



The National
CONSUMER VOICE
for Quality Long-Term Care

January 9, 2023

Alberta Mills, Secretary
Office of the Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814

RE: Docket No. CPSC-2013-0022
Safety Standard for Adult Portable Bed Rails

Submitted electronically: www.regulations.gov

Dear Secretary Mills:

The National Consumer Voice for Quality Long-Term Care (Consumer Voice) commends the Consumer Product Safety Commission (CPSC) for its commitment to addressing the ongoing deaths and injuries associated with the use of adult portable bed rails (APBRs). Consumer Voice is a national non-profit organization that advocates on behalf of individuals receiving long-term care in all settings. We promote quality care and consumer protection through legislative reform, policy, and consumer education. Our membership consists primarily of consumers of long-term care services, their families, long-term care ombudsmen, individual advocates, and citizen advocacy groups. We appreciate the opportunity to submit comments on these proposed rules.

A decade ago in 2013, Consumer Voice and 61 other organizations petitioned CPSC to develop mandatory standards for adult portable bed rails or to ban them if they cannot be made safe. This petition was driven by an urgent need to protect long-term care consumers from the well-documented dangers of these devices, including death from strangulation or suffocation; injuries such as skin bruising, abrasions, and cuts; circulatory impairment; fractures, and more.

We thank CPSC for granting our petition request and issuing this proposed rule regarding bed rails. Such action is essential and tragically overdue given the many deaths and injuries that have continued to occur since the submission of our petition.

Consumer Voice supports the proposed regulation with the modifications to ASTM F3186-17 made by agency staff. The proposed regulations include many of the requests we set forth in the petition, including requirements for:

- Design standards that substantially reduce the entrapment, strangulation and asphyxiation hazard posed by portable bed rails.
- Permanent labels alerting users to the risk of asphyxiation and entrapment.
- Permanently affixed manufacturer and model number on the product.

At the same time, we believe that other changes to the proposed rule, as well as additional action by CPSC would provide even greater protection to long-term care consumers. These recommendations, along with responses to specific CPSC requests for comment, are presented below.

A. Suggested changes to proposed rule § 1270.2(b)

*In the following, the current ASTM standard is referred to as “current standard” and the CPSC-modified standard set forth in the Federal Register is referred to as “modified standard”. Text in **red italics** indicates new language.*

1. Current standard: ASTM F3186-17 Section 3.1.3

We are concerned that the definition of “conspicuous” in this section is too narrow in scope. First, it would only require warning labels to be visible from one position around the unit, which significantly reduces the chances of the labels being seen. Second, the definition would only need to be visible to a person standing near the unit. This means that the consumer for whom the product is being used would not be able to see the warning labels. The consumer above all has the right to know about the product’s dangers.

Revise: *Instead of complying with section 3.1.3 of ASTM F3186-17, comply with the following:*

*Conspicuous, adj. – visible, when the product is in the manufacturer’s recommended use position, to **both the consumer and** a person standing near the unit **from at least two different positions** around the unit but not necessarily visible from all positions.*

2. Current standard: ASTM F3186-17, Sections 6.1.5

The use of straps to attach the product to the bed greatly increases the danger of improper assembly and likelihood of harm. Further, straps can stretch and become

loose over time. In order to reduce this unreasonable risk of injury and death, straps should not be permitted on adult portable bed rails.

Revise: Instead of complying with section 6.1.5. of ASTM F3186-17, comply with the following:

Straps shall not be used to attach the product to the bed.

3. Current standard: ASTM F3186-17, Section 8.7

Consumer Voice is pleased that the standard calls for manufacturers to retain all records of compliance testing. However, given the importance of this testing, manufacturers should also be required to make these records available to the public upon request.

Add: In addition to complying with section 8.7 of ASTM F3186-17, comply with the following:

The manufacturer shall make these records available electronically to the public upon request.

4. Current standard: ASTM F3186-17, Section 9

The labeling and warnings requirements for retail packaging, instructions, and the product are laid out in ways that are confusing and, in some instances, even contradictory. For example, Section 9.2.5 requires instructions to include one specific warning, while Section 9.2.6 mandates instructions to include a different warning. It is unclear whether this means that the instructions must include two warnings.

