U.S. CONSUMER PRODUCT SAFETY COMMISSION
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BETHESDA, MARYLAND 20814-4408

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Chairman Hal Stratton
Commissioner Nancy Nord
Commissioner Thomas H. Moore

ITEM:

Proposed Revisions to 16 C.F.R. Part 1115, Substantial Product Hazard Reports (Briefing package dated May 9, 2006)

DECISION:

The Commission voted unanimously (3-0) to approve the publication of the *Federal Register* notice seeking public comments on the proposed revisions to Commission regulations on Substantial Product Hazard Reports at 16 C.F.R. Part 1115. Commissioner Moore submitted a statement explaining his vote. (A copy of the statement is attached.) The revisions are: to the definition of "defect" at 16 C.F.R. § 1115.4, adding four new factors for consideration; to 16 C.F.R. § 1115.12(g)(1)(ii), adding a factor to be considered by the Commission when determining the number of defective product distributed in commerce; and a proposed new section at 16 C.F.R. § 1115.8, adding guidance on compliance with voluntary and mandatory product safety standards.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due May 19, 2006

STATEMENT OF THE HONORABLE THOMAS H. MOORE
ON THE PUBLICATION OF THE FEDERAL REGISTER NOTICE SEEKING
PUBLIC COMMENTS ON PROPOSED REVISIONS TO 16 C.F.R. PART 1115
May 19, 2006

I am voting today to seek public comment on a Federal Register notice that proposes changes to Part 1115 of Title 16 of the *Code of Federal Regulations*. I have serious concerns about the proposed revisions and I hope that the public will take the opportunity that this notice affords them to provide us with their views. For some time, various business groups have been urging the Commission to make changes to our interpretation of the section 15 reporting requirements (see, for example, letters to James Fuller, former Chief of Staff, from AHAM and TIA dated June 16, 2004 and August 23, 2004, respectively and the meeting log of the public meeting held on June 24, 2004, on the AHAM proposals). The revisions being offered for public comment are apparently being proffered in response to those overtures. The rationale given in this Federal Register notice for these revisions is to "provide further guidance, clarity and transparency to the regulated community on reporting obligations under section 15 (b) ...." I certainly have no quarrel with the goals of "guidance, clarity and transparency" but I am not sure these revisions accomplish them.

DEFINITION OF "DEFECT"

No reasons are given for the additions to the definition of "defect," other than that the "Commission" has concluded, "based on experience and practice in applying the criteria, that the four proposed additional factors ... will enable a better analysis of whether the risk of injury associated with a product is the type of risk which will render the product defective." But how will these criteria accomplish this? Upon what Commission experience are they based? And why these four criteria? Examples of their use in a defect situation would be instructive because I am not sure how relevant these factors are in determining a "defect" or how often our staff really considers them in a defect determination.

A defect, by its very nature, results in an unintended consequence, and, therefore, there would not likely be warnings or instructions to mitigate the risk with regard to it.[1] The obviousness of the risk[2] and consumer misuse[3] seem to stem from the AHAM letter mentioned above, in which we are urged to adopt an approach that allows

[1] We do take warnings and instructions into account, but not in the narrow way described by this revision. See example (d) in our current Part 1115.4, which describes **the failure to have** adequate warnings and safety instructions as a defect.

[2] Note that in the infamous knife example it was not the obviousness of the risk, but the utility of the product that determined it was not defective. Considering the utility and the necessity of the product (factors already listed in our current interpretation) would seem to cover concerns raised by the obviousness of a risk.

[3] Consumer misuse can be the direct result of a defect, rather than a mitigating factor, such as the lack of adequate instructions mentioned in the first footnote.

" ... manufacturers to take into account and **require** the Commission to consider the reasonableness of consumer use and hazard obviousness." [Emphasis added.] The AHAM letter goes on to state that "the need for consumers to be responsible for their own behavior goes much beyond [the 'ultra-simple' knife example]" and that manufacturers should be able to "rely on adults to reasonably exercise care for their own affairs and, within reason, supervise their children." The Commission was created to protect consumers, sometimes even from what might be viewed as an obvious risk and, with regard to children, sometimes even from the inattentiveness of their own parents. Our work on child-resistant cigarette lighters and baby walkers are evidence of that.

The section 15 reports that we receive have led to changes in voluntary standards and to the creation of new voluntary or mandatory standards. We should not only be concerned that the *volume* of reports does not decline under any new interpretation, but we should also make certain that the types of potential hazards being reported are not diminished.

The power of section 15 (b) is its requirement that information that could prevent the injuries or deaths of consumers be reported to the Commission. Even with these revisions, the Commission's position remains, **when in doubt, report**. It is the Commission that will ultimately decide whether a product defect presents a substantial product hazard, not the manufacturer. Adding more unexplained factors that manufacturers might grasp at to decide they do not need to report is likely to do the manufacturers (not to mention consumers) a disservice and adds nothing by way of real guidance, clarity or transparency.

NUMBER OF DEFECTIVE PRODUCTS STILL IN USE

The intent of the next proposed revision is to indicate that, as the number of defective products still in consumers' hands declines, the Commission will "recognize" that the risk of injury from these products may also decline. The number of defective products still in consumer hands has played a role in determining whether to initiate a recall in one recent case of which I am aware. However, I worry that, as drafted, this criterion could encourage companies that manufacture a defective product, particularly those with a shorter useful life, not to report promptly, but rather to wait to report until the product is near the end of its useful life, in order to minimize or avoid the cost of a recall. The Commission should make clear that in such a case, the few number of products left in consumers' hands at the time the Commission was notified of the product hazard will be irrelevant to the penalty determination.

