

UNITED STATES CONSUMER PRODUCT SAFETY COMMISSION

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ACTING CHAIRMAN ROBERT ADLER

Statement of Acting Chairman Robert S. Adler re: Vote on Final Rule to Establish a Safety Standard for Infant Sleep Products

June 15, 2021

On June 2, 2021, a majority of the U.S. Consumer Product Safety Commission voted to approve a final rule establishing a safety standard under section 104 of the Consumer Product Safety Act for infant sleep products.¹ I strongly support the rule and believe it will save many precious lives.

In brief, the rule adopts a voluntary standard, ASTM F3118-17a, as a mandatory rule with substantial modifications to make the voluntary standard more stringent in accordance with section 104 of the Consumer Product Safety Act.² The rule's greater stringency arises from expanding the scope of the standard by including a maximum seat back angle of 10 degrees or less and by requiring that all infant sleep products meet the CPSC rule on bassinet and cradles.³

Alas, during the deliberations on this rule, my colleague, Peter Feldman, without providing any details, asserted that this rule contained many "procedural deficiencies" that rendered it vulnerable to legal challenge. To say the least, I could not disagree more. Setting aside the possibility that Commissioner Feldman's invitation to disgruntled parties will be a self-fulfilling prophecy to invite legal challenges, I believe the rule easily meets or exceeds all applicable legal requirements.

To explain my conclusion, I will address what I consider the most common legal objections raised by various stakeholders involved in this rule.

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¹ The rule defines "infant sleep products" as products intended to provide sleeping accommodations for infants that are not currently covered by the existing agency rules for bassinets/cradles, cribs (full size and non-full size), play yards, and bedside sleepers.

² Briefly, section 104 requires the agency after consultation with interested parties such as consumer groups, juvenile product manufacturers, independent child product engineers and experts, to promulgate consumer product safety standards for durable infant or toddler products that are the same as or more stringent than existing voluntary standards. The section directs the Commission to adopt more stringent standards when the agency determines that they would further reduce the risk of injury associated with such products.

³ 16 CFR Part 1218.

Failure to Consult

Several commenters claimed that CPSC failed to consult with ASTM, the voluntary standards group that drafted F3118-17a, as required by section 104.⁴ To the contrary, there was extensive consultation. Agency staff consulted regularly and comprehensively with ASTM and various other stakeholders during the years of development of the standard. Numerous meeting records, correspondence, and ballot votes attest to this.⁵ What did not occur, however, was staff's agreement with many of the objectors. To be clear: ASTM and other stakeholders had the right to have CPSC staff consult with them – which staff clearly did. What they didn't have was the right to have staff agree with them – which staff didn't.⁶ The first right does not require the second.

Failure to Share All Relevant Incident Information With ASTM

I note that several commenters claimed that staff failed to share all relevant incident information with ASTM during the pendency of either the ASTM voluntary standard or the development of CPSC's mandatory rule. This is wrong. A more accurate statement would be that when the agency first proposed a much narrower rule in 2017, CPSC had limited injury and fatality data. Over time, as more data accumulated, including hundreds of incidents that occurred from 2005 through June 2019 that were not known when the 2017 NPR was published, CPSC obtained a clearer picture of infant sleep product hazards – and fully shared this data as the agency acquired it.⁷

Of course, on a purely technical legal note, nothing in section 104 requires the agency to provide all incident data it possesses. It merely requires the agency to consult with ASTM regarding the adequacy of the group's voluntary standard. Setting that point aside, however, I note that one of the things that CPSC most effectively and thoroughly does on an ongoing basis is to share incident data whenever the agency is involved in drafting a voluntary standard. Frankly, I have no idea where this objection originated, but the facts belie the claim.

Failure to Provide Adequate Notice That the Rule Would Require All Infant Sleep Products to be Flat

Several commenters claimed that the agency never provided adequate notice that its mandatory rule would require all infant sleep products to be flat. This baffles me. The main thrust of the proposed rule

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⁴ See note 2, supra.

⁵ As noted in the Supplemental Notice of Proposed Rulemaking (SNPR):

The consultation process for the inclined sleep products rulemaking commenced in 2011, and CPSC staff has been actively participating in the development of the new standard since that time. 84 Fed. Reg. 60949, 60950 (November 12, 2019).