Consider organizing the requirements for labeling and warnings by what they apply to, e.g. labeling and warnings for retail packaging, labeling and warnings for instructions, and labeling and warnings for the product. Such an approach would be more straightforward and detail in one place exactly what the manufacturer must include for packaging, instructions and the product. As a result, the requirements would be clearer and easier to understand.

5. Current standard: ASTM F3186-17, Sections 9 & 11

Neither the labeling nor the warning requirements indicates what the product is designed to do and for whom the product is intended. Such information is essential because it helps consumers decide if the product is right for them and decreases the possibility that the product is utilized for purposes for which it is not designed. Because of the information's importance, Consumer Voice and other organizations

specifically called for this change in their comments on the docketing of the petition¹ dated August 5, 2013.

Revise: In addition to complying with sections 9 and 11 of ASTM F3186-17, comply with the following:

The product labeling and instructions must state for whom the bed rails are intended and the intended use of the product.

6. Current standard: ASTM F3186-17, Section 9.1.1.1

Because email is increasingly used for communication, including the email address as well as the mailing address would make contacting manufacturers easier for consumers.

Revise: Instead of complying with section 9.1.1.1 of ASTM F3186-17, comply with the following:

The name, place of business (city, state, email address, and mailing address, including zip code), and telephone number of the manufacturer, importer, distributor, or seller. The listed entity must be one who can answer technical questions about installation and use and receive complaints.

7. CPSC-modified standard: Proposed rule § 1270.2(b)(3)(i) & § 1270.2(b)(8)(i)

Although it is critical that the APBR be used with the right mattress, there are contradictions within the proposed rule about whether the applicable range of mattress heights or thickness must be specified by the manufacturer. For instance, § 1270.2(b)(16)(i) would require that the product **“be used only with the type and size of mattress and bed, including the range of thickness of mattresses, specified by the manufacturer of the product,”** yet the following proposed rules indicate that a manufacturer does not necessarily have to provide this information:

Under Section 6.2.1.1: if the manufacturer does not recommend a specific range of mattress heights or thicknesses...

Under Section 7.1.3: mattress thickness ranges used for testing may be up to 1.5 in (38 mm) larger or smaller than the range specified by the manufacturer.

¹ Consumer Voice letter to Office of the Secretary, Consumer Product Safety Commission. Re: Adult Portable Bed Rail Petition, Docket No. CPSC-2013-0022. August 5, 2013. <https://theconsumervoice.org/uploads/files/issues/BedRailPetitionComments-CV-8-5-13.pdf> (accessed January 6, 2023).

If the manufacturer does not recommend a particular range of mattress heights, ...

Because using an inappropriate mattress can result in entrapment and subsequent injury and/or death, manufacturers must be required to include the applicable range of mattress heights or thicknesses.

Revise: Delete the following language from § 1270.2(b)(3)(i)

... if the manufacturer does not recommend a specific applicable range of mattress heights or thicknesses, the test personnel shall choose a mattress that provides the most severe condition per test requirement.

Revise: Delete the following language from § 1270.2(b)(8)(i)

... if the manufacturer does not recommend a particular range of mattress heights, the testers shall choose a mattress that provides the most severe condition per test requirement.

8. CPSC-modified standard: Proposed rule § 1270.2(b)(17)(i)

Consumer Voice supports the following language about falls that appears in Figure 2 to paragraph (b)(17)(i): “People attempting to climb over this product are at increased risk of injury or death from falls.” It states what the risks are in a clear and direct way. People with Alzheimer’s disease or dementia, or those who are sedated, confused or frail, are also at increased risk of injury or death when using these devices, yet the current warning language does not mention increased risk of injury or death. We urge CPSC to rewrite the language relating to people with dementia in a similar manner in order to be equally clear and direct, and better gain the attention of consumers.

