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CONSUMER PRODUCT SAFETY COMMISSION
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STATEMENT OF COMMISSIONER ANNE M. NORTHUP ON THE VOTES TO APPROVE THE FINAL RULE ON TESTING AND LABELING PERTAINING TO PRODUCT CERTIFICATION, AND THE FINAL RULE ON CONDITIONS AND REQUIREMENTS FOR RELYING ON COMPONENT PART TESTING OR CERTIFICATION, OR ANOTHER PARTY'S FINISHED PRODUCT TESTING OR CERTIFICATION, TO MEET TESTING AND CERTIFICATION REQUIREMENTS

October 26, 2011

I am greatly disappointed by the Consumer Product Safety Commission Democrat majority's decisions to issue prematurely a final rule establishing the protocols and standards for the third party testing of children's products to ensure continued compliance with applicable standards; and, to publish a rule, intended to create a market for third party tested and/or certified component parts, containing in a preamble language that may sabotage any chance the rule had to reduce the cost of third party testing for medium and small size domestic manufacturers.

The Third-Party Testing Rule Should Have Been Reproposed.

A Brief History of the CPSIA and H.R. 2715

The Consumer Product Safety Improvement Act (CPSIA) was enacted in 2008 in response to a media storm over a large number of Chinese manufactured children's toys that were recalled due to lead in paint that exceeded a standard in place since 1970. No child was injured by lead paint in the toys, and the offending manufacturers were soundly rebuked under existing law through mandatory recalls, the imposition of the largest penalty in the history of the CPSC, and a thirty million dollar class action lawsuit settlement for one manufacturer.

Notwithstanding the ability of existing law to address the issues, the news of the recalls created a political climate suited to the fulfillment of a long held goal of consumer advocates and liberal members of Congress: the reduction in the lead content of children's products virtually to zero, the elimination of phthalates without any known risk to children, and the requirement that all children's products be tested by third party laboratories before entering commerce to ensure compliance with these and all other applicable safety standards. Thus, the CPSIA requires every component in a children's product, with limited exceptions, to be individually tested and certified as free from lead and phthalates, and compliant with all other applicable product safety rules, through a third party laboratory test of sufficient samples of the product. The CPSC has no discretion in implementing that statutory mandate, and manufacturers have, with limited

exceptions, been required to perform initial third party tests to specific safety standards with each new notice of requirements issued by the CPSC for accreditation of laboratories to test to the standard.

But even before the CPSC began to implement the new "prevention" regime contemplated by the CPSIA, members of Congress from both parties realized that the law had imposed immense cost burdens far in disproportion to any benefit attained through a reduction in risk. As a result, the CPSC received regular and vocal bipartisan exhortations to implement the law as "flexibly" as possible in order to minimize its adverse impact.

The Democrat majority on the Commission failed to heed Congress's call, and, as reflected in its actions implementing the rule over the past two years, took every opportunity to increase the costs of compliance, without any consideration of whether proportional benefits in health or safety were realized. Soon, the inevitable consequences of the Commission's actions became apparent, as business after business reduced its children's product lines, exited the children's product market, or ceased operating completely.

Developing in the background as the Commission majority promulgated overly burdensome material and product specific rules, was the largest and most widely applicable rulemaking the Commission would ever undertake: the promulgation of protocols and standards for the *additional* third-party testing of "random samples" of a certified children's product to ensure continued compliance with all applicable safety standards, both when there is a material change in the product, and periodically during production even in the absence of a reason to believe a certified product is no longer compliant. This rule may be the most intrusive imposition of requirements on a segment of the manufacturing community ever. Its prescriptive mandates insinuate the Commission deeply into the production process of any company that manufactures a children's product for the United States market.

In 2010, the CPSC issued a notice of proposed rulemaking for a new 16 C.F.R. § 1107 setting forth onerous requirements for periodic continued third-party testing, including: the development of plans for testing at intervals that provide a "high degree of assurance" of continued compliance, based on a long list of factors; an alternative schedule of biennial periodic tests dependent upon adherence to a lengthy and overly prescriptive map for the development of a "production testing plan"; an unworkable definition of "random" sample selection; and, massive record keeping requirements that alone had the potential to overwhelm the resources of many manufacturers.

