 years. Its 200 employees in Lawrenceburg, Kentucky, are competing with foreign manufacturers with much lower labor costs. The YSU team succeeds through the quality of their products, their innovation and their manufacturing know-how.

YKK (U.S.A.) Inc.'s home base is in Macon, Georgia, where they have more than 700 employees making zippers. It is one of the largest YKK production facilities in the world, where a great number of our employees have over 20 years' experience. They are very much a family business there, where they can boast of a multi-generational employee base.

YKK's families have made safe products for decades. We are proud of the work we do, and believe we have earned the right to continue making safe products without the crushing weight of excessive regulation.

YKK SUPPORTS THE CPSIA

As parents, YKK's employees support the mission of the Consumer Product Safety Improvement Act. We support the lead levels imposed by the law, and our products have always been below those federally mandated levels. In fact, we have already reduced the lead levels in our substrate to less than 90 ppm, well ahead of the August 2011 target date. We are not seeking exemptions from or exceptions to these requirements.

We feel the CPSIA has already made noteworthy contributions to overall product safety. The increased penalties imposed by the CPSIA, for example, seem to have had a significant impact on manufacturers and importers. The threat of a $100,000 fine per product (with the potential to rise to $15,000,000) and potential criminal liability have a powerful deterrent effect. In addition, the powers granted State Attorneys General, whistleblowers and consumers to bring their own claims greatly increase the range of potential enforcers. From a manufacturer's perspective, noncompliance is simply no longer an option. To this extent, the CPSIA has already succeeded in its mission to ensure the safety of children's products.

CPSIA'S CONTINUING CHALLENGES AND OPPORTUNITIES

For any important piece of legislation covering a broad range of products, it takes time to determine what the unintended consequences are and where adjustments may be necessary. The objective of the CPSIA is to make children's products safer, but it will have the unintended consequence of putting manufacturers out of business. Congress, the CPSC and other stakeholders have thoroughly examined the issues of the law over the last three years. The time has come for us to make the necessary adjustments to the CPSIA. We at YKK applaud this latest draft amendment by the House Subcommittee and feel it makes tremendous strides in resolving the toughest issues around the CPSIA.

THE CHALLENGE OF THIRD PARTY TESTING

Of all the useful provisions in the amendment, YKK believes the changes to the third party testing requirements does the most to resolve the greatest challenges of the CPSIA. The third party testing requirements of the law in its current form are devastatingly burdensome. This latest proposed amendment strikes the appropriate balance by focusing third party testing on those most critical areas previously highlighted by Congress and the CPSC, such as lead paint, metal jewelry and cribs. The amendment also gives the CPSC the ability to expand third party testing to other areas as necessary.

The current requirement imposing third party testing on all children's products, no matter how fundamentally safe, will put manufacturers out of business without adding significant value to the underlying safety of children's products. YKK, for instance, is not seeking to exempt its products from the lead standards, and is not shying away from those increased responsibilities. YKK's products can meet the underlying safety requirements of the law, but we have not been able to "certify" our components under the law because of the current excessive third party testing requirements.

It is hard to understand the extent to which excessive third party testing creates problems for manufacturers like YKK without understanding a little bit about the complexity and scope of the manufacturing process. We offer over 375,000 different types of zippers. We offer these zippers in 578 different stock colors, but we also make zippers in thousands of different custom colors each year in order to meet our customers' seasonal requirements.

On an average day, our team in Macon, Georgia, will manufacture 4.5 million sliders in 50 different styles, and this is before they add unique zipper pulls or apply some of the 4,000 different custom colors we offer. On that same day, they will make 300,000 different cut zippers in 100 different styles. They will also produce 180,000 meters of zipper chain, and 40 tons of brass wire.

Our team in Lawrenceburg, Kentucky, currently offers more than 10,000 different types of buttons. During the course of the average workday, this team will make almost 200 different types of buttons. To further complicate the process, the button designs they offer are continuously changing. They develop up to 150 new designs each week to keep up with customers' demands for new and unique looks.

For the most part, the components YKK manufactures are not child-specific; the same zipper going into an adult's pair of jeans will also go into a child's pair of jeans. Although only a small portion of YKK's products will actually end up in children's products in the U.S. (we estimate less than 2%), we will not know which ones they are. As a consequence, YKK has no choice but to treat ALL of its components as if they were going into children's products, compounding the impact of excessive third party testing requirements.

The burden of excessive third party testing is all the more frustrating when one considers that YKK has a decades-long track record for making safe products. YKK's commitment to quality and safety is widely recognized in the industry, and is a primary reason for our success. We stand behind these commitments with rigorous internal testing protocols. In a single year, our Macon quality team will conduct over 5,000 lead tests. We believe these processes are sufficient to ensure the safety of our products, and our record supports this position.

THE COST OF EXCESSIVE THIRD PARTY TESTING

YKK's products meet the underlying safety requirements of the CPSIA, but we cannot certify these products as "CPSIA compliant" because of the excessive third party testing requirements. The enormous complexity of the global supply chain and the tremendous variables in the manufacturing process make third party testing of all products and components in all their variations impossible. YKK has therefore been forced to tell its customers "no" when it comes to CPSIA certification. The fact that there is no underlying safety problem with the products makes the dilemma all the more frustrating.

Our ability to maintain manufacturing in the U.S. requires a focus on those things that make U.S. manufacturers competitive: (1) total customer service (meeting all the needs of the customer, no matter how complex), (2) customization, (3) speed to market and (4)

innovation. Telling our customers "no" to CPSIA certification will push them away from us, which will in turn reduce our orders. Lost orders will lead to lost jobs, and a race to the bottom through pricing wars. These pricing wars are best fought in low cost labor markets like Mexico, Vietnam and Bangladesh. The bottom line is that the excessive third party testing requirements of the CPSIA add little underlying safety value, but will put manufacturers in the U.S. out of business.

CONCLUSION

YKK is confident in the ability of its products to meet the substantive underlying safety requirements of the CPSIA. YKK's testing procedures have been developed over the decades to fulfill the specific requirements of our products and the industries we serve.

We think the change to the third party testing requirements under the proposed amendment is the right way to ensure our children are protected, while avoiding putting manufacturers out of business with overly burdensome regulation.

YKK is here in the U.S. to attest to the fact that American manufacturing is not dead. We have been to the brink, and are fighting our way back, but the recovery is tenuous. Please do not push us back down with untenable regulatory burdens such as excessive third party testing.

Mrs. BONO MACK. All right. And as we wrap things up again, I want to thank our panelists for your patience today, your indulgence certainly through those long series of votes. I would like to thank you for your commitment to this very important issue. I look forward to hearing your thoughts further as we move this legislation forward.

But I would like to be perfectly clear. Our only goal is to correct the unintended consequences of CPSIA. This draft does not undermine the current law. Again, we are trying to fix the problems that we know of in CPSIA, hopefully get some common sense back into this thing. We are simply working to make it better for all Americans and to provide the Consumer Product Safety Commission with the flexibility that it is asking for.

As the mother of two children and three stepchildren, I am completely committed—like everybody in this room is—to the safety of children everywhere. So I hope we can put these political differences aside and pass a bill that will make them prouder and safer. The ranking member and I continue to have discussions about our hope and willingness to work together to get a good bill through Congress that not only we can be proud of but the American people can as well.

So I remind members they have 10 business days to submit their questions for the record and I ask the witnesses to please respond to any questions they receive. And the hearing is now adjourned. Thank you again.

[Whereupon, at 3:55 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Statement of Rep. Ed Towns (NY-10)
Before the US House of Representatives
Energy and Commerce Committee
Sub Committee on Commerce, Manufacturing and Trade.

Thank you Chairman Bono-Mack and Ranking Member Butterfield for holding this hearing today on the discussion draft to the Consumer Product Safety Improvement Act. CPSIA was passed in the 110th congress to help protect consumers against dangerous products that may do them harm. This legislation affects a broad spectrum of our economy, from the manufacturers of toys to the children that play with them. Our constituents want to know that we are doing everything in our power to make sure their children are kept safe. This is why I am seriously troubled by the proposed fixes to the legislation

that was passed during the 110th congress by a large bi-partisan majority.

Safety should be the number one goal of this committee. When we set aside the needs of our constituents to lift up the needs of special interests, we as members of congress must reevaluate what we hold dear. Consumers must be assured that children's products sold on the open market are safe. The proposed legislative fixes to CPSIA fall well below the safety standard set by the original legislation. I urge my colleagues to consider the consequences of this legislation because it will not ensure the safety of our children. I also understand that the original legislation had unintended consequences for manufacturers and small businesses however the legislation before us today is misguided in its approach.

During the 111th congress the Democratic majority had several months of consultation with industry officials to alleviate the burden placed on them by CPSIA's new standards and regulations. These common sense reforms such as allowing flexibility for the CPSC to exempt specific products and exclude for certain used children's products were supported by many of the stake holders that are here today but unfortunately these common sense reforms were not able to garner the support needed to move forward.

The draft legislation we are considering today will have a serious affect on the safety of our children and I urge my colleagues to work together to protect the standards of safety that our constituents demand of us.

Thank you Madam Chair, I yield back my time.

[DISCUSSION DRAFT]

MARCH 29, 2011

112TH CONGRESS
1ST SESSION

H. R. _____

To amend the consumer product safety laws...[*to be provided*]

IN THE HOUSE OF REPRESENTATIVES

_____ introduced the following bill; which was referred to the Committee on _____

A BILL

To amend the consumer product safety laws...[*to be provided*]

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 **SECTION 1. DEFINITION OF CHILDREN'S PRODUCT.**
4 (a) DEFINITION.—Section 3(a)(2) of the Consumer
5 Product Safety Act (15 U.S.C. 2052(a)(2)) is amended—
6 (1) in the matter preceding subparagraph (A)—
7 (A) by striking "intended primarily for
8 children 12 years of age or younger" and in-

1 serting "primarily intended for use by children
2 [____] years of age or younger"; and
3 (B) by striking "intended for a child 12
4 years of age or younger" and inserting "in-
5 tended for use by a child [____] years of age
6 or younger";
7 (2) in subparagraph (B), by striking "children
8 12 years of age or younger" and inserting "children
9 [____] years of age or younger"; and
10 (3) in subparagraph (C), by striking "child 12
11 years of age or younger" and inserting "child
12 [____] years of age or younger".
13 (b) TECHNICAL AMENDMENT.—Section 101(a)(1) of
14 the Consumer Product Safety Improvement Act of 2008
15 (15 U.S.C. 1278a(a)(1)) is amended by striking "(as de-
16 fined in section 3(a)(16) of the Consumer Product Safety
17 Act (15 U.S.C. 2052(a)(16)))" and inserting "(as defined
18 in section 3(a) of the Consumer Product Safety Act (15
19 U.S.C. 2052(a)))".
20 **SEC. 2. APPLICATION OF LEAD LIMIT.**
21 (a) EXTENSION OF DEADLINE FOR LEAD LIMIT.—
22 Section 101(a)(2) of the Consumer Product Safety Im-
23 provement Act of 2008 (15 U.S.C. 1278a(a)(2)) is amend-
24 ed—

1 (1) in subparagraph (C), by striking "3 years"
2 and inserting "4 years"; and
3 (2) in subparagraph (D), by striking "3 years"
4 and inserting "4 years".
5 (b) AUTHORITY TO APPLY LIMITS TO OTHER PROD-
6 UCTS.—Such section is further amended by adding at the
7 end the following:
8 "(F) AUTHORITY TO APPLY LIMITS TO
9 OTHER PRODUCTS.—The Commission may, by
10 regulation, apply the limit set forth in subpara-
11 graph (A) to any consumer product other than
12 a children's product (as such terms are defined
13 in section 3(a) of the Consumer Product Safety
14 Act (15 U.S.C. 2052(a))) that is designed or
15 primarily intended for use by children 12 years
16 of age or younger, or to any class of such con-
17 sumer products, if it determines after a hearing
18 that the lead content in such product or class
19 of products presents an unreasonable risk to
20 children's health.".
21 (c) PROSPECTIVE APPLICATION OF LEAD LIMIT FOR
22 CHILDREN'S PRODUCTS.—Section 101(a) of the Con-
23 sumer Product Safety Improvement Act of 2008 (15
24 U.S.C. 1278a(a)) is further amended by adding at the end
25 the following:

1 "(3) APPLICATION.—Each limit set forth in
2 paragraph (2) shall apply only to a children's prod-
3 uct (as defined in section 3(a) of the Consumer
4 Product Safety Act (15 U.S.C. 2052(a))) that is
5 manufactured after the effective date of such respec-
6 tive limit.".
7 (d) ALTERNATIVE LIMIT AND DE MINIMIS EXCEP-
8 TION.—Section 101(b) of such Act (15 U.S.C.
9 1278a(b)(1)) is amended—
10 (1) by redesignating paragraphs (2) through 5
11 as paragraphs (3) through (6), respectively; and
12 (2) by striking paragraph (1) and inserting the
13 following:
14 "(1) ALTERNATIVE LIMIT FOR CERTAIN MATE-
15 RIALS AND DE MINIMIS EXCEPTION FOR CERTAIN
16 PARTS.—
17 "(A) ALTERNATIVE LIMIT.—For a compo-
18 nent part of a children's product that is made
19 of steel, copper, or aluminum alloys, the limit
20 referred to in subsection (a)(1) shall be **[____]**
21 parts per million unless—
22 "(i) the product into which such part
23 is incorporated fits entirely within the
24 small parts cylinder described in section

1501.4 of title 16, Code of Federal Regulations; or

"(ii) after any necessary assembly of the product and after the product has been subjected to reasonably foreseeable conditions of use and abuse, the part or any portion of the part becomes detached from the product and such part or portion of the part fits entirely within such cylinder.

"(B) DE MINIMIS EXCEPTION.—

"(i) IN GENERAL.—The limits established under subsection (a) shall not apply to any component part of a children's product if, under reasonably foreseeable conditions of use and abuse, it is unlikely that a child who is exposed to the product would ingest more than a de minimis amount of lead, unless—

"(I) the product into which such part is incorporated fits entirely within the small parts cylinder described in section 1501.4 of title 16, Code of Federal Regulations; or

"(II) after any necessary assembly of the product and after the prod-

1 uct has been subjected to reasonably
2 foreseeable conditions of use and
3 abuse, the part or any portion of the
4 part becomes detached from the prod-
5 uct and such part or portion of the
6 part fits entirely within such cylinder.
7 "(ii) METHODOLOGY FOR ESTIMATING
8 AMOUNT OF LEAD INGESTED.—
9 "(I) ESTABLISHMENT BY COM-
10 MISSION.—The Commission shall, by
11 regulation, establish a methodology
12 for estimating the amount of lead a
13 child would likely ingest from expo-
14 sure to a component part. Such meth-
15 odology shall distinguish, at a min-
16 imum, between parts that can be
17 placed in the mouth and parts that
18 cannot be placed in the mouth.
19 "(II) INTERIM METHODOLOGY.—
20 Until the Commission has issued a
21 final rule under subclause (I), a man-
22 ufacturer may use any reasonable
23 methodology to estimate the amount
24 of lead a child would likely ingest
25 from exposure to a component part.

1 The manufacturer shall document the
2 methodology used.
3 "(iii) DE MINIMIS AMOUNT DE-
4 FINED.—In this subparagraph, the term
5 'de minimis amount' means [____]
6 micrograms per day. The Commission may
7 revise such amount by regulation.
8 "(2) EXCLUSION OF CERTAIN USED CHIL-
9 DREN'S PRODUCTS.—
10 "(A) GENERAL EXCLUSION.—The lead
11 limits established under subsection (a) shall not
12 apply to a used children's product.
13 "(B) DEFINITION.—The term 'used chil-
14 dren's product' means a children's product that
15 was obtained by the seller for use and not for
16 the purpose of resale or was obtained by the
17 seller, either directly or indirectly, from a per-
18 son who obtained such children's product for
19 use and not for the purpose of resale. Such
20 term also includes a children's product that was
21 donated to the seller for charitable distribution
22 or resale to support charitable purposes. Such
23 term shall not include—
24 "(i) children's metal jewelry; or

"(ii) any children's product for which the donating party or the seller has actual knowledge that the product is in violation of the lead limits in this section; or

For purposes of this definition, the term 'seller' includes a person who lends or donates a used children's product.".

SEC. 3. APPLICATION OF THIRD PARTY TESTING REQUIREMENTS.

(a) APPLICABLE CHILDREN'S PRODUCTS.—Section 14(a) of the Consumer Product Safety Act (15 U.S.C. 2063(a)) is amended—

(1) in paragraph (2)—

(A) in the matter preceding subparagraph (A), by inserting "described in clauses (i) through (iv) of paragraph (3)(B)" after "a children's product safety rule";

(B) in subparagraph (B), by striking "the children's product safety rule" and inserting "such children's product safety rule"; and

(C) by striking the flush sentence following subparagraph (B); and

(2) in paragraph (3)—

(A) in subparagraph (A), by inserting "described in clauses (i) through (iv) of subpara-

1 graph (B)" after "a children's product safety
2 rule"; and
3 (B) in subparagraph (B), by striking
4 clauses (v) and (vi).
5 (b) THIRD PARTY TESTING REQUIREMENTS.—Sec-
6 tion 14(b) of the Consumer Product Safety Act (15 U.S.C.
7 2063(b)) is amended to read as follows:
8 "(b) TESTING PROGRAMS.—
9 "(1) IN GENERAL.—The Commission may, by
10 rule, prescribe reasonable testing programs to be
11 used as the basis for certification under subsection
12 (a).
13 "(2) TESTING BY AN INDEPENDENT THIRD
14 PARTY.—Any test or testing program on the basis of
15 which a certificate is issued under subsection (a)
16 may, at the option of the person required to certify
17 the product, be conducted by an independent third
18 party qualified to perform such tests, unless the
19 Commission, by rule and in accordance with para-
20 graph (3), requires testing by an independent third
21 party for—
22 "(A) a particular rule, regulation, stand-
23 ard, ban;
24 "(B) any portion of a particular rule, regu-
25 lation, standard, or ban; or

1 "(C) a particular class of products.

2 "(3) REQUIREMENTS FOR TESTING BY AN
3 INDEPENDENT THIRD PARTY.—The Commission
4 may not require testing by an independent third
5 party under paragraph (2) until the Commission has
6 completed each of the following:

7 "(A) ACCREDITATION OF CONFORMITY AS-
8 SESSMENT BODIES.—Established and published
9 notice of the requirements for accreditation of
10 third party conformity assessment bodies who
11 are determined to be qualified by the Commis-
12 sion to conduct such testing.

13 "(B) TESTING CAPACITY.—Determined
14 that the testing capacity of the accredited third
15 part conformity assessment bodies is sufficient
16 to prevent unreasonable delays due to testing.

17 "(C) EXEMPTIONS AND ALTERNATE TEST-
18 ING PROCEDURES.—

19 "(i) IN GENERAL.—Established, by
20 rule—

21 "(I) exemptions for works of art
22 and other one-of-a-kind products; and

23 "(II) exemptions or alternative
24 testing procedures for the certification
25 of specialty products for the disabled,

1 and products that are produced in
2 small quantities such that the cost of
3 testing by an independent third party
4 is not economically practicable.
5 "(ii) PRODUCED IN SMALL QUAN-
6 TITIES DEFINED.—In this subparagraph,
7 the term 'produced in small quantities'
8 means that not more than [____] units of
9 the same product (or substantially similar
10 products) are produced in one year by a
11 manufacturer and any affiliated manufac-
12 turer. A manufacturer may not subdivide
13 the production of such manufacturer into
14 small quantities in order to evade third
15 party testing requirements.
16 "(D) RULEMAKING CONSIDERATIONS.—
17 Made a reasoned determination—
18 "(i) that the benefits from requiring
19 third-party testing justify the costs (recog-
20 nizing that some costs are difficult to
21 quantify); and
22 "(ii) that any rule issued pursuant to
23 this paragraph is tailored to impose the
24 least possible burden, taking into account

1 to the extent practicable, the costs of cu-
2 mulative regulations.
3 "(4) REVIEW OF PREVIOUS RULES.—The Com-
4 mission may not enforce a third party testing re-
5 quirement that became effective during the period
6 after August 14, 2009, and before the date of the
7 enactment of the [_____ Act of 2011]
8 (or that was stayed by the Commission during such
9 period) until the Commission has reviewed such re-
10 quirement and promulgated any revisions as nec-
11 essary to ensure compliance with the requirements
12 of paragraph (3).".
13 (c) CONTINUING TESTING.—Section 14(d)(2) of the
14 Consumer Product Safety Act (15 U.S.C. 2063(d)(2)) is
15 amended—
16 (1) in the matter preceding subparagraph (A),
17 by striking "Not later than 15 months after the date
18 of enactment of the Consumer Product Safety Im-
19 provement Act of 2008, the" and inserting "The";
20 (2) in the matter preceding subparagraph (A),
21 by striking "shall";
22 (3) in subparagraph (A), by striking "initiate"
23 and inserting "not later than 15 months after the
24 date of enactment of the Consumer Product Safety
25 Improvement Act of 2008, shall initiate"; and

1 (4) in subparagraph (B), by striking "estab-
2 lish" and inserting "may establish".