⁶ As noted in the Briefing Package on *Final Rule: Safety Standard for Infant Sleep Products*, at 121, nothing in section 104 of the CPSIA requires CPSC to delay addressing risks of harm until all members of ASTM have reached a consensus on the rule. Moreover, the lengthy record of staff's participation with stakeholders on infant sleep products is available on *regulations.gov*.

⁷ The SNPR specifically provided updated fatal and nonfatal incident reports associated with the use of an infant sleep products. 84 Fed. Reg. at 60952.

⁸ Of all the ways that CPSC participates in the development of voluntary standards, providing epidemiological and health science information and explanations of hazards for consumer product has to be at the top of list. See 16 CFR Part 1031.7(a). On occasion, I have urged staff to be more proactive in recommending certain requirements for voluntary standards, but I have never seen an instance in which staff failed to share relevant incident information.

change in 2019 – set forth in the agency's Supplemental Notice of Proposed Rulemaking (SNPR)⁹ – was to move from a standard that permitted inclined sleepers to one that did not allow them. When the Commission issued its SNPR, it specifically stated that all infant sleep products not otherwise covered by a sleep standard must (1) have a seat back angle equal to or less than 10 degrees, i.e., be flat, and (2) meet the requirements for CPSC's standard on bassinets/cradles. To be even more explicit on the point, in the SNPR, staff answered the question of whether additional testing of infant sleep products should address angles between 10-20 degrees. Staff determined that such testing was unnecessary because:

Staff concludes that a <u>flat</u> surface that does not exceed 10 degrees offers the safest sleep environment for infants [emphasis added]. This conclusion comports with staff's recommendations to remove the term "inclined" from the proposed mandatory standard, and to require that all sleep products not otherwise specified as cribs (full-size or non-full-size), play yards, or bedside sleepers meet the requirements in 16 CFR 1218 Safety Standard for Bassinets and Cradles, which, among other things, mandates that the seat back surface angle intended for sleep be 10 degrees or less. ¹⁰

It's hard to see how the Commission could have been any clearer about the requirement that infant sleep products be flat.

The Requirement That All Flat Infant Sleep Products Meet the Agency's Bassinet Standard

A related objection from the manufacturers of sleep products such as in-bed sleepers or baby boxes was not the requirement for flat products – their products are flat. Their disagreement arose from the fact that having to meet the bassinet standard would make their products noncompliant, thereby removing allegedly "safe" products from the market. In making this argument, these commenters claimed that the unintended consequence of removing their products would be that many parents would simply move from using in-bed products to placing their unprotected infants directly – and unsafely – in bed with them.

As a starting point, these objections seem to be more policy arguments than legal objections. And, I note that they were carefully considered by CPSC staff over the course of years as the manufacturers of in-bed sleepers and baby boxes sought to persuade ASTM and CPSC to declare their products to be compliant with CPSC's bassinet standard. CPSC staff consistently opposed any effort to narrow the bassinet standard to accommodate these arguments and fully explained its opposition.¹¹

With respect to any argument that removing these products would be arbitrary and capricious under the test for rulemaking in 5 USC § 553, 12 given staff's careful consideration of these issues over the

⁹ 84 Fed. Reg. 60949 (November 12, 2019). The SNPR was posted on CPSC's website even earlier, on October 16, 2019.

¹⁰ 84 Fed, Reg.60949, 60954, 60955 (November 12, 2019). See, also 84 Fed. Reg. at 60949-60956 for numerous repeated statements about removing the term "inclined" from the standard and requiring a maximum angle of 10 degrees, i.e., flat.

¹¹ Staff's opposition stems, in part, from several factors, including that a number of the in-bed sleep products had excessively padded sides and none provided stands – thereby creating a hazard of sliding off sofas and beds. See *infra* notes 14, 16.

