STAFF BRIEFING PACKAGE

UPDATE ON PETITION CP 13-1,
PETITION REQUESTING A BAN OR STANDARD ON ADULT PORTABLE BED RAILS

JULY 15, 2020

For additional information, contact:

Vineed K. Dayal, Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences
Office of Hazard Identification and Reduction
Phone: 301-987-2292
Email: vdayal@cpsc.gov

U.S. Consumer Product Safety Commission
5 Research Place
Rockville, MD 20850

EXECUTIVE SUMMARY

On April 25, 2013, and May 9, 2013, the U.S. Consumer Product Safety Commission (CPSC) received requests from two different groups to initiate rulemaking under sections 8 and 9 of the Consumer Product Safety Act (CPSA) to address reported hazards associated with adult portable bedrails (APBRs). The requests were docketed in a single petition, CP-13-1, *Petition Requesting a Ban or Standard for Adult Portable Bed Rails*.

In 2013, ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for APBRs. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

CPSC staff has worked with ASTM throughout the development of the voluntary standard process for APBRs. In August 2017, ASTM published the voluntary standard ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. Staff updated the Commission on July 18, 2018, regarding the progress responding to petition CP 13-1. Staff's 2018 update memo indicated that staff planned to test 35 randomly selected APBR models to determine whether they conformed to the new standard.

In this briefing package, staff explains how they reviewed whether ASTM F3186 – 17 is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition and whether there is substantial market compliance with the standard, as required by section 9(i) of the CPSA, 15 U.S.C. § 2058(i).

First, staff evaluated the standard and concluded that compliance with the standard likely would result in an adequate reduction of the risk of injury identified in the petition. Although staff concluded that the standard likely would adequately reduce this risk, staff identified several sections of the standard that should be clarified to improve the likelihood that manufacturers will understand the requirements and test methods.

Second, staff assessed compliance to the standard by testing a market sample of 35 APBR products. Staff found that none of the tested products fully comply with the standard. Based on these test results, staff cannot conclude that there is substantial compliance with the standard.

Staff believes that additional effort would be needed to increase compliance with the standard. Staff plans to allow additional time for industry to adopt the standard and for the voluntary standards committee to address staff's concerns with the performance requirements in the standard. Then staff will be able to further assess the likelihood of future market compliance to the standard. Resources have been included in the development of the FY21 Operating Plan to reflect this follow-on work. Given current operational limitations, staff believes it would likely be able to provide an update to the Commission in FY22 with a recommendation on petition action.

TABLE OF CONTENTS

Briefing Package: Update on Petition CP 13-1

Technical Memoranda

Appendicies

United States
Consumer Product Safety Commission
Bethesda, MD 20814

This document has been electronically approved and signed.

Memorandum

DATE: July 15, 2020

TO: The Commission
Alberta Mills, Secretary

THROUGH: John G. Mullan, General Counsel

Mary T. Boyle, Executive Director

DeWane Ray, Deputy Executive Director for Safety Operations

FROM: Duane Boniface, Assistant Executive Director,
Office of Hazard Identification and Reduction

Vineed K. Dayal, Project Manager,
Division of Mechanical Engineering, Directorate for Laboratory Sciences

SUBJECT: Update on Petition CP 13-1, Requesting a Ban or Mandatory Standard on Adult Portable Bed Rails

INTRODUCTION

In 2013, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition CP 13-1, *Petition Requesting a Ban or Standard on Adult Portable Bed Rails*.[1] ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for adult portable bed rail (APBR) products.[2, 3] On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR

[1] Petition CP 13-1, *Petition Requesting a Ban or Standard on Adult Portable Bed Rails*, Public Citizen, Gloria Black, Consumer Federation of America, Consumer Voice, et al., June 4, 2013. Retrieved from: https://www.regulations.gov/document?D=CPSC-2013-0022-0001.

[2] The CPSC has a consumer product safety standard for children's portable bed rails, which incorporates ASTM F2085-19, and is codified at 16 CFR part 1224. (85 FR 10565).

[3] Staff's 2014 Briefing Package discussed the distinction between bed rails that are considered medical "devices" under the FDA's authority, and other bed rails that fall under CPSC's jurisdiction. Bed rails that are an accessory or an appurtenance to regulated hospital beds are considered by FDA to have medical purpose and are devices under FDA. Bed rails intended for use with a non-FDA-regulated bed, and that are not considered by the FDA to have a medical purpose, and are not medical devices, would fall under the CPSC's jurisdiction, irrespective of where the bed is used (*i.e.*, nursing home, long-term care facility, or residence).

voluntary standard had been developed and evaluated by staff.[4] On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition to allow staff additional time to work with ASTM in the standard development process.

Starting in 2013, CPSC staff worked with ASTM to help develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*.[5] The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

Under the Consumer Product Safety Act (CPSA), the Commission may not deny a petition on the basis of a voluntary standard, unless[6]:

- the voluntary standard is in existence at the time of the denial of the petition,
- the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and
- it is likely that there will be substantial compliance with the standard.

In this briefing package, staff reviewed the ASTM F3186 – 17 voluntary standard to assess whether it is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and evaluated whether there is substantial market compliance with the standard. Specifically, staff:

- updated and analyzed incident data to identify the hazard patterns and compared hazard patterns with the requirements of ASTM F3186 – 17 to evaluate whether the standard adequately reduces the risk of injury from the hazards in the incident data; and
- conducted an APBR market analysis to identify the number of unique product models and number of manufacturers, acquired a market sample of 35 APBR products based on the number of unique models on the market, and tested the samples to determine compliance to the ASTM F3186 – 17 standard.[7]

[4] Staff Briefing Package, *Petition CP-13-1 Requesting a Ban or Standard for Adult Portable Bed Rails*, April 23, 2014. Retrieved from: https://www.cpsc.gov/s3fs-public/pdfs/foia_PetitionCP131RequestforBanorStandardforAdultPortableBedRail.pdf

[5] ASTM F3186-17, *Standard Specification for Adult Portable Bed Rails and Related Products*, ASTM International, West Conshohocken, PA, 2017, www.astm.org.

[6] 15 U.S.C. § 2058(i).

[7] Staff observed that several APBR models that were essentially the same model (*e.g.*, same supplier and specifications) could be marketed across multiple channels, but under different names. To enumerate APBR models accurately, staff considered all APBRs that appeared to have the same supplier and same specifications to constitute one unique model, even though the model might be offered under multiple names or brands.

INCIDENT DATA & HAZARD ANALYSIS[8,9,10]

The Petitioners asserted that APBRs on the market at the time were responsible for many injuries and deaths among users, particularly the elderly and frail. The Petitioners stated that many of these deaths resulted from asphyxiation caused by entrapment within openings of the rail or between the rail and the mattress or bed frame. Staff completed an updated review of death and injury incidents since the analysis in the 2014 briefing package to evaluate the nature and extent of the hazards caused by APBRs.

INCIDENT DATA

CPSC staff from the Directorate for Epidemiology, Division of Hazard Analysis (EPHA), reviewed incident data received from January 2003 through December 2019 involving bed rails. Upon review, staff determined that a total of 260 incidents involved APBRs, including 247 fatalities and 13 nonfatality or "injury not reported" cases. CPSC staff's analysis found that the overwhelming majority of the reported decedents were age 70 or older. In addition, the majority of incidents involved victims with underlying medical conditions.

NEISS Data Summary [11]

EPHA reports National Electronic Injury Surveillance System (NEISS) estimates of approximately 69,300 possible APBR injuries treated at hospital emergency departments (ED) between 2003 and 2019. Using the CPSC's Injury Cost Model (ICM), CPSC's Directorate for Economic Analysis (EC) staff estimates that there were another 127,585 non-ED treated injuries believed to be associated with APBR use from 2003 through 2019. This includes an estimated 125,608 injuries treated at outpatient facilities, such as doctor's offices or clinics, as well as another 1,977 victims treated through direct admission to hospitals. The total estimate of injured victims treated comes to about 196,848, or approximately 11,579 per year over the 17 years examined. [12]

EC staff estimates that between 90,000 and 425,000 APBRs are sold annually, and estimates that the preliminary annual societal costs of fatal and nonfatal APBR injuries could be as high as $464 million per year ($135 million in fatalities + $329 million in nonfatal injuries). However, in many cases, the NEISS record did not include enough information to determine whether the bed rail in question was an APBR, or whether the incident involved an injury that could be addressed by a standard. Therefore, this societal cost estimate could be an overestimate.

---

[8] Tab A, Qin, A. EPHA Staff Memorandum, *Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries*.
[9] Tab B, Bretford, G. EC Staff Memorandum, *Market for and Societal Cost of Injuries Associated with Adult Portable Bed Rails*.
[10] Tab C, Wanna-Nakamura, S. HSPP Staff Memorandum, *Health Sciences Assessment for Petition CP 13-1, Requesting a Ban or Standard for Adult Portable Bed Rails*.
[11] The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system.
[12] The ICM is fully integrated with NEISS and uses empirical relationships between the characteristics of injuries and victims initially treated in hospital EDs and those treated elsewhere, to estimate the number of medically attended injuries treated outside of hospital EDs.

HAZARD PATTERN ANALYSIS

HSPP staff, along with EPHA staff, reviewed the 260 incidents (247 fatal and 13 nonfatal or "injury not reported") from January 2003 through December 2019 reported to CPSC to identify hazard patterns associated with APBRs. Staff identified four distinct hazard types: rail entrapments, falls, structural integrity, and miscellaneous.

Rail Entrapments

There were 226 incidents related to rail entrapments; all incidents were fatal. This hazard pattern accounts for 89 percent of all reported incidents, and includes incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail; between the bed rail bars; between a commode and rail; and between the floor and rail. Based on the incident narratives provided, the neck and head were the most frequently injured body parts.

Falls

There were 20 incidents related to falls; 19 were fatal, and one was nonfatal. This hazard pattern includes incidents in which the victim fell and hit the bed rail; fell after climbing over the bed rail; and other similar scenarios.

Structural Integrity

There were eight incidents related to structural component problems; all incidents were nonfatal. This hazard pattern includes incidents in which some part of the product either broke or reportedly was not sturdy.

Miscellaneous

There were six incidents with miscellaneous problems, including two deaths related to garments getting caught, one wrist injury, one unspecified injury, and two noninjury incidents reported.

STAFF'S ASSESSMENT OF ASTM F3186 – 17 ON THE IDENTIFIED HAZARD PATTERNS [5,13,14]

This section provides staff's analysis of the various sections and requirements in ASTM F3186 – 17 and how the requirements are expected to reduce the risk of injury from APBRs.

[13] Tab D, Smith, T.P. & Talcott K.A. ESHF Staff Memorandum, *Human Factors Assessment of ASTM F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard*.
[14] Tab E, Dayal. V. LSM Staff Memorandum, *Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails*.

SCOPE AND DEFINITION

ASTM F3186 – 17 establishes performance requirements for APBRs, including requirements for resistance to entrapment, marking and labelling, instructional literature and advertising.

The definition of an APBR is provided in section 3.1.1 of ASTM F3186 – 17, which defines "adult portable bed rail" as:

> [A]n adjacent type bed rail, grab bar, assistive bar, transfer aid, cane or rail (henceforth identified as the product or products) intended by the manufacturer to be installed on, against, or adjacent to an adult bed. The product may vary in lengths (for example, full, half, or partial rails, grab bar or handle or transfer post or pole), and is intended by the manufacturer to provide assistance to the bed occupant in moving on the bed surface, in entering or exiting the bed, to minimize the possibility of falling out of bed, or for other similar purposes. This includes similar products that are likely to be used for these purposes even if this is not explicitly stated by the manufacturer. However, the standard does not address *all* products that might be so used, for example, a chair.

ASTM F3186 – 17 (section 3.1.2) defines "adjacent type bed rail," a term used in the definition of "adult portable bed rail," as:

> [A] portable bed rail or related product in which the guard portion (portion that an adult would contact when rolling toward the mattress edge) is essentially a vertical plane or pole that is positioned against the side of the mattress.

Staff worked with the ASTM subcommittee to develop these definitions, based on the scope of the petition and the types of portable bed rails that are not covered by CPSC's existing regulations. CPSC staff reviewed bed rails under CPSC's jurisdiction, including products that are installed or used along the side of a bed by consumers intended to:

- reduce the risk of falling from the bed;
- assist the consumer in repositioning in the bed; or
- assist the consumer in transitioning into or out of the bed.

These ABPRs were described in detail in staff's 2014 briefing package, and typical examples of APBR products are shown in Figure 1.

Figure 1: General examples of APBR types – (1) Full-Length Bed Rail, (2) Bed Cane, (3) Bed Handle, and (4) Half-Length Bed Rail

GENERAL REQUIREMENTS

ASTM F3186 – 17 includes general requirements in Section 5. In Section 5.1, requiring there will be no hazardous sharp points or edges; in Section 5.2, stating that any exposed parts will be smooth and free from rough edges; and in Section 5.3, mandating that products covered by the standard that are installed on a bed that articulates (*i.e.*, is adjustable) must meet the performance requirements when the bed is in the flat and articulated positions.

General requirements mandating smooth edges on exposed parts improve safety by preventing potential lacerations or skin injuries on APBRs. In addition, staff finds that testing APBR products on articulating beds is essential to assess openings that could potentially lead to entrapments when the bed is adjusted from the flat position to the articulated position.

PERFORMANCE REQUIREMENTS

There are a number of performance requirements in ASTM F3186 – 17 that are intended to address the risk of injury associated with APBRs. These include requirements for assembly, structural integrity, retention system performance, and fall and entrapment protection.

Misassembly and Mis-installation

Staff identified 226 fatal incidents related to rail entrapments. This hazard pattern is the most prevalent among the incidents, accounting for 89 percent of all incidents. Effectively addressing the entrapment hazard associated with APBRs depends on consumers assembling and installing the product properly. ASTM F3186 – 17 includes performance requirements intended to improve the likelihood that the APBR will be assembled and installed properly. For example:

- Section 6.1 sets forth a requirement for products to include a retention system, which maintains the installed product in position without requiring readjustment of the components. This retention system must be permanently attached to the APBR once it has been assembled, and must be removable only with a tool.

- Section 6.2 includes structural integrity requirements that call for the product to be tested without changing dimensions.

- Section 6.5 includes a requirement that structural components and retention system components must not be capable of being misassembled, which the standard defines as the APBR being assembled in a way that appears functional, but would not meet the retention system (section 6.1), structural integrity (6.2), entrapment (6.3), or openings (6.4) requirements.

Staff's review shows that the performance requirements requiring retention systems to be permanently attached to the APBR once it has been assembled, and removable only with a tool, reduce the likelihood that consumers will misplace the retention system, and increase the likelihood that consumers, including secondary users, will continue to use the retention system. The requirement that structural and retention system components not be misassembled reduces the risk of injury or death that could arise from the consumer omitting key parts of the APBR (*e.g.*, a center rail) during assembly, in ways that could result in entrapment or other hazards.

Falls

Falls were the second most common hazard pattern in the incident data, accounting for 20 incidents (8 percent). Staff found that most falls associated with APBRs involve the victim falling against or striking the APBR, but these incidents often include few details. Therefore, the APBRs might have played an incidental role in some of these cases. If the fall was triggered by the APBR becoming dislodged or its position shifting, then these incidents would likely be addressed by the voluntary standard's structural integrity testing and the performance requirement for a permanently attached retention system that must maintain the installed product in position.

A minority of fall-related incidents, based on staff's review of up to five incidents, involved the victim deliberately climbing over the APBR. Section 6.2 of ASTM F3186 – 17 also includes a "structural integrity" requirement that calls for a 4-inch minimum height requirement for the APBR to extend over the top of the thickest recommended mattress. The minimum height requirement for APBRs may address fall incidents, by limiting the ability of consumers to climb

over these products. However, this requirement may not fully prevent consumers from falling, particularly those who deliberately climb over APBRs.

Entrapment Testing

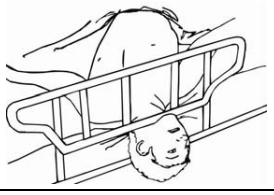
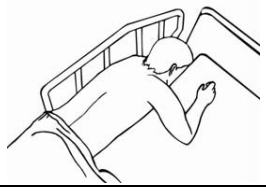
As stated, staff identified entrapment as the most prevalent hazard pattern among the incidents. In accordance with the entrapment test methods specified in section 8 of the standard, Section 6.3 of ASTM F3186 – 17 requires products to be tested to assess the potential for entrapment in four different zones in and around the APBR. These zones represent four of the seven sectors identified as potential areas of entrapment in hospital bed systems by the U.S. Food and Drug Administration (FDA), in its 2006 guidance document titled, Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment (FDA, 2006).[15] The guidance outlined in the document is based on recommendations from the Hospital Bed Safety Workgroup (HBSW), which was formed in 1999, to address reports of patient entrapment.[16]

Section 8.4 identifies the four entrapment zones tested under ASTM F3186 – 17. Entrapment testing in ASTM F3186 – 17 is performed using an "entrapment test probe," which is the cone and cylinder tool described in the 2006 FDA guidance document (Section 7.2). In addition, some entrapment zones require the use of a force gauge to test the force of the test probe (Section 7.3). Table 1, below, describes the four entrapment zones with illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

[15] The FDA guidance document is available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment. (FDA, 2016). Three of the zones identified in the FDA guidance (Zone 5, Zone 6, and Zone 7) were not applicable to APBRs, or could not be tested for entrapment under ASTM F3186-17, and therefore, they are excluded from the standard.

[16] The HBSW was formed by the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau, and representatives of national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers. The 2006 document includes a full list of HBSW participating organizations. The HBSW also worked in cooperation with the Joint Commission on Accreditation of Healthcare Organizations, the U.S. Centers for Medicare and Medicaid Services, and the U.S. Consumer Product Safety Commission to improve patient safety associated with the use of hospital beds.

Table 1: ASTM F3186 – 17 Entrapment Zones[17]

Zone 1: Within the Product Entrapment in any open space within the perimeter of the APBR	
Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress	
Zone 3: Between the Product and the Mattress Entrapment in the space between the inside surface of the APBR and the side of the mattress	
Zone 4: Between the Underside of the End of the Product and the Mattress Entrapment under the lowermost portion of the end of the APBR, against the mattress	

Staff's review of the rail entrapment incidents, test requirements, and test methods showed that almost all of the reported entrapment-related fatalities involved the four zones of an installed APBR that are tested for entrapment (Zones 1 through 4). Specifically, staff could determine the entrapment location in 166 of the 260 incidents, and all but six of these cases occurred in one of the four zones of entrapment tested in ASTM F3186 – 17, as shown below, in Table 2. Based on this analysis of the data, it seems reasonable to conclude that most rail entrapment incidents that could not be identified based on the provided information would also involve one of these four zones.