3 **SEC. 4. APPLICATION OF AND PROCESS FOR UPDATING DU-**
4 **RABLE NURSERY PRODUCTS STANDARDS.**

5 (a) APPLICATION OF STANDARD.—Section 104 of the
6 Consumer Product Safety Improvement Act of 2008 (15
7 U.S.C. 2056a) is amended—

8 (1) in subsection (c), by redesignating para-
9 graph (3) as paragraph (4) and inserting after para-
10 graph (2) the following:

11 "(3) APPLICATION.—

12 "(A) IN GENERAL.—Paragraph (1) shall
13 not apply to any revision of the standard pro-
14 mulgated under subsection (b)(1)(B) subse-
15 quent to the initial promulgation of a standard
16 under such subsection.

17 "(B) SPECIAL RULE FOR FIXED-SIDE
18 CRIBS SUBJECT TO CERTAIN STATE OR LOCAL
19 LAW REQUIREMENTS.—Paragraph (1) shall not
20 apply to a fixed-side crib offered or provided for
21 use in a licensed child care facility that is sub-
22 ject to the following requirements under the law
23 of a State or a political subdivision of a State:

1 "(i) The facility may not allow a child
2 to remain in a crib for any significant
3 amount of time while the child is awake.
4 "(ii) The facility may not place in a
5 crib a child over the age of [12 months].
6 "(iii) An adult must be present when-
7 ever a child is in a crib.".
8 (b) UPDATING STANDARD.—Section 104(b) of the
9 Consumer Product Safety Improvement Act of 2008 (15
10 U.S.C. 2056a(b)) is amended by adding at the end the
11 following:
12 "(4) PROCESS FOR CONSIDERING SUBSEQUENT
13 REVISIONS TO VOLUNTARY STANDARD.—
14 "(A) NOTICE OF ADOPTION OF VOL-
15 UNTARY STANDARD.—When the Commission
16 promulgates a consumer product safety stand-
17 ard under this subsection that is based, in
18 whole or in part, on a voluntary standard, the
19 Commission shall notify the organization that
20 issued the voluntary standard of the Commis-
21 sion's action and shall provide a copy of the
22 consumer product safety standard to the orga-
23 nization.
24 "(B) COMMISSION ACTION ON REVISED
25 VOLUNTARY STANDARD.—If an organization re-

1 vises a standard that has been adopted, in
2 whole or in part, as a consumer product safety
3 standard under subparagraph (A), it shall no-
4 tify the Commission. The revised voluntary
5 standard shall be considered to be a consumer
6 product safety standard issued by the Commis-
7 sion under section 9 of the Consumer Product
8 Safety Act (15 U.S.C. 2058), effective 180 days
9 after the date on which the organization notifies
10 the Commission (or such later date specified by
11 the Commission in the Federal Register) unless,
12 within 90 days after receiving that notice, the
13 Commission notifies the organization that it has
14 determined that the proposed revision does not
15 improve the safety of the consumer product cov-
16 ered by the standard and that the Commission
17 is retaining the existing consumer product safe-
18 ty standard.".

19 **SEC. 5. APPLICATION OF SECTION 106 TO FDA-REGULATED**
20 **PRODUCTS.**

21 Section 106(a) of the Consumer Product Safety Im-
22 provement Act (15 U.S.C. 2056b(a)) is amended by in-
23 serting "or any provision that restates or incorporates a
24 regulation promulgated by the Food and Drug Adminis-

1 tration or any statute administered by the Food and Drug
2 Administration" after "or by statute".

3 **SEC. 6. APPLICATION OF PHTHALATES STANDARD.**

4 (a) PROSPECTIVE APPLICATION, ACCESSIBLE, PLAS-
5 TICIZED COMPONENT PARTS.—Section 108 of the Con-
6 sumer Product Safety Improvement Act of 2008 (15
7 U.S.C. 2057c) is amended—

8 (1) by redesignating subsections (c) through (e)
9 as subsections (d) through (f), respectively; and

10 (2) by inserting after subsection (b) the fol-
11 lowing:

12 "(c) APPLICATION.—

13 "(1) ACCESSIBLE COMPONENT PARTS.—Sub-
14 sections (a) and (b)(1) and any rule promulgated
15 under subsection (b)(3) shall apply to any children's
16 toy or child care article containing any accessible,
17 plasticized component part that is manufactured
18 after the respective effective dates in each such sub-
19 section and any such final rule.

20 "(2) COMMISSION AUTHORITY.—The Commis-
21 sion may, by rule, exempt any children's toy or child
22 care article described in paragraph (1) or any class
23 of such products or materials used in such products
24 from any of the prohibitions under subsections (a)
25 and (b)(1) and any rule promulgated under sub-

1 section (b)(3) where the Commission determines that
2 compliance with any such prohibition is not nec-
3 essary to protect children's health.".
4 (b) EFFECT OF CONCLUSIONS OF THE CHRONIC
5 HAZARD ADVISORY PANEL.—Section 108(b)(3) of such
6 Act (15 U.S.C. 2057c(b)(3)) is amended—
7 (1) by striking "Not later than" and inserting
8 the following:
9 "(A) RULEMAKING REQUIRED.—Not later
10 than";
11 (2) by redesignating subparagraphs (A) and
12 (B) as clauses (i) and (ii), respectively;
13 (3) in clause (i) (as so redesignated), by insert-
14 ing "or terminate such prohibition" after "margin of
15 safety"; and
16 (4) by adding at the end the following:
17 "(B) DEADLINE AND EFFECT ON PROHIBI-
18 TION.—If the Commission does not commence a
19 rulemaking proceeding within 90 days after re-
20 ceiving the report required by paragraph (2)(C)
21 or does not issue a final rule as required by
22 subparagraph (A) within [_____] after
23 receiving such report, the prohibition in para-
24 graph (1) shall terminate.".

1 (e) DEFINITIONS.—Section 108(f) of the Consumer
2 Product Safety Improvement Act of 2008 (15 U.S.C.
3 2057e(f)) (as redesignated by subsection (a)) is amend-
4 ed—
5 (1) in paragraph (1)—
6 (A) in subparagraph (B), by striking "con-
7 sumer product" and all that follows and insert-
8 ing "children's product that is subject to the
9 standard made mandatory by section 106(b) or
10 any successor standard";
11 (B) in subparagraphs (C), by striking
12 "consumer product" and inserting "children's
13 product"; and
14 (C) in subparagraph (D)—
15 (i) by striking "consumer product"
16 and inserting "children's product";
17 (ii) by striking "section 3(a)(1)" and
18 inserting "section 3(a)"; and
19 (iii) by striking "2052(a)(1)" and in-
20 serting "2052(a)"; and
21 (2) by amending paragraph (2) to read as fol-
22 lows:
23 "(2) DETERMINATION GUIDELINES.—For pur-
24 poses of this section, a toy can be placed in a child's
25 mouth if any part of the toy can actually be brought

1 to the mouth and kept in the mouth by a child so
2 that it can be sucked and chewed. If the children's
3 product can only be licked, it is not regarded as able
4 to be placed in the mouth. If a toy or part of a toy
5 in one dimension is smaller than 5 centimeters, it
6 can be placed in the mouth.".

7 **SEC. 7. EXEMPTION AUTHORITY FOR TRACKING LABELS**
8 **REQUIREMENT.**

9 Section 14(a)(5) of the Consumer Product Safety Act
10 (15 U.S.C. 2063(a)(5)) is amended—
11 (1) by striking "Effective 1 year" and inserting
12 "(A) Effective 1 year";
13 (2) by redesignating subparagraphs (A) and
14 (B) as clauses (i) and (ii), respectively; and
15 (3) by adding at the end the following:
16 "(B) The Commission may, by regulation, exclude a
17 specific product or class of products from the require-
18 ments in subparagraph (A) if the Commission determines
19 that it is not economically practicable for such product or
20 class of products to bear the marks required by such sub-
21 paragraph. The Commission may establish alternative re-
22 quirements for any product or class of products excluded
23 under the preceding sentence consistent with the purposes
24 described in clauses (i) and (ii) of subparagraph (A).".

1 **SEC. 8. REQUIREMENTS FOR PUBLIC DATABASE.**

2 (a) REQUIREMENTS FOR SUBMISSIONS TO THE
3 DATABASE.—Section 6A(b) of the Consumer Product
4 Safety Act (15 U.S.C. 2055a(b)) is amended—

5 (1) in paragraph (1)(A)—

6 (A) in clause (i), by striking "consumers"
7 and inserting "persons who suffer harm or risk
8 of harm related to the use of a product, their
9 next of kin or members of their household, their
10 legal representative, or another person expressly
11 authorized by any such person"; and

12 (B) in clause (v), by striking "public safety
13 entities" and inserting "police, fire, ambulance,
14 emergency medical services, Federal, State, and
15 local law enforcement entities, and other related
16 public safety officials"; and

17 (2) in paragraph (2)(B)—

18 (A) in clause (i), by inserting "and its lo-
19 cation and availability" after "concerned";

20 (B) in clause (iv), by inserting "and if
21 such person is not the person harmed by the
22 product, the name and contact information of
23 the person who suffered the harm or risk of
24 harm related to the use of the product" after
25 "report"; and

1 (C) in clause (v), by inserting "that such
2 person is the consumer who used the product
3 that gave rise to the harm, the user's next of
4 kin, a member of the user's household, the legal
5 representative of the user, or another person ex-
6 pressly authorized by any such person and"
7 after "person submitting the information".
8 (b) ADEQUACY AND ACCURACY OF INFORMATION RE-
9 PORTED TO THE PUBLIC DATABASE.—Section 6A(c)(2) of
10 the Consumer Product Safety Act (15 U.S.C.
11 2055a(c)(2)) is amended—
12 (1) in subparagraph (A), by striking "to sub-
13 mit" and all that follows and inserting "to—
14 "(i) notify the Commission within
15 [___] days after receipt of the report
16 that the information provided in the report
17 is insufficient for determining which of the
18 manufacturer's products is the subject of
19 the complaint, in which case the manufac-
20 turer shall provide the Commission (and
21 the person submitting the complaint, if
22 that person has consented to disclosure of
23 contact information) with information to
24 assist the person submitting the report to

1 sufficiently identify or provide an adequate
2 description of the product;
3 "(ii) notify the Commission within
4 [____] days after receipt of the report
5 that the information provided in the report
6 is materially inaccurate and to provide the
7 Commission with any additional informa-
8 tion supporting the manufacturer's claim
9 of inaccuracy; and
10 "(iii) submit other comments to the
11 Commission on the information contained
12 in such report."; and
13 (2) by redesignating subparagraphs (B) and
14 (C) as subparagraphs (C) and (D), respectively, and
15 inserting after subparagraph (A) the following:
16 "(B) ACTION BY THE COMMISSION.—
17 "(i) INSUFFICIENT INFORMATION.—If
18 a manufacturer notifies the Commission of
19 the insufficiency of the information in a re-
20 port pursuant to subparagraph (A)(i), the
21 Commission shall provide the information
22 provided by the manufacturer to the per-
23 son submitting the report (unless such in-
24 formation has already been provided di-
25 rectly by the manufacturer) and seek to

1 obtain from such person an adequate de-
2 scription of the product.
3 "(ii) MATERIALLY INACCURATE IN-
4 FORMATION.—If a manufacturer notifies
5 the Commission of a material inaccuracy in
6 a report pursuant to subparagraph (A)(ii),
7 and the Commission determines that the
8 claim is potentially valid, the Commission
9 shall seek to resolve the inaccuracy by any
10 of the following:
11 "(I) Obtaining from the person
12 submitting the report such additional
13 information necessary to correct the
14 inaccuracy.
15 "(II) Investigating the incident
16 giving rise to the report in order to
17 correct any such inaccuracy.
18 "(III) Providing the manufac-
19 turer a reasonable period of time to
20 investigate and provide additional in-
21 formation to correct any inaccuracy.
22 "(iii) STAY ON INCLUSION IN DATA-
23 BASE.—The Commission shall not include
24 in the database a report described in
25 clauses (i) or (ii) until the product can be

1 specifically identified and any material in-
2 accuracy corrected.".
3 (c) MISREPRESENTATION PROHIBITED.—Section
4 19(a)(13) of the Consumer Product Safety Act by insert-
5 ing "related to a submission of information to the data-
6 base established under section 6A, or" after "misrepresen-
7 tation to such an officer or employee".

8 **SEC. 9. SUBPOENA AUTHORITY.**

9 Section 27(b) of the Consumer Product Safety Act
10 (15 U.S.C. 2076(b)) is amended—
11 (1) in paragraph (3), by inserting "and phys-
12 ical" after "documentary";
13 (2) in paragraph (8), by striking "and";
14 (3) by redesignating paragraph (9) as para-
15 graph (10) and inserting after paragraph (8) the fol-
16 lowing:
17 "(9) to delegate to the general counsel of the
18 Commission the authority to issue subpoenas solely
19 to Federal, State, or local government agencies for
20 evidence described in paragraph (3); and"; and
21 (4) in paragraph (10) (as so redesignated), by
22 inserting "(except as provided in paragraph (9))"
23 after "paragraph (3)".

1 **SEC. 10. AVAILABILITY OF CERTAIN PERSONAL AND MED-**
2 **ICAL INFORMATION TO THE CPSC.**

3 Section 5 of the Consumer Product Safety Act (15
4 U.S.C. 2054) is amended by adding at the end the fol-
5 lowing new subsection:

6 "(e) AVAILABILITY OF PERSONAL AND MEDICAL IN-
7 FORMATION UNDER HIPAA.—In order to carry out its
8 investigative and enforcement activities under this Act and
9 under any of the Acts enforced by the Commission, the
10 Commission shall be deemed a public health authority
11 within the meaning of section 164.512(b)(i) of title 45,
12 Code of Federal Regulations, for purposes of permitted
13 disclosures of protected health information authorized
14 under such section. For purposes of such section informa-
15 tion about deaths, injuries, diseases, and other health im-
16 pairments possibly relating to consumer products shall be
17 deemed protected health information authorized to be dis-
18 closed to such public health authorities under such sec-
19 tion.".

20 **SEC. 11. EFFECTIVE DATE.**

21 The amendments made by this Act shall be treated
22 as having taken effect on the date of enactment of the
23 Consumer Product Safety Improvement Act of 2008.

American Academy of Pediatrics

DEDICATED TO THE HEALTH OF ALL CHILDREN™

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June 8, 2011

The Honorable Mary Bono Mack
Chair
Subcommittee on Commerce, Trade and Consumer Protection
Committee on Energy and Commerce
Washington, D.C. 20515

Dear Chairwoman Bono Mack:

Thank you for the opportunity to answer additional questions related to my testimony before the Subcommittee on Commerce, Manufacturing, and Trade on April 7, 2011, at the hearing entitled "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act."

Attached you will find responses to the questions submitted by members of the Subcommittee. If you require further information, please contact Kristen Mizzi with the American Academy of Pediatrics at 202/347-8600.

Sincerely,

Dana Best, MD MPH FAAP

Attachment

cc: The Honorable G. K. Butterfield, Ranking Member,
Subcommittee on Commerce, Manufacturing, and Trade

The Honorable Mary Bono Mack

1. ***You have testified that your analysis became the basis for choosing the lead levels in CPSIA. Was your analysis ever published in a peer-reviewed journal?***

The American Academy of Pediatrics' recommendations on lead limits for children's products were developed by the environmental health pediatricians who serve on the AAP's Committee on Environmental Health and reviewed and approved by the AAP leadership. As testimony, it is considered official AAP policy and given equal weight to our policy statements. AAP policy statements are developed by board-appointed expert committees and then published in the AAP's scholarly journal, *Pediatrics*. Publication in *Pediatrics* would have been redundant because the recommendations had already been reviewed extensively by experts and were approved as policy by Academy leadership.

2. ***On page 5 of your written testimony, you state that children who already have an elevated blood lead level may lose IQ points more readily than those with no detectable blood lead level. How do you reconcile this with the "key studies" you mention on page 3 of your testimony, which you interpret as showing greater IQ loss from one to ten micrograms per deciliter than for a change from ten to twenty micrograms per deciliter?***

Neurological damage from lead exposure does not take place on a strictly linear dose-response curve. The impacts of lead exposure on children with no detectable lead level are currently unknown; lead exposure at the lowest levels may cause some loss of IQ points, or it may not begin to cause harm until blood lead levels reach at least 3 micrograms per deciliter (mcg/dL), the level at which studies now confirm that IQ loss begins to take place. As blood lead levels increase from 3 to 10 mcg/dL, approximately 1 IQ point is lost for every increase of 1 mcg/dL. Above a blood lead level of 10 mcg/dL, the loss of IQ points proceeds less rapidly. When a blood lead level of 10 mcg/dL is reached, the child is expected to have lost approximately 7 IQ points; as blood lead level rises further, the IQ loss continues to accumulate but at a slower rate.

3. ***You mentioned that the Food and Drug Administration has long had a recommendation that daily intake of lead be no more than 6 micrograms per day for children age 6 and younger. Does the FDA have a different recommendation for older children? What is the recommendation for adults? Is there a separate recommendation for pregnant women?***

The Food and Drug Administration (FDA) issues a range of recommendations for daily tolerable lead intake. It should be noted, however, that these are daily intakes for food only, which do not take into account other possible exposures from sources like air, dust, and consumer products. These intake levels recognize the fact that it is impossible to

remove lead from food in cases where, for example, a plant absorbs lead from the soil. The FDA's current daily tolerable intake levels for lead are as follows:

Provisional Total Tolerable Intake Levels for Lead (Pb)

Population Group	PTTI (µg Pb/day)
Young children (0-6 years)	6
Older children (7+ years)	15
Pregnant or lactating women	25
Adult women	75

4. ***You mentioned that older children sometimes put ballpoint pens or jewelry in their mouths. You also mentioned that toys may be shared among multiple children in the same household. But aren't there many items which older children do not mouth and to which young children rarely, if ever, have access?***

It is likely that there are children's products which older children do not mouth and to which younger children rarely have access. Older children may, however, still be exposed to lead from hand-to-mouth contact (i.e. touching an object and then putting their hands in their mouths or eating with their hands). Given that lead exposure poses a significant hazard and usually can be replaced by safer alternatives in children's products, the AAP recommends ensuring that all children's products contain the lowest possible levels of lead.

5. ***Are you familiar with the studies claiming that eating junk food can cause the loss of IQ? Did the IQ studies on lead control for junk food?***

In February 2011, Northstone et.al. published a study in *the Journal of Epidemiology & Community Health* titled, "Are dietary patterns in childhood associated with IQ at 8 years of age? A population-based cohort study." The study concluded, "There is evidence that a poor diet associated with high fat, sugar and processed food content in early childhood may be associated with small reductions in IQ in later childhood, while a healthy diet, associated with high intakes of nutrient rich foods described at about the time of IQ assessment may be associated with small increases in IQ." In essence, poor diet and lower IQ tend to be found together, but the study designs examining "junk food" have not been robust enough to determine specific dietary nutrient differences causing IQ changes in the children.

It should not come as a surprise that poor nutrition during key periods of early brain development would cause IQ loss. Other studies have demonstrated the importance of balanced nutrition on children's developmental abilities. Poor nutrition can also contribute to a child's vulnerability to lead exposure. Children with nutritional deficiencies, particularly with regard to iron, are known to absorb lead into their bodies at a higher rate and therefore suffer a greater degree of associated harm.