Revise: Change to the following:

Each product’s retail package and instructions shall include the following warning statements:

ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS

*Gaps in and around this product can entrap and kill. People with Alzheimer's disease or dementia, or those who are sedated, confused, or frail are at increased risk of **serious injury or death from entrapment, strangulation, and suffocation**. People attempting to climb over this product are at increased risk of injury or death from*

falls. Always make sure this product is properly secured to bed. If product can move away from bed or mattress, it can lead to entrapment and death.

9. Current standard: ASTM F3816-17, Section 9.2.6

The same revision made to the warning in the previous section should be made to the warning in Section 9.2.6.

Revise: *Instead of complying with section 9.2.6 of ASTM F3186-17, comply with the following:*

*If product is installed incorrectly or moves from its initial position gaps can occur which can entrap and kill. People with Alzheimer's disease, dementia or other neurological conditions, or those who are sedated, confused, or frail, are at increased risk of **serious injury or death from** entrapment, suffocation and strangulation.*

10. CPSC-modified standard: Proposed rule § 1270.2(b)(18)(i)

The proposed rule at § 1270.2(b)(18)(i) deletes the word “conspicuous” when referring to the component of the product that must be labeled with the entrapment warning. The elimination of this word would weaken the requirement and make the product less safe since the warning could be placed where it might be difficult or even impossible to see.

Revise: *Add the following to § 1270.2(b)(18)(i)*

*... at least one **conspicuous** installation component of the product must be labeled with the entrapment warning in Figure 3 to paragraph (b)(18)(i).^[17]_{SEP}*

11. CPSC-modified standard: Proposed rule § 1270.2(b)(18)(i)

The language about serious injury or death that we have suggested in the two previous warnings should also be used in Figure 3 to paragraph (b)(18)(i) in order to be consistent.

Revise: *Change to the following:*

*NEVER use product without properly securing it to bed. Incorrect installation can allow product to move away from mattress, bed frame and/or head or foot boards, which can lead to **serious injury or death from entrapment, suffocation, and strangulation.***

12. Current standard: ASTM F3186-17, Section 11.1

We are pleased that written instructions for how to assemble, operate, and maintain the product, as well as drawings and diagrams for set up and operation must be included in the instructional literature. This information is responsive in many ways to the request we and others made in our petition. Nevertheless, the required information does not go far enough. The mandated drawings and diagrams only show a bed with arrows indicating the entrapment zones with an APBR. These drawings/diagrams are not sufficient because they do not specifically show what the different types of entrapment look like. This information is best conveyed using the drawings/diagrams in the Appendices of the ASTM standards, under XI. EXAMPLES OF ENTRAPMENT. These figures allow the consumer to picture exactly how a person can become entrapped and are essential in order for consumers to be adequately informed about the possible risks of using these devices.

Revise: Instead of complying with section 11.1 of ASTM F3186-17, comply with the following:

Product instructions provided shall be easy to read and understand. Assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable, shall be included. Drawings and diagrams shall be used to provide better understanding of set up and operation for use and will also include examples of entrapment. Manufacturers shall include drawings depicting:

- All of the entrapment zones, such as those available from the FDA or as applicable to the product, and*
- Examples of entrapment from ASTM F3186-17, Appendices, XI.*

In addition, since proper assembly and installation is crucial, Consumer Voice recommends that the CPSC consider requiring manufacturers to create a video to be posted on YouTube or any subsequent iteration. Many individuals find that watching a demonstration, along with written instructions and diagrams, is most helpful.

B. Responses to specific CPSC requests

Below are Consumer Voice's responses to a number of CPSC's requests.

Comment solicited: Whether the retention system in the proposed rule sufficiently reduces the risk or if other measures are needed

Every step in the assembly, installation, operation, and maintenance of an APBR creates an opportunity for error. This opportunity is amplified when danger is already associated with a particular part of the set up and operation. This is the case with straps. The danger posed by straps is so serious that the ASTM itself calls for a specific warning:

ASTM F3186-17, Section 11.1.2

Products which use straps to meet the requirements of this specification shall include the following warning:

WARNING: If the strap provided is not properly secured the product may move into an unsafe position which increases the danger of entrapment.