Table 2: Fatalities by Entrapment Location

Reported Rail Entrapment Location	Entrapment Test Location	No. of Fatalities
Between APBR and mattress	Zones 2, 3, or 4	157
Within APBR itself	Zone 1	3
Against outside of APBR	None	4
Between APBR and headboard	None	2
Unknown location	Unknown	60
Total		226

[17] The zone names in this table are taken directly from ASTM F3186 – 17.

Staff's finding that the preponderance of rail entrapments occur in Zones 1 through 4 is consistent with the FDA's finding that these four zones accounted for about 80 percent of entrapment events reported to the FDA associated with hospital bed systems.[15] This finding was the basis for the FDA recommending dimensional limits for these zones.

Staff Concerns with Performance Requirements

Although staff concludes that the ASTM F3186 – 17 performance requirements would adequately reduce the risk of injury and death associated with APBRs, staff believes that the language of some sections of the voluntary standard should be clarified to improve the likelihood that manufacturers will understand the requirements and test methods. The section 6.4.1 test requirement for finger openings refers to two different sets of diameters in two different unit systems. In addition, Section 6.3.3 states that for entrapment zone 3, the highest point on the cylinder of the test probe must remain at or above the uncompressed mattress plane. In contrast, section 8.4.5.4(2) states that a product shall fail the zone 3 entrapment test when the probe's center line is at or below the surface of the mattress. Accordingly, staff notes that these two requirements are inconsistent about the distance the test probe can travel, whether the entire height of the probe, or only half of the height. Figure 2 illustrates the difference between the requirements. Staff believes section 6.3.3 should be revised to refer to the probe's horizontal line, the halfway height. Consequently, on September 5, 2019, staff sent the chairman of the ASTM subcommittee a letter discussing these issues and proposed potential solutions.[18] Staff met with the ASTM subcommittee to review the letter on June 12, 2020. The subcommittee agreed that changes to the standard were needed, and indicated that working groups would be established after updated incident data is provided and analyzed.

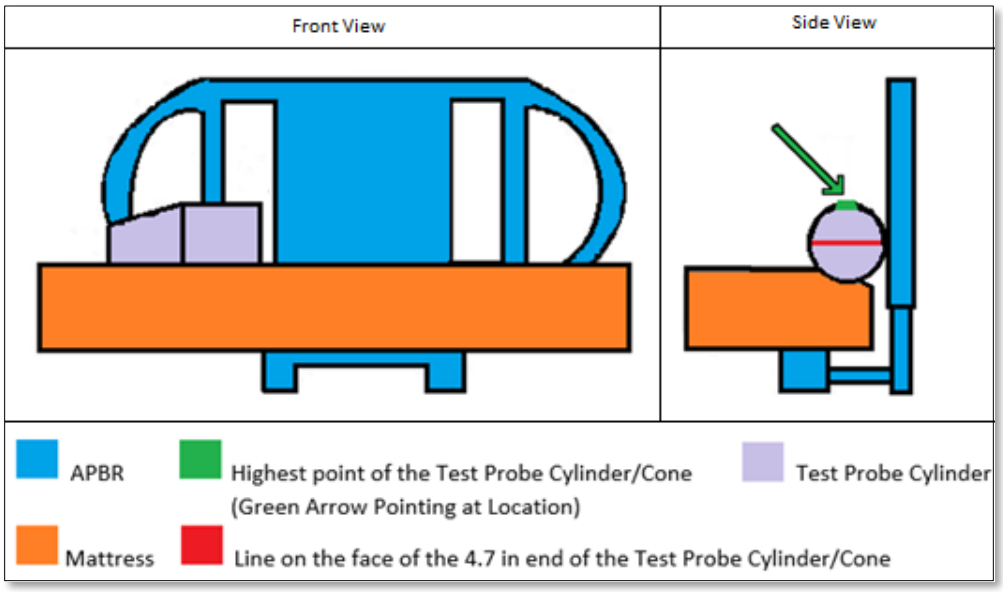


Figure 2: Zone 3 Entrapment Test, Section 6.3.3 and 8.4.5.4(2) requirement difference – Highest point of the Test Probe vs Line on the Test Probe

[18] Hall, Ian B. "Potential changes to ASTM F3186 – 17 Adult Portable Bed Rails," 5 September 2019. Attached in Appendix A: CPSC letter to ASTM Subcommittee Chairman.

LABELING, WARNING, AND INSTRUCTIONAL LITERATURE REQUIREMENTS

Section 9.1 specifies that the labeling on the APBR and its retail packaging, must be marked with the type and size of beds and mattresses, including the mattress thickness range, for which the APBR is intended, as well as specify the appropriate distance between an installed APBR and the headboard or footboard of the bed. This section also specifies that all on-product labels must be permanent.

Section 9.2 specifies requirements for warning statements that must appear on the APBR and its retail packaging, instructions, digital, or print advertising. The warning statements must be permanent; easy to understand; at least in English; and that any other labels or written instructions, provided in addition to those required by the standard, cannot contradict or confuse the meaning of the required warnings, or otherwise be misleading.

Section 11 specifies requirements for instructional literature, or "instructions," that must accompany APBRs. The instructions provided must be easy to read and understand; include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable; include drawings or diagrams to provide a better understanding of set up and operation of the product; must include drawings that depict all of the entrapment zones; and must include all warning statements specified in section 9.2, as well as additional warnings, if the product becomes damaged or misaligned.

CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF) staff found that compliance with the current standard would adequately reduce the risk of injury identified in the petition. Although staff found the standard to be adequate, staff has identified some areas of the standard that are confusing and inconsistent. These include confusing installation instruction requirements and inconsistent warnings. *See* Tab D. While staff believes that the standard as written would adequately reduce the risk of injury identified in the petition, staff believes that revising these confusing and inconsistent statements would improve the likelihood that manufacturers will comply with the standard. Thus staff intends to continue working with ASTM to further improve the standard and increase the likelihood of compliance with the standard.

STAFF'S ASSESSMENT OF MARKET COMPLIANCE TO ASTM F3186 – 17 [9,13,14]

CPSC staff tested 35 randomly selected APBR models for compliance to ASTM F3186 – 17. APBRs were purchased in Fiscal Year 2018 (FY18); F3186 was published and became effective in August 2017. LSM staff tested the products to determine conformance to the general requirements and the performance requirements of the standard. ESHF staff tested conformance to the labeling, warning, and instructional literature requirements. Staff found that none of the 35 sampled products conformed to the voluntary standard, indicating that compliance to the standard by the market as a whole was likely low when staff purchased the samples in 2018, after the standard had become effective. As shown below in Table 3, compliance varied by section of the standard; however, 33 APBR models did not meet the entrapment performance requirements, specifically, and all 35 did not meet the labels, warnings, and instructional literature requirements of the standard.

Table 3: ASTM F3186 - 17 APBR Market Compliance Testing Result Summary

Section		Title	# of Failed Samples (of 35 Total Samples Tested)	Failure Rate
General Requirements	5.1	Hazardous Points/ Edges	0	0%
	5.2	Jagged Surfaces	0	0%
	5.3	Articulated Beds	0	0%
Performance Requirements	6.1	Retention Systems	28	80%
	6.2	Structural Integrity	15	43%
	6.3	Entrapment	33	94%
	6.4	Openings	0	0%
	6.5	Misassembled Products	8	23%
Labels and Warnings Requirements	9.1	Labeling	35	100%
	9.2	Warning Statements	35	100%
Instructional Literature	11	Instructional Literature	35	100%

The entrapment hazard pattern is the most prevalent among the 260 reported incidents. Of the 35 APBR samples staff tested to assess the potential for entrapment in the four different zones in and around the APBR: 14 of 35 samples (40%) failed the Zone 1 entrapment requirements; 27 of 35 samples (77%) failed the Zone 2 entrapment requirements; 11 of 35 samples (31%) failed the Zone 3 entrapment requirements; and 6 of 35 samples (17%) failed Zone 4 entrapment requirements. Only 2 of 35 samples passed all of the Zone 1 through Zone 4 tests.

The results of staff's testing also revealed high failure rates in several other sections, including the retention system requirements (28 of 35 samples, or an 80% failure rate) and structural integrity requirements (15 of 35 samples, or 43%).

Retention system failures occurred when components were not permanently attached to the product, the retention strap permanently deflected or detached during the free end pull test, or the retention system did not restrain the product during entrapment testing.

Structural integrity failure occurred when the APBR did not extend at least 4 inches over the top of the thickest recommended mattress, or when fasteners loosened or detached during testing, causing the product to change dimensions.[19]

[19] Most products did not include a maximum recommended mattress height. In those cases, staff considered any mattress readily available to the general public. In addition, the voluntary standard requires all products to be tested fully assembled in accordance with the manufacturer's instructions; however, several did not specify or instruct the user how to set the product's adjustable features. In the absence of direction from the manufacturer, CPSC staff adjusted the product's height to the most onerous detent.

All 35 samples failed the labeling, warning, and instructional literature requirements. None of the 35 sample APBRs fully met the requirements of Section 9.1 for retail packaging and product labels. None of the 35 samples fully met the requirements under Section 9.2, which specifies that warning statements must appear on the product, its retail package, and its instructions. None of the 35 samples fully met the requirements under Section 11 to include instructional literature with required warning statements.

Although it is clear that the sample products purchased in 2018 do not comply with ASTM F3186 – 17, and it is likewise clear that market compliance most likely was not substantial when these samples were purchased, the question of whether the current products available on the market in 2020 substantially comply with the voluntary standard has yet to be determined. Because ASTM F3186 – 17 is a relatively new standard, and has only been in effect since August 2017, it is possible that some of the samples collected for conformance testing by staff in 2018 may not have been fully updated by manufacturers to comply with the new standard. Staff could not verify the manufacturing dates of many of the samples purchased in 2018, because most manufacturers did not include this information with the product, even though it is required by the 2017 standard. Furthermore, in 2018, EC staff distributed questionnaires to a non-statistical sample of six firms, of which five responded. At that time, four of the five firms indicated that they were familiar with the standard, but only one indicated that its products currently conformed.

As discussed, staff intends to continue participating in upcoming ASTM meetings to clarify the requirements and test methods in the standard. Staff will alert stakeholders to the importance of complying with the standard. In addition, Office of Compliance staff plan to contact manufacturers about their product's failure to conform to the standard. After taking these steps, staff plans to conduct a second round of market sample testing, to assess whether compliance levels have improved with time and increased awareness.

STAFF CONCLUSION

Based on the information provided in this briefing package, staff found the standard appears to be adequate to address the hazards with some further refinements needed to clarify testing details and labeling and instructional requirements. Given the lack of compliance to the standard in all tested samples, staff plans to continue to work with ASTM and the industry to increase market awareness of, and compliance with, the voluntary standard, and to report back once an additional round of testing is completed. Resources have been included in the development of the FY21 Operating Plan to reflect this follow-on work. Given current operational limitations, staff believes it would likely be able to provide an update to the Commission in FY22 with a recommendation on petition action.

TAB A:
MEMORANDUM BY THE DIRECTORATE FOR EPIDEMIOLOGY, DIVISION OF HAZARD ANALYSIS

United States
Consumer Product Safety Commission
Bethesda, MD 20814

Memorandum

DATE: July 15, 2020

TO: Vineed K. Dayal
Adult Portable Bed Rails Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Stephen Hanway
Associate Executive Director
Directorate for Epidemiology

Risana Chowdhury
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM: Angie Qin
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT: Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries[1]

INTRODUCTION

In 2013, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for adult portable bed rail (APBR) products. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

Since then, CPSC staff has worked with ASTM to develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

[1] This memorandum does not evaluate the addressability of the incidents, but rather, quantifies the number of fatalities and injuries reported to CPSC staff. If the date of incident or injury is not reported, date of entry is used.

In this memorandum, the Directorate for Epidemiology, Division of Hazard Analysis provides the statistics on deaths and injuries associated with, and it characterizes the types of hazard patterns related to, adult portable bed rails. The counts are based on reports CPSC staff received for incidents that occurred from January 2003 to December 2019. The memorandum also includes the estimated number of emergency department-treated injuries from January 2003 to December 2019.

The ASTM International (ASTM) voluntary standard for adult portable bed rails is F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. According to the voluntary standard's definition, an "adult portable bed rail" is a product that is not designed as part of the bed by the bed manufacturer, and is installed on, against or adjacent to the side of an adult bed and is for use by adults to reduce the risk of falling from the bed, assist in repositioning in the bed, assist in transitioning into or out of the bed, or other similar purposes as stated by the manufacturer. Adult portable bed rails that meet the definition of a "medical device" are under the jurisdiction of the U.S. Food and Drug Administration (FDA), and adult portable bed rails that are not classified as "medical devices" fall under the jurisdiction of CPSC. In this memorandum, CPSC staff limited the data to non-medical devices; staff excluded incidents specifying hospital or commercial beds. Staff also limited the data to cases reporting user age to be 13 years or older; and excluded incidents specifying children's bed rails.

INCIDENT DATA[2]

CPSC staff received data on 260 incidents, which included 247 fatalities and 13 nonfatal incidents related to adult portable bed rails that occurred from January 2003 to December 2019, and that were reported from January 2003 to March 2020. The majority (92%) of the reports comprised death certificates and medical examiner/coroner reports. These reports contain limited information on the incident scenarios. The remaining reports were submitted to CPSC staff through various sources, such as newspaper clippings, consumer reports, and reports from retailers and manufacturers. Staff identified and removed possible duplicate incident reports. The victims' ages ranged from 14 to 103 years. There were 14 incidents (5%) with unknown or unreported age information. The reporting is ongoing, especially for 2017 through 2019. The number of reported fatalities, injuries, and noninjury or "injury not reported" incidents, may change in the future.

[2] Staff searched CPSC databases in the Consumer Product Safety Risk Management System (CPSRMS). These reported deaths and incidents are not a complete count of all that occurred during this time period. However, the data do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to adult portable bed rails.

Staff extracted all data coded under product code 4075 for patients ages 13 years or older or with unknown age. Product code 4075 included both portable and fixed bed rails. Upon careful joint review by Laboratory and Health Sciences staff, staff considered some cases out of scope for purposes of this memo. Staff excluded cases specifying hospital bed, bed with fixed railings, and incidents occurring in hospitals. Medical condition and injury location categories were reviewed jointly with Health Sciences staff.

FATALITIES

There were 247 fatal adult portable bed rail-related incidents that occurred from January 2003 to December 2019, and that ultimately were reported from January 2003 to March 2020. Table 1 presents the distribution of the incidents by year.

Table 1. Distribution of Reported Adult Portable Bed Rail-Related Incidents by Year
1/1/2003 to 12/31/2019

Year of Incident*	**Fatalities**	**Non-Fatalities**
2003	14	0
2004	23	0
2005	19	0
2006	24	1
2007	18	1
2008	16	0
2009	8	1
2010	10	0
2011	9	0
2012	9	0
2013	17	1
2014	9	2
2015	10	1
2016	11	2
2017	*30*	*0*
2018	*11*	*2*
2019	*9*	*2*
Total	247	13

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS)

* If the date of incident is not reported, the date reported to CPSC is used.
Note: Data in italics indicate reporting is ongoing for 2017−2019.

The fatality victims' ages ranged from 14 to 103 years old. The majority of the decedents were age 80 and over (Table 2).

Table 2. Distribution of Reported Adult Bed Rail-Related Incidents by Age
1/1/2003 to 12/31/2019

Age	Fatalities	Non-Fatalities
13 to 29 years	6	0
30 to 59 years	26	0
60 to 69 years	17	0
70 to 79 years	40	1
80 to 89 years	95	1
90 years and over	60	0
Not reported	3	11
Total	247	13

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

Of the fatal incidents, there were 226 (91%) related to rail entrapment, 19 (8%) related to falls, and two related to miscellaneous other issues, such as strangulation due to clothing getting caught on the bed rail.

About half of the incidents occurred at home. The remaining incidents occurred at nursing homes, assisted living facilities, hospice facilities, and "other," or unspecified locations. Table 3 presents the distribution of the incidents by injury location.

Table 3. Distribution of Reported Adult Portable Bed Rail-Related Incidents by Injury Location
1/1/2003 to 12/31/2019

Injury Location	Fatalities	Non-Fatalities
Home	129	2
Nursing home	40	0
Assisted living facility	29	1
Hospice	4	0
Other*	24	0
Not reported	21	10
Total	247	13

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

*Other category included a care home, a residential institution, a foster home, a group home, a retirement center, a rehab center, and an adult family home.

Of the fatal incidents, more than half indicated that the victim had an underlying medical condition, and 78 incidents (32%) indicated that the victim had multiple medical conditions. Table 4 shows the breakdown of the incidents by the primary, or most severe, reported pre-existing medical condition.

Table 4. Distribution of Reported Adult Portable Bed Rail-Related Incidents by Medical Conditions*
1/1/2003 to 12/31/2019

Primary Medical Conditions	Fatalities	Non-Fatalities
Cardiovascular disease	52	0
Alzheimer/dementia/mental	23	0
Mobility/paralysis/stroke	14	0
Parkinson's	10	1
Pulmonary disease	7	0
Cerebral palsy	6	0
Cancer	5	0
Multiple sclerosis	4	0
Other**	16	0
Not reported	110	12
Total	247	13

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

* For patients with multiple medical conditions, staff used the primary or the more severe condition.
** Other category included tracheotomy and G-tube, severe burn, post-surgery, fracture, seizure, Lesch–Nyhan syndrome, amyotrophic lateral sclerosis, multiple drug ingestion, renal disease, depression, diabetes, sepsis, and general weakness.

NONFATAL INCIDENTS

There were 13 nonfatal, adult portable bed rail-related incidents that occurred from January 2003 to December 2019. Of the nonfatal incidents, eight incidents were related to structural issues of the bed rail, such as breakage of the bed rail weld, or the bed rail not being sturdy. One incident was related to a fall. The remaining four incidents were categorized as miscellaneous incidents, including reports involving a misleading label, a noncompliant bed rail, an unspecified manufacturer-related issue, and one wrist injury resulting from a radial nerve pinching against the bed rail. This category included one knee fracture, one wrist injury, one laceration, three unspecified injuries, and seven noninjury incidents and complaints.

HAZARD PATTERNS

CPSC staff reviewed all 260 incidents, fatal and nonfatal, to identify hazard patterns associated with adult portable bed rails. The hazard patterns were grouped into four categories. The category list is ordered from the highest frequency of occurrence to the lowest.

A. *Rail entrapment:* There were 226 incidents related to rail entrapment. This category includes incidents in which the victim was caught, stuck, wedged, or trapped between the mattress/bed and the bed rail, between bed rail bars, between a commode and rail, between the floor and rail, or between a dresser and rail. Based on the narrative, the most frequently injured body parts were the neck and head. All incidents were fatal.