6. ***How many "potent neurotoxins" are known to science?***

"Potent neurotoxin" is not a term of classification for hazardous substances. The Environmental Protection Agency publishes a consolidated list of approximately two thousand chemicals and other substances subject to the Emergency Planning and Community Right-to-Know Act, Comprehensive Environmental Response, Compensation and Liability Act, and Section 112(r) of the Clean Air Act that includes lead and numerous compounds of lead. These substances are not, however, further classified based on the body systems or functions they impact.

6. ***Has science been able to identify a safe level for most toxins, lead being exceptional?***

Many known toxins are poorly studied, particularly in sensitive populations like children and pregnant women. This lack of data should not, however, be interpreted as evidence of safety. For some substances, science has identified a level below which no human health harm can be identified or detected with current research techniques. For example, the Food Quality Protection Act of 1996 (FQPA) sets a health-based standard of "reasonable certainty of no harm" that requires EPA, when setting tolerances for pesticide residue, to take into account cumulative sources of exposure (e.g., occupational, drinking water) as well as exposure to other pesticides with a common mechanism of toxicity. FQPA also requires an explicit determination that a given tolerance is safe for children and imposes an additional safety factor of up to tenfold to account for uncertainty in data relative to children.

7. ***You testified before the CPSC regarding the technological feasibility of the 100 parts per million standard. You testified that lead affecting one half of one percent of all children – even those older than age 12 – could potentially affect 3.75 million children. How did you reach that conclusion? You also stated that swallowing an object containing 300 parts per million lead would raise a child's blood lead level enough to lower his IQ 4 points. Could you please explain? How much lead were you assuming the child ingested?***

My testimony before the Consumer Product Safety Commission on February 16, 2011 stated:

Based on the AAP's previously-noted calculations, an object containing 77ppm of lead is capable of raising a child's blood lead level to a level that would result in the loss of one IQ point. Please note that this is not meant to be interpreted as a definitive statement for each exposed individual; rather, it is a public health statement representing what will be true for the majority of children. Individual children will have factors that either increase or decrease their vulnerability.

For the majority of children, ingestion of an item containing 300ppm of lead would result in the loss of almost 4 (3.9) IQ points. Ingestion of an object containing 100ppm lead would result in the loss of just over one (1.3) IQ points.

Given that the ingestion of an item containing 300ppm of lead will cause the loss of 1 IQ point for each 77ppm of exposure, an object weighing one gram (about one standard paper clip) could cause the loss of almost 4 IQ points (300/77=3.896).

If one limits calculations only to the roughly 50 million children under the age of 12, one-half of one percent of all such children would mean that approximately 250,000 children would be affected – the equivalent of the entire population of Olympia, Washington.

8. ***When you testified before the Committee on the original introduced bill in November 2007, the legislation contained a lead standard that was similar to the current total lead standard with a final total lead standard of 100 ppm, but also provided an alternative soluble lead standard if any part did not exceed 90 ppm. You testified in support of the standard:***

> *H.R. 4040 allows manufacturers to choose between satisfying one of two standards for lead content in children's products. Manufacturers may choose to limit total lead content to a level that is initially set at 600 parts per million and is reduced to 250 parts per million after two years, then to 100 parts per million another two years later. Alternatively, manufacturers may choose to limit soluble lead content to 90 parts per million.* ***"The standards of 90 and 100 parts per million are significant goals which, if met, will measurably reduce exposure to lead in children's products.***

Your only comments seemed to have been to ensure the solubility standard was set by the CPSC to be rigorous. Would you still support a solubility standard? Is solubility a more accurate calculation of potential lead exposure? Isn't the "dose make the poison" more applicable to a soluble standard than a total lead standard? Is there any difference between a solubility standard and the de minimis exposure standard in the legislative draft?

Given that no standard existed to limit lead in any part of a children's product except paint prior to 2008, the limits in the original draft of H.R. 4040 were indeed a major step forward. The AAP's November 2007 testimony also noted, "The results of lead tests on products can vary considerably depending upon the methodology used to assess solubility. Further, the relationship of solubility to bioavailability and absorption will

vary by method used to determine solubility. ... the lead standard that drops from 600 to 100 parts per million should state explicitly that it refers to total lead."

Based on a thorough exploration of the issues over the past four years, the AAP considers a total lead standard to be superior to a soluble lead standard. Individual children have factors that either increase or decrease their vulnerability to lead exposure; the federal standard should be protective of all children, including those most vulnerable.

As noted in a question above, the health effects of lead do not adhere to a linear dose-response relationship, meaning that "the dose makes the poison" is not necessarily an accurate representation of its health effects.

There could be a significant difference between a solubility standard and the 'de minimis' exposure standard proposed in the legislative draft. The discussion draft failed to provide any definition of what constitutes a 'de minimis' risk. The National Institutes of Health Toxicology Glossary defines risk de minimis as, "Risk that is negligible and too small to be of societal concern... can also mean 'virtually safe.'" There is no scientific basis for deeming any level of lead exposure to be 'virtually safe.' If such a level of lead exposure exists, research has not identified it to date.

The Honorable G. K. Butterfield

1. ***Please provide a discussion of the relationship between the hand-to-mouth behavior of children and lead ingestion. In particular, address the following:***

   a. ***Is hand-to-mouth behavior the primary route for lead ingestion by children?***

   b. ***Please explain how lead is ingested from hand-to-mouth behavior.***

   c. ***Please discuss any research regarding the relationship between hand-to-mouth behavior and blood lead levels.***

Children engage in a range of normal mouthing behaviors from infancy through school age and sometimes into adolescence. Exposure to lead can take place through ingestion of objects containing lead (such as paint chips), hand-to-mouth behavior, breathing airborne lead, and consumption of lead in food and drink, including water. Lead is ingested from hand-to-mouth behavior when lead gets on the child's hands and the child then puts his hands in his mouth or eats with his hands.

A voluminous literature exists documenting children's mouthing behaviors, some of which also explores the impact of those behaviors on blood lead levels. One particularly high quality study involved observation of children playing in a yard; researchers video-observed their hand-to-mouth behavior and then evaluated relationship of oral behaviors to children's blood lead levels. Children with higher hand-to-mouth occurrences had correspondingly higher blood lead levels. Investigators video-observed children ages 1-5

years putting a hand in their mouth 7 times hourly (maximum 67 times/hour) and an object or food in their mouth 17 times hourly (maximum 125 times/hour).[i]

2. Please provide a discussion of any research regarding the mouthing behaviors of older children, in particular those between ages 6 and 12.

A review of reports that describe children's mouthing was published by the U.S. Environmental Protection Agency (EPA) in 2009.[ii] The EPA report has a significant quantity of similar data, with frequency of oral behaviors and minutes/day of mouthing. The amount of lead that would be transferred to a child may depend on mouthing behavior (times/hour and minutes/day) and the transfer rate of lead from the object to the hand (if the object is touched and not directly mouthed). Children as old as 10-12 years put their hand in their mouth an average of 4 times hourly. This rate is much higher among younger children, and exposures from mouthing behaviors can be occurring for several hours daily per child. Even for adult workers, hand lead is associated with blood lead level.[iii]

In addition, the Centers for Disease Control and Prevention's Mortality and Morbidity Weekly Report (CDC MMWR) has published cases of lead poisoning not related to ingestion of objects. Most recently, the MMWR published a case study of a toddler poisoned by a metal charm on a necklace he wore and mouthed regularly.[iv] The MMWR has also published cases of lead poisoning from eating off lead-tainted dishware;[v] lead dust contamination of family vehicles;[vi] and exposure to lead at a firing range among adolescent members of a shooting team.[vii]

3. Please provide a discussion of any research regarding the mouthing behaviors of disabled children.

Children with certain developmental delays and other disabilities are known to be at risk for mouthing behaviors that persist in frequency and duration beyond those exhibited by non-disabled children. Given the wide array of different sorts of special health care needs, however, it would be difficult to craft a study that could accurately represent mouthing behaviors of all children with disabilities. The studies that exist in this area tend to focus on mouthing behaviors associated with specific disabilities and mitigation of these behaviors.

4. Robert J. Howell, the Assistant Executive Director for the Office of Hazard Identification and Reduction at the Consumer Product Safety Commission, in response to questioning from the Subcommittee contended that "one would expect that the risk [from lead-bearing items] decreases as you move from swallowing to mouthing, from mouthing to touching. And the management of that risk at that point then becomes a decision on how the child interacts with the product."

a. This seems to suggest that if a child cannot swallow the lead-bearing item, the child's risk of harm is inherently low. Do you agree? If not, please discuss the

harms associated with mouthing (i.e. sucking or licking) or touching lead-bearing items.

b. ***This concept also suggests that all children will play with that item the same way. Do different aged children play with the same item in different ways?***

While the risk of lead exposure may be lower from mouthing than from ingestion, such exposure is not necessarily "inherently low." As noted in the response to the preceding question, significant lead exposures have been documented from a number of sources that would not have been obvious hazards. In addition, children of different ages will play or interact with the same item in different and sometimes unexpected ways.

5. The final statutory total lead content limit of 100 ppm set to take effect in August is more than double the 40 ppm recommendation that the American Academy of Pediatrics developed following a rigorous scientific review in response to a request from Congress to make specific recommendations regarding lead content in products. Nonetheless, some manufacturers, such as those of ATVs and bikes, have convincingly argued that they cannot make products that are durable and affordable without certain components that exceed the lead limits.

a. ***I understand the AAP would prefer to see lead eliminated from consumer products, but to the extent that there is bipartisan agreement that Congress should create an exemption process to provide targeted relief from the lead limits for the narrow universe of manufacturers who contend they cannot reasonably comply, do you agree any exception process must, as a fundamental matter, consider whether a particular product needs to have lead in it?***

The American Academy of Pediatrics would urge Congress not to permit levels of lead in excess of the CPSIA's limits in any children's product for which safer, effective alternatives exist. The CPSIA's section 101(b) specifically provided for the exclusion of certain materials or products if it could be demonstrated that exposure to the lead involved would not adversely impact child health. If Section 101(b) has proven to be unworkable, it should be revised to serve the purpose that Congress intended.

6. ***I understand that some materials used in children's products can crack and degrade over time, and that this is particularly true of vinyl and plastic products. As this happens, the amount of lead and other substances available for ingestion is greater than when the product was new.***

a. ***Can you please confirm that vinyl and plastic products behave in this way and provide any additional information you think may be useful to understanding this degradation and exposure process?***

b. ***Are you aware of any other materials that exhibit similar characteristics to vinyl and plastic (i.e. material that can crack and degrade over time and release more lead or other harmful substances than when new)? Please describe these materials and what happens as those material ages.***

c. ***Assuming we applied the de minimis exception in the Republican discussion draft, should foreseeable use and abuse include degradation of a material? And if so, how would you account for that in the estimation of the amount of lead a child is likely to ingest from that material?***

It is correct that many materials containing lead will deteriorate over time and liberate higher levels of lead than when they were new or first produced. While the AAP can provide some information in this regard, more detailed authoritative information can best be obtained from chemical or biomolecular engineers.

7. ***During the hearing, the Subcommittee heard repeatedly that the traditional model for the regulation of lead and other harmful substances has been to use risk assessment, and that manufacturers should be allowed to apply this model to children's products. However, last year this Subcommittee in a hearing regarding the regulation of toxic substances received testimony arguing that the traditional risk assessment model is not appropriate for substances that are persistent, bioaccumulative and toxic (PBTs) because these characteristics affect how the environment and human body treat these substances and make exposure inevitable. I understand that lead is a PBT.***

a. ***Can you please confirm that lead is a PBT?***

b. ***Can you please discuss the characteristics of PBTs that make the traditional risk assessment approach for limiting exposure an inappropriate model for dealing with lead?***

c. ***Do you agree with the Centers for Disease Control's recommendation that the nonessential uses of lead in consumer products should be restricted or eliminated to prevent exposure to this harmful substance?***

Lead is classified as persistant, bioaccumulative and toxic (PBT), and releases must be reported to EPA's Toxic Release Inventory. Traditional risk assessment tends to examine one-time exposures in isolation from other exposures. In the case of lead and other PBT substances, individual low-level exposures accumulate over time to reach harmful levels. Children may be exposed to lead through the air, water, soil, household sources like paint, and consumer products. As a result, these cumulative exposures may raise a child's blood lead level to a dangerous point even though no single exposure occurs at high levels. The AAP fully agrees with the CDC's recommendation that nonessential uses of lead in consumer products be restricted or eliminated to prevent exposure.

8. ***The Republican discussion draft draws a distinction between lead-containing products and parts that can and cannot be swallowed, with items that can be swallowed remaining subject to the health-protective lead content limits in CPSIA. The basis for determining whether an item can be swallowed is the "small parts cylinder" described***

in regulations that I understand are aimed at preventing children under 3 from choking on or swallowing small objects.

a. ***Do you believe the "small parts cylinder" is an appropriate tool for determining whether children over 3 years old can swallow an object?***

b. ***Are you aware of any cases where children over 3 years old swallowed objects that likely would not fit into the small parts cylinder (and therefore not be deemed a small part capable of being swallowed and not subject to CPSIA's strict lead content limits)? Please describe those cases and provide any additional available documentation.***

The small parts cylinder is a widely-used and well-established tool for determining whether children *under* the age of 3 years can swallow or choke on an item. The small parts cylinder is not designed for determining choking hazards for children *over* the age of 3 years.

The AAP does not maintain individual case reports or conduct studies related to incidents of choking hazards or ingestion of non-food items.

9. ***The Republican discussion draft provides that manufacturers of "specialty products for the disabled" must either be excluded from any third-party testing rules CPSC may issue under the onerous process setup in the draft or be allowed to comply through alternative testing procedures. The draft provides no definition for the term "specialty products for the disabled." I understand that certain toys are recommended and marketed as particularly useful for engaging disabled children; however, these toys are available and appealing to all children.***

a. ***Are you aware of any toys or other similar children's products (i.e. not medical or other adaptive devices for the disabled) that are intended only for disabled children and that are not appealing or susceptible to being played with by all children?***

b. ***Are you aware of any toys or other similar children's products (i.e. not medical or other adaptive devices for the disabled) that the medical community recognizes as "specialty products for the disabled"?***

c. ***Assuming this Subcommittee or CPSC is capable of identifying "specialty products for the disabled," would it concern you if manufacturers of products specifically for disabled children were held to a lower bar or no bar at all with respect to assuring the safety of these products? Please explain these concerns.***

It is unclear what may be considered to be "specialty products for the disabled." The AAP does not closely monitor the marketplace of toys designed specifically for children with special health care needs. However, any products designed for children with special health care needs should be held to the same high safety standards as other children's products.

The Honorable John Dingell

1. ***CPSIA defines a "children's product" as one "(primarily) intended for a child 12 years of age or younger." The discussion draft would change this definition to "intended for use by a child [age to be determined] years or younger." What effect would the words "for use by" have on the number and type of products covered by this definition?***

It would appear that this change in wording could exclude from coverage products that are not specifically used by the child, but may be used by a parent or caregiver in caring for the child. Such products might include bathing products, changing table and diapering supplies, or décor items.

2. ***The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a de minimus amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."***

   a. ***Are you aware of a uniform reasonable methodology in use by manufacturers of children's products?***

   b. ***Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?***

   c. ***If so, do you believe this is could pose a risk to the health of children who use such products?***

The CPSIA requires all manufacturers to comply with a limit on total lead in children's products, which does not vary based upon any estimate of the amount of lead a child would likely ingest from exposure to a component part. As a result, it would seem unlikely that any manufacturer is currently attempting to estimate exposure, since such calculations would be irrelevant to compliance. The term "reasonable methodology" is ambiguous; manufacturers could conceivably use a wide range of methodologies, which would in turn result in a significant variance in test results. Any practice that resulted in a child's exposure to elevated lead levels could pose a risk to that child's health.

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http://www.ncbi.nlm.nih.gov/pubmed/16941017

[ii] U.S. Environmental Protection Agency. Child-Specific Exposure Factors Handbook. August 2009, (EPA/600/R-08/135).

[iii] Rodrigues E, Virji M, McClean M, Weinberg J, Woskie S, Pepper L. Personal exposure, behavior, and work site conditions as determinants of blood lead among bridge painters. *J Occup Environ Hyg*, 2010 Feb;7(2):80-7.

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[v] Childhood Lead Poisoning from Commercially Manufactured French Ceramic Dinnerware – New York City, 2003. *MMWR*, July 9, 2004. 53(26);584-586.
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[vi] Childhood Lead Poisoning Associated with Lead Dust Contamination of Family Vehicles and Child Safety Seats – Maine, 2008. *MMWR*, August 21, 2009. 58(32);890-893.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5832a2.htm

[vii] Lead Exposure from Indoor Firing Ranges Among Students on Shooting Teams – Alaska, 2002-2004. MMWR, June 17, 2005. 54(23);577-579.
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5423a1.htm

May 6, 2011

Representative Mary Bono Mack
Chairman, Subcommittee on Commerce, Manufacturing, and Trade
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

VIA E-MAIL

RE: Responses to Member questions regarding Dr. Beck's April 17, 2011 testimony at the hearing titled "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act."

Dear Representative Bono Mack:

Attached are my responses to the Member questions submitted on April 27, 2011. As requested, I have included the full text of each question, followed by my response.

Please do not hesitate to contact me with any questions. Thank you again for the opportunity to provide testimony at the Subcommittee on Commerce, Manufacturing, and Trade Hearing.

Sincerely yours,

GRADIENT

Barbara D. Beck, Ph.D., DABT, FATS
Principal

email: bbeck@gradientcorp.com

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Attachment A – Responses to Member Questions

The Honorable Mary Bono Mack

1. *Can children's products that have higher total lead content nevertheless pose a lower risk than products with lower total lead content? Please explain.*

Dr. Beck Response:

Yes, it is possible that some children's products that have a higher total lead content may result in a lower risk than products with lower total lead content. As I explained in my written testimony (Beck, 2011), the actual risk would be based on numerous factors, including the actual dose of lead, exposure duration and frequency, exposure route (for example, through the skin *versus* mouthing), lead intake (the amount of lead available for absorption by the skin, lungs, or the gastro-intestinal tract), solubility of lead, and subsequent uptake (absorbed dose).

2. *You state a soluble lead standard is generally preferable to a standard based on total lead because it more accurately reflects the amount of lead that could be released from the product.*

   a. *Does that mean the current total lead standard does not account for the amount of lead that can be released from a product? How then would you grade the effectiveness of a total lead standard in protecting health?*

Dr. Beck Response:

The effectiveness of the current total lead standard is uncertain because it is not directly linked to exposure. The current standard is therefore less relevant to health protection than a standard based on actual exposure. Rather than focus on the effectiveness of a total lead standard in protecting public health, it would be better to consider a standard that is more directly linked to actual potential exposures of the population of interest.

   b. *Why should exposure be taken into account instead of a simple numeric limit?*

Dr. Beck Response:

It is important to take exposure into account instead of a simple numeric limit. Simple numeric limits based on concentration are not directly linked to health. Thus, it is very difficult to evaluate their effectiveness. In contrast, a more effective approach would be to develop a standard by setting a target blood lead increment, then calculating the amount of lead released from a toy or other product that would limit any impact to be at or below the target blood lead increment. Health-based limits for lead in other media, such as air, water, or soil, have been developed in this same manner, using exposure parameters specific to that medium (see, for example, US EPA, 2001, 2002).

The Honorable G. K. Butterfield

For each project listed on the curriculum vitae you provided to the Subcommittee, please identify the specific law firm and client or specific entity for which you provided any services and the amounts paid to you or Gradient for these services.

Dr. Beck Response:

This is confidential business information. Thus, I am unable to meet this request.

The Honorable John Dingell

1. *CPSIA defines a "children's product" as one "(primarily) intended for a child 12 years of age or younger." The discussion draft would change this definition to "intended for use by a child [age to be determined] years or younger." What effect would the words "for use by" have on the number and type of products covered by this definition?*

Dr. Beck Response:

I am uncertain as to the intent of this question. Thus, I am unable to provide an answer at this time.

