



**U.S. CONSUMER PRODUCT SAFETY COMMISSION  
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**COMMISSIONER NANCY A. NORD**

**Statement on the Commission's decision to adopt  
a safety standard for bassinets and cradles, 16 C.F.R. part 1218**

September 30, 2013

Bassinets and cradles will soon be subject to a new safety standard under a final rule that the U.S. Consumer Product Safety Commission approved this past week. The standard is based on one developed by industry, consumer advocates, and others, known as ASTM F2194-13. However, the rule before us contains changes added by CPSC staff. I joined my colleagues in voting to approve the standard, but with an amendment that unfortunately was not agreed to. As explained below, with my amendment, the safety standard would have had the same level of safety—as shown by all the real-world evidence that we have now—while hewing more closely to the principles that Congress gave us to follow in promulgating safety standards for durable nursery products. The failure to adopt this amendment reflects the flawed process that the Commission follows and our unwillingness to correct those flaws.

### **Background**

Bassinets have had a number of incidents—fatal and otherwise—over the years. These are heart-wrenching tragedies, and this rule seeks to address them. One specific incident drew the agency's attention, and rightly so—the suffocation death of a three-month-old infant. This tragic death prompted a response from the agency and industry, who together developed a test to ensure that segmented mattresses in bassinets (which are today found in bassinet accessories for multi-use products like play yards) would not pose the same suffocation hazard. To perform the test, a tester places a cylindrical weight (meant to serve as a surrogate for an infant) on a seam and then measures the angle between the mattress and the weight. Although both staff's proposal and ASTM's standard use the same test and use pass-fail criteria meant to ensure that the angle created is 10° or less, the criteria are slightly different. Under ASTM's standard, the test may be performed up to three times per seam. If the first angle is 10° or less, the seam passes. If the first angle falls between 10° and 14°, the test must be repeated two more times, and the average of the three angles must fall at or below 10°. If the average is above 10°, or if any angle is measured above 14°, the mattress fails the test. Under the staff's draft, the test is performed only once, and any measurement above 10° fails.

After reviewing the evidence available and staff's analyses of it, I am convinced that the two criteria are materially identical. As staff described it, they “could find no example of a compliant product that would fail [staff's draft criterion] but pass [ASTM's

criterion].”<sup>1</sup> Though one can hypothesize a product that would pass one test but fail the other, there is no evidence to demonstrate that any such product does or will exist, or that even such a product would truly pose any greater safety risk than a product that passes both tests. After all, the test and pass-fail criteria represent extreme situations unlikely to be replicated in the real world. Thus, even a product that performs on the edge of the pass-fail line is exceedingly unlikely to create a hazard in the real world. Given this, against a blank slate, the evidence does not provide guidance as to which criterion to choose because the choices are safety neutral. But the Commission does not decide against a blank slate. Statutory and policy concerns counsel us to adopt ASTM’s criterion on this point, as explained below.<sup>2</sup>

## **Voluntary consensus standards**

### Legal & policy concerns supporting the use of voluntary standards

In the agency’s normal process, we defer to voluntary consensus standards that are effective at reducing the risks they address. These are standards developed by private bodies in an open process with the participation of industry, advocacy groups, and government representatives. These bodies respect due process and use an appeals process; their standards are adopted by consensus among the participants. Thus, the standards represent a balance of interests. The entire federal government is generally encouraged to prefer such standards to government-designed rules,<sup>3</sup> and the CPSC is required to defer to such standards under its organic statute, so long as the voluntary standards adequately reduce or eliminate a risk and are likely to be substantially

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<sup>1</sup> Stephen J. Hanway, Memorandum to the Commission, Bassinet Mattress Bright-Line Criterion versus the Threshold-Plus-Averaging Criterion, \*3 (Sep. 4, 2013) (emphasis deleted), <http://www.cpsc.gov/Global/Newsroom/FOIA/CommissionBriefingPackages/2013/ResponsetoCONNOFRBassinetMattressvstheThresholdPlusAveragingCriterion.pdf>.

<sup>2</sup> I have discussed the § 104 and the voluntary standards development process in other statements. See Nancy Nord, *Statement on the Commission’s Vote to Issue a Notice of Proposed Rulemaking on Soft Infant and Toddler Carriers* (Mar. 27, 2013), <http://www.cpsc.gov/Global/About-CPSC/Nord/nord032813.pdf>; Nancy Nord, *Statement on the notice of proposed rulemaking on hand-held infant carriers* (Dec. 11, 2012), <http://www.cpsc.gov/PageFiles/135013/nord12112012.pdf>; Nancy Nord, *Statement on the final rule for safety standards for play yards* (July 11, 2012), <http://www.cpsc.gov/PageFiles/123739/nord07112012.pdf>.

<sup>3</sup> See Office of Mgmt. & Budget, Exec. Office of the President, OMB Circular No. A-119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and Conformity Assessment Activities*, 63 Fed. Reg. 8546 (Feb. 19, 1998).

complied with.<sup>4</sup> Absent some failure, the agency cannot regulate above and beyond that voluntary standard.

The rationale behind deferring to voluntary standards makes particular sense for a small agency like the CPSC. With such a broad jurisdiction, there is much expertise outside the agency that we could not hope to tap into without the voluntary standards development process. Moreover, we can use voluntary standards to address more hazards than we could ever hope to if we did all analysis, testing, and drafting inside the agency to assure an appropriate standard. And when a standard is the result of consensus among groups with divergent interests, an implicit balancing of those interests takes place, giving the agency confidence that the rule is neither too burdensome nor too lenient, that safety has been achieved at near-optimal cost.