B. *Falls:* There were 20 incidents related to falls. This category includes incidents in which the victim fell and hit the bed rail, fell after climbing over the bed rail, and other similar scenarios. This category includes 19 deaths and one nonfatal knee fracture.

C. *Structural integrity:* There were eight incidents related to structural component problems (*i.e.*, weld of bed rail broke, or bed rail not sturdy). This category includes one laceration, two unspecified injuries, and five noninjury incidents.

D. *Miscellaneous:* There were six miscellaneous incidents and non-incident complaints (two incidents where the victim died from hanging on the bed rail after a garment got caught, one wrist injury resulting from a radial nerve pinching against the bed rail, a complaint about a misleading label, a complaint about a bed rail that was noncompliant with the ASTM standard, and a claim against a bed rail manufacturer about an unspecified issue). This category includes two deaths, one wrist injury, one unspecified injury, and two noninjury incidents.

The distribution of Incidents by Hazard Type is shown in Table 5.

Table 5. Distribution of Reported Adult Portable Bed Rail-Related Incidents by Hazard Type
1/1/2003 to 12/31/2019

Hazards	Fatalities	Non-Fatalities
Rail entrapment	226	0
Falls	19	1
Structural integrity	0	8
Miscellaneous	2	4
Total	247	13

Source: CPSC epidemiological databases in the Consumer Product Safety Risk Management System (CPSRMS).

NATIONAL INJURY ESTIMATES[3]

There were an estimated 69,300 adult bed rail-related injuries (sample size=1,702, coefficient of variation=0.07) that were treated in U.S. hospital emergency departments from January 2003 to December 2019 (Table 6). There was no statistically significant trend observed from January 2003 to December 2019 (p value=0.41). However, in many NEISS cases, there was insufficient

[3] The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid injury surveillance system. NEISS injury data are gathered from emergency departments of hospitals selected as a probability sample of all U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable the CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.

Staff extracted all data coded under product code 4075 for patients ages 13 years or older. Product code 4075 included both portable and fixed bed rails. Staff excluded cases specifying hospital beds and commercial hotel beds. Staff also excluded cases involving bed rail injuries resulting from playing, running, and tripping. However, in many cases, there was not enough information to determine whether the bed rail in question was an adult portable bed rail or another type of bed rail, or whether the injury involved an activity, such as playing, running, or tripping. Consequently, the NEISS estimate may be overstated.

information available to determine whether the incident involved an adult portable bed rail or a fixed bed rail.

Table 6. Adult Bed Rail-Related Injury Estimates by Year
1/1/2003 to 12/31/2019

Year	Cases	Estimates
2003	98	4,500
2004	82	3,400
2005	94	3,900
2006	72	3,400
2007	98	4,300
2008	102	4,200
2009	98	3,600
2010	100	4,000
2011	95	3,700
2012	81	3,100
2013	127	4,700
2014	108	4,400
2015	112	4,600
2016	91	3,700
2017	128	4,900
2018	104	4,300
2019	112	4,500
Total*	1,702	69,300

Source: National Electronic Injury Surveillance System (NEISS)

*Columns may not sum to totals due to rounding.

No deaths were reported through NEISS. The data included an age range from 13 to 103 years old. The injuries were distributed fairly evenly among age groups. Thirty percent were 80 years and older; 22 percent were 60 to 79 years old; 30 percent were 30 to 59 years old; and 17 percent were younger than 30 years old. Most of the injured (89%) were treated and released. The injury characteristics that occurred most frequently:

- Injured body part – head (18%), foot and toe (15%), lower leg (12%), upper trunk (9%)
- Injury type – contusions/abrasions (29%), laceration (26%), fracture (13%).

COMPLIANCE WITH ASTM STANDARD

To assess the compliance of adult portable bed rails with the new ASTM voluntary standard, CPSC staff considered sampling and testing all known adult portable bed rail models (per CPSC's Directorate for Economic Analysis staff,[4] 66 currently in the market). This is the first

[4] The Amazon.com model listed as "not available" was excluded from this sampling evaluation.

sample set of compliance testing completed by CPSC staff with the current voluntary standard. Given that no prior testing data are available regarding the compliance proportion, staff considered a range of possible compliance percentages for 95 percent confidence intervals, with two possible precision levels: 0.1 and 0.15. Considering the resource limitations, EPHA staff recommended using a sample size of 35 and precision 0.15 to perform the compliance testing. Because of the lack of information, staff considered a simple random sample to be the best option for a representative sample.

Based on the CPSC's Directorate for Laboratory Sciences staff test results, the proportion of fully compliant models in the market is zero. All samples failed the mechanical and label tests. EPHA staff concludes that there was not significant compliance with the new voluntary standard for adult portable bed rails at the time the samples were purchased.[5]

[5] Using Binomial test, p-value was <0.05. The conclusion is limited to the list of bed rails that were identified by ECON.

TAB B:
MEMORANDUM BY THE DIRECTORATE FOR ECONOMIC ANALYSIS

United States
Consumer Product Safety Commission
Bethesda, MD 20814

Memorandum

DATE: July 15, 2020

TO: Vineed K. Dayal
Adult Portable Bed Rails Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Gregory B. Rodgers
Associate Executive Director
Directorate for Economic Analysis

FROM: Robert Franklin
Senior Staff Coordinator
Directorate for Economic Analysis

Bretford Griffin
Economist
Directorate for Economic Analysis

SUBJECT: Market for and Societal Cost of Injuries Associated with Adult Portable Bed Rails

BACKGROUND

In 2013, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for adult portable bed rail (APBR) products. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

Since then, CPSC staff has worked with ASTM to develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

In this memorandum, the Directorate for Economic Analysis updates the market information that was provided in staff's briefing package in 2014, regarding adult portable bedrails and the societal cost of injuries associated with the product.

MARKET FOR ADULT PORTABLE BEDRAILS

According to the petitioners, the APBRs of concern include side rails, split rails, half rails, bed handles, full-length rails, bed canes, and similar products sold and marketed directly to the public and intended to be used with a home bed, rather than a hospital bed.[1] Generally, these products are advertised and marketed as (1) rails intended to prevent consumers from falling out of bed, or (2) assistive devices intended to aid weak or unsteady consumers with getting in and out of bed or repositioning within the bed. Some APBRs claim to serve both functions.

In 2018, during the months of January and February, CPSC staff conducted an online search to identify manufacturers and importers of adult portable bed rails.[2] We identified 15 firms that either manufactured or imported a total of 66 unique APBR models.[3] This number is down only slightly from 2014, when we identified a total 16 suppliers and 74 unique models. The retail prices of the models we identified ranged from $35 to $250, with a median price of about $104.

To obtain additional information about the market for APBRs, and to assist CPSC staff in assessing whether there might be substantial compliance with the voluntary standard, between January and February 2018, we distributed questionnaires to a nonstatistical sample of six firms, and five responded. Based on their responses, we believe that the five responding firms might account for 60 percent to 85 percent of the APBR market. Using information obtained from the five firms on estimates of their own market share and revenue, along with estimates obtained from ReferenceUSAGov (2018), we believe that a very rough estimate of the wholesale and direct-to-consumer APBR market in the United States could be between $14 million and $22 million. Using reasonable estimates of the price of APBRs, this suggests that between 90,000 and 425,000 APBRs are sold annually.[4]

VOLUNTARY STANDARD

To find evidence on whether there was substantial compliance in the market, between January and February of 2018 we contacted five firms to learn whether they were familiar with the ASTM standard, whether they believed their products conformed to the standard, and whether they believed other suppliers would conform to the standard. Four firms indicated that they were familiar with the standard, but only one indicated that their products currently conform. Two indicated that some modifications must be made to bring their products into compliance. Two of the firms expressed some uncertainty about whether they would put the warning labels required by the voluntary standard on the product. One firm expressed concern that if they applied the

[1] Bed rails designed for use on hospital beds are considered medical devices and are under the jurisdiction of the U.S. Food and Drug Administration (FDA).
[2] The staff conducted the search using Google and employed terms such as: adult portable bed rail, bed rails, and portable rail in singular and plural forms.
[3] We observed that several APBR models that were essentially the same model (e.g., same supplier and specifications) could be marketed across multiple channels, but under different names. To accurately enumerate APBR models, we considered all APBRs that appeared to have the same supplier and same specifications to constitute one unique model even though the model might be offered under multiple names or brands.
[4] We assumed that the actual average price was between $52 (one-half of the median price of $104) and $156 (1.5 times the median price). The estimated sales were obtained by dividing the low-revenue estimate by the high price and the high-revenue estimate by the low price. We emphasize that this is a rough estimate of the annual unit sales, and therefore, the estimate should be used cautiously.

required warnings to their product, and some other firms did not, they would lose market share because consumers would believe erroneously that their products were more hazardous than competing APBRs that do not carry the warning labels. When asked whether they believe most APBR manufacturers would conform to the voluntary standard, only one firm expressed the belief that at least 90 percent of the market would conform. Based on these responses, we could not find evidence that there would be substantial compliance with the voluntary standard. To provide the Commission with evidence that could support or reject a conclusion of substantial compliance, staff decided to collect and test a representative sample of APBR models on the market. Staff discusses the results of this analysis in the Laboratory Sciences memo (Dayal, 2020) (TAB E) and the Human Factors memo (Smith and Talcott, 2020) (TAB D).

SOCIETAL COST OF INJURIES

Fatalities

CPSC staff is aware of 247 fatal injuries associated with adult portable bed rails that occurred during the period January 2003 through December 2019, or at an average of about 14.5 fatalities a year (Qin, 2020).[5] Although some victims may have been as young as 13 years old, 79 percent were over the age of 70.The societal costs associated with these fatalities is estimated by applying the value of a statistical life (VSL) to the estimated deaths (OMB, 1993). The VSL is a measure of the amount people are willing to pay for a small reduction in risk of death, but it is not a measure of the value of a life.[6] CPSC staff is following the U.S. Environmental Protection Agency's (EPA) recommendation regarding the value of a statistical life, which is based on a number of studies using the "willingness to pay" methodology. EPA recommends using a VSL of $7.4 million in 2006 dollars in their analyses. EPA also recommends that the VSL be adjusted for price levels, using the Consumer Price Index, All Urban Consumers (CPI-U) for all goods and services, or the GDP deflator (EPA, 2014). Using the CPI-U, one obtains a VSL of $9.3 million in 2018 dollars. Consequently, the societal cost of the deaths associated with adult portable bed rails is about $135 million annually (an average of 14.5 deaths × $9.3 million).

Nonfatal Injuries

We used CPSC's Injury Cost Model (ICM) to estimate the societal costs of nonfatal injuries. The ICM is fully integrated with NEISS and uses information in the NEISS case records to estimate the cost of injuries initially treated in a hospital's emergency department (ED). In addition to injuries treated in EDs, the ICM uses empirical relationships between the characteristics of injuries and victims initially treated in hospital EDs, and those initially treated elsewhere, to estimate the number of medically attended injuries treated outside of hospital EDs, such as in physician's offices, urgent care centers, or that were admitted directly into a hospital bypassing the ED (Lawrence et al., 2018). It also estimates the societal cost of these injuries. Therefore, the

[5] Because the reporting is still ongoing for the years 2017 through 2019 the average number of deaths per year during this period could increase.

[6] For example, if 100,000 people, on average, were willing to pay $90 more for a product that reduced the probability of death by 1 in 100,000 people, then summing up the values that those 100,000 people would pay is $9 million to prevent 1 statistical death among the 100,000 people.

ICM produces comprehensive national estimates of both the number and societal costs of all medically attended injuries.

The ICM breaks the societal cost estimates into three major components: medical costs, work losses, and the intangible costs associated with lost quality of life or pain and suffering. Medical costs include both the short-term and long-term costs of medical services required to treat an injury victim. Costs associated with lost work include the forgone earnings by the victim (including paid employment and household work), the lost work of friends and family members in caring for or visiting the injury victim, and the cost to employers that results from the need to rearrange schedules or recruit replacement workers for those who have been injured (or are caring for family members who have been injured). The final component is the cost of pain and suffering. This component represents the intangible costs of injury and reflects physical and emotional trauma of injury, as well as the mental anguish of victims and caregivers. Estimates for pain and suffering are based on a regression analysis of jury awards for pain and suffering in nonfatal product liability cases. For greater detail on the methodology and databases used in the ICM, see Lawrence et al. (2018).

The NEISS product code for bed rails is 4075, which includes adult portable bed rails and other types of bed rails outside the scope of the product hazard. To produce statistical injury estimates, staff extracted all NEISS records coded under product code 4075 for patients age 13 years or older, and then removed other bed rail types and injuries believed to be outside the scope of the product hazard. The cases that were excluded involved fixed bed rails, bed rails designed for use on hospital beds, bed rails designed for use on commercial hotel beds, and bed rail injury cases resulting from playing, running, and tripping. Even with these exclusions, in many cases, there was not enough information in the NEISS record to determine whether the bed rail in question was an APBR, or whether the injury involved an activity, such as playing, running, or tripping. Consequently, there may be significant overestimates of the actual values.

The Directorate for Epidemiology reports NEISS estimates of approximately 69,263 possible adult portable bed rails injuries initially treated at hospital emergency departments between 2003 and 2019. Although some of these victims could have been as young as 13 years of age, most were over the age of 70 years. This figure includes 62,403 injuries where the victim was released after treatment and another 6,861 injuries where the victim was subsequently admitted to the hospital. Using the ICM, staff estimates that there were another 127,585 non-ED-treated injuries believed associated with APBR use from 2003 through 2019. This includes an estimated 125,608 injuries treated at outpatient facilities, such as doctor's offices or clinics, as well as another 1,977 victims treated through direct admission to the hospital. The total injured victims treated comes to about 196,848 over the 17 years, or approximately 11,579 per year.[7] These cases resulted in societal costs, on average, of about $28,399 per case. This includes $3,300 in medical costs, $4,100 in costs from work losses, and $21,000 in pain and suffering costs per incident. Thus, using the NEISS cases identified as possibly involving APBRs, the average annual cost of these injuries, from 2003 through 2019, was about $329 million. However, as noted, in many cases, there was not enough information in the NEISS record to determine whether the bed rail in

[7] The ICM is fully integrated with NEISS and uses empirical relationships between the characteristics of injuries and victims initially treated in hospital EDs and those treated elsewhere, to estimate the number of medically attended injuries treated outside of hospital EDs

question was an APBR, or involved an injury that could be addressed by the subject voluntary standard. Therefore, this societal cost estimate may be a significant overestimate.

In sum, annual societal costs of fatal and nonfatal APBR injuries may be as much as $464 million per year ($135 million in fatalities + $329 million in nonfatal injuries). This total too may be an overstatement depending on the degree to which nonfatal costs are lower than estimated.

SUMMARY

We found that 15 firms supply about 66 unique models of adult portable bed rails. Based upon market share information obtained from a few firms, estimates of revenue, and the observed prices, we believe that the number of adult portable bed rails sold annually is between 90,000 and 425,000. We solicited information from a nonstatistical sample of firms to find evidence of whether there would be substantial compliance with the voluntary standard. The information obtained, however, did not allow us to conclude that there would be substantial compliance with the voluntary standard.

An average of 14.5 fatalities involving adult portable bed rails occur annually. Although some victims were as young as 13 years of age, the majority were over the age of 70 years. The societal cost of fatal APBR injuries results in about $135 million annually. The injury cost model estimates 11,579 nonfatal APBR injuries occur annually, costing society $329 million, for a total of $464 million in fatal and nonfatal injury costs per year. However, societal cost estimates may be overstated, if the NEISS estimates for APBR-related injuries contain other types of bed rails and injuries not associated with the product hazard at issue. The degree to which these societal costs will translate into societal benefits of the standard will depend on compliance with the standard, as well as the effectiveness of the standard at mitigating the estimated injuries and their resulting injury cost.

REFERENCES

Environmental Protection Agency. (2014). Appendix B: Mortality Risk Valuation Estimates, in *Guidelines for Preparing Economic Analysis*. National Center for Environmental Economics, U.S. Environmental Protection Agency. url: https://www.epa.gov/sites/production/files/2017-08/documents/ee-0568-50.pdf.Dayal, V. (2020) *Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails.* CPSC Memorandum to Vineed Dayal, Adult Portable Bed Rails Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD. (TAB E.)

Lawrence, B., Miller, T., Waehrer, G., Spicer, R., Cohen, M., Zamula, W. (2018) The *Consumer Product Safety Commission's Revised Injury Cost Model*. Pacific Institute for Research and Evaluation, Calverton, MD 20705–3111, available at: https://www.cpsc.gov/s3fs-public/ICM-2018-Documentation.pdf?YWuW4Jn0eb2hExeA0z68B64cv6LlUYoE.

Office of the Management and Budget, 2003. *Circular A-4*. White House, 1600 Pennsylvania Ave NW, Washington, DC 20500. Published September, 17 2003, url:

https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/regulatory_matters_pdf/a-4.pdf.

Qin, A. (2020) *Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries: January 2003 to December 2019*. CPSC Memorandum to Vineed Dayal, Adult Portable Bed Rails Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD. (TAB A.)

ReferenceUSAGov (2018) *U.S. Businesses Database: Query on Adult Portable Bed Rail Suppliers.* Infogroup, 1020 E. 1st, Papillion, NE 68046. Accessed February 2018.

Smith, T. P. and Talcott, K. A. (2020) *Human Factors Assessment of ASTM F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard.* CPSC Memorandum to Vineed K. Dayal, Project Manager, Adult Portable Bed Rails Petition, U.S. Consumer Product Safety Commission, Rockville, MD. (TAB D)

TAB C:
MEMORANDUM BY THE DIRECTORATE FOR HEALTH SCIENCES, DIVISION OF PHARMACOLOGY AND PHYSIOLOGY ASSESSMENT

United States
Consumer Product Safety Commission
Rockville, MD 20814

Memorandum

DATE: July 15, 2020

TO: Vineed K. Dayal
Adult Portable Bed Rails Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Michael Babich, Ph.D.
Acting Associate Executive Director
Directorate for Health Sciences

FROM: Suad Wanna-Nakamura, Ph.D. Physiologist
Division of Pharmacology and Physiology Assessment

SUBJECT: Health Sciences Assessment for Petition CP 13-1, Requesting a Ban or Standard for Adult Portable Bed Rails

INTRODUCTION

In 2013, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for adult portable bed rail (APBR) products. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

In August 2017, ASTM International (ASTM) published a voluntary standard (F3186 – 17) for "Adult Portable Bed Rails and Related Products." CPSC staff is assessing the adequacy of the voluntary standard's requirements and industry's conformance to the standard. This memorandum provides information on hazard patterns and related injuries.