2. *The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a de minimus amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."*

    a. *Are you aware of a uniform reasonable methodology in use by manufacturers of children's products?*

Dr. Beck Response:

I am not aware of a uniform methodology currently in use by manufacturers. However, in my written testimony (Beck, 2011), I do point to some possible methods to consider as a basis for developing such a methodology, including CPSC's saline extraction method for evaluating cadmium leaching from metal jewelry during a mouthing scenario (CPSC, 2010), or a modification of CPSC's method for assessing migration of diisononyl phthalate (DINP) from polyvinyl chloride (PVC) children's products (CPSC, 1998).

b. *Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?*

Dr. Beck Response:

Yes, the term "reasonable methodology" may be ambiguous and could lead to variance in test results. I recommend that the language of the Bill be revised to recommend the development of guidance and criteria for a reasonable and appropriate methodology for evaluating mouthing exposure to children's products. Sample extraction and preparation methods should be recommended with the objective of achieving comparable testing results. I would also propose that CPSC be tasked with oversight and development of the "reasonable methodology." As described in my written testimony (Beck, 2011), there are some existing saliva extraction methods that could potentially be used to evaluate mouthing exposure to children's products.

c. *If so, do you believe this is could pose a risk to the health of children who use such products?*

Dr. Beck Response:

If a reasonable methodology is clearly defined in the Bill, there should be no impact on risk or health.

References

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US Consumer Product Safety Commission (CPSC). 2010. "Staff Report: Cadmium in Children's Metal Jewelry." Accessed on February 3, 2011 at http://www.cpsc.gov/LIBRARY/FOIA/FOIA11/os/ cadmiumjewelry.pdf, 109p, October.

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House Committee on Energy and Commerce
Subcommittee on Commerce, Manufacturing, and Trade
Hearing: "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act"
April 7, 2011

Responses of Robert J. Howell to Questions for the Record

Questions from the Honorable Mary Bono Mack

1. **How does the CPSC staff go about deciding whether a chemical substance poses a risk to children? What factors are important?**

   For substances not regulated by specific statutory provisions, such as lead, the Federal Hazardous Substances Act (FHSA) generally requires assessment of exposure and risk, considering reasonably foreseeable handling and use. Assessments are generally conducted on a case-by-case basis, considering the specific characteristics of the product, the intended consumers of the product, and the interaction between the consumer and the product. The CPSC Health Sciences, Engineering Sciences Human Factors, and Laboratory Sciences Chemistry Division staff conducts these assessments.

   For a specific product, staff assesses the toxicity of the chemical, conducts a dose-response assessment, and derives limits for exposure that, if exceeded, could result in adverse health effects (acceptable daily intake). Staff also conducts testing of products to estimate the level of exposure to the chemical that could occur during use, and then evaluates whether a consumer might experience excess exposure during use of the product. CPSC Chronic Hazard Guidelines provide definitions and guidance for the analysis of toxicity and exposure information (http://www.cpsc.gov/BUSINFO/chronic.pdf).

   Many different factors may be important to consider in an evaluation of toxicity, dose-response, and exposure. Staff assesses the relevance and quality of available toxicity data for a chemical, including information on adverse effects in exposed people, when available, and whether certain populations of people, such as children, may be more or less susceptible to experiencing adverse effects. Staff then assesses whether the data are sufficient to describe the relationship between exposure or dose and the occurrence of adverse health effects. The analysis also considers whether a chemical poses a risk because of the likelihood that a child could be exposed to it from the use of the product.

2. **When the CPSC staff evaluates chemical substances in consumer products, is there a particular age it focuses on? How do you take children's age into account?**

   The scientific assessment of a product is generally a case-by-case evaluation of the product which considers the intended or likely consumer and the expected behaviors associated with the product (this is also known as Human Factors staff analysis). Excess exposure would be expected to be more likely to occur with certain conditions and behaviors. For example, children under three years of age have the highest rates of mouthing behaviors (i.e., placing objects in the mouth, or handing objects and then placing fingers or parts of hands in the

mouth) and accidental or intentional ingestion of objects. The rate of mouthing and swallowing objects decreases significantly through childhood.

Children's exposure to a chemical from a product tends to be the highest in situations involving ingestion of a product, compared to touching or handling a product, or inhalation, because of the action of stomach acid that could leach a chemical from the product. In adults, exposures to chemicals in products may be more likely to occur through routes other than ingestion of the product, and again are product-specific.

Certain product types might be more likely to be associated with excess exposure in young children. For example, small jewelry items may be frequently mouthed or even swallowed. Moreover, certain materials may result in more exposure than others may; e.g., metals tend to be more soluble in stomach acid than plastics.

Therefore, prioritization of staff project work may focus on products for younger children or on products with expected behaviors and exposure patterns that might result in excess exposure, or on both of these factors. Routine analysis of products obtained by CPSC is based on all of the considerations above, and is specific to the product being evaluated.

3. Does lead affect humans differently at different ages? If so, how?

Factors related to exposure to lead may be more important than the toxicity of lead in different populations. For example, children under three years of age have the highest rates of mouthing behaviors (i.e., placing objects in the mouth, or handing objects and them placing fingers or parts of hands in the mouth) and accidental or intentional ingestion of objects. The rate of mouthing and swallowing objects decreases significantly through childhood. Therefore, the youngest children have the highest exposures to lead (other than occupational exposures in adults).

With respect to lead toxicology, the scientific literature includes studies of children of all ages, but predominantly younger children, probably because of the knowledge of children's sensitivity to lead compared to adults. The susceptibility of children stems both from factors relating to physiology, such as their immature and developing nervous system, and rapid growth and development rate, and to common childhood behaviors that tend to increase exposure, such as mouthing, ingesting objects, and hand-to mouth activity. In addition, lead accumulates in the body, so that exposures at younger ages may result in adverse health effects later in life.

Among children of all ages, the relationship between a specific age and vulnerability to lead toxicity is not well understood, so that no specific window of exceptional susceptibility has been defined. Further, available information does not support a conclusion that there are populations not at risk to effects from lead exposure. Literature on the toxic effects of lead exposure in adults has expanded in recent years, showing consistent associations between lead exposure and increased risk of health effects involving the organs systems such as the cardiovascular system and kidneys, as well as neurocognitive effects. Thus, lead exposure can cause adverse health effects in people of all ages.

In general, children are susceptible to the effects of lead throughout childhood and beyond. While the specific effects and the relationship between the level of exposure and the outcome are likely related to the age of the exposed person, detailed information is not available to clearly separate vulnerable children by age.

4. **The Commission set higher lead limits for certain metal alloys in electronic products for children. When the Commission granted a stay of the lead content limits for ATVs and bicycles, it set temporary limits at the same or very similar levels. In the Commission's view, does the lead content allowed in these products pose a significant risk to children? Please explain why or why not.**

   Section 101(b)(4) of the CPSIA provides that if the Commission determines that it is not technologically feasible for certain electronic devices to meet the lead content limit, the Commission must issue requirements or minimize the potential for exposure to and accessibility of lead in such electronic devices. Accordingly, by rule, the Commission established that it is currently not technologically feasible for certain component parts of electronics to meet the CPSIA lead limits (e.g., cathode ray tube glass) which are necessary for the proper electronic functioning of the component part.

   The exempted parts of electronic devices and the parts of ATVs and bicycles with lead content that might exceed the statutory lead limits are generally parts of products that are not expected to be frequently contacted or to be mouthed or swallowed by children. Because exposure to the exempted parts would be minimal, very little, if any, exposure to lead that might be present in the part of product is likely.

5. **The Government of Canada is in the process of addressing lead in consumer products. How does Canada's new approach compare to ours? Does it treat different types of products differently based on exposure?**

   A new regulation in Canada applies to what is referred to as "Group 1 products," which are products used in the mouth (other than kitchen utensils which are considered separately) or by children under three. The total lead content limit is 90 mg/kg (ppm) for accessible parts, but there is an exemption if the lead is necessary, cannot be substituted, and the migratable lead is no more than 90 mg/kg (based on the tests specified in the toy safety standard EN 71-3).

   The regulatory analysis for this regulation includes the conclusion that stakeholders have no issue with the regulation after it was amended to apply only to accessible parts and to allow for exemptions based on lead migration. The analysis includes a discussion of component parts that are not expected to have a lot of contact by children and that therefore justify the exemption clause (e.g. wheel axles on toy cars/trucks, the heads of nuts, bolts, screws, and other fasteners, and the tips of inner tube valves on tricycle wheels).

   Canada is also proposing regulations for "Group 2" products, which would include products for children ages 3-13 years. The proposal is also for a 90 mg/kg total lead content.

Information on the Canadian government website indicates that a consultation will begin this year, providing for stakeholder input.

In the U.S., the Consumer Product Safety Improvement Act of 2008 restricts lead in children's products to 300 ppm, based on the total lead content by weight, for any part of the product. As of August 14, 2011, the limit will change to 100 ppm, unless the Commission determines that the lower limit is not technologically feasible for a product or product category. A children's product is defined as a consumer product designed or intended primarily for children 12 years of age or younger.

The law exempts inaccessible component parts from the lead restrictions, and authorized the Commission to address the technological feasibility of certain electronic devices. With regard to electronic devices, the Commission has provided for exemptions and alternate requirements for certain electronic parts where use of lead is necessary for the proper electronic functioning of the component part.

The law also contains an exception for certain products or materials where the Commission determines, after notice and hearing, that lead in the product or material will not result in the absorption of any lead into the human body. To date, the Commission has not been able to make any exceptions under this provision.

6. **The Commission has approved the use of x-ray fluorescence (XRF) devices to measure lead content in homogeneous plastics. To what extent can these devices be used to measure lead content in metal parts of products?**

In addition to approving the use of x-ray fluorescence (XRF) for lead content in homogeneous plastics, the Commission also recently approved the use of high-definition XRF for determining compliance with the standard for lead (Pb) in paint and other similar surface coatings. *See Third Party Testing for Certain Children's Products; Notice of Requirements for Accreditation of Third Party Conformity Assessment Bodies – Lead Paint*, 76 *Fed. Reg.* 18,645 (April 5, 2011).

To date, CPSC has not approved any XRF method for testing the compliance of children's products to the limits for lead in metal substrate set forth in Section 101 of the CPSIA. While XRF technology has the potential to measure lead in metal products, *in situ* measurements of consumer products are made difficult due to the common occurrence of electroplating and other inhomogeneities. XRF has very limited penetration depth into metals, and lead in the base metal can be "hidden" by the coating layer.

CPSC staff has published guidance on this issue: Study on the Effectiveness, Precision, and Reliability of X-ray Fluorescence Spectrometry and Other Alternative Methods for Measuring Lead in Paint, August 2009, available at http://www.cpsc.gov/about/cpsia/leadinpaintmeasure.pdf. An update, "Update on Use of X-ray Fluorescence Spectrometry for Measuring Lead in Paint" (December, 2010) is also available at http://www.cpsc.gov/about/cpsia/leadinpaintmeasure_update.pdf.

7. **What methodology does the Commission use to measure the total lead content in metal alloys? How long does the process take? In general terms, what methodology would the Commission use to determine the amount of lead a child would be exposed to from a metal part that can be mouthed but not swallowed?**

The CPSC staff employ Test Method: CPSC-CH-E1001-8.1 Standard Operating Procedure for Determining Total Lead (Pb) in Metal Children's Products (including Children's Metal Jewelry), Revision June 21, 2010 [http://www.cpsc.gov/about/cpsia/CPSC-CH-E1001-08_1.pdf].

The general approach is to grind any accessible component part of a sample to a powder, digest completely in a combination of hot concentrated nitric and hydrochloric acids and analyze by Inductively Coupled Plasma – Optical Emission Spectroscopy (ICP-OES). Other analytical methods such as Inductively Coupled Plasma – Mass Spectrometry (ICP-MS) and Flame Atomic Absorption Spectroscopy (FLAA) and Graphite Furnace Atomic Absorption Spectroscopy (GFAA) may be used under appropriate conditions as an alternative to ICP-OES using applicable, recognized analytical techniques for the alternative method. The time required for testing one sample is more than the time required per sample when testing many, as there are economies of scale as a "production line" is set up. A single chemist can test one sample in one full day, with about one hour of hands-on work and the balance being waiting time while processes complete themselves. That same chemist could test 10 metal items in a full day with perhaps two hours of hands-on work. Analysis time may vary depending on the complexity of the results.

Under current law, CPSC staff rely on the regulations limiting total lead content of children's products. Were staff to evaluate possible lead exposure from mouthing but not swallowing objects, the test methodology would depend on the object and manner in which a child interacts with it. For a piece of metal jewelry, such as a large pendant, which is too large to be swallowed, but would fit inside the mouth, CPSC staff have historically relied on extractions using a saline solution of 0.9 percent sodium chloride in water. For these extractions, a weight of saline equal to 50 times the weight of the jewelry would be used to evaluate how much lead leached out in a period of time. For items of this type, staff has used a time of six hours for the extraction. The methodology is essentially that given in the Cadmium extraction method given at http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelrytest.pdf, with a 0.9 percent saline solution used in place of acid and with a duration of six hours.

For very large items that could have a portion placed in the mouth, staff has sometimes used only a portion that would correspond to a child's mouth size. For example, when looking at lead in vinyl bibs, staff used a 25 cm^2 portion of the vinyl sheeting, which is the approximate size of a child's mouth. For electroplated metal items though, cutting the sample to a smaller size exposes the base metal directly, which would alter the leaching of lead compared to an intact electroplated coating. The methodology for a sample like that could involve suspending the sample so that only a portion of it was wetted by the extraction solution, but with the item maintained intact.

8. **In its rulemaking on continued compliance testing, does the Commission have a legal obligation to consider the costs of the testing programs it requires? Does the Commission have a legal obligation to consider the costs in relation to the benefits of such testing? Please provide citations or copies of any statutes, regulations, Executive Orders or other sources of law bearing on this issue.**

   The underlying statute determines whether the CPSC engages in a cost-benefit analysis for a particular rule. For example, section 9(c) of the Consumer Product Safety Act (CPSA) requires a description of the potential benefits and costs of a proposed rule, "including any benefits or costs that cannot be quantified in monetary terms, and an identification of those likely to receive the benefits and bear the costs." Section 9 of the CPSA establishes the procedure for consumer product safety rules. Section 3 of the Federal Hazardous Substances Act (FHSA) establishes the rulemaking procedures under the FHSA and contains language that is almost identical to section 9(c) of the CPSA.

   In contrast, the general rulemaking authority for the Consumer Product Safety Improvement Act of 2008 (CPSIA) does not contain a cost-benefit analysis requirement for rules issued pursuant to the CPSIA. Because the rule in question was issued under the CPSIA, there was no legal obligation to consider costs or costs in relation to benefits.

   Nevertheless, in developing the rule, staff was sensitive to cost concerns (as evidenced by the proposed rule's provisions regarding periodic testing and low volume production), and a related rule (pertaining to component part testing) was designed to reduce testing costs by allowing for the testing and certification of components. For example, if a manufacturer used the same component in two different products, the component part testing rule would enable the manufacturer to test the component once and apply the test results or certification to the two products rather than test the same component twice (once for each product).

   Additionally, for all rules that are published pursuant to the notice and comment rulemaking requirements of the Administrative Procedure Act or other laws, we comply with the Regulatory Flexibility Act. This statute requires us to evaluate whether the rule will have a significant economic impact on a substantial number of small entities. While this analysis is not as comprehensive as a cost-benefit analysis, it does consider the potential beneficial and adverse impacts on small businesses.

9. **Has the Commission ever postponed compliance with a third-party testing requirement due to concerns about whether there was enough available testing capacity? If so, please describe the circumstances.**

   Yes. The Commission has stayed enforcement for testing and certification of youth model ATV's because current testing capacity is inadequate to support industry demand.

10. **Is the Commission staff aware of any deaths in fixed-side cribs in licensed child-care facilities? If so, did the Commission find evidence of a defect in the design or**

manufacture of the crib? If the Commission conducted investigations of such cases, please provide a copy of all reports relating to the investigation.

Based on a review of the data going back as far as 1997, there are no reported fatal incidents known to have occurred in a total fixed-side crib that were attributed to a structural failure of the crib, in a child care environment. A fixed-side crib is defined as one without a movable side (i.e., a side that lowers or otherwise moves to provide easier access to the occupant).

However, CPSC staff is aware of five fatalities that were associated with a structural failure of a stationary (non-movable) side of a drop-side, drop-gate or unknown style crib. All five occurred in home day care environments, three of which were known to be licensed.

The three incidents involving a drop-gate crib were similar in that a folding side (used to collapse the crib for storage) separated from the corner post due to a missing screw. All three of these incidents involved the same make and style crib.

The incident involving a drop-side crib occurred when a bolted connection on the stationary side (opposite the drop-side) came loose.

The unknown incident has only one picture showing the detached corner of the crib where the incident took place. It is clear that detached side is not a movable side, but the picture does not provide enough information to determine whether the crib contains a drop-side or drop-gate.

Thus, no movable sides (either a drop side or drop gate) were directly involved in any the five deaths. All the crib failures were determined to be associated with missing hardware. Because of the construction and integrity of cribs containing movable sides, however, the presence of a movable side on these cribs cannot be ruled out as a contributory factor.

11. Has the Commission made a determination that all fixed-side cribs currently in use or currently for sale in commerce are unsafe unless they comply with the new crib standard? If so, does the Commission intend to order or negotiate recalls of those cribs?

In December of 2010, the Commission issued a safety standard for cribs as directed by section 104 of the CPSIA. 75 Fed. Reg. 81766 (Dec. 28, 2010). As required by section 104(b) of the CPSIA, CPSC's crib rule is substantially the same as the relevant voluntary standards, ASTM F 1169-10 (full-size cribs) and ASTM F 406-10a (non-full-size cribs). Both of these ASTM standards prohibit traditional drop side cribs. Because CPSC's crib rule incorporates by reference the ASTM standards, with some modifications, it also prohibits traditional drop side cribs. The Commission did not make a finding that all fixed side cribs are unsafe. Rather, it followed the statutory mandate to issue a mandatory crib rule substantially the same as or more stringent than the voluntary standards.

It should also be noted that the new mandatory crib rule contains numerous other provisions from the voluntary standard that improve crib safety, such as requirements for enhanced

hardware, mattress supports, and slats. Again, the Commission did not make a specific finding that cribs that do not conform to these requirements are unsafe, but recognized, in issuing the rule, that these enhancements addressed issues identified by the voluntary standards committee and will likely reduce the risk of injury.

The Commission has negotiated many recalls of cribs over the past several years. These recalls have been focused on particular cribs that may pose specific hazards and can be found on saferproducts.gov. The voluntary standards group, aware of the hazards addressed by these recalls, worked to ensure the standard also addressed those hazards, including the unreasonable risk of injuries presented by drop side cribs, hardware failures, and mattress support failure.

12. There have been conflicting press reports as to whether the Commission is resolving claims of "material inaccuracy" before posting "reports of harm". The Commission's proposed rule stated that it would not post reports until such claims were resolved but in the preamble to the final rule, it said that it lacked authority to postpone the posting beyond the tenth day. Nevertheless, some have said that the Commission does not post reports within 10 days where the manufacturer to which the report was sent indicates it did not, in fact, make the product. Can you please explain how these issues are being resolved? In particular, please clarify whether the Commission believes that the requirement to post in 10 days does not apply where certain claims of material inaccuracy are raised. If the requirement to post within 10 days does not apply in certain cases, does the Commission nevertheless have discretion to post the report of harm in such cases or does it believe that it legally must resolve certain types of claims before posting?

A claim that a report of harm (report) contains potentially materially inaccurate information (MII) is resolved by the CPSC as required by section 6A of the Consumer Product Safety Act (CPSA) and the Commission's regulation at 16 C.F.R. 1102.26 and 1102.28. Section 6A(c)(3)(A) of the CPSA requires the Commission to publish reports that meet statutory minimum requirements "not later than the 10th business day after the date on which the Commission transmits the report . . ." to the identified manufacturer, importer, or private labeler (collectively referred to herein as the manufacturer). Thus, the 10-business day report publication date is calculated based on the date CPSC sends a report that meets the minimum requirements for publication to the manufacturer of the consumer product.

If a manufacturer files an MII claim before the end of the 10 business days, there are two instances when the CPSC may withhold a report beyond this 10 business day report publication date: (1) CPSC makes a decision, within the 10 business days prior to posting a report, that the report contains materially inaccurate information (Section 6A(c)(4)(A) of the CPSA); or (2) CPSC is in the process of determining whether a Report meets the eight minimum requirements for publication (Sections 6A(b)(2)(B), 6A(c)(1), and 6A(c)(3)(A) of the CPSA).