¹² Section 104 rulemaking is governed by 5 USC § 706(2)(A) of the Administrative Procedure Act, which sets the standard for review as arbitrary and capricious. Most commentators view this as the least stringent bar for agency rulemaking. That said, this rule must meet the requirement that it "examine the relevant data and articulate a

years, I see no basis for such an argument. Based on these years of analyzing epidemiological data and applying its considerable technical expertise, staff carefully and thoughtfully made a considered judgment regarding the application of the infant sleep rule to these products. What I fail to see is any rational justification for excluding them from the rule other than the potential loss of business – a legitimate concern, but not one that outweighs the need for protecting children's lives.¹³

Whether In-Bed Sleepers Present a Serious Safety Hazard

I'm aware that in-bed sleeping and in-bed sleepers have many strong supporters.¹⁴ Here, I need to reiterate a point that some observers may have missed. Nothing in the infant sleep rule will apply to parents sleeping with children in their beds. That is a choice for parents to make – one that too often leads to tragedies. CPSC regulates <u>products</u>, not behavior. So, the issue before the agency was simply whether to permit in-bed sleepers.¹⁵

I have heard the argument that in-bed sleepers are safer than in-bed sleeping by itself. Even if true — and the point is debatable — it does not mean that in-bed sleepers are safe, which is the real issue that CPSC had to address. There is no question that in-bed sleepers present serious safety issues. ¹⁶ In fact, staff has long expressed concerns about how low, soft-sided in-bed sleepers may provide parents with a false sense of security when using these products for bed sharing. ¹⁷ And, compelling anecdotal data support these concerns. ¹⁸

satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Assn. of United States, Inc. v State farm Mutual Automobile Ins. Co.*, 463 US 29, 43 (1983). I have little doubt that CPSC's rule more than meets this standard.

We would like to be clear that based on our evaluation of incident data related to in-bed sleepers, we have great concerns regarding the safety of in-bed sleepers and the feasibility of developing any safety standard that fully addresses potential hazards. Based on the 12 deaths discussed with the In-bed Sleeper Data Task Group members, CPSC staff cannot foresee how these products can be designed and regulated to ensure safe use for infants. Staff is not confident that an in-bed voluntary standard that differs from the current bassinet standard will result in a safe sleep product.

See, July 8, 2020 letter from C. Kish to ASTM Subcommittee for In-bed Sleepers, cited in Briefing Package on *Final Rule: Safety Standard for Infant Sleep Products, at 50.*

¹³ To mitigate the economic impact of the rule, staff recommended that the Commission set the effective date for the standard at 12 months, which we did. See, Briefing Package on *Final Rule: Safety Standard for Infant Sleep Products, at 147-148.*

¹⁴ As staff stated in Briefing Package on *Final Rule: Safety Standard for Infant Sleep Products, at 97* The Commission recognizes that bed-sharing is a common practice of parents, both in the United States and abroad. However, we cannot recommend bed-sharing as a safe sleep practice, due to the increased risk of SIDS, overlay, and other hazards. AAP [American Academy of Pediatrics] safe sleep recommendations encourage infants to room-share with parents, but to provide infants with their own firm, flat space, near the parents, but not in the same bed.

¹⁵ To anticipate an objection, cost is unlikely to be a persuasive reason for permitting such products because low cost bedside sleepers are widely available at prices from \$50-\$100. Briefing Package on *Final Rule: Safety Standard for Infant Sleep Products, at 17.*

¹⁶ CPSC technical staff clearly think in-bed sleepers are not safe. In a July 8, 2020 letter to the Subcommittee Chairman for ASTM's in bed sleeper Committee, CPSC staff stated:

¹⁷ Id. at 99.

¹⁸ According to staff

^{...} the Directorate for Epidemiology staff identified 183 incident reports related to non-inclined, flat products marketed as infant sleep products, such as in-bed sleepers and compact bassinets. The incident

Notwithstanding objections to including these products in CPSC's rule, I have yet to see any reputable group of experts support the objections. To the contrary, groups with a long-standing focus on children's safety such as the American Academy of Pediatrics, Consumer Reports, Kids in Danger, Consumer Federation of America, and Public Citizen strongly favor the rule, including its coverage of inbed sleepers – all of which leads me to the same conclusion: CPSC's rule is a careful, measured, and protective standard.

Conclusion

I cannot think of a rule that CPSC has promulgated that advances consumer safety more than the infant sleep rule. I truly believe that any thoughtful, objective review of the rule will lead to no other conclusion than that it is a major and legally sound step forward in protecting children.

data reported to have occurred from January 1 2019 through December 31, 2020, identified 11 fatalities and 16 injury reports.

Id. at 97.