BACKGROUND AND PRODUCT DESCRIPTION

ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, describes "portable bed rails and related products" as products installed by consumers and "not designed as part of the bed by the bed manufacturer." These products are used to reduce the risk of falling from the bed, and to assist users in getting in/out of bed, as well as sitting and repositioning in the bed (Figure 1).

Figure 1. Examples of adult bed rails and grab bar images copied from various retailer and manufacturer websites.

Side rails and grab bars can be similar in design and overall shape and are secured to the side of the bed primarily by two base rails, angled perpendicular to the main rail or bar, that slide between the mattress and box springs (Figure 2). Others have attachments that are product-specific. Although similar in design, these products may have different functions. Some designs are meant to keep the occupant from rolling out of bed, and others are intended by the manufacturer to assist an occupant in getting in or out of bed, and moving, and repositioning on the bed surface.

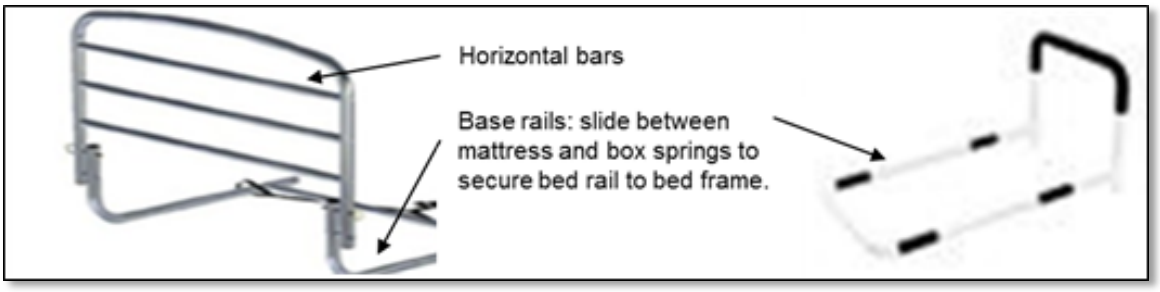


Figure 2. Bed rail components

Some products can serve both functions. Because of the similarity in design and mechanism of attachment to the side of the bed, both products pose the same potential entrapment hazards.

Health Sciences (HS) staff has identified three sites where entrapments have occurred. Listed in order of prevalence, the three sites are: (1) in gaps between the mattress and side rail, with victim's face pressed against the mattress or in a downward position, and their neck resting on the lower bar—this is the most common entrapment zone (Figure 3, zone # 3); (2) in openings within, or under the horizontal bars of the side rail, which can lead to neck compression (Figure 3, zones # 1, 2, & 4); and (3) in the space between the headboard/footboard and vertical end bar of the side rail (Figure 3, zone # 6), which is the least-prevalent entrapment zone, most likely involving only two of the 247 bed rail-related deaths. Upper body entrapment, between the mattress and rail after sliding out of bed, can lead to positional asphyxia by neck flexion and

compression between the rails or chest compression. Similar entrapments in hospital beds have been reported in the literature (US FDA, 2006 and Miles and Parker, 1998).

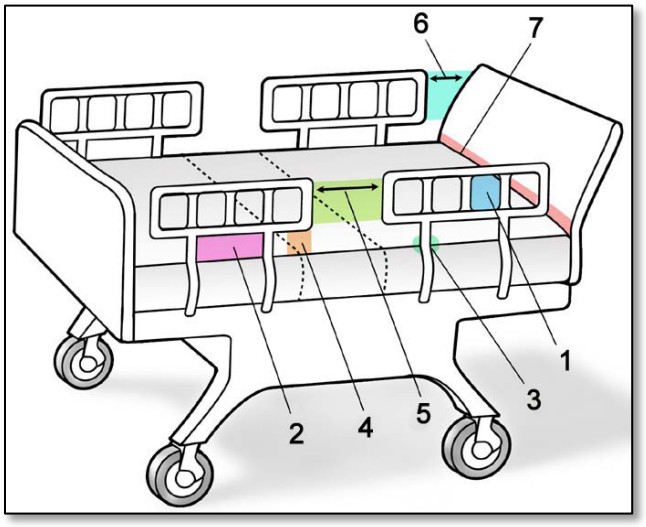


Figure 3. Image source U.S. Food and Drug Administration (FDA).[1]

INCIDENT DATA

The Directorate for Epidemiology Division of Hazard Analysis (EPHA) staff conducted searches of CPSC databases in the Consumer Product Safety Risk Management System (CPSRMS) for the period January 2003 to December 2019 (Qin, 2020, Tab A). EPHA staff identified a total of 260 incident reports for this period. Of these, 247 were reports of fatalities, and 13 were incidents reporting noninjuries or "injury not reported." CPSC staff conducted 30 In-Depth Investigations (IDIs), with 10 of the 30 IDIs terminated after attempts to reach the consumer failed. All deaths were unwitnessed and appear to have occurred while the victim was in bed. The majority of the incidents (89%) were identified from death certificates, medical examiner reports, and coroner reports. The remaining incidents were extracted from newspaper clippings, consumer reports, and manufacturer and retailer reports to CPSC. These documents contained limited information on incident scenarios for staff to assess actual causes. The age range of victims in the 247 fatal incidents was 14 to 103 years, with most fatalities involving adults ≥ 80 years (155 of 247), and the vast majority of fatal incidents involving adults ≥ 70 years (195 of 247) (see Table 1).

[1] Zone identification: 1. Within the rail, 2. Under the rail, between the rail supports or next to a single rail support, 3. Between the rail and the mattress, 4. Between the rail, at the ends of the rail, 5. Between split bed rails, 6. Between the end of the rail and the side edge of the head or foot board, 7. Between the head or foot board and the mattress end. https://www.fda.gov/consumers/consumer-updates/practice-hospital-bed-safety, last accessed March 2020.

Table 1. Distribution of Reported Adult Bed Rail-Related Fatalities by Age 1/1/2003 to 12/31/2019

Age	Fatalities
13 to 29 years	6
30 to 59 years	26
60 to 69 years	17
70 to 79 years	40
80 to 89 years	95
90 years and over	60
Not reported	3
Total	247

Source: Qin, A., Tab A Table, 2, modified for fatal incidents only

HS staff jointly reviewed and analyzed the incident data with EPHA staff for medical condition and injury location categories. EPHA staff extracted all data under product code 4075 for patients age 13 years or older; staff found that 226 of the fatal 247 incidents (91%) were related to body entrapment, including cases in which the victim was entrapped between the bed rail bars. Staff also identified 19 fatal incidents (8%) related to falls, and two miscellaneous strangulations due to clothing entanglement in the bed rail (Qin, 2019; Tab A, Table 5). In about half of the reported fatalities, the victim's condition was not reported, while in the other half of reported fatalities, the victims had a preexisting chronic medical condition, such as cardiovascular disease, Alzheimer's disease/dementia/other mental limitations, seizures, strokes, mobility limitations or paralysis, Parkinson's disease, cerebral palsy, multiple sclerosis, cancer, or pulmonary disease. Moreover, many victims had multiple disorders. The list of reported disorders included patients with a tracheotomy and G-tube (feeding tube), severe burns, fractures, seizures, Lesch–Nyhan syndrome,[2] amyotrophic lateral sclerosis, multiple drug ingestions, renal disease, depression, and general weakness or heavy sedation (*i.e.*, factors that limit mobility and mental acuity). Patient entrapments happened in private homes and in patient-care settings (*e.g.*, hospice, assisted living, or long-term care facilities).

A review of the 20 completed IDIs confirmed that product types similar to those in Figure 1 were involved in one or more incidents. The victim was typically found with their torso between the product and the mattress frame, with their neck resting on the lower bar (14 out of the 20 incidents). Two other hazard patterns were also reported: (1) chin resting on the bar; and (2) patient slumped backwards, partially suspended with the thorax lodged and compressed in the gap between the rail and mattress (Figure 4). The cause of death in this latter case was listed as "positional asphyxia," with an additional list of "underlying factors" or "contributory causes."

[2] A rare genetic disease characterized by neurological and behavioral abnormalities and occurs almost exclusively in males.

Figure 4. Images showing areas and manner of entrapment; red arrow depicts where the victim's neck was resting when found Source: IDIs.

HS staff's analysis of all the data revealed that the head or neck was the body part most frequently entrapped, with positional asphyxia (neck against rail) identified as the most common cause of death. Sustained external pressure on the neck can lead to "asphyxia," defined in the literature as the failure of cells to thrive in the absence of oxygen. Neck compression, with or without airway blockage, can result in death, even when the body remains partially supported. This deprivation can be partial (hypoxia), when there is an inadequate oxygen supply to the lungs, or total (anoxia), when there is total impairment of oxygen transport to tissues, often accompanied by carbon dioxide retention. A reduction of oxygen delivery rate (per unit time) to the tissue can result in tissue injury and permanent, irreversible damage (Feldman, 1980). The brain is particularly sensitive to oxygen deprivation and is the most affected organ (DiMaio VJ, DiMaio D., 2001; Spitz, 2006; Oehmichen et al., 2005; Saukko, and Knight, 2004; Shapiro, G, 1982; McNie, 1980; Adams et al., 2006; and Saukko and Knight, 2004). Blood vessels, taking blood to and from the brain, and the carotid sinuses are located in soft tissues of the neck and are relatively unprotected. Compression of either the jugular veins or the carotid arteries can lead to death (Hoff, 1978; Iserson, 1984; and Polson, 1973). The amount of force required to cause mechanical vascular occlusion and blockage of blood flow is small, because compression of the jugular veins in the neck requires as little as 2 kg (4.4 pounds) of force (Brouardel, 1897; Iserson, 1984).

CONCLUSION

HS staff evaluated the possible role that bedrails may have played in entrapment deaths. For most of the deaths, there is limited information available describing how the victims became entrapped, and most of the incidents appear to have been unwitnessed. The death certificates provided little detail. Although information related to the incident scenarios is limited or lacking to reach firm conclusions on events leading to entrapment, HS staff believes that in most of these cases, the cause of death is asphyxia due to entrapment, as determined by the medical examiner or coroner.

There are a number of factors to be considered in such an evaluation. The vast majority (195/247) of the fatalities involving APBR entrapment were adults 70 years and older. This is a potentially vulnerable population associated with an overall progressive decline in muscle strength, balance, and cognitive abilities. This population is also increasingly susceptible to a variety of ailments prevalent among the elderly. In addition to these age-related issues, more than half of the entrapment victims had other serious risk factors, physical and/or neurological in nature, which would have increased their vulnerability and risk of entrapment and falls. Because of these factors, users often are unable to self-rescue, if entrapped. In some reported instances, bedrails may have been installed improperly, which led to life-threatening entrapment when the victim was not rescued in time.

REFERENCES

Adams VI, Flomenbaum MA, Hirsch CS. Trauma and disease. In: Spitz WU, Spitz DJ, editors. Spitz and Fisher's medicolegal investigation of death: guidelines for the application of pathology to crime.

DiMaio VJ, DiMaio D. Asphyxia. In: Geberth VJ, series editor. Forensic pathology, 2nd edn. Boca Raton, FL: CRC Press, 2001:229–77.

Gordon I, Shapiro HA. Deaths usually initiated by hypoxic hypoxia or anoxic anoxia. In: Gordon I, Shapiro HA, editors. Forensic medicine: A guide to principles, 2nd ed. Edinburgh, UK: Churchill Livingstone, 1982; 95–129.

Hoffman SB, Powell-Cope G, MacClellan L, Bero K. BedSAFE. A bed safety project for frail older adults. J Gerontol Nurs. 2003 Nov: 29(11):34-42.

Iserson, KV. Strangulation: A review of ligature, manual, and postural neck compression injuries. Ann. Emerg. Med. 13:179-185, 1984.

McNie AB. Asphyxial deaths. In:Fisher RS, Petty CS, editors. Forensic pathology. United Kingdom: Castle House Publications, 1980:123–8.

Miles, S and Parker K. Letters to the Editor: Pictures of Fatal Bedrail Entrapment. Am Fam Physician. 1998 Nov 15;58(8):1755-1760.

Oehmichen M, Auer RN, Kçnig HG. Forensic types of ischemia and asphyxia. In: Oehmichen M, editor. Forensic neuropathology and associated neurology. Berlin: Springer-Verlag, 2005:293–313.

Polson CJ. Hanging In: Polson CJ and Gee DJ (eds.) Essentials of forensic medicine Oxford England, 1973 371-404.

Saukko P, Knight B. Suffocation and 'asphyxia'. In: Ueberberg A, project editor. Knight's forensic pathology, 3rd edn. London, UK: Arnold Publishers, 2004; 352–67.

Saukko P, Knight B. Fatal pressure on the neck. In: Ueberberg A, project editor. Knight's forensic pathology, 3rd ed. London, UK: Arnold Publishers, 2004:368–94. 960:110–45.

Spitz WU. Asphyxia. In: Spitz WU, Spitz DJ, editors. Spitz and Fisher's medico-legal investigation of death: guidelines for the application of pathology to crime investigation, 4th edn.

Qin, A. Adult portable bed rail-related deaths, injuries, and potential injuries: Qin, A. (2020). Adult portable bed rail-related deaths, injuries, and potential injuries: January 2003 to December 2019. CPSC staff memorandum to Vineed Dayal, Adult Portable Bed Rails Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD.

U.S. Food and Drug Administration (FDA). (2006). Guidance for industry and FDA staff: Hospital bed system dimensional and assessment guidance to reduce entrapment. Retrieved from: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf. (Last accessed April, 2020).

TAB D:
MEMORANDUM BY THE DIRECTORATE FOR ENGINEERING SCIENCES, DIVISION OF HUMAN FACTORS

United States
Consumer Product Safety Commission
Rockville, MD 20814

Memorandum

DATE: July 15, 2020

TO: Vineed K. Dayal
Adult Portable Bed Rails Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Mark Kumagai, Associate Executive Director
Directorate for Engineering Sciences

Rana Balci-Sinha, Ph.D., Director
Division of Human Factors, Directorate for Engineering Sciences

FROM: Timothy P. Smith, Senior Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

Kristen A. Talcott, Ph.D., Human Factors Engineer,
Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products*, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard

BACKGROUND

In 2013, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. Subsequently, ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for adult portable bed rail (APBR) products. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

Since then, CPSC staff has worked with ASTM to develop a draft voluntary standard. In August 2017, ASTM published the voluntary standard F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

This memorandum, prepared by staff of CPSC's Directorate for Engineering Sciences, Division of Human Factors (ESHF), assesses the adequacy of the ASTM F3186 – 17 requirements in addressing the APBR hazards relevant to the petition. The memorandum also summarizes staff's

findings regarding likely industry compliance with the labeling, warning, and instructional literature requirements of the standard.

THE PRODUCTS AND APPLICABLE STANDARDS

According to the petitioners, the APBRs of concern include side rails, split rails, half rails, bed handles, full-length rails, bed canes, and similar products sold and marketed directly to the public and intended to be used with a home bed, rather than a hospital bed.[1] Generally, these products are advertised and marketed in one of two ways: (1) rails intended to prevent consumers from falling out of bed, or (2) assistive devices intended to aid weak or unsteady consumers with getting in and out of bed, or repositioning within the bed. Some APBRs claim to serve both functions.

The Commission regulates portable bed rails under the Consumer Product Safety Act (CPSA), and the regulation is codified at 16 CFR part 1224. This regulation incorporates by reference the ASTM voluntary standard on portable bed rails, ASTM F2085 – 12, Standard Consumer Safety Specification for Portable Bed Rails. However, this standard specifically applies to portable bed rails intended for use with children, and is not intended to address APBRs or the hazards that portable bed rails might pose to adults.

In August 2017, ASTM published F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, which includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs. Section 3.1.1 of ASTM F3186 – 17 defines "adult portable bed rail" as

> [A]n adjacent type bed rail, grab bar, assistive bar, transfer aid, cane or rail (henceforth identified as the product or products) intended by the manufacturer to be installed on, against, or adjacent to an adult bed. The product may vary in lengths (for example, full, half, or partial rails, grab bar or handle or transfer post or pole), and is intended by the manufacturer to provide assistance to the bed occupant in moving on the bed surface, in entering or exiting the bed, to minimize the possibility of falling out of bed, or for other similar purposes. This includes similar products that are likely to be used for these purposes even if this is not explicitly stated by the manufacturer. However, the standard does not address ALL products that might be so used, for example, a chair.

ASTM F3186 – 17 (section 3.1.2) also defines "adjacent type bed rail," a term used in the definition of "adult portable bed rail," as

> [A] portable bed rail or related product in which the guard portion (portion that an adult would contact when rolling toward the mattress edge) is essentially a vertical plane or pole that is positioned against the side of the mattress.

[1] Bed rails designed for use on hospital beds are considered medical devices and are under the jurisdiction of the U.S. Food and Drug Administration (FDA).

INCIDENT DATA REVIEW

Staff of CPSC's Directorate for Epidemiology, Division of Hazard Analysis (EPHA), has identified 260 incidents—247 fatalities and 13 nonfatal incidents and complaints—associated with adult portable bed rails that occurred from January 2003 through December 2019 (17 years) (Qin, 2020; see Tab A). The victims in these incidents ranged in age from 13 to 103 years old. Ninety-two percent of the incident reports are death certificates and medical examiner or coroner reports, and therefore, have limited details surrounding the circumstances of the incident.

The majority of fatalities, close to two-thirds,[2] occurred to victims at least 80 years old. About half of all fatal victims had at least one underlying medical condition, and nearly one-third (32 percent, or 78 victims) had multiple medical conditions. At least 32 fatal victims had Alzheimer's disease, dementia, or some other mental medical condition.[3] The 13 nonfatal incidents include 6 incidents with injury,[4] 4 incidents without injury, and 3 nonincident complaints.

RAIL ENTRAPMENTS

The most common hazard pattern among all reported incidents is rail entrapment, which accounts for 226 incidents (91 percent), all of which are fatalities. These incidents include cases in which the victim was caught, stuck, wedged, or trapped between the bed rail and the mattress or bed, between bed rail bars, or similar entrapment scenarios; in other words, these are cases in which the victim was entrapped in or against the APBR. The petitioners state that entrapment fatalities like these are an unreasonable risk that requires mandatory rulemaking.