MII claims received thus far can be divided into three types: (1) identification of a wrong manufacturer of the product; (2) submission of inaccurate information on the report, other

than the manufacturer; and (3) allegation that CPSC lacks jurisdiction over the product or that the submitter has failed to identify a harm or risk of harm related to the use of the product. The type of claim submitted bears on how the claim is resolved and whether it affects the report publication date.

For example, the identification of a manufacturer has both substantive and procedural connotations. Manufacturer name is a required field for a report to be published in the Database; if the name is removed, rather than corrected, the report is ineligible for publication. Moreover, the 10-business day report publication date is calculated based on the date a manufacturer is notified. If a manufacturer name is corrected, the report publication date must be re-calculated based on notice to the correct manufacturer. A description of the procedures related to each type of claim appears below.

MII claims alleging that the wrong manufacturer has been identified are generally made quickly by the business receiving the report, and can be handled quickly by the CPSC. A staff member verifies the information provided in the MII claim, and then replaces the incorrect business name with the corrected name. CPSC may lawfully withhold publication of such a report to correct the manufacturer name and to notify the corrected manufacturer of the report. Neither the law nor the CPSC's regulation requires the CPSC to post a report 10 business days after notifying an *incorrect* manufacturer. In fact, section 1102.28 of the final rule states that when the wrong manufacturer is notified, the 10-business day clock for posting a report will be reset when the correct manufacturer is notified, so that the correctly identified manufacturer has 10 business days to review and respond to the report before it is published. The law requires this result, because the report publication date is calculated based on the date the manufacturer of the consumer product is notified.

Similarly, with regard to MII claims that are not alleging a wrong manufacturer, if the CPSC makes a decision on an MII claim prior to posting the report and concludes that a report contains materially inaccurate information, it must correct the inaccuracy before publishing the report. If such correction extends the report publication date beyond the 10th business day, it is a lawful extension because the CPSC has already determined that inaccurate information in the report must be corrected. Although CPSC is not required by law to make MII claim decisions within the 10-business day period before a report is posted, CPSC attempts to resolve all timely made MII claims before a Report is published. If we cannot make a decision on an MII claim by the report publication date, the report will be published, as is, on the 10th business day after the manufacturer was notified. If CPSC determines that a report contains materially inaccurate information after it is published, the law requires us to correct the report within seven business days of such determination.

Finally, manufacturers have been using the MII claim function in the Business Portal to challenge more than just the accuracy of the information contained on a report. Some businesses have made claims that a report does not meet the eight minimum requirements for publication. Typically, these types of claims allege that the CPSC lacks jurisdiction over the product, or that the report does not describe a harm or risk of harm.

Unlike a true MII claim, the essence of these types of claims is not necessarily inaccuracy of the information on the report. Rather, these claims are essentially positing that even if all of the information on the report is true, the report fails to satisfy the statutory minimum requirements for publication. While we try to resolve any dispute of eligibility within the 10-business day time period before posting a report, when a credible claim is made that a report is ineligible for publication, the CPSC may lawfully withhold publication until a decision on whether CPSC has jurisdiction over the product, or whether the submitter has described a risk of harm, is made.

CPSC is considering whether to create another process in the Business Portal for firms to challenge the eight minimum requirements for publication, as these types of claims do not generally involve consideration of whether information in the report is materially inaccurate. Rather, such claims involve an assessment of whether the information in the report, if taken as true, is sufficient to meet eligibility requirements for publication.

13. How many reports of harm have been received by CPSC between the official launch of the database (on or about March 11, 2011) and April 14, 2011? How many reports have been transmitted to manufacturers? How many responses were received from manufacturers? How many claims of "material inaccuracy" were made? How many of the reports that were challenged as "materially inaccurate" were posted before the claim was resolved by CPSC?

During the period March 11, 2011, through April 15, 2011, CPSC received 2012 reports in submitter categories that are potentially eligible for the public database. Of these, 798 reports have qualified as reports of harm, which are eligible for publication in the database. The number of qualified reports of harm can be expected to rise slightly over time as additional consent and verification forms are returned for reports submitted through channels other than CPSC's public portal. 797 of the qualified reports of harm have been transmitted to manufacturers. To date we have received 331 manufacturer comments, 85 claims of materially inaccurate information, and no confidential information claims related to these 797 reports. Four reports were published before the claim of materially inaccurate information was resolved by CPSC and 11 claims were submitted after publication.

14. How many reports of harm relate to an incident that is more than one year old?

Fifty seven of the 798 qualified reports of harm received between March 11, 2011, and April 14, 2011, describe an incident that occurred more than a year before the report submission date.

15. How many reports of harm relate to an incident involving a product that has previously been recalled? Do any of them involve an incident occurring after the recall?

Our system does not yet link reports of harm to recalls, so it is not possible to determine how many reports of harm involve previously recalled products. We have received reports describing incidents occurring after a recall and in some cases, manufacturers have posted comments alerting the submitter and readers to the existence of a recall on the product.

Questions from the Honorable G. K. Butterfield

1. **In response to questioning from the Subcommittee, you contended that "one would expect that the risk [from lead-bearing items] decreases as you move from swallowing to mouthing, from mouthing to touching. And the management of that risk at that point then becomes a decision on how the child interacts with the product." Your response suggests that you believe risk assessment is an appropriate approach for regulating lead in children's products.**

   Last year, this Subcommittee in a hearing regarding the regulation of toxic substances received testimony that convincingly suggests that the traditional risk assessment model is not appropriate for substances that are persistent, bioaccumulative and toxic (PBTs) because these characteristics affect how the environment and human body treat these substances and make exposure inevitable. I understand that lead is a PBT.

   a. **Please discuss your familiarity, or that of your staff, with PBTs in general and the emerging school of thought that risk assessment is not appropriate for PBTs.**

      CPSC staff is aware of the challenges related to evaluating chemicals that are persistent and bioaccumulative, but believe that on a case-by-case basis, potential chemical exposures from products can be assessed using the tools available within the broad field of risk assessment. The Federal Hazardous Substances Act, one of the federal laws that provide CPSC the authority to regulate hazardous products, states the conditions under which a product can be deemed a hazardous substance or a banned hazardous substance. Such determinations require assessment of exposure and risk.

      Accordingly, staff applies appropriate risk assessment procedures to evaluations of products containing specific chemicals, although lead in children's products is regulated based on lead content as provided by section 101 of the Consumer Product Safety Improvement Act of 2008 (CPSIA). Approaches to risk assessment of persistent or bioaccumulative chemicals include assessing a specific consumer product exposure in the context of other sources of exposure, including potential changes in exposure over time.

   b. **Please discuss what consideration CPSC gives to whether a substance present in a consumer product is a PBT and whether it presents an unreasonable risk of injury to consumers.**

      One of the basic principles of toxicology is that there are conditions of exposure to chemicals, including the level of exposure, that determine whether the exposure could result in adverse health effects (i.e., not all exposures to a chemical are hazardous). When appropriate, CPSC staff considers "background" exposures and other specific exposure sources when evaluating a consumer product containing the chemical.

      In the case of lead, prior to the enactment of the CPSIA, staff evaluated lead in children's products based on a risk assessment that assessed the effects of lead exposure from

products in the context of the overall level of exposure to lead in the population from other sources, using blood lead levels as the measure of exposure.

c. **Do you agree with the Centers for Disease Control's recommendation that the nonessential uses of lead in consumer products should be restricted or eliminated to prevent exposure to this harmful substance?**

CPSC staff agree with recommendations to reduce wherever possible exposures to harmful chemicals. In many cases where the use of a product could cause substantial personal injury or substantial illness, the Commission has restricted uses of chemicals in products, using its regulatory authority under the Federal Hazardous Substances Act.

2. **In response to questioning from the Subcommittee regarding implementation of the de minimis exception proposed in the Republican discussion draft, you testified that CPSC would have to develop multiple methodologies for manufacturers to determine whether they qualify for the exception given the variety of children products and the different ways children might be expected to interact with those products. However, you stated that developing these several methodologies would not require a substantial investment of CPSC's limited resources.**

a. **Please explain why you believe developing multiple methodologies to account for how children interact with an unknown and ever changing universe of products would not require the investment of substantial resources by CPSC. In framing your response, please also account for the fact that CPSC generally applied its own risk assessment methods on a case-by-case and after-market basis, and not on a market-wide and pre-market basis.**

The proposed language calls for the Commission to establish, by regulation, a methodology for estimating the amount of lead a child would likely ingest from exposure to a component part. Developing multiple methodologies for manufacturers to determine whether they qualify for the proposed *de minimis* exception would not require the investment of substantial resources by CPSC staff because the testing methodologies required to determine the amount of potentially toxic heavy metals that can leach from various materials have been in use at CPSC for many years.

For example, the general methodology outlined in CPSC's Cadmium extraction method, which can be found at http://www.cpsc.gov/library/foia/foia11/os/cadmiumjewelrytest.pdf, can be used to determine the amount of lead that would be extracted from a component part if ingested. Replacing the acid solution with a 0.9 percent saline solution, and adjusting the duration period to six hours, would be used to determine the amount of lead that would be extracted from a component part that is mouthed.

3. **In response to a question from the Subcommittee regarding the cost of third-party testing for a bicycle, you stated that "the cost to test a $50 bicycle for all the applicable standards would run somewhere in excess of $10,000."**

a. **Please clarify this response by providing a list of all standards applicable to a children's bike and that indicates whether a third-party testing requirement regarding that standard has been stayed by the Commission.**

Children's bicycles are covered by the bicycle safety standard, which is codified at 16 CFR Part 1512 – Requirements for Bicycles. The stay of enforcement for this standard has expired, except for bicycles with non-quill type stems. Bicycles with non-quill type stems are currently excluded from the requirement to certify compliance with the handlebar stem insertion mark requirement of 16 CFR Part 1512.

Any paint used on a children's bicycle must meet the lead-in-paint standard, which is codified at 16 CFR Part 1303--Ban of Lead-Containing Paint and Certain Consumer Products Bearing Lead-Containing Paint. The third-party testing requirement for lead-in-paint has not been stayed.

Each accessible component of a children's bicycle is subject to the requirements for children's products containing lead, Section 101 of the Consumer Product Safety Improvement Act. According to the owner of a bicycle testing laboratory, a typical multispeed children's bicycle will have 140 to 150 accessible parts that must be tested for lead content. The third-party testing requirements pertaining to this standard have been stayed through December 31, 2011.

b. **Please clarify this response by providing information, in general, about how many bikes you would expect to be part of a production run. How many of these do you believe are now being third-party tested to any applicable standards? How many of these would you expect to be third-party tested if all testing requirements were in effect?**

Our information about how many bikes would be expected to be part of a production run is limited. However, based on the available information, we expect annual production runs may range from several hundred (or even fewer) units for some models to several thousand or more for other models.

We would expect that all children's bicycles that are being manufactured or imported today would be third-party tested for compliance with the standards that are not currently subject to stays, which are the requirements for bicycles (16 CFR Part 1512) and the lead-in-paint standard (16 CFR Part 1303). Although the third party testing requirements for lead content have been stayed, CPSC has received testimony that some manufacturers are obtaining third party test results for lead content of their components to ensure that they meet the legal requirements of Section 101 of the CPSIA.

Questions from the Honorable John Dingell

1. **CPSIA defines a "children's product" as one "(primarily) intended for a child 12 years of age or younger." The discussion draft would change this definition to "intended for use by a child [age to be determined] years or younger." What effect would the words "for use by" have on the number and type of products covered by this definition?**

   The interpretative rule on the definition of "children's product" already considers the effect of the words "for use by a child." (75 FR 63067) In that interpretative rule, the Commission stated that a determination of whether a product is a "children's product" will be based on consideration of the four specified statutory factors. These factors include: 1) a statement by a manufacturer about the intended use of such product, including a label on such product if such statement is reasonable; 2) whether the product is represented in its packaging, display, promotion, or advertising as appropriate for use by children 12 years of age or younger; 3) whether the product is commonly recognized by consumers as being intended for use by a child 12 years of age or younger and 4) the Age Determination Guidelines issued by the Commission staff in September 2002 and any successor to such guidelines.

   Because the statutory factors incorporate the concept of "use" by the child, the Commission interpreted "for use" by children 12 years or younger generally to mean that children will physically interact with such products based on the reasonably foreseeable use of such products. For example, a diaper would be considered a children's product because a child will interact or have direct physical contact with the diaper, but a diaper bag would be used by the caregiver, and not considered a children's product. The words "for use by" by themselves would not have any impact on the number and types of products covered by this definition.

2. **The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a de minimus amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."**

   a. **Are you aware of a uniform reasonable methodology in use by manufacturers of children's products?**

      CPSC staff is not aware of a uniform "reasonable methodology" currently in use by manufacturers of children's product.

   b. **Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?**

It is possible that ambiguity in the definition of "reasonable methodology" could lead to the use of different test methodologies, which would likely lead to some variance in test results across manufacturers of similar products.

c. **If so, do you believe this is could pose a risk to the health of children who use such products?**

The potential impact of the variance in test results on the health of children cannot be determined without knowledge of the level of variation and determination of the *de minimis* amount.

3. The draft legislation would allow the CPSC, subject to conditions, to require third party testing for children's products. Under the draft bill, the CPSC could require third party testing only if the Commission first verifies the testing capacity of "accredited third party conformity assessment bodies," as well as establishes and publishes notice of the requirements for accreditation of such assessment bodies.

a. **Is it your understanding that the term "accredited third party conformity assessment bodies" includes both domestic and international bodies?**

Yes. The term conformity assessment body for purposes of third party testing required by the CPSIA is more commonly known as a testing laboratory, and includes domestic and international bodies.

b. **If so, how many such assessment bodies are there worldwide?**

As of April 26, 2011, the CPSC has accepted the accreditation of over 300 testing laboratories (worldwide) and posted these laboratories on the CPSC website. There are many more testing laboratories worldwide, an unknown portion of which may have an interest in conducting testing for CPSC rules.

c. **Further, does the Commission have the resources with which to verify the testing capacity of all third party conformity assessment bodies?**

Verifying testing capacity may involve a detailed assessment of the market for the particular product in question and an assessment of the number and testing capacity of available laboratories that have an interest in conducting the testing. The resources are difficult to estimate and could depend on the product safety rule.

d. **Moreover, is it your understanding of the draft legislation that the Commission would have to accredit all third party conformity assessment bodies?**

The language of the draft legislation does not appear to require the Commission to accredit all third party conformity assessment bodies. Section 3(b) of the language of the draft legislation would not allow the Commission to require testing by an independent third party until two conditions have been met: (1) a notice of requirements has been

established and published for accreditation of third party conformity assessment bodies who are determined to be qualified by the Commission to conduct third party testing; and, (2) the Commission has determined that there is sufficient testing capacity by accredited third party conformity assessment bodies to prevent unreasonable delays due to testing.

The draft legislation appears to maintain the same process currently used by the Commission for accreditation of third party conformity assessment bodies. Currently, the Commission establishes the baseline criteria for accreditation of a third party conformity assessment body for a particular children's product safety rule when it publishes a notice of requirements.

Interested third party conformity assessment bodies submit applications under a particular notice of requirements to the Commission to demonstrate that they meet the criteria necessary to have their accreditation accepted by the Commission. The Commission accredits only third party conformity assessment bodies that submit applications for acceptance of their accreditation and that meet the requirements for accreditation.

e. If so, do you believe the Commission has the resources with which to accomplish this?

If the draft legislation allows the Commission to designate outside entities to conduct the accreditations and for the CPSC to recognize or accept those accreditations (as the CPSIA currently allows), then the resource burden is considerably less than if the CPSC itself had to conduct the accreditations. The CPSC by itself does not have the resources to conduct accreditations of conformity assessment bodies.

f. In summary, do you believe the practical effect of these requirements would be that the Commission would seldom, if ever, require third party testing of children's products?

Depending on the flexibility afforded by revised legislation in how the CPSC establishes third party testing and conformity assessment body accreditation rules (refer to answer above) the CPSC may consider third party testing after examining the risk associated with non-compliance, the history of non-compliance, the burdens and complexity associated with third party testing, and other factors. The detailed cost-benefit analysis findings required under section 3(b) of the draft legislation, however, make it highly unlikely that the Commission could ever impose third-party testing requirements beyond those specifically permitted under section 3(a) of the draft bill.

4. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?

No, this is not an accurate statement of the law. Section 6A(c)(3)(A) of the CPSA requires the Commission to publish reports that meet the minimum requirements for publication "not later

than the 10th business day after the date on which the Commission transmits the report . . ." to the identified manufacturer, importer, or private labeler (collectively referred to herein as the manufacturer). One of the minimum requirements for publication is that the submitter verifies the truth and accuracy of the report. A report will not be published without that verification.

If a business receiving notice of a submitted report alleges that information in the report is materially inaccurate, they have the burden of proof to establish their claim. Information on the report is considered part of a verified report unless and until someone demonstrates otherwise. The CPSC endeavors to make a decision on all timely submitted "materially inaccurate information" claims before the report publication date. Thus far, we have been successful at resolving these claims in a reasonably short time frame.

If CPSC makes a decision on a materially inaccurate information claim after a report is published, the law requires that the CPSC correct the inaccuracy in the Database within seven business days. While the mere allegation of an inaccuracy cannot delay publication, manufacturers can, and have been, stating their position with regard to the report in their comment that displays in the database along with the report. Thus, regardless of the CPSC's determination on an MII claim, manufacturers have a way to allege inaccuracies in any report that can be seen and read by the public as soon as the Report is published.

Finally, the CPSC does not guarantee that every piece of information in the database is accurate. The statute requires that we post a clear and conspicuous notice to people using the database that the CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Publicly Available Consumer Product Safety Information Database.

5. Is it your understanding that section 5 of the draft bill exempts FDA-regulated products from CPSIA's mandatory toy safety standards?

a. Are FDA-regulated products already exempt from CPSC regulations? If so, why is this exemption necessary?

While drugs, devices, cosmetics, and foods cannot be "consumer products" under section 3(a)(5) of the Consumer Product Safety Act, the draft bill would eliminate potential confusion over the provisions in ASTM F963 that are to be considered "consumer product safety standards."

ASTM F963 refers to various FDA regulations pertaining to food and cosmetics, and section 106 of the Consumer Product Safety Improvement Act of 2008 (CPSIA) declares that the provisions of ASTM F963, with certain limited exceptions, "shall be considered consumer product safety standards issued by the Commission under section 9 of the Consumer Product Safety Act." The omission of the FDA regulations from the limited exceptions in section 106 of the CPSIA creates uncertainty as to whether the FDA regulations are "consumer product safety standards" pursuant to section 106 of the CPSIA.

If the FDA regulations are to be considered "consumer product safety standards," then additional uncertainty exists as to CPSC's ability to enforce the FDA regulations and whether CPSC would need to engage in joint rulemaking with FDA whenever FDA revises those regulations. Furthermore, because children's products that are subject to a children's product safety rule are subject to third party testing under existing law, questions have arisen as to whether manufacturers need to have third party testing to demonstrate compliance with the FDA regulations.

b. Further, what types of products would section 5's exemption include, and why should they be exempted from CPSIA's mandatory toy safety standards?

The effect of the exemption would be to clarify that FDA retains authority over food, food additives, color additives, and cosmetics that are supplied with toys and that CPSC has authority over the toys covered by ASTM F963. For example, ASTM F963 states that food products supplied with toys must be manufactured and packaged in compliance with FDA's good manufacturing practice regulations that apply to food. If FDA's good manufacturing practice regulations for foods are considered "consumer product safety standards," then CPSC would need to enforce those regulations and also issue a notice of requirements to provide for third party testing to demonstrate compliance with those FDA regulations.

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115

Majority (202) 225-2927
Minority (202) 225-3641

April 27, 2011

Ms. Caroline Cox
Research Director
Center for Environmental Health
2201 Broadway, Suite 302
Oakland, CA 94612

Dear Ms. Cox,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on April 7, 2011, to testify at the hearing entitled "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for 10 business days to permit Members to submit additional questions to witnesses, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and then (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, May 11, 2011. Please also e-mail your responses to the Legislative Clerk in Word format at Alex.Yergin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing, and Trade

cc: The Honorable G. K. Butterfield, Ranking Member,
Subcommittee on Commerce, Manufacturing, and Trade

Attachments

The Honorable Mary Bono Mack

1. **You state you prefer a total lead (concentration) standard rather than an exposure standard. Do you maintain that a concentration standard for total lead is always more health protective than a standard that regulates how much lead is actually available to a child?**

   Yes. There is no way to test accurately and consistently for "how much lead is actually available to a child." Thus, a total lead test, which is far more likely to be accurate and consistent, is also more health protective. Total lead testing is relatively inexpensive and can be done quickly, so it is easier for product manufacturers, vendors, and retailers to do comprehensive testing. This means that supply chain problems are corrected more quickly resulting in more health protective products.