While the cumulative risk of injury may decline over time as the number of defective products decreases, the relative risk to any one consumer owning that product does not. In addition, we have seen products that fail near the end of their useful life, so that the number of injuries may actually increase as the products age although the number in use declines. Looking at the number of products without factoring in the injury trend could give a very misleading picture of the hazard. We should also recognize that

estimating the number of products actually still in use is an inexact exercise at best. For products that have the potential to kill or cause serious injury, there can never be so few left on the market that we would not require a recall.

VOLUNTARY STANDARDS

I am not sure what the paragraphs about compliance with voluntary standards are meant to convey or what they add by way of additional guidance. Take this sentence from the preamble, for example: "Therefore, by this provision the Commission urges firms to consider compliance with voluntary standards in evaluating whether or not a substantial product hazard should be reported to the Commission." Our statute makes clear that substantial product hazards must be reported to the Commission immediately. It makes no difference what standards such a product does or does not meet. To suggest otherwise creates confusion, not clarity. The language from the preamble is transformed somewhat in the actual text of the revision to read: "... whether a product is in compliance with applicable voluntary safety standards may be relevant to the Commission staff's preliminary determination of whether that product presents a substantial product hazard under section 15 of the CPSA." I would be very interested in learning of any examples where compliance with a voluntary standard has had any impact on the determination of whether a product defect presented a substantial product hazard. This new language could be read as a "safe harbor" provision for industry at the expense of the safety of American consumers. It appears to flow from the suggestion in the AHAM letter that we should make clear "that there is a positive inference that products are not defective if they are listed with UL, CSA or other recognized SDOs and if the product can be shown to comply with that listing."

The Commission has, and will continue, I trust, to make hazard determinations based on the particular aspect of the product that is alleged to be capable of causing, or that has already caused, injury. These determinations can result in recalls and they can also lead to changes to the relevant voluntary standard. Voluntary standards are continually evolving and changing as new injury and incident data comes to light. In addition, many voluntary standards have never been reviewed by the Commission and the efficacy of their requirements is unknown to us. To treat them at any point in time as if they were the gold standard in consumer protection by giving them special weight in a hazard determination would be a mistake.

If you look at the **non**compliance side of the issue, it is worth emphasizing that companies act at their peril by not complying with voluntary safety standards. On a case-by-case basis, there have been many instances where a failure to comply with an important safety provision of a voluntary standard has resulted in a determination of a substantial product hazard and a recall. There have also been instances where Compliance has told entire industries in a blanket policy statement that the failure of their products to comply with provisions of certain voluntary standards will be considered to be a defect. Getting that message out is an important one and I would encourage the Commission to make that message clearer in any revisions that are adopted.

MANDATORY STANDARDS

The section on mandatory standards indicates that a product's compliance with a mandatory standard could make a difference as to whether a product that would otherwise be deemed to create a substantial product hazard would be subject to a recall. Failure to comply with a mandatory standard is clearly a prohibited act under our statute. Compliance staff already has the authority to allow a company to do a corrective action that is less comprehensive than a consumer-level recall when the failure to comply pertains to a relatively minor part of a mandatory rule, such as an incorrect type font on a required label. But any significant failure to meet a mandatory standard should require an appropriate recall remedy.

This proposed revision may be suggesting that if the alleged defect stems from some aspect of the product's manufacture that is not covered by the relevant mandatory standard for that product, that, nevertheless, complying with the mandatory standard is a relevant factor to take into account in determining whether a recall is warranted—a version of the "safe harbor" interpretation discussed above. Every company is expected to meet all mandatory requirements. No standard, whether mandated by the Commission or developed by industry is guaranteed to cover every possible way a product could fail or otherwise present a substantial product hazard. No mandatory standard is an immutable solution to all possible safety problems a product may have. The way products are made can change over time or new injury scenarios may arise with an old product. Whenever a product *could* present a potential hazard, the company's responsibility is to report that to the Commission and to work with our staff to find the best way to protect consumers. Sometimes that will entail a recall, but many times our staff finds no substantial product hazard and deems a recall unnecessary. The only true safe harbor for a company is to report promptly and fully, and then the safe harbor is protection from the assessment of civil penalties, not necessarily protection from a recall.

One other problem with the revisions that appears in both the voluntary and mandatory standards paragraphs is that the language in the preamble and the language in the revisions to Part 1115 are not consistent. Within the preamble to the voluntary standard language it says both that the Commission "may" consider compliance with a voluntary standard and that it "will" consider it. While the actual change to Part 1115 uses the word "may," the inconsistent Preamble language causes unnecessary confusion. The same "may" versus "will" language confuses the Preamble and the change to Part 1115 with regard to mandatory standards. If some language with regard to standards is finally approved, there is no reason to tie the Commission's hands by forcing it to consider factors that may or may not be relevant in any given situation.

Finally, I note the sentence in the Summary that states that in the future the Commission may consider an interpretive regulation on the statutory factors for assessment of civil penalties. Our statute is quite specific as to what we **shall** consider in determining the amount of a civil penalty. It is not clear that we have the authority to go

beyond these enumerated factors and we should be extremely careful in adding additional factors that Congress did not specifically address.