Since there are currently APBRs on the market that do not require straps, it is clearly possible to manufacture a product that is free of straps. Given the dangers and since production should not be a problem, Consumer Voice believes that the retention system can and should be made safer by prohibiting APBRs from using straps.

Comment solicited: Whether stockpiling should be prohibited

We agree that stockpiling must be prohibited. If not, manufacturers will accumulate enough of their current product to sell for an unforeseeable time after the rule goes into effect. This would allow them to bypass the regulations because APBRs made prior to the rule's effective date would not apply. As a result, consumers would have access to bed rails that are not subject to the mandatory standards and face the risk of injury and death that these standards are designed to resolve.

Comment solicited: Information regarding any analysis and/or tests done on APBRs in relation to the risks of injury or death they present

Consumer Voice believes that the findings of the analysis done by CPSC staff and reported in the preamble abundantly demonstrate that APBRs present both the risk of injury and death.

Comment solicited: Information regarding any potential costs or benefits of the proposed rule that were not included the foregoing preliminary regulatory analysis

We find that the CPSC preliminary regulatory analysis, which is very thorough, is sufficient and that no additional information is needed.

Comment solicited: The testing procedures and methods of the proposed rule and whether they sufficiently reduce the risk associated with APBRs, or whether other measures are necessary and information demonstrating how these measures address the identified risks

We commend CPSC for proposing testing procedures and methods that should significantly improve safety and go a long way to reducing the risks posed by these devices. At the same time, Consumer Voice urges CPSC to require one additional measure that would greatly increase both safety and consumer confidence in APBRs: **verification by an independent third party that new, mandatory safety standards have been met by the manufacturer in question prior to allowing said product to be introduced to the market.** This requirement was included in the petition Consumer Voice and other groups submitted to CPSC on April 25, 2013.

Such verification is already mandated for children's bed rails.² Older adults - many of whom have dementia, and/or are frail - are often no less at risk than children and deserve similar protection.

Independent third-party verification is necessary to better ensure safety. Currently, there is no process in which CPSC or any government agency regularly inspects APBRs to determine if the manufacturer complies with the requirements. The most that is required is that the manufacturer complete a General Certificate of Conformity certifying that the product complies with all applicable consumer product safety rules (or similar rules, bans, standards, or regulations under any law enforced by the Commission for that product).³ This would continue under the proposed rule. However, public confidence that manufacturers will complete the certificate accurately has been severely compromised. This stems from the almost total disregard of the voluntary standards by manufacturers⁴ - even with CPSC staff outreach and additional time allowed for compliance.

Without CPSC-accepted third party laboratory verification, the Certificate of Conformity is likely to be mostly meaningless to consumers and carry little weight. Many consumers will not have the peace of mind to trust that the APBRs they purchase meet the standards. Requiring such verification would better protect consumers and give them greater assurance that bed rails they use for themselves, or

² Portable Bed Rails Business Guidance & Small Entity Compliance Guide. Consumer Product Safety Commission. <https://www.cpsc.gov/Business--Manufacturing/Business-Education/Business-Guidance/Portable-Bed-Rails>.

³ General Certificate of Conformity, Consumer Product Safety Commission. <https://www.cpsc.gov/Business--Manufacturing/Testing-Certification/General-Certificate-of-Conformity>.

⁴ Federal Register/Vol. 87, No. 216/Wednesday, November 9, 2022/Proposed Rules, p. 67594-67596.

their loved ones will not seriously harm or even kill them.

Comment solicited: Potential alternatives to APBRs if they are banned, and the impact that a ban on APBRs would have on consumers (e.g., lost consumer utility from not having the product)

Alternatives to APBRs

To prevent falling out of bed, the bed can be lowered as near to the floor as possible. An adjustable height bed can go very low to the floor for sleeping and be raised for transfers and care. In addition, mats can be placed by the side of the bed to cushion any fall that might occur.