To Congress's credit, while the Commission reviewed comments in response to the § 1107 NPR, Congress continued to take an active interest in the impact of the CPSIA. Chairman Tenenbaum or Commissioner Adler, and I, participated in several hearings in which the CPSC's oversight and appropriations committees in the House sought testimony and evidence regarding ways in which the CPSIA could be improved. The focus of these hearings was often the destructive economic impact of third-party testing

and the failure of the CPSIA to impose its costs in proportion to any improvement in children's health and safety.

On August 1, 2011, almost two months before the CPSC posted its draft final rule of § 1107, Congress passed H.R. 2715. The statute, signed into law by President Obama shortly thereafter, requires the Commission to seek public comment on opportunities to reduce the cost of third party testing requirements, based on seven questions prescribed by Congress. Based on the public comments, the Commission is to consider issuing new or revised third party testing regulations if doing so will reduce third party testing costs while still assuring compliance with applicable standards. Congress even invited the Commission to propose changes to the law to provide it with additional authority to address the costs of third-party testing, if necessary. H.R. 2715 also substituted "representative samples" for "random samples" as the basis for selecting samples for periodic continued testing, and requires the Commission to undertake notice and comment rulemaking to define the new statutory phrase. Finally, the new law requires the Commission to create alternative testing requirements for limited run products manufactured by businesses meeting a gross revenue limit.

The Failure to Repropose Violates the APA and is an Indefensible Policy Choice.

H.R. 2715 enacts changes that go to the core of the CPSIA's third-party testing regime. It mandates a new and, as yet, undefined method for selecting samples for continued periodic testing; it requires new and, as yet, unwritten rules to govern the testing obligations of certain small manufacturers; and, it requires consideration of seven very specific methods to reduce the cost of third-party testing that were not addressed in the draft version of §1107 published for public comment last year. Under these circumstances, the final § 1107 rule voted by the majority is based upon the statute as it was originally passed by Congress, but is insufficiently tied to the underlying statute as Congress has revised it. Courts have held that even existing regulations, let alone ones still under development, were required to be changed to address statutory changes comparable in scope. *See McGavock v. City of Water Valley, Miss.*, 452 F.3d 423, 427-28 (5th Cir. 2006) (holding that a regulation became "obsolete and without effect" after a statute changed the definition of a term used in the regulation); *American Transfer & Storage Co. v. ICC*, 719 F.2d 1283 (5th Cir. 1983) (acknowledging that an agency must substantially revise existing regulations after significant changes are made to the underlying statute that the regulations implemented). Indeed, it is black letter law that a second cycle of notice and comment rulemaking is appropriate in response to "supervening legal developments such as statutes, regulations, or court decisions that significantly affect the rulemaking." J. Lubers (ABA), *A Guide to Federal Agency Rulemaking*, (4th Edition) at 292-93.

Even if the Commission was not legally obligated to repropose § 1107 to solicit public comment on the new issues raised by H.R. 2715, its failure to do so irrationally complicates compliance by the regulated community. The final rule to be codified at 16 C.F.R. § 1107 requires manufacturers to undertake a complex analysis and formulate a

detailed periodic testing plan or production testing plan[1], or obtain ISO/IEC 17025:2005 accreditation for an in-house laboratory, in order to be prepared to begin compliance with the rule's periodic testing requirements on the effective date fifteen months from now. A detailed periodic testing or production testing plan must be written for each product manufactured at each manufacturing site, even where the product manufactured at the site changes frequently, such as on a daily basis. But in the meantime, the Commission will be considering ways to change those very same provisions in order to reduce the costs of third-party testing. Ironically then, the Commission's response to H.R. 2715 is to *increase* the costs of third-party testing by requiring manufacturer's to waste resources in order to satisfy "protocols and standards" that may change substantially in the name of reducing costs.