In reviewing the incidents, ESHF staff tried to identify the entrapment location, or entrapment type, for each rail entrapment incident. Although most of these incidents were unwitnessed and details are limited,[5] most entrapments appear to have occurred between the APBR and the mattress, or bed, rather than within the structure of the APBR itself. Staff's specific findings regarding these rail entrapment locations include the following:

- One hundred fifty-seven (157) cases appeared to involve entrapment between the APBR and the mattress.[6] Even though staff was unable to narrow down the specific entrapment location for many of these cases, 22 appear to have occurred in a gap or space between the inside surface of the APBR and the side of the mattress, typically because the APBR

[2] EPHA staff found that 155 of the 247 reported fatalities, or 63 percent, were to victims 80 years old or older. Three fatalities did not report the victim's age, so these 155 fatalities account for 64 percent of fatalities for which age was reported.
[3] EPHA staff concluded that Alzheimer's disease, dementia, or another mental medical diagnosis was the primary medical condition in 32 reported fatalities. Additional reported fatalities involved victims who suffered from multiple medical conditions, including one of these conditions, but the mental medical condition was not considered the *primary* one.
[4] These six incidents resulted in one fracture, one laceration, one wrist injury involving a pinched nerve, and three unspecified injuries.
[5] Staff was unable to determine the entrapment location for 60 of the 226 reported rail-entrapment fatalities.
[6] In some cases, the incident report stated that entrapment was between the APBR and the "bed." ESHF staff treated "bed" as being synonymous with "mattress," unless the incident included details that suggested otherwise (for example, the incident specifically identified the headboard).

shifted away from the mattress, creating the entrapping space. In one of the 22 cases, the APBR was deliberately installed with a gap between it and the mattress, because doing otherwise purportedly made it difficult for the victim to get out of bed. Four of the 157 mattress-entrapment cases were entrapments "under" the APBR.

- At least three cases involved entrapment in a space within the perimeter of the APBR. These are cases in which the incident specifically identified entrapment through the product or between its components. Some additional incidents refer to entrapment "in" the APBR, but staff was unable to confirm that the entrapment was truly within, rather than against, the product.

- Four cases involved entrapment between the APBR and an object other than the mattress, bed, or bed components, such as a commode or a dresser. In these cases, entrapment was likely against the exterior, or outside, of the APBR.

- One case, and potentially a second, involved entrapment between the APBR and a bed headboard.[7]

Some additional details surrounding the rail entrapment incidents are notable:

- In nine incidents, the APBR appeared to have been installed within about a foot of the headboard or footboard.[8] In many of these cases, staff could only estimate this distance from available photographs of the scene. Even though this was not necessarily the entrapment location, an APBR secured that close to a headboard or footboard could lead to entrapment within this space.

- Two incidents involved the use of an APBR with an atypical bed. One incident involved a waterbed, and the other involved an air mattress.

- Some incidents involved APBRs that did not "secure" to the bed and appeared to rely on the friction of the rails, or "arms," of the product that extend between the mattress and box spring to hold the APBR in place. In one case, the product reportedly did not come with "safety straps" to secure the APBR, but the product instructions pictured them. In another case, the APBR was not secured to the bed with a "safety strap," even though the product currently is sold with one.[9]

The prior ESHF staff memorandum regarding the petition discussed adult-aging issues that can contribute to entrapments, including age-related declines in muscular strength, muscular power, motor control and coordination, and balance (Smith, 2014).[10] Consumers 80 years and older,

[7] The uncertain case referred to entrapment against the side of the "raised head of his bed." This phrase might be referring to a headboard, but it also could be referring to a bed in which the headboard end of the mattress was inclined, which would suggest that entrapment was against the mattress, below the end of the APBR.
[8] One additional case involved entrapment between the APBR and a wall. The incident report did not include enough details to know whether the wall was in the headboard or footboard position.
[9] Whether the product was sold with one at the time of purchase is unknown.
[10] See Smith (2005) for a detailed discussion of these and other age-related differences in the adult consumer population.

who represent the majority of fatalities, are especially vulnerable to such declines. About half of all fatalities involved a victim who had at least one underlying medical condition, and it seems reasonable to conclude that some of these conditions contributed to the incidents. Also, given that consumers commonly purchase and use APBRs because they require help when getting in or out of bed—for example, some cases involved a consumer who was bedridden or used a wheelchair—APBR users would be less capable of escaping an entrapment scenario than the general population.

FALLS

EPHA staff identified falls as the second most common hazard pattern associated with APBRs, accounting for 20 incidents (8 percent). Nineteen of the 20 incidents resulted in fatality. One fall involved the vertical rail of the APBR not being raised to an upright position. Another incident apparently involved a consumer who fell despite, rather than because of, the presence of the APBR. Thirteen incidents involved the victim falling against or otherwise striking the APBR; the product might have played more of an incidental role in these cases:

- Five of these 13 cases occurred while the victim was in bed, getting out of bed, or trying to sit on the bed. However, the incident reports do not include any details suggesting that the APBR contributed to the fall.

- Three cases involved the victim falling from a standing position and striking the APBR.

- Five cases include no details about the circumstances of the incident.

Falls resulting from consumers trying to climb over APBRs are identified by the petitioners as another reason, besides rail entrapment, for seeking Commission rulemaking. However, only five incidents reportedly involved the victim climbing over the APBR, and one of these five cases simply reported that the victim "apparently" climbed over the product. In another one of the five climb-over cases, the victim apparently resorted to climbing over the APBR because he was unable to lower the product.

STAFF ASSESSMENT OF VOLUNTARY STANDARD REQUIREMENTS

The Consumer Product Safety Act (CPSA) states that the Commission may not deny a petition on the basis of an existing voluntary standard, unless the Commission has determined that the voluntary standard is likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and compliance with that standard is likely to be substantial.[11] In this section, ESHF staff assesses whether the current voluntary standard for APBRs, ASTM F3186 – 17, adequately addresses the hazards associated with these products.

[11] See section 9(i) of the CPSA, 15 U.S.C. 2058(i). In addition, the CPSA states that if the Commission were to grant the petition and begin rulemaking, the Commission could not issue a rule, unless the Commission finds that: (1) compliance with the voluntary standard is unlikely to eliminate or adequately reduce the risk of injury, or (2) substantial industry compliance with the voluntary standard is unlikely. See section 9(f)(3)(D) of the CPSA, 15 U.S.C. 2058(f)(3)(D).

PERFORMANCE REQUIREMENTS

ASTM F3186 – 17 includes various performance requirements intended to address hazards associated with APBRs. These performance requirements include

- entrapment testing in various entrapment zones in and around the installed APBR;
- permanently attached retention systems that must maintain the installed product in position without readjustment;
- a 4-inch minimum height requirement for the APBR to extend over the top of the thickest recommended mattress; and
- the inability of structural components and retention system components to be misassembled, which the standard defines as being assembled in a way that appears functional but would fail the other performance requirements.

Entrapment Testing

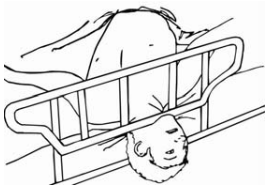
As staff mentioned, rail entrapments—that is, entrapments in and around the APBR—comprise most fatalities associated with APBRs, accounting for 226 of the 247 reported fatalities. The main performance requirement intended to address this hazard is entrapment testing, which is used to assess the potential for entrapment in four different zones in and around the APBR.

These zones represent four of the seven zones identified as potential areas of entrapment in hospital bed systems by the U.S. Food and Drug Administration (FDA), in its 2006 document titled, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*.[12] The guidance outlined in the document is based on recommendations from the Hospital Bed Safety Workgroup (HBSW), which was formed in 1999 to address reports of patient entrapment (FDA, 2006).[13]

Table 1 identifies[14] and briefly describes the four entrapment zones tested in ASTM F3186 – 17, and includes illustrations from the 2006 FDA guidance document of sample entrapments within each of these zones.

[12] As of the date of this memorandum, this document (FDA, 2006) can be found online here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment.
[13] The HBSW was formed by the FDA, in partnership with the U.S. Department of Veterans Affairs, Health Canada's Medical Devices Bureau, and representatives of national health care organizations and provider groups, patient advocacy groups, and medical bed and equipment manufacturers. The 2006 document includes a full list of HBSW participating organizations. The HBSW also worked in cooperation with the Joint Commission on Accreditation of Healthcare Organizations, the U.S. Centers for Medicare and Medicaid Services, and the U.S. Consumer Product Safety Commission to improve patient safety associated with the use of hospital beds.
[14] The zone names are from section 8.4 of ASTM F3186 – 17.

Table 1. Four Entrapment Zones of ASTM F3186 – 17

Zone 1: Within the Product Entrapment in any open space within the perimeter of the APBR	
Zone 2: Between Rail Support(s) and the Bed Mattress, When Applicable, Under the Product Entrapment under the bottom edge of the APBR, between the rail supports or next to a single rail support, against the mattress	
Zone 3: Between the Product and the Mattress Entrapment in the space between the inside surface of the APBR and the side of the mattress	
Zone 4: Between the Underside of the End of the Product and the Mattress Entrapment under the lowermost portion of the end of the APBR, against the mattress	

The other three entrapment zones identified by the FDA are not applicable to APBRs or do not lend themselves to entrapment testing:

- Zone 5 involves entrapment between two side rails on the same side of the bed. Only a single APBR is installed on any given side of a bed, so CPSC staff has not found entrapment incidents involving APBRs that are consistent with this scenario.

- Zone 6 involves entrapment between the end of the rail and side edge of the bed headboard or footboard. Although this location is relevant to APBRs, these products are installed by the consumer, so the potential for entrapment depends on the consumer's placement of the APBR on the bed. This is addressed later, in staff's discussion of the labeling and warning requirements.

- Zone 7 does not involve a rail at all, and instead, involves the space between the end of the mattress and the headboard or footboard. So, this zone is not applicable to APBRs.

Although the details surrounding many rail-entrapment incidents are limited, the four zones of an installed APBR that are tested for entrapment (Zones 1 through 4) appear to cover virtually all of the known entrapment-related fatalities. ESHF staff's review of the available incident data found that about 157 of the 226 reported fatalities involved entrapment between the APBR and the mattress.[6] Even though staff was unable to narrow the location for many of these 157 cases, 22

appear to have been between the inside surface of the APBR and the side of the mattress, or Zone 3, and four cases were entrapments "under" the APBR and against the mattress, meaning Zone 2 or 4. The remaining mattress-entrapment cases most likely were in Zones 2, 3, or 4, which cover all known entrapment scenarios between the APBR and the mattress. Staff also concluded that at least 3 of the 226 reported fatalities involved entrapment within the APBR itself, or Zone 1.

Four cases appear to involve entrapment against the exterior of the APBR by another object, such as a commode or dresser. This location is outside the four zones tested by the standard. One case, maybe two, involved entrapment between the APBR and a headboard.[7] This area is identified as Zone 6 in the 2006 FDA guidance document, but is not tested for entrapment because it depends on where the consumer chooses to install the APBR on the bed. Staff was unable to determine the specific entrapment location in the remaining 60 cases. Table 2 briefly summarizes these conclusions.

Table 2. Rail entrapment incident locations relative to ASTM F3186 – 17 entrapment zones.

Rail Entrapment Location	Entrapment Testing Location	No. of Fatalities
Between APBR and mattress	Zones 2, 3, or 4	157
Within APBR itself	Zone 1	3
Against outside of APBR	None	4
Between APBR and headboard	None (Zone 6)	2
Unknown location	Unknown	60
		226

These results illustrate that nearly all cases of rail entrapment for which ESHF staff could determine the entrapment location—160 of the 166 cases—occurred in one of the four zones of entrapment tested in ASTM F3186 – 17. So, most rail entrapment incidents in an unknown location probably also involve one of these four zones. Staff's finding that the preponderance of rail entrapments are in Zones 1 through 4, is consistent with the FDA's finding that these four zones accounted for about 80 percent of entrapment events reported to the FDA associated with hospital bed systems; this finding was the basis for the FDA recommending dimensional limits for these zones (FDA, 2006).

Entrapment testing in ASTM F3186 – 17 is performed using an "entrapment test probe," which is the cone and cylinder tool described in the 2006 FDA guidance document. An image of the probe appears in Figure 1. The probe design is based on the anthropometric dimensions of key

body parts—the head, neck, and chest—of at-risk adults, and takes into account the effects of age, such as the loss of muscle mass in the neck[15]:

- The diameter of the large end of the cone represents the width of a small adult head.
- The diameter of the cylinder represents the size of a small adult neck.
- The cone and cylinder together weigh 15 pounds, which represents the combined weight of an adult head (12 pounds) and neck (3 pounds).
- The cylinder includes a red area that defines contact angles in which the neck could become wedged (up to 60 degrees).

Figure 1. Entrapment test probe. From FDA (2006).

These dimensions appear to represent the users of APBRs adequately. Thus, ESHF staff concludes that entrapment testing in the four zones identified in ASTM F3186 – 17, using the entrapment test probe, should effectively address the entrapment hazard posed by a properly installed APBR.

Misassembly and Misinstallation

As suggested, the ability of an APBR to address the entrapment hazard effectively depends on consumers properly assembling and installing the product. ASTM F3186 – 17 includes performance requirements intended to improve the likelihood that the APBR will be assembled and installed properly. For example:

- Section 6.1 includes a requirement that retention systems—a method for maintaining the installed product in position—must be permanently attached to the APBR once it has been assembled, and must be removable only with a tool. Including this requirement reduces the likelihood that consumers will misplace this critical part of the APBR, and increases the likelihood that consumers, including secondary users, will continue to use the retention system.
- Section 6.5 includes a requirement that structural components and retention system components must not be capable of being misassembled, which the standard defines as the APBR being assembled in a way that appears functional, but would not meet the

[15] FDA used international anthropometric data references (*e.g.*, Peebles & Norris, 1998 as cited in FDA, 2006) to determine the relative sizes of the body parts for the population at greatest risk of entrapment. For example, the diameter of the large end of the cone is 120 mm (4¾ inches), which encompasses the 5th percentile female head breadth in all examined data sources. The diameter of the cylinder is 60 mm (2⅜ inches), which reflects the 1st percentile female neck diameter, reduced by about 25 percent to account for the compressibility of neck tissue. FDA (2006) includes details about their selection of dimensional limits and a complete listing of the anthropometric references they consulted.

retention system (section 6.1), structural integrity (6.2), entrapment (6.3), or openings (6.4) requirements. This misassembly requirement reduces the risk of injury or death that could arise from the consumer omitting key parts of the APBR (for example, a center rail) during assembly, in ways that could result in entrapment or other hazards.

In addition, some of the requirements and associated test methods depend upon information communicated to the consumer by the manufacturer:

- Section 6.2.1 requires the top of the product to be at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer.

- Section 7.1.1 requires testing to be conducted on each mattress, mattress support, and bed type that the manufacturer specifies as suitable for use with their product.

- Section 8.4.6.3, related to Zone 4 entrapment, requires the product to be adjusted to the manufacturer's recommended height or heights above the mattress, if the height is consumer adjustable.

- Zone 3 entrapment testing depends on the lateral distance at which the product is installed from the mattress.

In these cases, the effectiveness of the performance requirements rely on consumers receiving and acting upon the pertinent information. The *Labeling, Warning, and Instructional Literature Requirements* section, below, discusses these types of issues.

Falls

As staff mentioned, falls are the second most common hazard pattern associated with APBRs, accounting for 20 reported incidents, nearly all fatalities. Although APBR-related incidents of falls are considerably less common than rail entrapments, these fall incidents also were identified by the petitioners. Rail entrapments and falls, combined, account for virtually all reported fatalities associated with APBRs.

ESHF staff's review of the incidents reveals that most falls associated with APBRs involve the victim falling against or striking the APBR. As discussed, these incidents often include few details, and the APBR might have played an incidental role. For example, some incidents appear to involve the victim striking the APBR, while falling from a standing position. Five falls occurred while the victim was in bed, getting out of bed, or trying to sit on the bed. The incident reports for these five cases do not include details suggesting that the APBR contributed to the fall. However, if the fall was triggered by the APBR becoming dislodged or shifting position, then these incidents would likely be addressed by the entrapment testing and the performance requirement for a permanently attached retention system that must maintain the installed product in position.

As many as five fall-related incidents involve the victim deliberately climbing over the APBR. Addressing these climbing incidents with a performance requirement is challenging. Section 6.2 of ASTM F3186 – 17 includes structural integrity requirements that call for a 4-inch minimum

height requirement for the APBR to extend over the top of the thickest recommended mattress. This minimum height requirement for APBRs may address such incidents by limiting the ability of consumers to climb over these products. However, consumers who deliberately climb over APBRs might be motivated to do so, despite the height of the product. The most feasible approach to addressing this residual climbing-related fall hazard may be to warn potential APBR purchasers about this issue. ASTM F3186 – 17 includes fall-related warning requirements for retail packaging and instructions. These requirements are discussed briefly, later in this memorandum.

LABELING, WARNING, AND INSTRUCTIONAL LITERATURE REQUIREMENTS

As Smith (2014) discussed in the prior ESHF staff memorandum regarding the petition, hazard-control measures that rely on consumers to alter their behavior to avoid the hazard are less effective than designing the hazard out of the product, or guarding the consumer from the hazard. For this reason, hazard communication through labeling, warnings, and instructions should be viewed as a "last resort" measure that supplements, rather than replaces, redesign or guarding efforts, unless these higher-level, hazard-control efforts are not feasible. This issue becomes especially important when older adults are at risk, because this group of consumers is a potentially vulnerable population. Smith (2014) provides additional details about the vulnerability of these consumers and the likely ineffectiveness of warnings aimed at these consumers. Smith also points out that APBR design changes or performance requirements that prevent entrapment in the first place would be a far more effective solution.

Although the primary hazard associated with APBRs, rail entrapment, is addressed by performance requirements in ASTM F3186 – 17, some of these requirements and associated test methods depend upon manufacturer-provided information about compatible beds and mattresses. This implies that for the performance requirements to be effective during real-life use, consumers must install the product based on this same information, which would appear in labeling, warnings, or instructions directed at the consumer.[16] In addition, labeling, warnings, and instructions might offer some benefit as a supplemental safety measure for risks that cannot be eliminated through design. Examples of these risks include entrapments in the space between an APBR and the headboard or footboard of the bed, and falls associated with climbing over APBRs.

The labeling, warning, and instructional requirements in ASTM F3186 – 17 are somewhat complicated, and there is a lot of overlap in the types of information that must appear on the product, on its retail packaging, and in the product instructions, or instructional literature. Staff summarizes these requirements below.

Labeling Requirements

Section 9 of ASTM F3186 – 17 specifies requirements for APBR labeling and warnings. The labeling requirements, specified in section 9.1, include requirements for the product, and its retail package, to be marked or labeled with

[16] The "consumer" in this case might be the product user or the product user's caregiver.

- the type and size of beds and mattresses, including the mattress thickness range, for which the product is intended (that is, compatible beds and mattresses); and

- the appropriate distance between an installed APBR and the headboard or footboard of the bed.

This section also specifies that all on-product labels must be permanent.