APBRs are also often used to prevent a person with cognitive impairment (e.g. Alzheimer's Disease or other dementia) from getting out of bed and moving about unsupervised and unassisted and even leaving the home. In this case, the best alternative is frequent monitoring and individualized care - understanding and responding to the person's individual needs, routines and preferences before he or she attempts to get up on their own. Examples include:

- Determining how frequently the person needs to go to the bathroom and setting a schedule to help him/her to the bathroom at those times.
- Evaluating why the person is trying to get out of bed (for instance, are they thirsty, hungry or in pain?) and providing food, beverages and/or pain medication before the person goes to bed and/or at certain times while the person is in bed.

Lastly, when the APBR is used for mobility, alternatives include:

- Utilizing a secured vertical pole to assist in getting in and out of bed.
- Installing a bed trapeze to help reposition while in bed and to get in and out of bed.

Impact of a ban

The greatest concern about a ban Consumer Voice has heard from consumers is fear that they will no longer have access to APBRs to assist in movement. These individuals are not able to turn or reposition themselves in bed or get in/out of bed alone or even with a caregiver. A ban could lead to a decline in their mobility and functioning and increased dependence. It could also result in decreased quality of life due to greater isolation if their ability to leave their beds is limited.

Comment solicited: Any qualitative or quantitative evidence concerning the utility

that APBRs have for consumers relative to alternative products that might be used as substitutes in the event APBRs are banned.

We are unaware of any such evidence.

Comment solicited: The appropriateness of the 30-day effective date, and a quantification of how a 30-day effective date would affect the benefits and costs of the proposed rule

Consumer Voice finds the 30-day effective date to be appropriate and fair. Consumers should not have to wait even longer for protection from a potentially deadly product they should have been protected from decades ago. Furthermore, manufacturers should not need more than 30 days. As noted by CPSC, manufacturers are well aware of the regulations since the ASTM standards went into effect in 2017. Five years is more than enough time to understand the standards and take the steps necessary to comply.

Comment solicited: Whether the proposed adoption of the modified ASTM standard sufficiently addresses the hazard and whether a ban is warranted, and if so, what the impact of a ban would be on consumers (e.g., lost consumer utility from not having the product).

CPSC is right to pursue a rule

CPSC's decision to issue a proposed mandatory standard is well reasoned and appropriate. CPSC is correct in its analysis that none of the less burdensome alternatives (taking no regulatory action; conducting a recall of APBRs instead of promulgating a final rule; conducting an educational campaign; banning APBRs from the market entirely; requiring enhanced safety warnings; and implementing a longer effective) date would reduce the risk of deaths and injuries associated with APBRs. Regulations are the best option at this time for protecting consumers for several reasons.

To-date it is evident that the voluntary standard has not worked to reduce serious injuries and deaths. Findings of the research conducted by CPSC revealing that there were 310 deaths between January 2003 and December 2021, and 79,500 injuries related to APBRs is shocking.⁵ In addition, as noted by family advocate Gloria Black in her comments, there was a 12% increase for the last two reported years over the number of injuries reported in 2019. She states, "The 5,100 injuries reported for 2020

⁵ Federal Register/Vol. 87, No. 216/Wednesday, November 9, 2022/Proposed Rules, p. 67588, 67590.

and again for 2021 show an all-time high for records obtained from 2003 onward.”⁶ This failure to decrease the harm caused by APBRs is not at all surprising given the industry’s blatant disregard of the standards. In testing conducted in 2018 and 2019 and again in 2021, all products failed at least one critical mechanical requirement – failing even one such requirement can result in a fatal entrapment.⁷ CPSC research has led staff to preliminarily determine that substantial compliance with these voluntary standards is “unlikely.”⁸

CPSC also evaluated the ASTM standards and concluded that in their current form they are insufficient to eliminate or adequately reduce the unreasonable risk of injury.⁹ However, these standards have been significantly improved and strengthened with the important modifications made in the proposed rule by CPSC staff.

CPSC asks whether these modified ASTM standards are sufficient to reduce the hazards. We cannot answer that question at the moment because the lack of compliance with the ASTM standards provides us with no useful data and the proposed rule is untested. Nevertheless, we know that according to CPSC, the proposed rule with modification is expected to address 92 percent of deaths caused by entrapment. Given this positive information, Consumer Voice finds that adopting the modified ASTM standard is the best and most judicious next step.