While the potential for cost reducing changes may be speculative – and public statements by Commissioner Adler suggest he has no intention of supporting any – other material elements of proposed § 1107 have already changed. Thus, manufacturers are expected to begin preparing to perform periodic third party tests during production, without knowing how the Commission will construe the requirement that "representative samples" be

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[1] Periodic testing plans must include the tests to be conducted, the intervals at which the tests will be conducted, and the number of samples tested. Manufacturers are directed to consider at least all of the following factors when determining the appropriate testing interval for a product:

(i) High variability in test results, as indicated by a relatively large sample standard deviation in quantitative tests;
(ii) Measurements that are close to the allowable numerical limit for quantitative tests;
(iii) Known manufacturing process factors which could affect compliance with a rule. For example, if the manufacturer knows that a casting die wears down as the die nears the end of its useful life, the manufacturer may wish to test more often as the casting die wears down;
(iv) Consumer complaints or warranty claims;
(v) Introduction of a new set of component parts into the assembly process;
(vi) The manufacture of a fixed number of products;
(vii) Potential for serious injury or death resulting from a noncompliant children's product;
(viii) The number of children's products produced annually, such that a manufacturer should consider testing a children's product more frequently if the product is produced in very large numbers or distributed widely throughout the United States;
(ix) The children's product's similarity to other children's products with which the manufacturer is familiar and/or whether the children's product has many different component parts compared to other children's products of a similar type; or
(x) Inability to determine the children's product's noncompliance easily through means such as visual inspection.

16 C.F.R. § 1107.21(b)(2)

A production testing plan must contain, among other things, a description of the production testing plan, including, but not limited to, a description of the process management techniques used, the tests to be conducted, or the measurements to be taken; the intervals at which the tests or measurements will be made; the number of samples tested; and the basis for determining that the combination of process management techniques and tests provide a high degree of assurance of compliance if they are not the tests prescribed for the applicable children's product safety rule. A manufacturer must also document the production testing methods used to ensure continuing compliance and the basis for determining that the production testing plan provides a high degree of assurance that the product being manufactured continues to comply with all applicable children's product safety rules. 16 C.F.R. § 1107.21(c)(2)

collected for testing. The NPR on representative samples may provide a clue, but if the extensive changes from the § 1107 NPR to final rule are any indication, reliance upon it may be perilous. Similarly, "small batch" manufacturers of "covered products", as those terms are defined in H.R. 2715, must await a separate rulemaking to learn how their obligations may differ from final § 1107. In the meantime, they can do nothing to prepare for compliance.

Not surprisingly based on these considerations, our CPSC career staff recommended that the final testing rule be reproposed along with the NPRs on cost reduction and representative samples, so that a final comprehensive rule could emerge that addresses Congress's H.R. 2715 mandate and protects regulated industries from detrimental reliance on a tentative "final" rule. This conflict between staff's expert opinion and the political directive from the majority explains why, on at least 18 occasions, the preamble to § 1107 published in the *Federal Register* evokes the cost saving comments to be solicited under H.R. 2715 as a reason to defer rather than respond fully to a comment proposing means to ameliorate the excessive costs of the rule as originally proposed. Setting aside so many of the comments without a full response mocks the due process requirements of notice and comment rulemaking under the APA. The majority's preferred course of finalizing a burdensome rule now and paying lip service to considering comments later, is not a permissible alternative to the mandatory APA procedures.

The transparent weakness of the Majority's rationale for refusing to repropose the testing rule suggests that a hidden political motive related to the impending vacancy of a Democrat Commission seat may have been at work. They point to a post-passage colloquy among three Senators, who urge the Commission to finalize the rule before soliciting additional comment under H.R. 2715. But it is well recognized that "the statements of individual Members of Congress (ordinarily addressed to a virtually empty floor) . . . [are not] a reliable indication of what a majority of both Houses of Congress intended when they voted for a statute . . . The *only* reliable indication of *that* intent – the only thing we know for sure can be attributed to *all* of them – is the words of the bill that they voted to make law." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 390-91 (2000) (Scalia, *J.*, concurring in the judgment). *See also Barnbart v. Sigmon Coal Co.*, 534 U.S. 438, 457 (2002) (explaining that floor statements from a handful of Senators "cannot amend the clear and unambiguous language of a statue," and there is "no reason to give greater weight to the views of two Senators than to the collective votes of both Houses, which are memorialized in the unambiguous statutory text.").