ESHF staff supports the labeling requirements of ASTM F3186 – 17. Labeling about compatible beds and mattresses is important because the effectiveness of the performance requirements depends upon this information. For example, testing is performed on each mattress, mattress support, and bed type that the manufacturer specifies is suitable for use with their product. If the manufacturer fails to label the product properly with this information, consumers might choose to use the APBR with a bed or mattress that would fail the performance requirements, and this would place consumers at risk of entrapment between the APBR and mattress (Zone 2, 3 or 4). Staff is aware of two rail-entrapment fatalities in which the product was used with an atypical bed type that might not have been suitable for the APBR. One incident involved a waterbed, and the other one involved an air mattress. Neither incident includes details about any relevant labeling on the APBR.

Labeling about the appropriate distance between an installed APBR and a bed headboard or footboard also is important to address the potential entrapment hazard in this space, which is a recognized hazard (Zone 6).[17] ESHF staff's review of the available incident data identified one, possibly two, fatalities that appear to involve entrapment between the APBR and a headboard.[7] Neither incident includes details about labeling or warnings on the product that might have addressed this entrapment scenario. ASTM F3186 – 17 also requires the product warnings, discussed below, to include statements related to this entrapment scenario; so, the addition of a separate labeling requirement seems redundant. However, staff considers a warning that includes this information to meet the labeling requirement, if the warning is placed in the required labeling location. One relevant concern with the current labeling requirement is that section 9.1.1.3 permits the allowable distance to be greater than 12½ inches or less than 2.4 inches. A label that states that the APBR can be installed less than 2.4 inches from the headboard or footboard contradicts the required warnings, which state that this distance must be at least 12½ inches. ESHF staff believes that this section of the voluntary standard should be revised to avoid possible confusion.

Warning Requirements

Section 9.2 of ASTM F3186 – 17 specifies requirements for warnings that must appear on the APBR and its retail packaging, instructions, and Internet or print advertising. This section of the standard identifies three sets of warning statements. Although there is room for improvement in specific, individual warnings, ESHF staff concludes that the warning content, overall, is adequate.

[17] The mandatory standard for children's portable bed rails (16 CFR part 1224) also includes a warning statement about entrapment in this location.

Point-of-Purchase Warning Statements

The voluntary standard requires that the retail packaging, product instructions, and Internet or print advertising for the product include the warning statements below:

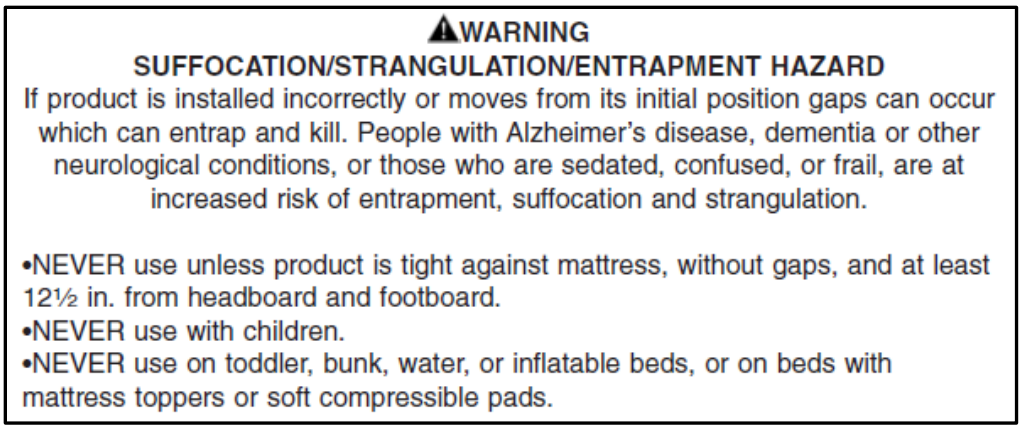
> **⚠WARNING**
> **ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS**
> Gaps in and around this product can entrap and kill. People with Alzheimer's disease or dementia, or those who are sedated, confused, or frail, and are at increased risk of entrapment and strangulation. People attempting to 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.

This warning is intended primarily to communicate, at the point of purchase, the potential hazards associated with APBRs, to improve the likelihood that consumers will purchase the correct product for their needs. The warning identifies the entrapment-related hazards associated with gaps in and around the APBR, and it emphasizes that consumers with Alzheimer's disease, dementia, or similar conditions are at increased risk of entrapment and strangulation. The warning also acknowledges the risk of injury or death from climbing over the product and falling. ESHF staff's review of the incidents revealed that few incidents involve the victim deliberately climbing over the APBR. However, staff agrees that alerting potential APBR purchasers about this potential hazard is valuable and may help consumers decide whether the users of this product might be prone to attempting this behavior.

ESHF staff acknowledges that certain aspects of this warning could be improved. For example, staff believes that the initial hazard statement, or heading, could be reduced from, "ENTRAPMENT, STRANGULATION, SUFFOCATION AND FALL HAZARDS," to the more concise, "ENTRAPMENT AND FALL HAZARD." In addition, staff questions the need for the final two sentences of the warning, which address proper installation. This information seemingly is not needed at the point of purchase. Lastly, there might be some benefit to rewording the warning to state explicitly that consumers should not purchase the product if the end-user is likely to engage in behavior that could put them at risk, such as trying to climb over the product.

Product Warning Statements

The voluntary standard also requires the following warning statements on the product, in the product instructions, and in Internet or print advertising for the product.



This warning focuses on the hazards associated with entrapment and the steps consumers should take to avoid the hazard. During ASTM subcommittee and task group meetings, the members discussed the possibility of including the fall hazard in this warning, but the consensus of the group was that the focus of the product warning should be on entrapment, as the primary hazard. Focusing this warning on the entrapment hazard, including appropriate steps to avoiding the hazard, seems reasonable.

The warning includes detailed descriptions of hazard-avoidance behaviors that consumers must take, including keeping the APBR tight against the mattress and at least 12½ inches from the headboard or footboard. ESHF staff believes that these are important elements to address in the required warnings. Although the voluntary standard's performance requirements should effectively prevent most entrapments in and around a properly installed APBR, their effectiveness still depends on proper installation by the consumer. ESHF staff identified at least one rail entrapment fatality involving an APBR that was deliberately installed with a gap between the product and the mattress (Zone 3) to make it easier for the consumer to get out of bed. So, emphasizing the importance of installing the product tight against the bed, without gaps, is essential to mitigating this entrapment hazard.

ESHF staff's review of the available incident data also identified one, possibly two, reported fatalities associated with entrapment between the end of an APBR and a headboard.[7] Entrapment in this location is a recognized hazard, identified as Zone 6 by the FDA (2006),[17] and avoiding such entrapment depends on the consumer installing the APBR at the appropriate distance from the headboard and similar bed structures. Neither incident includes details about warnings on the product that might have addressed this entrapment potential. ESHF staff's review identified seven additional incidents in which the APBR appeared to have been installed within about a foot of the headboard or footboard.[18] These seven incident reports include photographs of the APBR, and none of the products appear to include warnings or labeling about the appropriate installation distance between the product and a headboard or footboard.

Staff also agrees with the warning's recommendations to never use the product with children, for whom the product is not intended, or with certain types of beds. The voluntary standard provides

[18] These seven incidents plus the two potential entrapments between the APBR and the headboard account for the nine incidents in which the APBR appeared to be installed within about a foot of the headboard or footboard, as cited in ESHF staff's earlier review of the incidents.

flexibility with the listing of incompatible beds, if the manufacturer has "proven" that the product can comply with the performance requirements on some of these more atypical bed types, such as waterbeds or inflatable beds. So, a product whose warning does not include this statement must pass the performance requirements on all of these otherwise prohibited bed types.

Although staff concludes that the product warning is adequate, ASTM F3186 – 17 seems to contain an error: the warning language shown in Figure 4 of the voluntary standard does not match the required warning statements.[19] An image of this figure appears below. Staff believes that to avoid confusion, the figure's warning content and the required statements must match.

"Conspicuous Component" Warning Statements

Lastly, the voluntary standard requires that at least one "conspicuous component" of the product be labeled with these warning statements:

⚠WARNING – ENTRAPMENT HAZARD
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 entrapment and death.

The children's portable bed rail standard (16 CFR part 1224) includes a requirement for a similar warning to appear on at least one "installation component," which is defined as a component of the bed rail that is designed specifically to attach the bed rail to the bed and that typically is located under the mattress when in the manufacturer's recommended use position. The intent of the requirement was to improve the likelihood that consumers will use that component to properly install the product. ESHF staff recommended that a similar requirement be added to ASTM F3186 during its development, and the draft voluntary standard did include such a requirement. However, prior to the voluntary standard's publication, the requirement for this warning to be on an installation component was changed to say that it must be on a "conspicuous component." The standard does not define this term, but does define "conspicuous" (in section

[19] Figure 4 is supposed to be an example of the required warning statements, formatted according to the additional requirements of the standard.

3.1.3) as "visible, when the product is in the manufacturer's recommended use position, to a person standing near the unit at any one position around the unit but not necessarily visible from all positions." ESHF staff continues to believe that this warning should appear on an installation component, because

- the intent of this warning is to draw attention to the installation component and to encourage its use[20]; and

- the installation component is commonly located under the mattress during use, and therefore, would not be "conspicuous," or visible when in the manufacturer's recommended use position.[21]

Other Warning Requirements

In addition to specifying the warning content, section 9.2 includes other requirements related to warnings. For example, ASTM F3186 – 17 specifies the placement of warnings on the product by requiring warnings to be "conspicuous," which the voluntary standard defines as

> [V]isible, when the product is in the manufacturer's recommended use position, to a person standing near the unit at any one position around the unit but not necessarily visible from all positions.

Many ASTM voluntary standards include a similar "conspicuous" requirement for warnings, and define this term in a way that enables one to assess conformance for that particular product. The definition selected for APBRs requires the warnings to be visible to the consumer, even after the product has been installed (that is, the "manufacturer's recommended use position"), which improves the likelihood that warnings are visible when needed.

ASTM F3186 – 17 also includes the following format requirements for warnings:

- The warnings must be in highly contrasting colors and in non-condensed sans serif type.

- Each group of warning statements must be preceded by a safety alert symbol (⚠)[22] and the specified signal word (for example, "WARNING").

- The safety alert symbol and signal word must be in letters at least 0.2 inches (5 mm) high, and the rest of the warning text must be characters whose upper case is at least 0.12 inches (3 mm) high.

[20] Staff is aware of one rail entrapment fatality involving an APBR that was not secured to the bed with a "safety strap," even though the product currently is sold with one. However, whether the product was sold with such a strap at the time of purchase is unknown.
[21] In other words, requiring the warning to be on a "conspicuous component" most likely would not permit the warning to be placed on an installation component. Yet, drawing attention to the installation component was the original purpose of the warning.
[22] The version of the safety alert symbol shown here is based on the default symbol used in the ANSI Z535 series of standards. For consistency, ESHF staff uses this version throughout the memorandum for all instances of the safety alert symbol.

Although the warning format requirements used in many ASTM juvenile product standards tend to be more stringent, ESHF staff concludes that these requirements are adequate. The type-size requirements, in particular, are an improvement over similar requirements used in most other ASTM voluntary standards. For example, ASTM F3186 – 17 requires the text that appears in the message panel of each warning to be characters whose upper case is at least 0.12 inches tall. Most ASTM voluntary standards allow this type size to be as small as 0.1 inches; this is the type size recommended by the ASTM Ad Hoc Language Task Group, which was formed to develop standardized language across ASTM juvenile products standards, and has developed recommendations for warning format.[23] However, as ESHF staff pointed out in its prior memorandum related to this petition, age-related deficits in vision are likely to impair an older consumer's ability to read a warning, and even the caregivers of older adults also might be older adults who suffer from similar age-related deficits (Smith, 2014). Smith (2005) includes a detailed discussion of age-related changes in vision and visual functioning, and recommends at least 12-point type (about 0.12 inches) for information that must be read by older adults. For this reason, ESHF staff worked with the ASTM subcommittee to require warning message text for APBRs to be at least this size.

Lastly, ASTM F3186 – 17 requires that the warnings be permanent, easy to understand, in at least English, and that any other labels or written instructions provided in addition to those required by the standard cannot contradict or confuse the meaning of the required warnings, or otherwise be misleading. This latter requirement appears increasingly in other ASTM voluntary standards, and reduces the likelihood that manufacturers will provide consumers with information that might mislead consumers or cause consumers to question the credibility of the warnings.

Instructional Literature Requirements

Section 11 of ASTM F3186 – 17 specifies requirements for instructional literature, or "instructions," that must accompany APBRs. These requirements include the following:

- The instructions must be easy to read and understand.
- The instructional literature must include assembly, installation, maintenance, cleaning, operation, and adjustment instructions and warnings, where applicable.
- The instructions must include drawings or diagrams to provide a better understanding of set up and operation for use, and must include drawings that depict all of the entrapment zones.

[23] The ASTM Ad Hoc Language Task Group's latest set of recommendations appears in the document, "Recommended Language Approved by Ad Hoc Task Group, Revision E," dated May 28, 2019, and can be found here: https://myastm.astm.org/KEY_DOCUMENTS/PDF_FILES/f150000adhoc7.pdf. This link is accessible to Committee F15 members only.

- The instructions must include all warning statements specified in section 9.2 of the standard (discussed earlier in this memorandum).

- The instructions must include these additional warning statements[24]:

    - "Stop using immediately if damaged or broken, or if parts are missing."

    - "Stop using immediately if product shifts out of its original position until it is readjusted into the correct position."

    - "In addition to contacting the manufacturer directly, consumers should report problems to the CPSC at is [*sic*] website SaferProducts.gov or call 1-800-638-2772, or to the FDA at 1-800-332-1088."

    - "For further information, see: cpsc.gov/en/Safety-Education/Neighborhood-Safety-Network/Posters/Adult-Bed-Rails/ and www.fda.gov/bedsafety."

- Products that use straps to meet the requirements of the voluntary standard (for example, to secure the APBR), must include "WARNING: If the strap provided is not properly secured the product may move into an unsafe position which increases the danger of entrapment. See instructions for proper use of the straps."

- All warnings in the instructions must meet the same design or formatting requirement as the product warnings.

As discussed, the real-life effectiveness of the performance requirements in ASTM F3186 – 17 depends upon proper assembly, installation, and adjustment of the APBR. The instructional literature requirements specify that the instructions must address these topics, among others. Furthermore, instructional literature must include drawings or diagrams to provide a better understanding of set-up and operation for use. ESHF staff concludes that APBRs that include this information, as well as the other information specified in section 11, are more likely to be properly assembled and installed, than APBRs without this information. These actions should reduce the incidence of fatal entrapments. Thus, ESHF staff supports these instructional literature requirements. However, as noted with "[*sic*]" in the bullet list above, the statement in section 11.1.1.3 of ASTM F3186 – 17 includes a typographic error, with "is" used in place of "its." Staff recommends correcting this error in the voluntary standard.

INDUSTRY COMPLIANCE WITH VOLUNTARY STANDARD REQUIREMENTS

As mentioned, the CPSA states that the Commission may not deny a petition on the basis of an existing voluntary standard, unless the Commission has determined that the voluntary standard is

[24] Some required statements refer consumers to both CPSC and FDA because ASTM F3186 – 17 covers APBRs that meet the definition of a "medical device," and therefore, are under the jurisdiction of FDA, and also cover other APBRs that are under the jurisdiction of CPSC.

likely to result in the elimination or adequate reduction of the risk of injury identified in the petition, and compliance with that standard is likely to be substantial.[11]

In 2018, to assess industry compliance with ASTM F3186 – 17, CPSC staff collected 35 sample APBRs that staff of CPSC's Directorate for Economic Analysis (EC) determined to be representative of the market. Since then, staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), completed testing to assess sample conformance to the general requirements and performance requirements of ASTM F3186 – 17. The LSM staff memorandum (Dayal, 2020; see Tab E) discusses their findings. ESHF staff also examined the sample products to assess sample conformance to the labeling (section 9.1), warning (section 9.2), and instructional literature (section 11) requirements.

None of the 35 sample APBRs conform to all of the ASTM F3186 – 17 labeling, warning, and instructional literature requirements. Specifically, ESHF staff found the following:

- None of the samples fully conform to section 9.1, *Labeling*.
- None of the samples fully conform to section 9.2, *Warning Statements.*
- None of the samples fully conform to section 11, *Instructional Literature*.

The discussion below summarizes key findings from ESHF staff's examination of the samples.

LABELING REQUIREMENTS

A key labeling requirement that can directly impact whether the product meets the performance requirements of the voluntary standard is set forth in section 9.1.1.3, which requires the product and its retail packaging to specify that (1) the APBR can be used only with certain types and sizes of beds and mattresses, including specifying the required mattress thickness; and (2) the distance between an installed APBR and the headboard or footboard must be less than 2.4 inches or greater than 12.5 inches.[25]

None of the 35 sample APBRs fully meet this labeling requirement, and 12 samples do not include *any* of the required labeling specified in section 9.1.1.3, on the retail packaging or the product. ESHF staff's specific findings are summarized below.

Retail Package Labeling

Only one retail package sample appears to include all of the required information about the intended types and sizes of beds and mattresses,[26] including specifying the required mattress thickness. Thirteen retail package samples do not include any of this information. The remaining 21 retail package samples include some, but not all, of this information. Of these 21 samples, 6 only include vague descriptions of compatible beds and mattresses. Examples of these

[25] As ESHF staff mentioned, a label that states that the APBR can be installed less than 2.4 inches from the headboard or footboard contradicts the required warnings, which state that this distance must be at least 12½ inches.
[26] This sample states that the APBR is compatible with pillow-top mattresses, but does not specify mattresses that might not be compatible with the product.

descriptions include, “Fits most beds,” “Fits most twin, queen, and king size beds,” and “Fits most home beds with metal frame.” The remaining 15 samples include the following:

- Ten samples identify compatible bed sizes, typically using standard descriptors, such as “queen” or “king” size. Some of the samples assert that the APBR is compatible with “any” size bed.

- Five samples identify compatible bed types (for example, “home style” beds, “water beds”) or incompatible bed types (for example, “Not for use on mechanical beds”).

- Seven samples identify compatible mattress thicknesses. Most of these samples list the range of mattress thicknesses that the APBR “fit” or are intended for, but do not state explicitly that these are the *only* compatible mattresses, as required by the standard.

- Five samples identify compatible mattress types, stating that the product can be used with pillow-top mattresses.

None of the 35 retail package samples include information about the appropriate distance between an installed APBR and the headboard or footboard of the bed.