Data should be evaluated in five years to determine the need for a ban

Although the dangers of APBRs are well documented, it is important to note that they provide critical assistance to a number of individuals. As noted above, they aid some consumers in turning and repositioning in bed and with getting in and out of bed. Without this help, these individuals might be unable to move in bed or forced to remain in bed. Both their physical and psychosocial well-being could be at risk. For people who are alert and oriented, APBRs can serve to maintain their independence and promote mobility. Because APBRs benefit a certain number of long-term care consumers, Consumer Voice opposes a ban at this time.

Nevertheless, the impact of the rule must be assessed. While the rule should be implemented now, we urge CPSC to evaluate the data pertaining to deaths and injuries involving APBRs in five years to determine if the unreasonable risk of injury and death has been eliminated or significantly reduced. Should the data not show a significant decrease in injuries and deaths, the rule will not have achieved its goal. If

⁶ Comment from Gloria Black. Consumer Product Safety Commission. Posted December 9, 2022. ID: CPSC-2013-0022-0112.

⁷ Federal Register/Vol. 87, No. 216/Wednesday, November 9, 2022/Proposed Rules, p. 67594.

⁸ Federal Register/Vol. 87, No. 216/Wednesday, November 9, 2022/Proposed Rules, p. 67596.

⁹ Ibid.

this is the case, we call on the Commission to consider whether APBRs should be banned from the market entirely.

C. Additional CPSC actions

Consumer Voice applauds CPSC for moving forward with a rule for APBRs. But given the severity of the dangers to consumers, a multi-pronged approach is needed. To that end, we recommend CPSC also consider taking the following actions:

Improve the data about fatalities and injuries related to APBRs

While the number of deaths and injuries reported by CPSC is appalling, it is just the tip of the iceberg. As far back as 2012, the Commission said the data “probably understated the problem since bed rails are not always listed as a cause of death by nursing homes and coroners, or as a cause of injury by emergency room doctors.”¹⁰ Compounding the problem, manufacturers are not required to report each death and injury that they are aware of; they must only inform the agency when they obtain “information which reasonably supports the conclusion that such product—... creates an unreasonable risk of serious injury or death....”¹¹ Thus manufacturers are permitted to come to their own conclusion about whether the product creates an unreasonable risk, which means the death or injury may not be reported.

It is next to impossible to develop good public policy in the absence of reliable and accurate data. Unfortunately, the data pertaining to the harm associated with APBRs is woefully inadequate and inaccurate. In order to determine the true extent of the problems related to APBRs and evaluate if the APBR rules are effective in eliminating or reducing the risk of death or injury, Consumer Voice urges CPSC to assess how the quality of APBR data can be enhanced.

Exercise its recall authority more frequently

While recalls are not sufficient as the sole alternative because they are utilized after harm has occurred, increased use of this approach by CPSC, in conjunction with a mandatory standard, is an additional way to hold manufacturers accountable and better protect consumers.

¹⁰ After Dozens of Deaths, Inquiry into Bed Rails. New York Times. Ron Nixon. November 25, 2012.

¹¹ 15 U.S. Code § 2604(b)(4)

Conduct an educational campaign

Most consumers know little to nothing about adult portable bed rails. Consumer Voice commends CPSC (and the FDA) for the bed rail safety poster it created. Yet more widespread and comprehensive education is essential so that consumers can make better, more informed decisions about purchasing these devices.

Additionally, it has been our experience that APBRs are frequently used because caregivers do not know what else to do. As noted above, individualized care - knowing a person's needs, routines, and preferences - allows caregivers to anticipate when the person has to, or wants to, get out of bed. This permits the caregiver to assist the individual to do so safely. We recommend that an educational campaign include the development and dissemination of a resource on individualized care to reduce or avoid the use of APBRs.

Thank you for your important work on this issue and for your consideration of these comments.

Sincerely,

A handwritten signature in cursive script that reads "Lori Smetanka". The signature is written in black ink and is positioned below the word "Sincerely,".

Lori Smetanka
Executive Director