2. **You mentioned FDA's warning about children's lunch boxes containing lead, claiming that FDA interpreted CPSC's data differently than CPSC itself. How many lunchbox recalls did FDA order after it reviewed CPSC's data?**

   At the time, there was no single federal rule on lead in children's products. Given this regulatory uncertainty, FDA took action by sending a strongly worded warning to lunchbox makers, alerting them to the lead problem and advising them that since "some migration of lead [from lunchbox interiors] to food...may be reasonably expected, we urge companies to refrain from marketing such lead-containing lunchboxes." We are not aware that FDA ordered recalls

3. Your discussion of lunchboxes suggests that FDA would disapprove of a risk-based lead standard and insist on a total lead content standard. Does FDA have any concentration-based total content standard for lead? Does FDA have any standards that control the amount of lead a child would actually be exposed to?

   We have not made any suggestions about what FDA's thinking is on the matter. FDA has total content standards for lead in food, including food for consumption by children, and has developed guidelines for total lead content of candy intended for small children. With respect to the lunch boxes made with lead-containing vinyl FDA stated, "According to the CPSC data, a small amount of the lead present in the interior linings of the lunchboxes is transferable by a swipe test. This implies that a small amount of lead may reasonably be expected to transfer to food that contacts the interior lining and could be deemed to be an unsafe food additive within the meaning of section 409 of the FD&C Act, and therefore adulterated within the meaning of section 402(a)(2)(C) of the statute."

3. **On page 2 of your testimony, you list six categories of products that you found before the law was passed. Are you aware that half of them are within FDA's jurisdiction?**

   Yes, we are aware of FDA's jurisdiction. Our work is based on California law, and in each of these cases the products were in violation of California lead standards.

4. **You mentioned that CEH has found some 46 products that did not comply with the lead limits applicable under CPSIA. Did CEH provide details of its findings to CPSC on each of these items? If so, how quickly does CEH typically notify CPSC after obtaining test results? Does CEH prvide samples? How many of the 46 products did CPSC recall?**

   Our compliance testing is administered under a grant from the California attorney general's office. Under the terms of the grant, we report our findings to their office. It is our understanding that the attorney general's office reports to CPSC and follows up with them regarding potential recalls when they feel it is appropriate. In our experience, CPSC does its own product research rather than relying on CEH-purchased products from California. CPSC cooperated with companies on recalls of six products that were identified by CEH.

5. **Has CEH ever sought a CPSC recall of a product based on lead in metal parts other than jewelry?**

   Between 1999-2001, CEH found high levels of lead in the metal outflow pipes in several brands of home water filters. The filter industry reformulated the pipes to eliminate the lead. Since it was several years ago we are not sure if there was communication with CPSC.

6. **Have you found x-ray fluorescence devices equally useful for screening plastics and metals?**

   Yes. With an experienced operator and attention to testing homogeneous samples, the XRF is equally useful for screening both plastics and metal.

<u>The Honorable G. K. Butterfield</u>

1. **During the hearing, the Subcommittee heard repeatedly that the traditional model for the regulation of lead and other harmful substances has been to use risk assessment, and that manufacturers should be allowed to apply this model to children's products. However, last year this Subcommittee in a hearing regarding the regulation of toxic substances received testimony arguing that the traditional risk assessment model is not appropriate for substances that are persistent, bioaccumulative and toxic (PBTs) because these characteristics affect how the environment and human body treat these substances and make exposure inevitable. I understand that lead is a PBT.**

   a. **Can you please confirm that lead is a PBT?**

Lead is identified by US EPA as a PBT chemical under the Toxics Release Inventory program. See http://www.epa.gov/tri/trichemicals/pbt%20chemicals/pbt_chem_list.htm.

b. **Can you please discuss the characteristics of PBTs that make the traditional risk assessment approach for limiting exposure an inappropriate model for dealing with lead?**

Risk assessment traditionally identifies the health hazards of the chemical of interest and the estimated exposure to that chemical. The risk assessment process compares the estimated exposure to the amount of the chemical that causes the relevant health hazard to determine a "safe" level of exposure. This is a challenging, or even impossible, process for PBT chemicals, because exposures of concern are not only current exposures, but exposures far into the future as the chemical moves through humans and the environment. Accurately predicting those exposures is beyond current scientific knowledge. For lead it is even more challenging to complete a risk assessment because, as EPA has stated, "There is no level of lead exposure that can yet be identified, with confidence, as clearly not being associated with some risk of deleterious health effects." In this situation, the only acceptable exposure is zero.

2. **It is an established fact that lead occurs naturally at low levels in the environment, but it is also a fact that we have added lead to the environment by adding it to products like paint, gasoline, and even consumer products. It is also widely recognized that Americans produce large amounts of trash, including by throwing away products such as toys and other children's products. The result is that lead-laced toys and other children's products end up in landfills, where the lead can leach into soil and then into water and then into the food supply. From there, it is a straight route into the body.**

a. **Would you agree that use of lead in a child's product not only poses a direct threat to the health and safety of that child, but presents an ongoing and potentially more potent threat? Please explain.**

The Agency for Toxic Substances and Disease Registry estimates that environmental lead levels are 1000 times higher than they were 300 years ago. The cause of this increase is "human activity," including past use of leaded gasoline and lead-based paint as well as current use of lead in consumer products. Once this lead is in the environment, children are exposed to it when they breathe air, drink water, eat food, play, etc. This lead exposure is to a certain extent cumulative because lead can be stored for long periods in bones. There is widespread agreement that prevention, reducing lead exposure by reducing the sources of lead exposure, is the best way to protect children.

The Honorable John Dingell

1. **The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a de minimus amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."**

   a. **Are you aware of a uniform reasonable methodology in use hy manufacturers of children's products?**

   Currently the ASTM toy safety standard describes a methodology for estimating ingestion of lead from paint and other surface coatings. CPSC has suggested methodology for estimating ingestion of lead from metal jewelry. Uniform methodologies for other materials and other children's products do not yet exist.

   b. **Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?**

   It is virtually certain.

   c. **If so, do you believe this is could pose a risk to the health of children who use such products?**

   Yes. The risk of lead-tainted products ending up in children's hands, and possibly in their mouths, would increase dramatically.

2. **The draft legislation would allow the CPSC, subject to conditions, to require third party testing for children's products. Under the draft bill, the CPSC could require third party testing only if the Commission first verifies the testing capacity of "accredited third party conformity assessment bodies," as well as establishes and publishes notice of the requirements for accreditation of such assessment bodies.**

   a. **Is it your understanding that the term "accredited third party conformity assessment bodies" includes both domestic and international bodies?**

   Yes.

   b. **If so, how many such assessment bodies are there worldwide?**

Each assessment body is certified for certain kinds of testing. There are 29 US labs and 124 international labs certified for at least one of the CPSC lead test protocols.

c. **Further, does the Commission have the resources with which to verify the testing capacity of all third party conformity assessment bodies?**

It seems unlikely.

d. **Moreover, is it your understanding of the draft legislation that the Commission would have to accredit all third party conformity assessment bodies?**

Yes.

e. **If so, do you believe the Commission has the resources with which to accomplish this?**

No. The Commission has in the past stated that it is under-resources already.

f. **In summary, do you believe the practical effect of these requirements would be that the Commission would seldom, if ever, require third party testing of children's products?**

That seems highly likely.

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May 11, 2011

Via Electronic Mail: Alex.Yergin@mail.house.gov

The Honorable Mary Bono Mack, Chairman
The Honorable G. K. Butterfield, Ranking Member
Subcommittee on Commerce, Manufacturing, and Trade
Committee On Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Discussion Draft of H.R. _____, a bill that would revise the Consumer Product Safety Improvement Act; Response to Questions

Dear Chairman Bono-Mack and Ranking Member Butterfield:

Thank you for the opportunity to appear before the Subcommittee on April 7, 2011. I welcomed the opportunity to express my personal views about necessary revisions to the Consumer Product Safety Improvement Act of 2008 (CPSIA) to maintain strong protections for children's health and safety, consistent with recognized science-based approaches to managing risk used by many different agencies, while reducing unnecessary and costly burdens on regulated businesses. We provide responses to your additional questions below.

The Honorable Mary Bono Mack

1. **Does the FDA, CDC or other public health agencies recognize that humans can tolerate different amounts of lead at different ages?**

   Yes. The federal Food and Drug Administration (FDA) has adopted Provisional Tolerable Daily Intake (PTDI) limits[1] that vary depending on age for potential ingestion of lead through the diet. These levels are based on daily intake limits, which assume that these amounts will be consumed on a daily basis. The limits are:

   - children 0-6: 6 μg/day;
   - children over 6: 15 μg/day;
   - pregnant or childbearing women: 25 μg/day;
   - other adults: 75 μg/day.

[1] PTDI's are levels that are expected to give rise to a 1 μg/dL increase in blood lead levels in children and women of childbearing years, and a 3 μg/dL rise for others.

The U.S. Environmental Protection Agency's (EPA) Integrated Exposure Uptake Biokinetic (IEUBK) model predicts that low intakes of lead in the range of 1 – 2 μg/day would be difficult to detect because it is difficult to detect an impact of 2 μg/dL. The Centers for Disease Control (CDC) recommends that laboratories set internal quality control limits on blood lead measurements to +/- 2 μg/dL.[2]

2. What does "food grade" mean in terms of lead? Should items that are recognized by FDA as "food grade" be accepted by CPSC as having low lead?

Yes, materials safe for contact with food must be low in lead. Materials in contact with food used as, for example, food packaging (whether single or repeated use) are regulated as "food." "Food" is defined under Section 201(f) of the Federal Food, Drug and Cosmetic Act (FFDCA) as "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article."[3] In turn, a "food additive" is defined under Section 201(s) of the Act as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component … of any food …"[4] These provisions therefore establish that materials, and components of materials, in contact with food are subject to the requirements of the FFDCA.

Under Section 402(a)(1) of the FFDCA, a "food" is deemed to be adulterated if it "bears or contains any poisonous or deleterious substances that may render [the food] injurious to health." By virtue of Section 201(s), and its definition of "food additive," components of a food package are considered to be "food" subject to regulation by FDA if there is the potential for such components to migrate into food. FDA's Good Manufacturing Practices (GMP) regulation for food-contact materials requires that a food-contact material must be "of a purity suitable for its intended use."[5] Food-contact items that contain lead or other impurities that potentially migrate to food at unsafe levels would not be considered suitably pure under FDA's regulations because the lead could potentially adulterate the food.[6]

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[2] *Interpreting and Managing Blood Lead Levels < 10 μg/dL in Children and Reducing Childhood Exposures to Lead*, Recommendations of CDC Advisory Committee on Childhood Lead Poisoning Prevention, November 2, 2007, available at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5608a1.htm.

[3] 21 U.S.C. §321(f).

[4] 21 U.S.C. §321(s).

[5] 21 C.F.R. §174.5(a)(2).

[6] For these reasons, the Commission concluded that it would not make lead content determinations on foods used in consumer products. *See* 74 Fed. Reg 43031 at 43034 (August 26, 2009).

In addition to FDA regulations implementing the FFDCA, packaging products (both for foods and for non-foods) are subject to limits on total heavy metals, including lead, under the Coalition of Northeastern Governors (CONEG) Model Toxics in Packaging Legislation. These laws (1) prohibit the intentional use of *any amount* of lead, cadmium, mercury, and hexavalent chromium in packaging or individual packaging components, such as inks, adhesives, coatings, or labels,[7] and (2) restrict the total *combined* trace concentration level of unintentionally added lead, mercury, cadmium, and hexavalent chromium in packaging to no more than 100 parts per million (ppm) by weight. Nineteen states[8] have toxics in packaging laws based on the Model Legislation.[9] If regulated materials are unintentionally present, for example, as a contaminant in raw material feedstocks, the total concentration is limited to less than 100 ppm for the sum of all four metals in any package or individual packaging components. Thus, CONEG's standards require that total lead cannot exceed a maximum of 100 ppm lead, assuming that no other covered heavy metal is present. These limits are currently subject to enforcement by state authorities.[10] We are not aware of enforcement actions associated with food packaging under these state toxics in packaging laws. Materials that meet FDA requirements for food contact and/or CONEG requirements for packaging should be deemed low lead.

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[7] In particular, Section 3 of the Model Legislation defines "package" as containers providing a means of marketing, protecting, or handling a product and includes unit packages as well as intermediate packages and shipping containers, cross-referencing the packaging definitions found in ASTM D996 (American Society for Testing and Materials). The definition includes, but is not limited to, unsealed receptacles such as carrying cases, crates, cups, and other trays and wrappers. A "packaging component" is defined as any individual assembled part of a package including, but not limited to, any interior or exterior blocking, bracing, cushioning, coatings, closures, inks, and labels.

[8] These states include California, Connecticut, Florida, Georgia, Illinois, Iowa, Maryland, Maine, Minnesota, Missouri, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, Washington, and Wisconsin.

[9] A copy of the Model Legislation is available at: http://www.toxicsinpackaging.org/model_legislation.html.

[10] In August 2008, for example, retailer Forever 21, Inc. agreed to pay a total of $115,000 to the California Department of Toxic Substances Control (DTSC) to resolve allegations that the retailer had acquired and used plastic bags that failed to meet the state's restrictions on certain heavy metals, including lead. The final consent order is available at: http://www.dtsc.ca.gov/HazardousWaste/Projects/upload/Forever21_ENF_CO.pdf.

The Honorable G. K. Butterfield

1. **Please provide a list of every association or other entity that you have represented, consulted, or provided any other form of paid services with respect to any issues arising under the CPSIA in any forum and the amounts paid to you or your firm for these services.**

   I was asked by the Subcommittee staff to participate in the April 7 hearing in my capacity as an individual attorney with experience before a variety of different federal regulatory agencies, including the CPSC. I was not compensated for the preparation of my testimony or my appearance before the Subcommittee. I am a registered lobbyist on CPSIA matters only for the Fashion Jewelry and Accessories Trade Association; lobbying reports are on file and publicly available.

The Honorable John Dingell

1. **The draft legislation amends section 101(b) of CPSIA to exempt components of childreu's products from the Act's lead limits if such components do not cause a child to ingest more than a de minimus amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."**

   a. **Are you aware of a uniform reasonable methodology in use by manufacturers of children's products?**

   The CPSC and other health agencies use well-recognized techniques to evaluate potential exposures to chemicals and other substances in a variety of situations. Tests are available to assess surface migration, airborne migration, off-gassing, hand-to-mouth, mouthing, and ingestion exposures.[11] Specifically, CPSC has previously conducted lead migration tests to assess expected exposure conditions during reasonably foreseeable use and abuse conditions, such as wipe tests, simulating hand-to-mouth exposure; saliva tests simulating exposure by mouthing; acid extraction tests simulating exposure through accidental ingestion. Because CPSIA adopts a total content limit those tests are not currently used by the CPSC, but similar

[11] The log summary of a public meeting between CPSC, the Environmental Protection Agency, and the American Chemistry Council held on January 10, 2011 references some of these methods. See http://www.cpsc.gov/LIBRARY/FOIA/meetings/mtg11/epa01312011.pdf.

tests are done to evaluate exposure to phthalates and phthalates alternatives,[12] or to other substances. The CPSC recently updated a test method to simulate potential exposure to cadmium from ingestion of children's metal jewelry, for example.[13] Moreover, by adopting the toy safety standard, ASTM F-963, as a mandatory requirement, CPSIA requires testing of surface coatings of toys for heavy metals using a 2-hour extraction test. In short, a variety of scientifically acceptable methods to evaluate exposure using various migration tests suitable to the type of exposure and material are available.

b. Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?

No, within the limits of normal inter-laboratory variability. Extensive round robin testing of the migration procedure adopted under ASTM F-963 yielded information on specific statistical uncertainty factors that should be applied for particular metals subjected to the test. While experience has shown that there can be significant inter-laboratory variability in total lead or phthalate content tests, as the same materials do not yield identical results when tested in different laboratories, statistical uncertainty factors have not been adopted for total content tests. This issue could be addressed through round robin testing and additional method standardization by CPSC. Material variability could also be a factor as substances like lead may not always be evenly dispersed in the material tested.

c. If so, do you believe this is could pose a risk to the health of children who use such products?

No. Scientific approaches to establish inter-laboratory uncertainty factors are available and should be adopted for both total content and migration tests.

2. The draft legislation would allow the CPSC, subject to conditions, to require third party testing for children's products. Under the draft bill, the CPSC could require third party testing only if the Commission first verifies the testing capacity of "accredited third party conformity assessment bodies," as well as establishes and publishes notice of the requirements for accreditation of such assessment bodies.

a. Is it your understanding that the term "accredited third party conformity assessment bodies" includes both domestic and international bodies?

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[12] See Staff Memorandum, Phthalates and Phthalate Substitute in Children's Toys, March 31, 2010, available at http://www.cpsc.gov/ABOUT/Cpsia/phthallab.pdf.

[13] Method CPSC-CH-E1004-11, Standard Operating Procedure for Determining Cadmium Extractability from Children's Metal Jewelry. See http://www.cpsc.gov/LIBRARY/FOIA/FOIA11/os/cadmiumjewelrytest.pdf.

Yes, provided they meet the accreditation criteria.

b. If so, how many such assessment bodies are there worldwide?

Information on the total number of third party assessment laboratories currently accredited by the CPSC is available at the CPSC website; however, not every laboratory is certified or accredited to conduct every test that may be required pursuant to CPSC laws and regulations. The searchable database of laboratories is available at http://www.cpsc.gov/cgi-bin/labsearch/.

c. Further, does the Commission have the resources with which to verify the testing capacity of all third party conformity assessment bodies?

I have no knowledge of the Commission's resources to undertake this task.

d. Moreover, is it your understanding of the draft legislation that the Commission would have to accredit all third party conformity assessment bodies?

The Commission must determine that the third party conformity assessment body has the technical ability to conduct the relevant test or tests for which accreditation is sought *and* has the capacity to handle testing before accreditation is conferred by CPSC under the draft legislation. Third-party conformity assessment bodies that do not meet these requirements cannot receive accreditation. Manufacturers may use only a CPSC- accredited laboratory where legislation or rules require third party testing to support a certificate of compliance.

e. If so, do you believe the Commission has the resources with which to accomplish this?

I have no knowledge of the Commission's resources to accomplish this task.

f. In summary, do you believe the practical effect of these requirements would be that the Commission would seldom, if ever, require third party testing of children's products?

I am unable to speculate on the frequency with which the Commission would require third party testing beyond categories already covered. It will depend on the specifics of the test requirements, qualifications and capacity of third party assessment bodies who seek to be accredited to conduct such tests, and other factors.

3. I have several questions concerning the public database mandated by CPSIA.

a. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?

Yes.

b. Should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published?

Yes.

c. If a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should that dispute be resolved and by whom?

The CPSC should resolve the dispute by evaluating the facts presented to it.

d. The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe the draft legislation's narrowing of eligibility to submit complaints is necessary?

Yes. This change should help minimize duplicative complaints and assure that actual incidents, rather than speculative risks, are posted to the database.

I trust these responses are helpful.

Respectfully submitted,

Sheila A. Millar

May 10, 2011

VIA ELECTRONIC MAIL AND REGULAR MAIL

The Honorable Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing and Trade
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: Reponses to Questions for the Record from The Honorable John Dingell
"Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act," April 7, 2011

Dear Chair Bono Mack:

Attached please find my responses to the questions for the record from The Honorable John Dingell.

Thank you for the opportunity to testify at the hearing entitled "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act" on April 7, 2011.