The specter of delay has also inevitably been raised. By now it should be apparent that this majority falls back on the risk of "delay" whenever its precipitous and ill reasoned actions are challenged. The argument is particularly cynical in this case, because Commissioner Nord offered an alternative time line that would have allowed for consideration of cost saving alternatives, as well as rulemaking regarding the meaning of "representative samples" and the extent of small batch relief, while still finalizing the rule effective on the same date as the one published this week.

The Majority also grossly overstate the benefits of third party testing every component of every children's product to all applicable safety standards. Reading from one of the "thousands" of letters received (there were actually only about five unique letters, mostly forwarded by one advocacy organization), Chairman Tenenbaum trumpeted the supposed reductions in recalls the rule will produce. But she must be aware that most recalled products contain design or manufacturing defects that are unrelated to the Commission's product and material specific safety standards. Moreover, given the Commission's decision to reduce the lead in the substrate of children's products well below a level presenting any risk to health, recalls of products violating the new standard will not even necessarily protect against a real risk of injury.

My heart goes out to the parents of children who are injured or killed by defective products. But I cannot continue to remain silent while the Majority exploits the deaths of children to further a policy agenda that would not have saved their lives. Compounding the incredibly poor taste of displaying at the decisional meeting a morbid gallery of lost innocents, the Democrat's joint statement on the testing rule evokes by name the deaths of four children, to support their argument for third party testing to CPSC safety standards. But each one of those children died under circumstances that would not have been prevented by third party testing. One strangled on a baby monitor cord that met all safety standards, one swallowed a lead charm sold with a non-children's product that would still not be subject to third party testing, one died in a drop side crib that met all applicable safety standards at the time and would have passed all third party tests, and one died in a crib that had already been recalled. The deaths of these children are tragic, and should inspire us to strive to improve product safety and identify defective products. But they should not be used to justify regulatory overreach that would not have saved their lives.

In contrast to the limited benefits secured through third-party testing, the costs to small businesses are crushing. According to the CPSC's economists, "[t]he costs of the third-party testing requirements are expected to be significant for some manufacturers and are expected to have a disproportionate impact on small and low-volume manufacturers." Just the costs of testing alone -- excluding the costs of samples consumed in destructive tests, the costs of shipping the samples to the testing laboratories, and any related administrative and record keeping activity – is expected to consume over 11% of a small manufacturer's revenue. Given that a typical profit is only about five percent of revenue, it is reasonable to expect a large number of small business closures resulting from the third-party testing requirement. They cannot simply raise their prices and remain competitive. This is especially true in the children's product market, where most consumers are young families who are unable to pay higher prices. Moreover, in preparing its analysis, Commission staff relied upon the "low to middle part of the ranges" of third-party testing costs. Domestic manufacturers will be especially hard hit then, because the actual cost of testing varies significantly among testing labs, with the cheapest ones based in China.

Commission economists predict that in response to the "significant increase in their costs due to the final rule", manufacturers will redesign their products to reduce the features

and component parts, reduce the number of children's products they offer, exit the children's product market, or go out of business completely. The costs associated with the new rule are also expected to be a "barrier that inhibits new firms from entering the children's product market", including, in particular, ones serving a niche market, such as products for children with disabilities. Safety and performance related innovation will also be stymied, as manufacturers "delay implementing some improvements to a product's design or manufacturing process in order to avoid the costs of third party testing."

Congress mandated third-party testing in the CPSIA, and it is therefore responsible for the massive product, business and job losses the country will suffer once the full brunt of its costs are felt upon the effective date of § 1107. But Congress at least recognized its error and tried to encourage the Commission to explore ways to reduce the costs of third-party testing before it is too late. The Democrat majority's heedless rush to finalize § 1107 without even considering ways to do so represents the basest example of political expediency at the expense of the public interest that I have ever seen.

The Majority Sabotaged the Component Parts Rule.

I was the leading proponent of permitting the voluntary certification of component parts as a means to reduce the cost of third-party testing for medium and small sized domestic manufacturers and importers. As I envisioned it, an "upstream" manufacturer who sold components to many other manufacturers, could pass third-party tested and certified components down the stream of commerce. As each manufacturer in turn incorporated a certified component into a subassembly, it could then pass the subassembly on to the next manufacturer in line, along with the original component part certification and any additional certifications required for the subassembly. In this fashion, each certification would have "currency," until the finished product certifier could rely on all of the component part certifications passed down to it – as well as any testing required of the finished product – as a basis for its own finished product certification.