Product Labeling

Only 7 of the 35 products include any product labeling about compatible beds and mattresses, or about the appropriate distance between the APBR and a headboard or footboard:

- Five of the seven products identify compatible bed types and information about the appropriate distance between an installed APBR and the headboard or footboard of the bed, because these details are within one of the product warnings. None of these five products include labeling that identifies compatible bed sizes or mattress thicknesses. All five products were produced by the same manufacturer.

- The remaining two products include a statement within the product warning that the product is not for hospital beds. These products include no other labeling about compatible bed sizes, mattress thicknesses, or mattress types, or about the appropriate distance between an installed APBR and the headboard or footboard.

WARNING REQUIREMENTS

As staff mentioned, none of the samples examined by ESHF staff fully conform to the warning requirements in section 9.2 of ASTM F3186 – 17. Section 9.2 includes, among other requirements, specific warning statements that must appear on the product, its retail package, and its instructions. Staff’s review of the samples for conformance to the required warning statements is summarized below.

Retail Package Warnings

None of the 35 retail packages include the required warning statements specified in section 9.2.5 of ASTM F3186 – 17. In fact, none of the packages include any warnings whatsoever about entrapment, strangulation, suffocation, or falls, which are the hazards identified in the required warning statements.

Product Warnings

None of the 35 product samples include the required warning statements specified in sections 9.2.6 and 9.2.7 of the voluntary standard. In addition, staff found the following:

- Nine products include no warnings at all.
- Eleven products include warnings, but none are related to suffocation, strangulation, or entrapment, which are the hazards identified in the required warning statements.
- One product includes an entirely graphical warning, with no text. One of the pictograms appears to illustrate the potential for entrapment.
- The remaining 14 products include warnings related to at least one of the hazards identified in sections 9.2.6 and 9.2.7 (suffocation, strangulation, or entrapment), but the warning language does not match the required warning statements. For many of these products, the warnings begin with "Patient Entrapment Potential," rather than the signal word "WARNING," and lack any additional description of the hazard or how to avoid it. Instead, these products refer the reader to unspecified "directions and warnings." Five of the 14 products include warnings similar to the required warning statements, but they do not match in some respects. For example, the warnings use the wrong hazard statement or description, or omit certain words from the required statements. All five are produced by the same manufacturer.

Instructional Literature Warnings

None of the 35 samples include instructional literature that contains the required warning statements specified in sections 9.2.5 and 9.2.6. Three of the 35 samples do not include any instructional literature. ESHF staff found the following among the remaining 32 samples with instructions:

- One set of instructions consists of a single diagram with no warnings at all.
- Three sets of instructions do not include any warnings related to entrapment, strangulation, suffocation, or falls, which are the hazards identified in the required warning statements.
- The remaining 28 sets of instructions include warnings related to at least one of the hazards identified in sections 9.2.5 and 9.2.6 of the voluntary standard (entrapment, strangulation, suffocation, or falls), but the warnings do not match the required warning

statements. However, some of these 28 sets of instructions include warnings with content similar to what is required.

INSTRUCTIONAL LITERATURE REQUIREMENTS

Section 11 of ASTM F3186 – 17 includes requirements for instructional literature that must accompany APBRs. This instructional literature must include assembly, installation, maintenance, cleaning, operating, and adjustment instructions and warnings, where applicable. Because all APBRs must be installed on a bed, even a fully pre-assembled APBR that does not require or allow any adjustments would require installation instructions, at a minimum. Three of the 35 samples examined by staff do not include instructional literature at all. Three additional samples do not include specific instructions on how to install the APBR on a bed. One of the three samples lacking installation instructions consists of a single diagram that illustrates how the product is assembled; the other two samples do not include assembly instructions either, even though the product has to be assembled before use.

The remaining 29 samples include instructional literature with the most basic instructional topics, such as installation and assembly instructions. However, all 29 instructional literature samples

- fail to include the warning statements in section 9.2, as required by section 11.1.1; and
- fail to include the additional warning statements specified in sections 11.1.1.1 through 11.1.1.4, and in section 11.1.2.

In addition to their general lack of conformance to the required warnings, the instructional literature included with the sample products commonly lacks information about the proper installation and adjustment of the APBR, or provides conflicting information. LSM staff's testing revealed that this missing or conflicting information sometimes contributed to the inability of the APBR to meet the performance requirements. Examples of this issue, related to Zone 3 and Zone 4 entrapment testing, are discussed below.

Instructions Related to Zone 3 Entrapment

Zone 3 entrapment testing, which tests for entrapment in the space between the inside surface of the APBR and the side of the mattress, depends on the lateral distance at which the product is installed from the mattress. APBRs should be installed against the mattress, and the voluntary standard requires the instructional literature to include warning statements stating that APBRs should be "tight against mattress, without gaps."[27] Of the 32 samples that include instructional

[27] At least one rail entrapment fatality involved an APBR that was deliberately installed with a gap between the product and the mattress to make it easier for the consumer to get out of bed.

literature of some kind,[28] 8 instructional literature samples do *not* state explicitly that the APBR should be installed against the mattress. Five of these eight samples include recommendations suggesting that this lateral distance can be as large as 2 inches.[29]

The remaining 24 instructional literature samples generally convey the appropriate distance, explicitly or implicitly, by stating[30] that there should be no space between the product and mattress; that the product should be tight against, "butt" against, or be firmly in contact with the mattress, with no gaps; or that the product should be inserted between the mattress and box spring "as far as possible." However, staff also found the following:

- More than half (13) of these 24 samples also include entrapment zone information from the FDA that includes the FDA's recommendation that this lateral distance not be more than 4¾ inches.

- Nearly half (6) of those 13 samples also include recommendations that this lateral distance not exceed 2 inches.

In other words, one-quarter (6) of the 24 instructional literature samples that state the APBR should be installed against the mattress *also* suggest that the distance between the APBR and the mattress can be as large as 2 inches and as large as 4¾ inches. This information, taken as a whole, could reasonably lead consumers to conclude that a space as large as 4¾ inches is acceptable, particularly given that the instructions typically name the FDA as the source of this 4¾-inch recommendation.[31]

Instructions Related to Zone 4 Entrapment

Zone 4 entrapment testing, which tests for entrapment against the mattress under the lowermost portion of the end of the APBR, requires the product to be adjusted to the manufacturer's recommended height or heights above the mattress, if the height is consumer adjustable (section 8.4.6.3). Twenty of the 35 sample APBRs examined by staff are consumer-adjustable in height.

[28] Staff considered all 32 instructional literature samples, rather than the 29 referenced above, because some instructional literature included details about the recommended distance between the APBR and the mattress, even when the literature did not include specific instructions about how to install the product on the bed.
[29] In two of these five cases, the instructions stated that the APBR should be adjusted to be flush with the mattress *if* the space was greater than 2 inches.
[30] This statement was sometimes presented as part of a warning within the instructions.
[31] Although the instructional literature requirements state that manufacturers must include drawings depicting all of the entrapment zones, "such as those available from the FDA" (section 11.1), many manufacturers seem to be including not only FDA drawings, but also the FDA's spacing recommendations, even though those recommendations conflict with the required warnings. Product instructions that include seemingly contradictory recommendations such as these would not meet section 9.2.2 of ASTM F3186 – 17, which states that any labels or written instructions "shall not contradict or confuse the meaning of the required information, or be otherwise misleading to the consumer."

Four of these 20 samples are adjustable only during assembly.[32] One additional sample is adjustable during assembly, but it also can be adjusted during use.

Among the 20 samples with consumer-adjustable heights, most—15 samples—do not provide any specific manufacturer's recommendation on the appropriate height of the APBR relative to the mattress.[33] In many cases, the instructions either tell consumers to adjust the product to their preferred or desired height (6 samples), or describe how to adjust the height without saying why a consumer should do so (5 samples). Three of these 15 samples suggest that the mattress is relevant to the height at which the APBR should be adjusted; however, the instructions only refer to this ambiguously, such as stating that the consumer should assemble the product a certain way for "thick mattresses," or that consumers should adjust the product to the height "most suitable for your mattress thickness." These instructions do not specify what constitutes a "thick" or "suitable" mattress, or explain how the product height and mattress interact.

Only 5 of the 20 samples with consumer-adjustable heights include instructional literature with specific manufacturer's recommendations on the appropriate height of the APBR relative to the mattress:

- Two samples instruct consumers to adjust the product so that the bottom rail of the APBR is below the top of the mattress.

- One sample instructs consumers to adjust the product so that the bottom rail of the APBR is no more than 3 inches above the top of the mattress, and provides specific adjustment recommendations based on the combined mattress and box spring height.

- One sample instructs consumers to set the top of the APBR to *exactly* 4 inches above the top of the mattress, and states that positioning the product to a height higher or lower than 4 inches will create an entrapment hazard.[34]

- Four samples include entrapment zone information from the FDA, including the FDA's recommendations about the maximum height, or space, between the mattress and the lowermost rail of the APBR. This information recommends that this distance not exceed 2⅜ inches at the end of the APBR, and not exceed 4¾ inches between the rail supports. Three of the four samples include some of the additional height information described in the prior bullets.

As noted, 20 of the 35 sample APBRs have consumer-adjustable heights; 15 samples do not. Although consumers are not able to adjust the height of the product for these latter 15 samples, some of the instructions for these products still include information about the appropriate height

[32] Two samples can be assembled with two or three horizontal cross bars, depending on the mattress thickness. Staff is inferring the adjustability of the other two samples, based on the images in the instructions, which show the vertical panel at two different heights.
[33] One of these samples does not provide any instructional literature.
[34] Given that the height adjustment is in discrete steps and not continuous, it seems likely that a consumer's existing mattress will not be of a thickness that will enable the height to be adjusted to this exact 4-inch value. Consumers also might find it challenging to locate a mattress that is the precise thickness required to meet this 4-inch recommendation.

of the APBR relative to the mattress. For example, 9 of these 15 samples still include the FDA recommendations about the maximum height between the mattress and the lowermost rail of the APBR. In addition, among these nine samples, ESHF staff found the following:

- Four samples state that the bottom rail of the APBR must be 3 inches below the top of the mattress.

- Four samples state that the distance between the bottom rail of the APBR and the top of the mattress should be no greater than 3 inches, but they do not specify whether this distance should be above or below the mattress, or whether the direction of this measurement matters. The instructions for these four samples also state that this distance might be a concern "that would need to be addressed" for very thin mattresses.

Because the products above are not height adjustable, consumers presumably have to meet the recommended distances between the APBR and mattress by selecting an appropriate mattress thickness. However, only four of these nine samples identify an appropriate range of recommended mattress thicknesses for the APBR. As discussed, the voluntary standard requires testing to be conducted on each mattress, mattress support, and bed type that the manufacturer specifies as suitable for use with their product (section 7.1.1), and the structural integrity requirements specify that the top of the product must be at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer (section 6.2.1). So, specifying the appropriate mattress thicknesses is also important to meet these requirements.

CONCLUSIONS

Most incidents associated with APBRs are rail entrapments, in which the victim was entrapped in or against the APBR, and these incidents most commonly involve entrapment between the APBR and the mattress or bed. Consumers 80 years and older, who make up the majority of fatalities, are especially vulnerable to age-related declines in muscular strength, muscular power, motor control and coordination, and balance. Adult aging issues such as these, as well as preexisting medical conditions, most likely contribute to entrapments, and these consumers are less capable of escaping an entrapment scenario than the general population.

The primary performance requirement in ASTM F3186 – 17 intended to address APBR hazards is entrapment testing, which assesses the entrapment potential in four zones in and around an installed APBR. These zones account for virtually all known entrapment fatalities, and testing is performed using a probe that is based on key anthropometric dimensions of at-risk consumers. Thus, ESHF staff concludes that a properly installed APBR that passes this entrapment testing would effectively address the entrapment hazard. ASTM F3186 – 17 also includes performance requirements intended to address misassembly and misinstallation, as well as requirements for labeling, warnings, and instructional literature.

Although hazard control measures that rely on consumers to alter their behavior to avoid the hazard are less effective than designing the hazard out of the product or guarding the consumer from the hazard, particularly if the victims are older adults, ESHF staff believes that labeling, warnings, and instructions offer some benefit as a supplemental safety measure for risks that

cannot be eliminated through design. Examples of these risks include entrapments in the space between an APBR and the headboard or footboard of the bed, and falls associated with climbing over APBRs. Also, some requirements and test methods in ASTM F3186 – 17 depend upon information provided by the manufacturer about compatible beds and mattresses. ESHF staff has identified some areas for improvement in the labeling and warning requirements, but concludes that compliance with these requirements, and compliance with the instructional literature requirements, should reduce the risk of injury and death associated with APBRs.

Even so, ESHF staff's examination of APBR samples, determined to be representative of the market, suggests that industry compliance with the labeling, warning, and instructional literature requirements of ASTM F3186 – 17 was likely very low when the samples were sold. None of the samples fully conform to the labeling requirements, warning requirements, or instructional literature requirements. More than half of the sample products do not include warnings related to the entrapment hazard, and about half of those do not include any warnings at all. In addition, the instructional literature included with these samples is often deficient, lacking key information about compatible mattresses and beds and conflicting information about how to properly install or adjust the APBR. This missing and conflicting information commonly contributed to the inability of the APBR to meet the performance requirements.

REFERENCES

Dayal, V. (2020). *Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails.* CPSC staff memorandum to Vineed Dayal, Project Manager, Adult Portable Bed Rails, U.S. Consumer Product Safety Commission, Bethesda, MD. Available: Current briefing package (Tab E).

Qin, A. (2020). *Adult portable bed rail-related deaths, injuries, and potential injuries: January 2003 to December 2019.* CPSC staff memorandum to Vineed Dayal, Adult Portable Bed Rails Project Manager, U.S. Consumer Product Safety Commission, Bethesda, MD. Available: Current briefing package (Tab A).

Smith, T. P. (2005). *Older consumer safety: Phase I: A review and summary of the literature on age-related differences in the adult consumer population, and product-related interventions to compensate for those differences*. CPSC staff project report, U.S. Consumer Product Safety Commission, Bethesda, MD. Available: https://www.cpsc.gov/s3fs-public/Older-Consumer-Safety-Phase-I.PDF.

Smith, T. P. (2014). *Human factors assessment for Petition CP 13-1, petition requesting a ban or standard on adult portable bed rails*. CPSC staff memorandum to Richard McCallion, Project Manager, Adult Portable Bed Rails Petition, U.S. Consumer Product Safety Commission, Rockville, MD. Available: https://www.cpsc.gov/s3fs-public/PetitionCP131RequestforBanorStandardforAdultPortableBedRail.pdf (Tab E).

U.S. Food and Drug Administration (FDA). (2006). *Guidance for industry and FDA staff: Hospital bed system dimensional and assessment guidance to reduce entrapment*. Retrieved from

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072729.pdf.

TAB E:
MEMORANDUM BY THE DIRECTORATE FOR LABORATORY SCIENCES, DIVISION OF MECHANICAL ENGINEERING

United States
Consumer Product Safety Commission
Rockville, MD 20814

Memorandum

DATE: July 15, 2020

TO: Vineed K. Dayal
Adult Portable Bed Rails Project Manager
Division of Mechanical Engineering
Directorate for Laboratory Sciences

THROUGH: Andrew G. Stadnik, Assistant Executive Director
Directorate for Laboratory Sciences

Michael Nelson, Division Director
Division of Mechanical Engineering, Directorate for Laboratory Sciences

FROM: Vineed K. Dayal[1]
Mechanical Engineer
Division of Mechanical Engineering
Directorate for Laboratory Sciences

SUBJECT: Engineering Analysis of Petition CP 13-1, Requests for Ban or Standard on Adult Portable Bed Rails

INTRODUCTION

In 2013, the U.S. Consumer Product Safety Commission (CPSC) docketed Petition CP 13-1, Petition Requesting a Ban or Standard on Adult Portable Bed Rails. ASTM International (ASTM) formed the F15.70 subcommittee for Adult Safety Products and began developing a voluntary standard for adult portable bed rail (APBR) products. On April 23, 2014, staff delivered a briefing package to the Commission, recommending that the Commission defer a decision on the petition to allow the voluntary standard process to continue until the APBR voluntary standard had been developed and evaluated by staff. On April 29, 2014, the Commission voted unanimously (3–0) to defer the petition.

Since then, CPSC staff has worked with ASTM to develop a draft voluntary standard, and in August 2017, ASTM published the voluntary standard F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products. The voluntary standard includes performance requirements, labeling and warning requirements, and instructional literature requirements intended to minimize entrapment and strangulation hazards associated with APBRs.

This memorandum, prepared by staff of CPSC's Directorate for Laboratory Sciences, Division of Mechanical Engineering (LSM), reviews whether ASTM F3186 – 17 is likely to adequately

[1] Former CPSC Mechanical Engineer, Ian B. Hall, provided significant contributions to the development of this memorandum and CPSC staff's project work overall in response to this petition.

address the APBR hazards identified in the petition. Staff also reviews whether there is likely to be substantial compliance by manufacturers with the general requirements and performance requirements of the ASTM standard. To obtain a full understanding of CPSC staff's analysis of ASTM F3186 – 17, ESHF staff's analysis must be considered in conjunction with this memorandum.[2]

REVIEW OF ASTM F3186 – 17 REQUIREMENTS

ASTM published F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products,* on August 30, 2017. [3] The standard, intended to minimize entrapment and strangulation hazards, includes general and specific performance requirements. CPSC staff was involved with developing the standard and believes that the standard adequately addresses the risk of entrapment. However, staff believes that the standard requires clarification to ensure data quality and repeatability. Specifically, staff finds that parts of the standard are internally inconsistent, while other sections require significant interpretations to yield repeatable results. On September 5, 2019, staff sent a letter to the ASTM subcommittee chairman to identify some of these issues and suggest possible solutions.[4] Staff met with the ASTM subcommittee to review the letter on June 12, 2020.[5]

Staff identified two issues with the standard. The first issue concerned an internal inconsistency between the Zone 3 entrapment performance requirement and the performance requirement listed within the Zone 3 entrapment test methodology.[6,7,8] ASTM F3186 – 17 Section 6.3.3 states that the highest point on the cylinder of the test probe must remain at or above the uncompressed mattress plane, when tested in accordance with section 8.4.5. However, the test method specified in section 8.4.5 states that a product shall fail the Zone 3 entrapment test when the horizontal line marked on one face of the probe is at or below the surface of the mattress. As seen in Figure 1,

---

[2] Tab D, Smith, T.P. & Talcott K.A. ESHF Staff Memorandum, *Human Factors Assessment of ASTM F3186 – 17, Standard Specification for Adult Portable Bed Rails and Related Products, and Likely Industry Compliance to Certain Requirements of the Voluntary Standard.*

[3] ASTM F3186 – 17, *Standard Specification for Adult Portable Bed Rails and Related Products,* ASTM International, West Conshohocken, PA, 2017, www.astm.org.