Bearing these benefits in mind, Congress harnessed the voluntary consensus standards development process in a unique way with respect to durable nursery products. In the Consumer Product Safety Improvement Act, the agency is directed to make voluntary consensus standards mandatory for 12 durable nursery products, and to do so for two products every six months. Unlike other voluntary standards, the Commission cannot simply defer to them—the Commission must evaluate them, adopt them as its own, and enforce them. To do so, the Commission must promulgate rules that are “substantially the same as” the voluntary consensus standards. The Commission can make changes to such standards, but only if the changes are more stringent, addressing a real risk of injury.<sup>5</sup>

It is here where I depart from my colleagues. Some argue that there is a theoretical possibility that a dangerous angle could be created under the ASTM criterion. I see no evidence that such a possibility is reasonably or sufficiently likely to raise any more risk than whatever risk is present in the staff’s draft criterion. In other words, based on the evidence before the agency, it is difficult, if not impossible, to say that the staff’s draft criterion is any safer than ASTM’s. This being the case, I believe that it is our obligation to defer to the ASTM standard. I believe that in enacting the CPSIA, Congress meant to harness a process that worked and use it with minimal changes to create mandatory safety standards for durable nursery products. Unfortunately, some aspects of the law—and this agency’s implementation of it—have deformed that process.

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<sup>4</sup> See Consumer Product Safety Act § 9(f)(3)(D), Pub. L. 92-573, 86 Stat. 1207 (Oct. 27, 1972), *as amended*.

<sup>5</sup> Consumer Product Safety Improvement Act § 104(b)(1), Pub. L. 110-314, 122 Stat. 3016 (Aug. 14, 2008).

## Difficulties arise from the CPSC's implementation of § 104

Two key problems have arisen in adopting safety standards for durable infant products. The first concerns timing; the second, debate and consensus. Both are cut short under § 104, the former directly, the latter indirectly. And both detract from the ultimate quality of the standards that the Commission is asked to vote upon.

As noted, under § 104, the Commission is supposed to issue standards for two durable infant nursery products every six months. While this is a laudable goal, it has the unfortunate effect of pressuring our staff and voluntary standards development organizations to come to an agreement on a voluntary standard so quickly as to sometimes undermine the strength of the standard. Time pressure can induce participants to cut debate short, meaning that issues may either be left unresolved or disagreements ignored.<sup>6</sup> We can hope that the development process will continue with later updates, but members of the regulated community will not have the luxury of waiting until such issues or disagreements are resolved before they must retool, change manufacturing processes, and comply with the standard.

Moreover, some disagreements may never even come to light. Because the Commission can make alterations to the voluntary standards adopted under § 104—unlike the normal process at this agency—incentives are aligned differently. Members of voluntary standards development organizations who disagree with the agency's staff may be led to accept some staff preferences that they would otherwise reject. They may do this under the belief that accepting or modifying a staff suggestion is preferable to the futile process of rejecting a staff suggestion merely to have the Commission later adopt the voluntary standard with changes aligned with staff preferences. In combination with the tight schedule, we have every reason to fear that standards are less vetted before they reach the Commission than they would otherwise be.

To counteract this, the Commission and staff must be on guard to assure that the debate surrounding voluntary standards development is fully realized, that the consensus reached is substantial and based on a fair, reasonable, safety-focused foundation. Where the staff and Commission are convinced that a voluntary standard is inadequate to address a risk, we have the power to modify the standard before adopting it. In the absence of a compelling reason, to adopt a standard with changes undercuts the process by telling the participants that they have a limited time to raise their concerns

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<sup>6</sup> Although the initial notice of proposed rulemaking for this rule was issued in 2010, *see* Safety Standard for Bassinets and Cradles: Notice of Proposed Rulemaking, 75 Fed. Reg. 22,303 (Apr. 28, 2010), the relevant provision here was put into consideration much more recently. And more generally, the more substantive changes staff proposes to an ASTM standard in draft standard for the Commission to consider, the less time there is to discuss and refine those changes.

and that there is limited willingness to work through those concerns. In this case, I see no such compelling reason, and so voted to adopt the standard without changing ASTM's segmented-mattress-flatness test criterion.

### **Testing variability**

One other point deserves some mention here. Although no concrete evidence has been presented that demonstrates a difference in safety between the two criteria, and that alone is sufficient to convince me that the Commission should adopt ASTM's criterion, the voluntary standard also strives to address the variability inherent in manufacturing and testing, and that is something the agency equally should strive to address appropriately.

In a number of recent decisions, the agency has adopted bright-line measures where the acknowledgement of some gray area is called for. A bright-line criterion effectively sets a real world limit that is measurably lower than the stated limit. Given the acknowledged imprecision of the measurement instruments and the inherent variability of a soft product like a segmented mattress, it is difficult to make a product that could not be measured above 10° even if it actually falls at or under 10°. So the intent appears to be to require manufacturers to make products whose measured angles fall well under a 10° angle.

But if a lower limit is intended, the Commission should back up such a limit with scientifically valid and substantial evidence. And if certainty about a limit is desired, it is elementary that, given imprecise measurement tools, more measurements are more reliable. There appears to be reluctance to acknowledge the notion of testing variability and to use certain scientific tools and statistical principles to accommodate the realities of making products in the real world that we live in. This is an unfortunate failure to perform our responsibilities as regulators, and it limits the options available to the regulated community and to the American people.