Two essential elements are required for this system to reduce the costs of third party testing. A finished product certifier must be insulated from CPSA § 19(a)(6) liability for issuing a "false or misleading" certificate, even if its finished product certificate is based on a predecessor's certificate rather than its own third-party testing, so long as it relied reasonably on the predecessor certificate. And, such reasonable reliance must be defined in a way that does not impose on the finished product certifier such a costly and burdensome duty of due care that it is more economically rational to third-party test the finished product and each of its components to all applicable safety standards, than it is to risk relying on certifications issued by other parties.

I worked hard to ensure that the NPR for 16 C.F.R. § 1109 satisfied these two elements and struck the proper balance between ensuring the integrity of component part certificates and maintaining their economic value to downstream certifiers. I also believe that the definition of due care contained in the proposed rule did so. The proposed rule stated at § 1109.4(g): "*Due care* means the degree of care that a prudent and competent

person engaged in the same line of business or endeavor would exercise under similar circumstances." The proposed rule also provided at § 1109.5(h):

> A finished product certifier must exercise due care in order to rely, in whole or in part, on a component part certificate issued by a component part certifier or on component part testing by a testing party as the basis for a finished product certificate. If a finished product certifier fails to exercise due care in its reliance on a certificate for a component part, then the Commission will not consider the finished product certifier to hold a component part certificate issued in accordance with section 14(a) of the CPSA. Exercising due care in this context means taking the steps a prudent and competent person would take to conduct a reasonable review of a component part certificate and to address any concern over its validity. Such steps may vary according to the circumstances.

This is a common sense approach that would have permitted a finished product certifier to review a certificate and rely upon it absent a reason to inquire further. In the event the certificate raised concerns over its validity, a finished product certifier was reasonably expected to take the steps necessary to allay those concerns.

The version of 16 C.F.R. § 1109 approved by the Majority as a final rule contains two changes that I believe will inhibit the creation of a market for certified component parts. To begin with, due care is now defined at § 1109.4(g) to include the statement: "Due care does not permit willful ignorance."

Standing alone, this change is not substantive, and that fact is explained in the preamble to the rule. Willful ignorance is a concept well known to the law that presupposes predicate knowledge putting a party on inquiry notice to seek additional information. A party who fails to seek to learn of a problem he has reason to believe may exist can fairly be characterized as willfully ignorant.

However, language in the preamble intended to apply the concept of "willful ignorance" to the due care requirements imposed by § 1109 goes well beyond that established meaning of the term. The preamble invents new, broad and vague terms with no accepted legal meaning, and Commission staff has opined that the terms impose burdens well beyond what was contemplated in the NPR.

For example, in response to Comment 46 to the NPR for § 1107, the Commission states with respect to an importer's reliance on a foreign manufacturer's certification, that "due care by the importer involves ensuring that the foreign manufacturer conducts periodic tests." This language is problematic on its face, because it assumes that an importer exercises sufficient control over its foreign manufacturers to "ensure" they take particular action, and that an importer has the detailed knowledge of a manufacturer's production process necessary to evaluate in light of the ten factors set forth at 16 C.F.R. § 1107.21(b)(2) the appropriate frequency of periodic testing for the product. Considering the highly prescriptive protocols and standards for periodic testing in § 1107, this requirement for those wishing to depend on component part certificates is excessively

burdensome. I queried staff to better understand how "an importer will be able `to ensure' that a foreign manufacturer conducts periodic tests." Staff's response confirmed my fear that the language imposes an onerous burden. An importer cannot even rely on a review of the importer's periodic testing plan; it must obtain "evidence" that the plan "has been implemented", including potentially, by "conduct[ing] occasional site visits to his supplier's manufacturing facility" and obtaining its own third-party tests of "samples from product received from the supplier" to confirm the accuracy of the supplier's tests. *Response to Commissioner Anne M. Northup's Questions Relating to Pending Proposals for Testing and Certification and Component Parts* (October 18, 2011) at 4.