Respectfully submitted,

Paul C. Vitrano
General Counsel

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Responses to Additional Questions for the Record from The Honorable John Dingell

1. The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a *de minimus* amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."

a. **Are you aware of a uniform reasonable methodology in use by manufacturers of children's products?**

   No.

b. **Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?**

   While some variation in test results from different methodologies is possible, with respect to methodologies that provide a reasonable basis for estimating the amount of lead a child would likely ingest from exposure to a component part during reasonably foreseeable use and abuse of a particular product, we would not expect a wide variance in test results across manufacturers.

c. **If so, do you believe this could pose a risk to the health of children who use such products?**

   No. See response to b. above.

2. The draft legislation would allow the CPSC, subject to conditions, to require third party testing for children's products. Under the draft bill, the CPSC could require third party testing only if the Commission first verifies the testing capacity of "accredited third party conformity assessment bodies," as well as establishes and publishes notice of the requirements for accreditation of such assessment bodies.

a. **Is it your understanding that the term "accredited third party conformity assessment bodies" includes both domestic and international bodies?**

   Yes.

b. **If so, how many such assessment bodies are there worldwide?**

   Yes. Unknown. The CPSC website includes a list which currently contains more than 330 third party laboratories that have been accredited by the Commission for assessing conformity with various children's product safety rules.

c. **Further, does the Commission have the resources with which to verify the testing capacity of all third party conformity assessment bodies?**

Unknown. This question is better addressed to the Commission.

d. **Moreover, is it your understanding of the draft legislation that the Commission would have to accredit all third party conformity assessment bodies?**

Under the draft legislation, a manufacturer is required to use a third party conformity assessment body that has been accredited by CPSC to meet its testing and certification obligations with respect to specified children's product safety rules. A manufacturer could use an unaccredited third party to test for conformity with other product safety rules unless the Commission requires that manufacturers use an accredited third party to test for and certify conformity with particular additional safety rules or for particular classes of products.

e. **If so, do you believe the Commission has the resources with which to accomplish this?**

Unknown. This question is better addressed to the Commission.

f. **In summary, do you believe the practical effect of these requirements would be that the Commission would seldom, if ever, require third party testing of children's products?**

No.

3. **I have several questions concerning the public database mandated by CPSIA.**

a. **Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?**

The CPSC's final rule implementing the public database under the CPSIA provides that the Commission will publish a report of harm which meets specified minimum requirements for publication in the database not later than 10 business days after such report is transmitted to the manufacturer for review. *See* 16 C.F.R. Sections 1102.10(d) and 1102.28(a). This will be the case even in situations where there is a pending but as yet unresolved request by the manufacturer that materially inaccurate information be removed from the report or the report itself not be published because it is materially inaccurate.

b. **Should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published?**

Yes. Fundamental due process requires that a manufacturer be given a reasonable opportunity to do so.

c. **If a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should that dispute be resolved and by whom?**

A pending manufacturer request for removal of materially inaccurate information from a report of harm should be resolved prior to publication of the report. Such a request should be resolved in the first instance by the CPSC staff implementing the public database, with the manufacturer having the right to appeal an initial denial of the request to the CPSC General Counsel for a final agency decision with the right to seek further relief through judicial means.

d. The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe the draft legislation's narrowing of eligibility to submit complaints is necessary?

Yes. CPSC's rule implementing the database originally proposed an additional category of "others" that dramatically and improperly expanded the scope of persons who could submit reports of harm. In response to comments objecting to this improper expansion of potential reporters, CPSC simply folded the "others" category into the rule's definition of "consumers." This is not what Congress intended and must be corrected. As a point of clarification, the draft legislation amends the CPSIA to permit persons who suffer harm or risk of harm related to use of a consumer product, their next of kin or members of their household, their legal representative, or another person expressly authorized by them to submit a report of harm for publication in the database.

RESPONSES TO QUESTIONS FOR THE RECORD OF THE APRIL 7, 2011
HEARING BEFORE THE SUBCOMMITTEE ON COMMERCE, MANUFACTURING AND TRADE
COMMITTEE ON ENERGY AND COMMERCE

ERIKA Z. JONES
ON BEHALF OF
BICYCLE PRODUCT SUPPLIERS ASSOCIATION

The Honorable Mary Bono Mack

1. In your testimony, you state that there is too much variability in certain metal alloys to ensure that bicycles meet the next drop-down to 100 parts per million (ppm). Why is the lead content of alloys difficult to control?

   RESPONSE: Common alloys of aluminum, iron and copper used in bicycle manufacturing are sourced in Asia and typically have recycled metal content. Inevitably some lead finds its way into these alloys as a contaminant. Studies conducted by a CPSC certified third party laboratory have confirmed that the amount of lead in these alloys can vary above or below 100 ppm even within a single component part. The results of these studies have been submitted to the U.S. CPSC's docket on the 100 ppm issue. Use of virgin materials or other metal alloys such as certain grades of low-lead stainless steel is precluded by the high price of these materials, which would make the final product prohibitively expensive.

2. Under current law, how many different parts of a bike are accessible and need to be tested to the lead limits?

   RESPONSE: While the precise number varies from bicycle model to bicycle model, a typical bicycle has approximately 140 "accessible" component parts, as the term "accessible" has been defined by the U.S. CPSC.

3. Do you see other opportunities to reduce testing costs without undercutting the benefits?

   RESPONSE: Section 101 of CPSIA applies the lead substrate limits to all components of children's products except "any component part ... that is not accessible to a child through normal and reasonably foreseeable use and abuse of such product as determined by the Commission." The Commission has determined that all components that can be contacted by a specified probe are "accessible" for purposes of this requirement.

   In the case of bicycles and other outdoor recreational products, narrowing or modifying the definition of "accessible" to parts which are likely to be touched or mouthed during use of the product would narrow the list of component parts to those which are likely to

pose a risk of lead exposure to the child user. For example, contact points on a bicycle required for its use include the handlebars, brake levers, grips, and saddle. Most of the metal alloy parts are part of the structural frame or drive train of the bicycle and are likely to be touched only incidentally, if ever, during use.

The Honorable G. K. Butterfield

1. Dr. Best testified that "in the case of lead, there is no benefit to *exposure*." (Emphasis added.) In your testimony, you took issue with this statement, arguing: "I would like to address a comment made by . . . Dr. Best, who made a comment that there is no benefit to lead and therefore it should be inherently unnecessary. Lead in the quantities that we see it in metal alloys that are used in bicycles provide a tremendous benefit."

   Dr. Best's statement concerns the lack of any benefits to human health from exposure to lead, and not the benefits that accrue with respect to the affordability or durability of a product.

   a. Are you aware of any direct benefits to human health from exposure to lead?

   RESPONSE: In BPSA's view, there are many benefits to human health from the continued wide availability in the market of affordable bicycles for children. While BPSA strongly believes that there is no risk to human health from the extremely low levels of lead in metal alloys used in bicycles, the CPSC's current interpretation of CPSIA deems virtually all components of children's bicycles to be "accessible," and therefore subject to the lead substrate standard. Under this interpretation, the mere *presence* of lead has been equated to *exposure* to lead, even in minuscule quantities that cannot be measured in human blood. This is the reason why the CPSC denied the BPSA petition for a limited exclusion from the lead substrate standard in 2009, and it was in this context that Dr. Best's comment required a response.

2. In response to questioning from the Subcommittee, you argued that manufacturers have not been given enough time to comply with the 100 ppm lead content standard because it will apply "immediately on August 11[, 2011.]" You went on to state: "Normally, manufacturers are given lead time to plan for the new regulation, to redesign their products, to absorb the costs in a more orderly fashion, and to work out their inventory so that products sold after the effective date reach retail shelves in a compliant fashion. That is the proper, orderly way to regulate products for safety improvement, not to disrupt the market with these very abrupt changes that do not permit that kind of orderly transition."

   a. Is it correct that the text of CPSIA makes clear to manufacturers that three years from the date of enactment their products are expected to comply the 100 ppm lead content standard?

RESPONSE: No. The CPSIA requires the CPSC to lower the standard unless it makes a determination that application of the standard to a particular product or component part is "not technologically feasible." This provides no clear guidance for manufacturers of products who have struggled, so far unsuccessfully, to bring their products fully and consistently into compliance with a 100ppm lead substrate limit. If the manufacturer cannot now meet the standard, they have two choices as the August deadline approaches: (1) they can try and persuade the CPSC that this potential lack of compliance is because it is "not technologically feasible" to do so and wait for the Commission to rule and hope the ruling is favorable; or (2) they can cease making the products and suffer economic injury.

The Honorable John Dingell

1. The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a *de minimus* amount of lead. The draft legislation further requires the Commission to establish procedures for estimating the amount of lead a child would ingest from a given children's product. However, while the Commission establishes such procedures, the draft legislation would permit manufacturers to use "any reasonable methodology to estimate the amount of lead a child would likely ingest from exposure to a component part."

   a. Are you aware of a uniform reasonable methodology in use by manufacturers of children's products?

RESPONSE: BPSA's 2009 petition for a limited exclusion from the lead substrate standards relied on expert analysis of lead exposure, in which BPSA's retained expert (Dr. Beck, who also testified before this Subcommittee on April 7) used a reasonable methodology to estimate the increase in blood lead level based on means of exposure and absorption. BPSA is unaware of the extent to which this (or any other) methodology is uniformly in use by manufacturers of children's products.

   b. Is it possible the ambiguity of the term "reasonable methodology" could lead to a wide variance in test results across manufacturers of similar products?

RESPONSE: While use of different methodologies could lead to differing results, this would only be a temporary issue until the CPSC developed a uniform test procedure.

   c. If so, do you believe this could pose a risk to the health of children who use such products?

RESPONSE: No. Products that clearly pose the highest risk of lead ingestion (such as small items of jewelry or materials like leaded paints) will not be affected by the proposed changes to section 101(b), which address products with an inherently low risk of ingestion.

2. The draft legislation would allow the CPSC, subject to conditions, to require third party testing for children's products. Under the draft bill, the CPSC could require third party testing only if the Commission first verifies the testing capacity of "accredited third party conformity assessment bodies," as well as establishes and publishes notice of the requirements for accreditation of such assessment bodies.

   a. Is it your understanding that the term "accredited third party conformity assessment bodies" includes both domestic and international bodies?

RESPONSE: Yes.

   b. If so, how many such assessment bodies are there worldwide?

RESPONSE: The CPSC website lists all currently accredited third party conformity assessment bodies. BPSA does not have any additional information about the number of third party conformity assessment bodies.

   c. Further, does the Commission have the resources with which to verify the testing capacity of all third party conformity assessment bodies?

RESPONSE: BPSA is not familiar with the details of the resources available to the Commission for this task.

   d. Moreover, is it your understanding of the draft legislation that the Commission would have to accredit all third party conformity assessment bodies?

RESPONSE: No; the Commission would have to accredit only those third party conformity assessment bodies that meet the Commission's qualification standards for accreditation and the substantive standards set forth in the draft legislation. As is the case with the current law, the draft would require the Commission to accredit third party conformity assessment bodies before manufacturers could rely on tests performed by those bodies to support a certification of compliance.

   e. If so, do you believe the Commission has the resources with which to accomplish this?

RESPONSE: BPSA is not familiar with the details of the resources available to the Commission for this task.

f. In summary, do you believe the practical effect of these requirements would be that the Commission would seldom, if ever, require third party testing of children's products?

RESPONSE: No. Over the past few years, the testing industry has responded to the CPSIA and other international regulatory requirements by adding laboratories and capacity so that today the demand for testing resources for the bicycle industry is largely being met. However, whenever a new requirement is established or becomes effective, there needs to be sufficient time allowed for the testing industry to respond. When the testing entity is a third party laboratory, by definition manufacturers cannot control the finances or business decisions of those independent entities in deciding whether to apply for CPSC certification. The CPSC should have discretion to grant relief from the third party testing requirements when there are no certified labs or an insufficient number of certified labs to handle the testing requirements of the industry.

3. I have several questions concerning the public database mandated by CPSIA.

a. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?

RESPONSE: Yes.

b. Should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published?

RESPONSE: Yes.

c. If a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should that dispute be resolved and by whom?

RESPONSE: The CPSC should be required to resolve disputes about accuracy before product complaints are posted on the public website.

d. The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe the draft legislation's narrowing of eligibility to submit complaints is necessary?

RESPONSE: Yes. This will avoid the filing of unfounded complaints by persons or organizations that lack direct knowledge of the circumstances.

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May 11, 2011

Via Electronic Mail: Alex.Yergin@mail.house.gov

The Honorable Mary Bono Mack, Chairman
The Honorable G. K. Butterfield, Ranking Member
Subcommittee on Commerce, Manufacturing, and Trade
Committee On Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6615

Re: Discussion Draft of H.R. _____, a bill that would revise the Consumer Product Safety Improvement Act; Response to Questions

Dear Chairman Bono-Mack and Ranking Member Butterfield:

Please find my responses to the questions by Mr. Dingell and Mr. Butterfield.

a. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?

   CPSIA has been interpreted, unfortunately, by the Commission to require the posting of information to the database even if the Commission bas failed to resolve a timely and substantial claim of material inaccuracy submitted by the manufacturer. This is unfair and an inappropriate policy for a federal agency. There should be a higher premium placed by CPSC on valid, accurate, and useful information than could be found in blogs and other posts on the internet. Today, the Commission states that it is making these decisions within several days from the time the manufacturer replies so it is practical and there will be no hardship for the Commission to resolve these claims expeditiously.

b. Should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published?

   Yes, a timely and substantial claim by a manufacturer that a submission is inaccurate should be resolved by the Commission before any public posting. This is likely to occur only in a relatively few cases and can be resolved expeditiously by the Commission.

c. If a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should that dispute be resolved and by whom?

   The Commission has great experience in determining and evaluating the quality and accuracy of information. It is quite capable of quickly determining, for example, whether

a product has been misidentified or an alleged unsafe condition or injury causation is clearly incorrect. Other groups will continue to be able to communicate their concerns to the Commission outside of the database.

d. The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe the draft legislation's narrowing of eligibility to submit complaints is necessary?

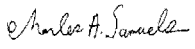
The draft legislation properly refocuses the universe of database submitters to those Congress originally intended – injured persons, their family and their representatives, first responders or medical personnel who have direct and substantial knowledge of an alleged risk or event of harm. Other persons are entitled to their opinions and advocacy, but the purpose of the public database is not to create an opinion forum. That function is filled by many groups, media and internet sites

Mr. Butterfield

Q: Please provide a list of every association or other entity that you have represented, consulted, or provided any other form of paid services with respect to any issues arising under the CPSIA in any forum and the amounts paid to you or your firm for these services.

A: I was asked by the Committee to testify on my own behalf as an expert on CPSC law and procedure. As I stated in my testimony, I am General Counsel for the Association of Home Appliance Manufacturers, and I have registered as a lobbyist for that organization. There is no other entity for which I lobby on CPSC or related matters.

Sincerely,



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May 11, 2011

Via Electronic Mail: Alex.Yergin@mail.house.gov

The Honorable Mary Bono Mack, Chairman
The Honorable G. K. Butterfield, Ranking Member
Subcommittee on Commerce, Manufacturing, and Trade
Committee On Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515-6615

Re: Response to Supplemental Questions re Discussion Draft of H.R. _____, a bill that would revise the Consumer Product Safety Improvement Act

Dear Chairman Bono-Mack and Ranking Member Butterfield:

Thank you again for your invitation of the Subcommittee to appear and provide testimony before the Subcommittee on Commerce, Manufacturing, and Trade on April 7, 2011, to testify at the hearing entitled "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act." Please find my responses to the supplemental questions by Mr. Dingell and Mr. Butterfield.

The Honorable John Dingell

1. I have several questions concerning the public database mandated by CPSIA.

a. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?

A. CPSIA has been interpreted by the Commission to limit its discretion to investigate the veracity and accuracy of complaints prior their posting to the database. The default presumption under the Commission database rule is that posting is required, without discretion, even if the Commission has failed to resolve a timely claim of material inaccuracy submitted by the manufacturer. The presumption under the rule is that CPSC is required to post within 10 business days of its mailing or making such complaint available to the affected manufacturer, importer of record or private labeler for comment. This limits the CPSC from asserting discretion as is customarily afforded independent federal regulatory agencies to reasonably investigate such claims. CPSC should be

afforded the discretion to assure that valid, accurate information is posted on a database put forth under the imprimatur of the U.S. Government, notwithstanding disclaimers and limitations of liability contained therein.

b. *Should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published?*

A. Yes, a timely claim by a manufacturer that a submission is materially inaccurate, so as to be false misleading or unfair should be required to be affirmatively resolved by the Commission prior to public posting. Since such requirement is first predicated upon a legitimate claim of material inaccuracy, under penalty of law, if the claim itself is false the Commission can be required and should be afforded the opportunity to validate the complaint prior to posting. This seems fundamentally fair.

c. *If a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should that dispute be resolved and by whom?*

A. The Commission already has experienced staff capable of reviewing hazard data, conducting investigations of hazards and discerning factual so as to screen data to assure reasonable accuracy of information. This was one of the very reasons for support of increased funding for the agency with the passage of the CPSIA.

d. *The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe the draft legislation's narrowing of eligibility to submit complaints is necessary?*

A. The draft legislation seeks to assure that duplicate complaints and issues related to "hearsay" complaints are resolved. We support database submissions by those persons reasonably intended by Congress to be eligible to submit claims namely injured person, their family and their representatives, first responders or medical personnel who have direct and substantial knowledge of an alleged risk or event of harm. Requirements that hew to the original purpose of Congress, yet provide a way for duplicative or hearsay information to be weaned from the database, will allow CPSC staff to better use their limited resources.

The Honorable G. K. Butterfield

1. Please provide a list of every association or other entity that you have represented, consulted, or provided any other form of paid services with respect to any issues arising under the CPSIA in any forum and the amounts paid to you or your firm for these services.

A. In my testimony I noted firm works as independent legal counsel to the Craft& Hobby Association (CHA), Toy Industry Association (TIA), Juvenile Product Manufacturers Association (JPMA), Halloween Industry Association (HIA), and individual companies.

These services include but are not limited to issues arising under the CPSIA. Indeed most of our legal services are unrelated to the CPSIA. Our client Associations employ independent or staff registered lobbyists. We have noted that our services are broader than just dealing with CPSIA issues. It was in my individual capacity that as a legal practitioner dealing with children's product safety standards and issues beyond the pale of the CPSIA that I was requested to appear and testify before this Subcommittee. I did not charge any client a fee for services to do so. In the aggregate I estimate that no more than $50,000. annually has been allocated in relation to fees providing member information, education, seminars, bulletins and specific client advice (subject to attorney client privilege) or in rendering technical and legal advice specifically related to CPSIA required rulemakings (conducted independently in accordance with due process requirements of the Administrative Procedure Act as part of the CPSC's rulemaking function).

2. *I understand that you represent the Juvenile Products Manufacturers Association (JPMA).*

   a. *Does JPMA have a third-party testing program for the durable nursery products for which the Republican discussion draft removes mandatory third-party testing requirements?*

A. Yes, the JPMA does have a Certification Program that includes testing by third party designated laboratories as part of the program. The program also will permit reliance on alternate test and component part test rules, related to selection and testing or representative samples from production and reliance upon component supplier certifications, to the extent permitted by the Consumer Product Safety Commission (CPSC). The revised discussion draft as currently being circulated would not eliminate such program or preclude the program's inclusion of testing requirements by independent third party internationally accredited testing laboratories. The CPSC is afforded the discretion to require such testing as part of a suitable quality assurance program under the current draft rules under discussion. As we understand the current draft third party testing as a component of such Certification program would not be eliminated.

   b. *Does JPMA support third-party testing for durable nursery products?*

A. First and foremost JPMA supports sound quality assurance programs and procedures as part of sourcing materials and in the production of products so that testing when the product is already entered into U.S. Commerce is obviated. Verification third party or firewalled laboratory testing as part of such production process is supported as part of its Certification Program. This is distinct from a requirement that the CPSC accredit laboratories performing such testing, if such accreditation process creates production bottlenecks or sourcing issues. CPSC should be afforded the discretion to recognize existing valid NIST recognized international accreditations for such laboratories; this could streamline the process and be used to avoid bottlenecks in sourcing, production and distribution of goods in commerce. JPMA supports affording the Commission the authority to prescribe reasonable testing programs, such as its Certification program, to be used as the basis for certification under CPSIA. In addition JPMA supports reasonable requirements that assure availability and capacity of internationally accredited, NIST recognized laboratories sufficient to timely conduct testing, so as not to impede the free flow of trade or create bottlenecks in the supply

chain. This is especially important to assure consumer supply and availability of new durable juvenile products that will be subject to increasingly stringent mandatory safety regulations under Section 104 of the Consumer Product Safety Improvement Act of 2008. We also support the flexibility needed by the Commission to assure that congressionally specified alternate test rules are recognized and implemented as part of this process.