Other preamble language is equally concerning. The preamble published with the final component parts rule explains that "willful ignorance" was added to the definition of "due care" "to emphasize that a party cannot, and should not, purposely avoid knowing a business partner's testing and certification practices to benefit from an exception contained in section 19(b) of the CPSA." The phrase "purposely avoid knowing" has no accepted legal meaning, and therefore begs the question of what obligation of affirmative inquiry it is intended to impose and under what circumstances. Theoretically, one could be found *post hoc* to have purposely avoided knowing anything about which it did not affirmatively inquire, even in the absence of any reasonable suspicion. Staff's attempted clarification in response to my inquiry was not comforting:

> [d]ue care requires taking some affirmative step to ensure the validity of the test report or certification being relied upon. . . . Actions taken by a certifier to ensure the reliability of test reports from a supplier may differ depending on the nature of the component part supplied, the risk of noncompliance, the industry involved, and the nature of the relationship with the supplier. . . . [a]ctions in furtherance of the due care obligation may include asking questions about testing and sampling procedures and the third party conformity assessment body the supplier uses, spot checking a supplier's test results, requesting written procedures, or visiting a supplier's factory or third party laboratory.

Response to Commissioner Anne M. Northup's Questions Relating to Pending Proposals for Testing and Certification and Component Parts (October 18, 2011) at 11.

Importers aware of the Commission's interpretations of "due care" and "willful ignorance" may understandably choose not to risk relying upon certified components or finished products. The Commission identifies a number of factors that impact what affirmative actions are required, but inadequately explains how each will be evaluated by the Commission or what importer actions are required under particular circumstances. This vagueness leaves importers guessing, while knowing that if a certified noncompliant product is discovered, they will likely be found to have guessed wrong no matter what course they choose. Importers wishing to rely on upstream certificates will therefore recognize the safest option to be undertaking the most onerous actions: traveling to China to visit manufacturer sites and third party labs, and procuring additional third-party tests of products whose wholesale prices already reflect that the manufacture has tested and certified them.

While these affirmative obligations are enough to chill a manufacturer's willingness to accept even a single certified component, the burdens grow exponentially when applied to a manufacturer's complex finished product or the numerous such products distributed by a single importer. Under § 1109, a finished product certification can be based on the separate certifications of all of the finished product's components. In order to satisfy the duty of due care as defined by the Majority, a finished product certifier could therefore need to visit multiple manufacturing sites and third-party labs around the world, and conduct numerous third-party tests, in order to exercise its duty with respect to each component. In other words, as Chairman Tenenbaum declared at the decisional meeting, the Commission expects importers and manufacturers relying on upstream certifications "to know everything in the supply chain." And indeed, these same tasks would need to be carried out by each subassembly manufacturer at every level of the supply chain. The result is the exact opposite of the cost spreading the component parts rule was intended to promote; duplication of onerous and costly affirmative actions required to satisfy the duty of due care will instead be the norm. Multiply those obligations by the number of children's products carried by a single importer, and it becomes obvious that procuring initial third-party tests of sufficient samples of each imported finished product is a much more economical option than is purchasing pre-certified products along with the onerous and costly duty of care that accompanies them.

I believe that even large manufacturers and importers may be unwilling to rely on the testing and certifications of other manufacturers under these circumstances. But there is no doubt that medium and smaller sized ones will simply be unable to bear the costs of doing so. Moreover, the Commission intends to hold manufacturers to the "degree of care that a prudent and competent person engaged in the same line of business or endeavor would exercise under similar circumstances." Because the "line of business" does not depend on the size of the business, small businesses will be held to the same standard as large ones, which have the means to hire full time staffs on location to oversee their foreign manufacturers.

My idea to give component part certificates currency had the potential to substantially reduce the cost of third-party testing, especially for those small businesses for which the requirement to third-party test is a death sentence. That potential has fallen victim to the Democrat majority's refusal to give any leeway in its crusade to hold all importers and manufacturers responsible for the third-party testing of all of the components of every children's product they sell, irrespective of cost or risk. My only remaining hope is that Congress will revisit the CPSIA again after the implementation of §§ 1107 and 1109 causes its full effects to be felt.