Thank you for your additional inquiries.

Sincerely,

Frederick Locker

Frederick Locker

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CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED TWELFTH CONGRESS

Congress of the United States
House of Representatives

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April 27, 2011

Mr. Dan Marshall
Vice President, Handmade Toy Alliance
Co-Owner, Peapods Natural Toys & Baby Care
2290 Como Avenue
St. Paul, MN 55108

Dear Mr. Marshall,

Thank you for appearing before the Subcommittee on Commerce, Manufacturing, and Trade on April 7, 2011, to testify at the hearing entitled "Discussion Draft of H.R. ___, a bill that would revise the Consumer Product Safety Improvement Act."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for 10 business days to permit Members to submit additional questions to witnesses, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and then (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Wednesday, May 11, 2011. Your responses can be emailed to the Legislative Clerk, in Word or PDF format, at Alex.Yergin@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Mary Bono Mack

Mary Bono Mack
Chairman
Subcommittee on Commerce, Manufacturing, and Trade

cc: The Honorable G. K. Butterfield, Ranking Member,
Subcommittee on Commerce, Manufacturing, and Trade

Attachments

May 9, 2011

The Honorable Fred Upton,
Chairman, Commerce and Energy Committee

The Honorable Mary Bono Mack
Chair, Subcommittee on Commerce, Manufacturing and Trade

The Honorable G.K. Butterfield
Ranking Member, Subcommittee on Commerce, Manufacturing and Trade

The Honorable John Dingell
Member, Subcommittee on Commerce, Manufacturing and Trade

Re: Questions for the Record from the April 7 Hearing on Reform of the Consumer Product Safety Improvement Act (CPSIA)

The Honorable G. K. Butterfield

1. During your oral testimony you stated that the Handmade Toy Alliance endorsed the Republican discussion draft "because of the relief it provides to our members." You went on to suggest that the draft provides your members an exemption from third-party testing or that your members would be allowed to follow alternative testing procedures. My understanding, based on the advice of lawyers on my staff, and on Chairman Bono Mack's opening statement, is that the draft does not provide any relief to your members from the mandatory third-party requirements for five specific products or hazards: (1) lead paint; (2) lead in children's metal jewelry; (3) small parts; (4) compliance with crib standards; and (5) compliance with pacifier standards. Relief is only available to your members from any additional testing requirements that CPSC might require in the future through the rulemaking process outlined in the draft. Small crafters will still have to have their children's products third-party tested for lead in metal jewelry, small parts, and compliance with the crib standards. In addition, ASTM F-963 will remain a mandatory standard, so your members will still have to comply with all of ASTM F-963 and certify that they have done so.

a. Assuming my understanding is accurate, do you and your members still support the Republican discussion draft even though it does not provide full relief from compliance with CPSIA? If so, please explain why.

First and foremost, we wish to restate that our primary goal is the passage of meaningful CPSIA reform

as soon as possible. Although the discussion draft would provide relief for our members in key areas, we remain concerned about many other provisions of the CPSIA which unfairly disadvantage small businesses. These include retroactivity, labeling requirements, the 100ppm lead content standard, lack of harmonization with the European Union, and testing requirements for small parts and lead in paint. In the interest of expediency, we have chosen to focus our efforts on providing the most relief for as many of our members as possible.

Our ideal solution to the unintended consequences of the CPSIA is outlined in our platform located at http://www.handmadetoyalliance.org/Resources/TheHTAPlatform.aspx . The discussion draft proposes relief through CPSC rulemaking as you indicate, but with the protecting stipulations that the benefits of third party testing justify the costs; that rules impose the least possible burden; and that an exemption is provided by default in the absence of rulemaking. These stipulations make compliance achievable for our membership. However, our preference remains a legislative exemption for micro-businesses.

Our purpose from the beginning of our organization has always been to mitigate the costs of third party testing on small batch children's product manufacturers. The CPSIA established requirements for many types of tests for many different types of products. In speaking with our members, our analysis is that the greatest burdens we face are mandatory third party testing for lead in substrate and ASTM F-963 testing for toys, both of which are scheduled to be implemented by the end of this year. We are not seeking exemptions from the standards themselves, but from the third party testing requirements. In both cases, we believe that small batch manufacturers should be allowed to self-certify based on a reasonable testing program. The discussion draft would make this possible.

We are not pursuing exemptions from testing requirements for lead in paint, metal jewelry, or crib standards. In the case of the lead in paint and metal jewelry standards, we recognize two realities. First, these were the two areas which caused the majority of product safety concerns prior to the enactment of the CPSIA. Second, although we disagree with the need for testing American and European products for lead in paint violations because lead paint has been outlawed in those countries for over 30 years, we recognize that the damage to these companies has already been done. The lead in paint testing requirement has been in place for almost a year and a half. Several respected companies have already ceased operations as a result. The damage has already been done. We hope that component-based testing will mitigate the cost of lead in paint testing in the future.

We are not at this time concerned with the crib standard. None of our members manufacturer cribs.

As for the small parts testing requirement, we believe that the CPSC can and should develop alternative testing methods which would allow small-batch manufacturers to self-certify. This standard is very straightforward and relatively easy to test for. In a perfect bill, the small parts standard would not be excluded from the exemptions available to small batch manufacturers.

Once again, we urge the House and the Senate to work together to mitigate the overwhelmingly negative impact of the CPSIA on small businesses.

The Honorable John Dingell

1. The draft legislation amends section 101(b) of CPSIA to exempt components of children's products from the Act's lead limits if such components do not cause a child to ingest more than a de minimus amount of lead. The legislation would require the Commission to specify procedures for manufacturers to test and estimate this de minimus amount. Do you believe small manufacturers and handcrafters will

be able to afford and/or carry out such test procedures?

No. We do not believe that small batch manufacturers will be able to avail themselves of the *de minimus* exemption process. The costs involved in meeting the requirements of this process would be beyond the reach of our members. However, we hope that the CPSC will rule on *de minimus* applications made by larger companies in such a way that smaller businesses may benefit as well. For example, if the CPSC rules that a given company's leaded crystal rhinestones meet the *de minimus* standards, we hope that it will make its ruling categorically, so that *all* manufacturers which use leaded crystals may also benefit. We would hope that committee report language would communicate the expectation that *de minimus* rulings should be made as generally as possible and not limited to only a specific product made by a specific manufacturer.

Responses from Rachel Weintraub to Questions for the Record from Hearing on "Discussion Draft of H.R. , a bill that would revise the Consumer Product Safety Improvement Act,"April 7, 2011

Questions from the Honorable Mary Bono Mack

Question

1. Which is more dangerous: a children's product containing 10,000 ppm lead that does not leach enough lead to result in a measurable increase in a child's blood lead level, or a product that contains 100ppm lead that leaches enough lead to result in a measurable increase in a child's blood lead level?

Answer

The first example is potentially dangerous and the second is definitely dangerous. If a child already has a moderately elevated blood level, exposure to a product that may not leach enough lead alone to measurably increase blood lead level could, in combination with other exposures, result in an increase in blood lead levels. Depending upon the composition of the item, it could leach higher levels of lead over time as the materials deteriorated. In addition, there are unexpected circumstances, such as a child ingesting a product, that can lead to higher absorption than expected. Given the long-established toxicity of lead to children's brains, the American Academy of Pediatrics strongly recommends eliminating all unnecessary sources of exposure.

Question

2. Do you think the Consumer Product Safety Commission should focus its efforts primarily on products where it can prevent the most harm to the public?

Answer

The Consumer Product Safety Commission should balance numerous factors when it prioritizes its work. The factors that should be balanced include: if the harm is preventable, how pervasive the harm is, and CPSC's resources and expertise available to address the harm. Importantly, as the only agency standing between consumers and potentially deadly products, as CPSC weighs numerous factors in determining what issues to address, CPSC cannot afford to completely ignore any hazard.

Question

3. You made a claim that the discussion draft will "keep babies in known unsafe cribs." Which cribs did you have in mind? What is your basis for claiming that they are unsafe? If they are known to be unsafe, why has CPSC not undertaken a recall (in which case, the costs of purchasing a new crib might be borne by the manufacturer of the unsafe product instead of the purchaser)?

Answer

Because the Discussion Draft will allow non-drop side cribs to be used in day care facilities if in compliance with state supervision laws, cribs that have other types of hazards could still be used. Cribs that have slats that are too far apart or corner posts are known hazards to babies. Cribs that have these elements have not been recalled by CPSC but rather voluntary standards have prohibited them over the years. CPSC has never recalled cribs because they do not meet the newer voluntary standard or even when they didn't meet the older mandatory standard.

Question

4. How does an inaccurate report aid a consumer in making a smart purchase?

Answer

This question presumes that there will be inaccurate reports in the database. I am not aware of data supporting the proposition that reports will not be accurate. The database includes criteria that require eight specific fields of information and allows manufacturers not only to place a comment on a posting but also to make a claim that the information in the report is materially inaccurate. We understand from the CPSC that manufacturers have been claiming material inaccuracy for about 20 percent of claims and that for more than half of them the claim involves a misidentification of the manufacturer. We understand that these claims are being resolved before they are being posted.

Question

5. How does an incomplete report aid a consumer in making a smart purchase? For instance, there are over 100 GRACO baby chair models. How does a report that identifies a product as GRACO, rather than by specific model, help a consumer?

Answer

First, the type of situation that this question presents is not reflective of the vast majority of information received in the database thus far. In fact, we understand from CPSC that over 80 percent of the reports submitted to the database contain model numbers.

Second, information such as this could help a consumer by confirming a similar hazard pattern that may have occurred to them or by reinforcing that steps should be taken to ensure against a potential hazard. For example, if the issue had to do with a tray breaking or not securing properly, it could remind a parent to always make sure that the tray is correctly latched, that the tray cannot be used as an effective restraint, and that the straps should always be used.

Question

6. You testified that "many organizations testif[ied] that testing to 100ppm was technologically feasible and that companies were already complying with that standard." The issue is not whether it can be tested but whether companies can consistently reach that very low level in metal-containing products and a number of organizations testified at that same proceeding that it is not feasible. Why are your organizations right when those that actually manufacture the products are wrong?

Answer

In my written testimony, I stated that, "At a recent CPSC hearing on this issue, many organizations testifying stated that testing to 100 ppm was technologically feasible and that companies were already complying with that standard." Further, Jay Howell who also testified before you on April 7, 2011, stated in his written testimony that,

> "In a recent Commission hearing on the technological feasibility of reducing lead limits to 100 ppm, a representative of SGA, a global inspection, verification, testing, and certification company, presented a statistical analysis of lead content testing data (89,273 data points) collected primarily from its Shenzen laboratory that specializes in the testing of children's toys and other children's products. In its analysis, SGS found that 96.29 percent of metal components tested at or below 100 ppm lead."

Thus, Mr. Howell's testimony expanded upon and confirmed my point that data is proving that compliance with the 100 ppm lead level is technologically feasible. This is the critical question since the CPSIA includes in section 101(a)(2)(c) that, the lead limit for children's products will be 100 ppm "unless the Commission determines that a limit of 100 parts per million is not technologically feasible for a product or product category."

Question

7. You criticize the phthalate provisions of this draft and I have a couple of questions on that.

   a. First, you disagree with the provision because the CSPC can carve out products where the prohibition on phthalates is not necessary to protect children's health. However, you also testified that the point of CPSIA is to protect children's health. If a prohibition does not exist to protect health – in what you consider a public health law - why should it remain on the books?

Answer

The phthalate provision in the Discussion Draft weakens public health by potentially reducing the number of products that would be required to meet the phthalate standard.As I stated in my written testimony, "The phthalate provision in CPSIA protects our children from the cumulative risks of hormonal chemicals that affect genital development and have been associated with testicular cancer and other fatal diseases and serious conditions. Narrowing the definition of the scope of the products covered by the phthalate provision and creating large opportunities to exempt products from coverage will undermine the health protection of the original phthalate provision of the CPSIA."

Question

   b. Second, you criticize the "tight timeline" in which this bill would require to act on the interim prohibition established in CPSIA once the Chronic Hazard Advisory Panel issues its report. However, this draft only requires that the CPSC commence its rulemaking in 90 days. What is your recommendation on a timeframe in which the CPSC should conclude its rulemaking on this matter? Begin in 90 days and end in 6 months…12 months…18 months?

Answer

The phthalate provision is the only provision in the Discussion Draft that contains a timeline at all. While the phthalate provision requires CPSC to begin a rulemaking in 90 days it also requires the rulemaking to be completed in a time yet to be determined. There is no clear reason why CPSC and industry should have to review the CHAP report and initiate a rulemaking within 90 days. As for the time frame in which CPSC should conclude its rulemaking, the CPSIA is already clear that the Commission must complete that within 180 days. The question is: how can Congress justify forcing the lifting of a ban of potentially toxic substances – regardless of what the science says- if the Commission doesn't conclude its rulemaking in 180 days?

Question from the Honorable Pete Olsen

1. Ms. Weintraub – the Chairman, myself, and Mr. McKinley all asked you during the hearing to provide us with verified statistics of the lead-in-substrate injuries you spoke of in your testimony. Because we did not receive an answer, I would like to ask you again - for the record - to provide us with verified statistics of instances where any children have been injured, sickened or killed by lead-in-substrate. Please substantiate these claims.

Answer

According to the CDC, "Approximately 250,000 U.S. children aged 1-5 years have blood lead levels greater than 10 micrograms of lead per deciliter of blood, the level at which CDC recommends public health actions be initiated. Lead poisoning can affect nearly every system in the body. Because lead poisoning often occurs with no obvious symptoms, it frequently goes unrecognized."[i] Since lead exposure often occurs without obvious symptoms, it is difficult to pinpoint the causes of the lead exposure. There are known symptoms of lead exposure. These include reduced I.Q., hyperactivity, behavioral problems, learning disabilities, health problems such as brain damage, and potential damage to the central nervous system, kidneys, and reproductive system.[ii]

CDC does not break down its data to identify whether children have been injured or killed by lead in the substrate of children's product but does list toys and children's jewelry as a source of potential lead exposure among other sources.

While chronic lead exposure is vastly more common, rare instances of acute lead exposure have been documented from consumer products, including a death to a child in Minnesota after swallowing a charm that was almost entirely lead,[1] and a report of a child suffering severe adverse health impacts in Oregon, after he swallowed a charm bought from a vending machine that was 38.8 percent lead.[2]

The goal of the lead provision in the CPSIA is to continue the successful work of the broad public health community that has reduced lead exposure to children and focus on known sources of lead in consumer products. The CPSIA seeks to help create a generation of safer children.

Questions from the Honorable G. K. Butterfield

Question

1. Prior to CPSIA, assurance for the safety of children's product safety relied on blind trust. Parents relied on what they thought were reputable and well-established companies to put only safe products into the marketplace. But those companies, in many cases, relied on the word of overseas suppliers to ensure the safety of their products. There was no mandatory system of independent verification. The recalls of 2007 and 2008 proved faith in manufacturers and suppliers to do the right thing was not an adequate safeguard for children's health and safety. I understand that the mandatory independent third-party testing required by CPSIA is all about independent verification of the safety of children's products.

    a. Please explain why a system that requires independent verification is particularly important when it comes to the safety of children's product.

Answer

The goal of independent safety verification is to prevent safety hazards before the product comes onto the market. The previous system in place before passage of the CPSIA relied upon a system that was essentially, "trust and maybe, possibly, verify" product safety recalls, and a hope that manufacturers were complying with existing voluntary standards. This system failed consumers. The recalls of 2007 and 2008 highlighted these failures and illustrated the need for a better more meaningful system in place.

Voluntary recalls were virtually the only method for CPSC to address product safety hazards before CPSIA passed. This was inadequate for two main reasons. First, the recall is reactive. The harm already

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[1] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm55d323a1.htm
[2] http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5323a5.htm

occurred, the product is already in consumer's homes and in children's hands. The recall process is a reaction to the known product hazards. Second, recalls aren't always effective. Recall compliance rates rarely exceed 20 or 30 percent. So, even when there is a reactive recall, not all the consumers who need to know about it actually find out about it and take the product out of their home.

Independent third party testing is important for children's products because it is proactive, it requires that manufacturers take efforts to ensure compliance with safety standards, and it seeks to prevent conflicts of interests that could emerge in non-independent testing. To best protect consumers from product hazards, products should be required to be tested for safety compliance with existing mandatory standards *before* they can enter the stream of commerce, and potentially pose risks to children. CPSC does not enter manufacturing facilities and is hard pressed, due to its budget, to police the marketplace even after products are in the stream of commerce. Therefore, to ensure that products meet the toy, lead, phthalate and infant durable product standards of the CPSIA, third- party testing is necessary.

The third-party testing requirement is proactive and helps ensure that products for vulnerable consumers, children, are safe from an earlier stage in the supply chain – as opposed to conducting costly recalls after consumers have been exposed to the hazard. This will save consumer lives and prevent costly recalls. For over 30 years, until the passage of the CPSIA, third-party testing was not required. In essence, the CPSC and consumers had to hope that products met the required standards. This wasn't happening and children suffered as a result. Relying on manufacturer assurances of safety has put children at risk: for example, CPSC relied upon assurances of magnet toy manufacturers that the toys they sold to the public *after* recalls would not pose the same hazards to children as the recalled toys. However, the same recalled toys continued to be sold without any changes to improve safety, because there was no third-party testing to check that manufacturers were following the law.

Question

b. Please explain why certification by manufacturers to mandatory safety standards – the system in place prior to enactment of CPSIA that still remains part of a manufacturer's compliance obligations – or even the increased civil penalties enacted under CPSIA are not enough to ensure that manufacturers comply with children's product safety rules.

Answer

Certification by manufacturers of mandatory safety standards and increased civil penalties are, alone, not enough to ensure that manufacturers comply with children's product safety rules because relying upon the manufacturers to ensure that their products will comply with the mandatory standards, of which there were very few before CPSIA was passed, failed to prevent millions of non compliant and potentially hazardous products from entering the marketplace. Certification is not necessarily a process conducted by an independent third party. In order to ensure that the product meets the standards, another entity without a financial interest in the sale of the product must be involved in ensuring compliance.

The increased civil penalties of the CPSC, just like product recalls, are reactive and occur much too late in the life cycle of a product, only after the violations have occurred and the safety hazard has exposed consumers to a risk of harm. While civil penalties need to be robust to deter wrongful conduct, it remains an important aspect of a robust product safety system. Civil penalties alone do not require specific actions to ensure compliance with safety standards.

Questions from the Honorable John Dingell

Question

1. I have several questions concerning the public database mandated by CPSIA.

a. Is it your understanding that CPSIA requires all information submitted to the consumer complaint database to be published online within 10 days of its receipt, regardless of such information's accuracy?

Answer

No, confidential business information will not be published in the database. Further, if reports are not complete, such that each of the all eight fields of information are not included, the reports are not posted, the time line is not yet started and CPSC works to complete the information provided. Once the fields are complete, the time clock begins to run.

Question

b. Should a manufacturer be given the opportunity to contest the accuracy of a consumer complaint before it is published?

Answer

Manufacturers already have the opportunity to contest the accuracy of a consumer complaint before it is published and the manufacturer has the ability to post a comment that would appear on the report indicating a concern about the accuracy of a report.

Question

c. If a manufacturer is allowed to dispute the accuracy of the information in a consumer's complaint, how should that dispute be resolved and by whom?

Answer

CPSC should resolve any dispute that arises based upon information provided by the manufacturer and by the consumer.

Question

d. The draft legislation amends CPSIA to permit only persons directly harmed by a consumer product, their family, their legal representative, or another person authorized on their behalf to submit a complaint to the database. Previously, CPSIA permitted anyone to submit complaints about a consumer product. Do you believe the draft legislation's narrowing of eligibility to submit complaints is necessary?

Answer

No. The draft legislation's narrowing of who can report to the database is not necessary.

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[i] http://www.cdc.gov/nceh/lead/

[ii] http://www.leadsafeillinois.org/facts/ripple-effects.asp