[4] Hall, Ian B. "Potential changes to ASTM F3186 – 17 Adult Portable Bed Rails," 5 September 2019. Attached in Appendix A: CPSC letter to ASTM Subcommittee Chairman.

[5] For more information about the meeting and staff's ongoing work with the subcommittee, contact ASTM International, West Conshohocken, PA, 2017, www.astm.org.

[6] U.S. Department of Health and Human Services. Food and Drug Administration. (2006) Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment. Retrieved from https://www.fda.gov/regulatory-information/search-fda-guidance-documents/hospital-bed-system-dimensional-and-assessment-guidance-reduce-entrapment.

[7] The ASTM standard referenced the FDA Guidance document for the description of the entrapment zones. The FDA Guidance document stated: "Zone 3 is the space between the inside surface of the rail and the mattress compressed by the weight of a patient's head."

[8] Figure from FDA guidance document showing an example of a Zone 3 entrapment.

the two sections refer to two different locations. Furthermore, CPSC staff identified multiple instances during testing where the highest point on the probe remained above the uncompressed mattress plane, while the horizontal line finished below the surface of the mattress. For example, in Figure 2 – the highest point on the dotted green curve remained above the blue line at the same time that the dashed red line finished the test below the blue line.

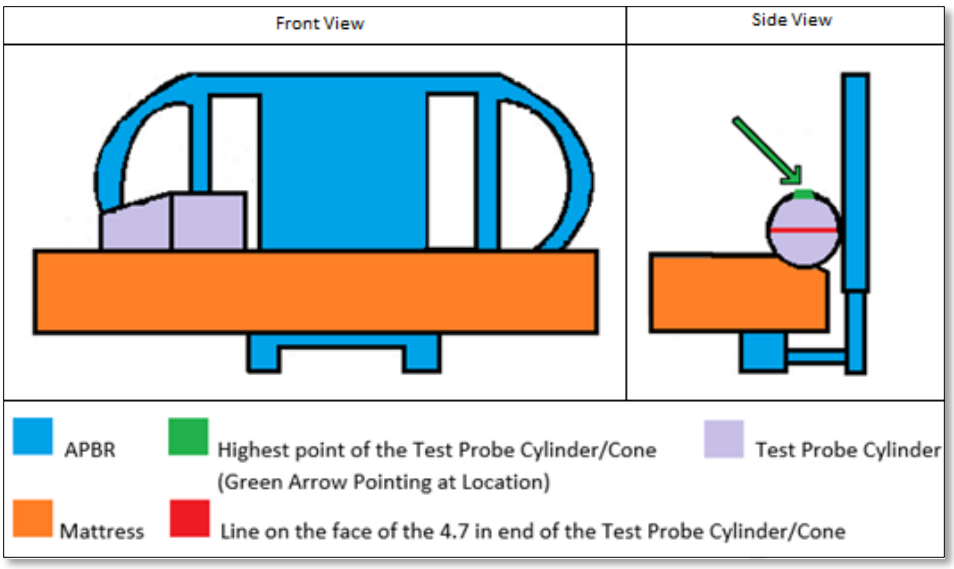


Figure 1. Zone 3 Entrapment Test – Highest point of the Test Probe vs Line on the Test Probe

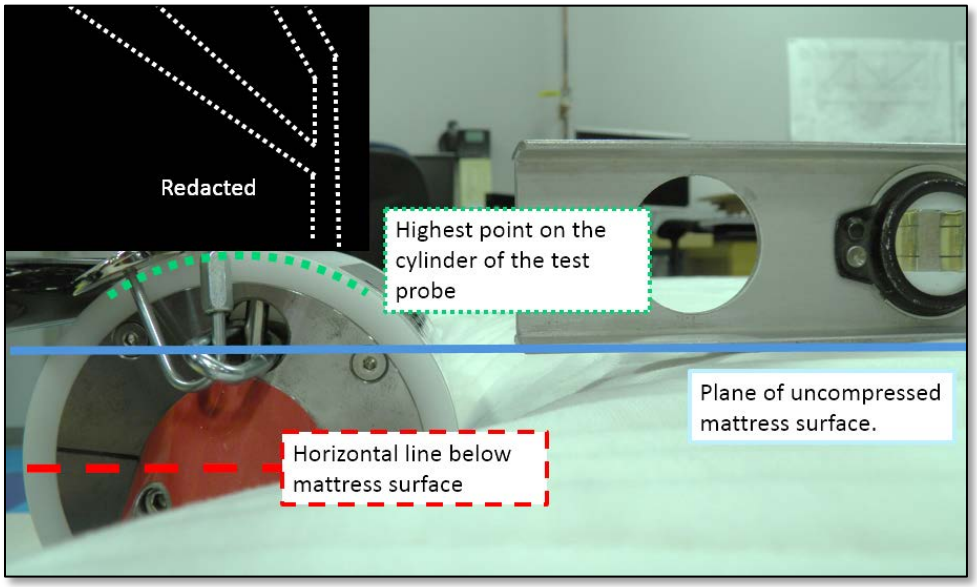


Figure 2. Section 6.3.3 and Section 8.4.5.4(2) requirements are inconsistent. [9]

[9] CPSC staff redacted manufacturer-specific identifying characteristics and added white dashed lines simulating non-specific product geometry.

Due to this inconsistency, CPSC staff suggested two changes set forth below (A double underline denotes added text, while a strikethrough denotes removed text.)

> **Proposed 6.3.3:** Zone 3—~~The highest point on the cylinder of the test probe (see 7.2) shall not pass completely below the horizontal uncompressed plane of the mattress when tested according to 8.4.5.~~ If the line on the face of the 4.7 in. (120 mm) end of the cone is above the surface of the mattress, the space passes the test. If the line on the face of the 4.7 in. (120 mm) end of the cone is at or below the surface of the mattress, the space fails the test.

> **Proposed 8.4.5.4:** Turn the cone until the line on the face of the 4.7 in. (120 mm) end is horizontal, and let the cone sink into the space by its own weight. ~~(1) If the line on the face of the 4.7 in. (120 mm) end of the cone is above the surface of the mattress, the space passes the test. (2) If the line on the face of the 4.7 in. (120 mm) end of the cone is at or below the surface of the mattress, the space fails the test.~~

The second issue concerned a lack of clarity in the finger opening requirement listed in Section 6.4.1. The requirement references two different diameter ranges in two different measurement systems. Because there were two different sets of diameters, CPSC staff was concerned that test labs would be confused about which diameters would be acceptable, and which would be unacceptable. In addition, the ¼-inch depth limitation is inconsistent with the dimension shown in ASTM F3186 – 17 Figure 2, 0.375 in (9.53 mm). CPSC staff proposed a revision to the finger opening requirement to clarify and harmonize the language with other product standards (A double underline denotes added text, while a strikethrough denotes removed text.). The proposed revision is set forth below:

> **Proposed 6.4 Openings:** ~~6.4.1 Holes or slots that extend entirely through a wall section of any rigid material less than 1⁄4 in. (6.35 mm) thick and admit a 5⁄8 in. (13 mm) diameter rod shall also admit a 1 in. (25.4 mm) diameter rod. Holes or slots that are between 8 mm and 25 mm and have a wall thickness less than 1⁄4 in. (6.35 mm) but are limited in depth to 1⁄4 in. (6.35 mm) maximum by another rigid surface shall be permissible (see Fig. 2).~~ 6.4.1 Holes or slots that extend entirely through a wall section of any rigid material less than 0.25 in. (6.4 mm) thick and admit a 5/8 in. (15.9 mm) diameter rod shall also admit a 1.0 in. (25.4 mm) diameter rod. Holes or slots that are between 5/8 in. and 1.0 in. (15.9 and 25.4 mm) and have a wall thickness less than 0.25 in. (6.4 mm) but are limited in depth to 0.375 in. (9.5 mm) maximum by another rigid surface shall be permissible (see Fig. 2 for examples). The product shall be evaluated in all manufacturer's recommended use positions.

Overall, CPSC staff believes that the standard addresses the risk of entrapment and strangulation injuries; nevertheless, staff recommends that ASTM revise the standard to clarify the standard's intent and improve data quality and repeatability. CPSC staff's epidemiological analysis indicates that the majority of APBR deaths were entrapment-related fatalities.[10] Even though the

[10] Tab A, Qin, A. EPHA Staff Memorandum, *Adult Portable Bed Rail-Related Deaths, Injuries, and Potential Injuries*.

ASTM standard does have entrapment performance requirements and test methodologies similar to those recommended in the FDA guidance document titled, "*Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*," significant issues with the ASTM standard remain, which could affect test quality and repeatability. [6,11] As indicated, some parts of the ASTM standard are internally inconsistent. Other sections require significant interpretation to yield repeatable results.

CONFORMANCE TO ASTM F3186 – 17

In addition to reviewing the voluntary standard, CPSC staff tested a sample set of APBR models available in the market to determine compliance with the new standard. The test consisted of 35 APBR models, which, according to CPSC epidemiological and economic analyses, were representative of the entire APBR market.[10,12] The samples included products from approximately 87 percent of all APBR manufacturer or importer firms known to staff, and the samples included products from the largest APBR manufacturers.[13] This memo will summarize the results of the mechanical tests and will include testing from section 9.1.2 Label Permanency, because it is predominantly a mechanical test. This memo will not cover other requirements addressing warnings, labels, or other informational literature.

The physical testing resulted in a 100 percent failure rate, and most samples failed multiple sections, as seen in Figure 3. These results strongly indicate that APBRs on the market do not substantially comply with the voluntary standard.

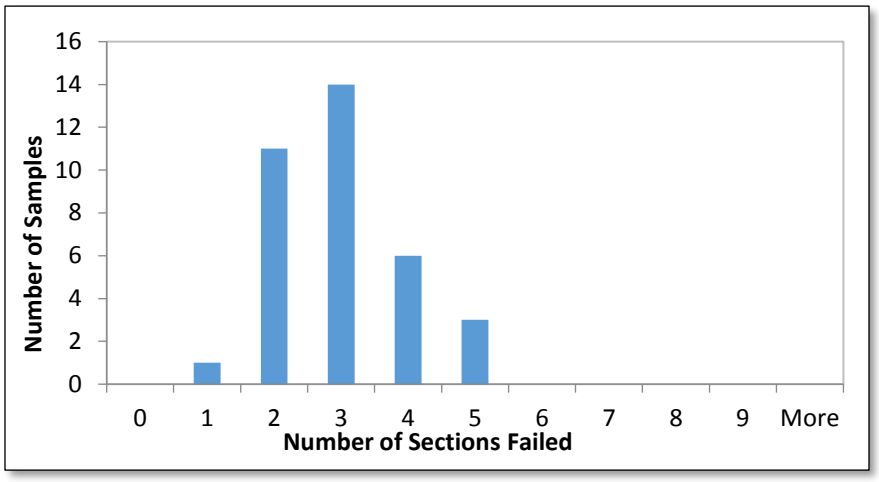


Figure 3. Number of Samples vs. Number of Sections Failed, all samples failed at least one section.

[11] Note that while ASTM F3186 – 17 Section 8.4 Note 1 specifically states: "[t]he tests described in this section are identical to those described in the referenced FDA Guidance Document[7] and in the [NST] video," the ASTM tests are, in fact, slightly different from those listed in the FDA guidance document.
[12] Tab B, Bretford, G. EC Staff Memorandum, *Market for and Societal Cost of Injuries Associated with Adult Portable Bed Rails.*
[13] Staff Memorandum. *July 2018 Update to Petition CP-13-1 Request for a Ban or Standard for Adult Portable Bed Rails*, July 18, 2018. Retrieved from: https://cpsc.gov/s3fs-public/July%202018%20Update%20to%20Petition%20CP%2013-1%20Adult%20Portable%20Bed%20Rails%20-%20July%2018%202018.pdf?4iH.nu0RcuJMBe2HefKigVGRFGvtQaM_.

As detailed in Table 1, the market sample did not meet the individual requirements for the retention system (80% failure rate), structural integrity (43% failure rate), entrapment (94% failure rate), misassembly (23% failure rate), and label permanency (54% failure rate). For each subsection, staff analyzed the major causes of failure, starting with Section 6.1 Retention System.

Table 1. Summary of Mechanical Testing Results

Section	Short Title	Not Met (#)	Not Met (%)
5.1	Hazardous Points/Edges	0	0
5.2	Jagged Surfaces	0	0
5.3	Articulated Beds	0	0
6.1	Retention System	28	80
6.2	Structural Integrity	15	43
6.3	Entrapment	33	94
6.4	Openings	0	0
6.5	Misassembly	8	23
9.1.2	Label Permanency	19	54

The performance requirements of Section 6.1, *Retention Systems*, state that each product must meet three requirements: (1) it must have a method of maintaining the product's position; (2) the retention system must be permanently attached to the product; and (3) the retention system shall not slip or permanently deform during testing. A total of 80 percent of samples failed at least one retention requirement. The primary reason samples failed was the retention system components were not permanently attached to the product, as shown below in Figure 4. In other cases, the retention strap permanently deflected or detached during the free end pull test, or the retention system did not restrain the product during entrapment testing.

Figure 4. Permanently attached – Only removable with the use of tools.

Section 6.2, *Structural Integrity*, has two main performance requirements: (1) during the static structural height test, the product shall extend at least 4 inches above the top surface of the thickest mattress recommended by the product manufacturer; and (2) the product shall not

change dimensions or create a hazardous condition during or after cyclic testing. A total of 43 percent of the market sample tested failed the structural integrity section, including 40 percent that failed the structural height requirement and 6 percent that failed a cyclic test requirement.[14] Most manufacturers did not specify a recommended mattress height; in such cases, CPSC staff considered any mattress readily available to the general public. In addition, section 8.1 requires all products shall be tested fully assembled in accordance with the manufacturer's instructions, but several did not specify or instruct the user how to set the product's adjustable features. In the absence of direction from the manufacturer, CPSC staff adjusted the product's height to the most onerous detent, which was most often the lowest setting. As seen in Figure 5, this resulted in many products measuring a height less than the required 4 inches above the top surface of the mattress. For 6 percent of the samples tested, the fasteners loosened or detached during cyclic testing, which caused the product to change dimensions, as seen in Figure 6. This constitutes a failure under ASTM F3186 – 17 Section 6.2.2.

Figure 5. Products did not extend at least 4 inches above the top surface of the mattress.

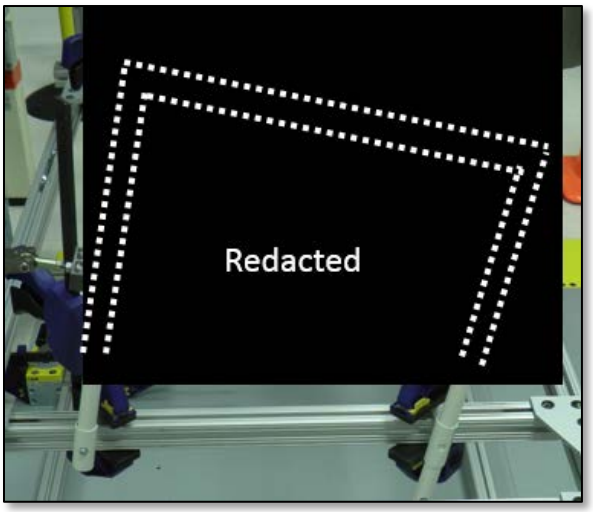


Figure 6. During the cyclic test, the right-side push button fastener joint failed and caused the product to change dimensions.

[14] One sample failed both the structural height and the cyclic requirements. Therefore, the total failure ratio will not sum to 43 percent.

As shown in Table 1, a total of 94 percent of the market sample did not meet the entrapment performance requirements set forth in the voluntary standard. As seen in Figure 7, the ASTM standard sub-divides entrapment performance requirements into four individual zones: (1) Zone 1 - Within the rail; (2) Zone 2 - Under the rail between the rail supports, or Under the rail next to a single rail support; (3) Zone 3 - Between the rail and the mattress; and (4) Zone 4 - Under the rail at the ends of the rail.

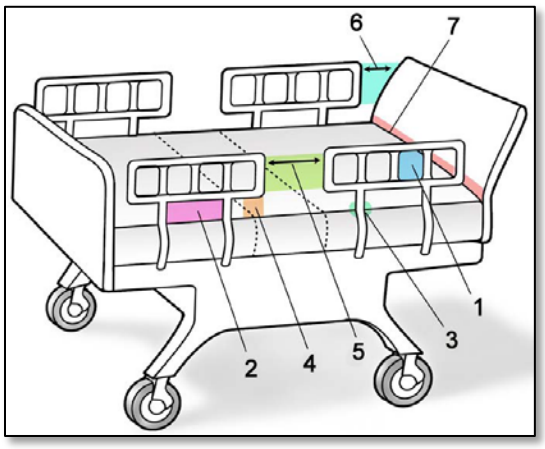


Figure 7. Entrapment Zones - Zones 1-4 are used by the FDA & ASTM standards, while Zones 5-7 is used by the FDA only. [6,15]

A total of 40 percent of the market sample failed the Zone 1 entrapment requirements. In the Figure 8 example, the samples did not have adequate internal structure to prevent the head probe from passing through a Zone 1 opening and failed the Zone 1 entrapment requirements.[16]

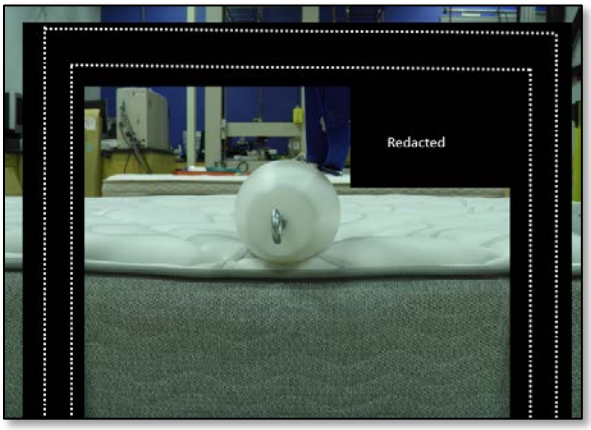


Figure 8. A product without sufficient Zone 1 internal structure.

[15] Due to potential intellectual property concerns, CPSC staff chose to reference a publically available figure from the FDA guidance document, instead of copying the figure directly from the ASTM standard. The FDA figure is substantially similar to the ASTM figure in terms of entrapment Zones 1 - 4.

[16] CPSC staff interpreted the Zone 1 opening language to include both fully bounded internal openings as per the FDA Guidance document and openings that were partially bounded by the rail and partially bounded by the mattress, as per ASTM F3186 – 17 Figure X1.1.

A total of 77 percent of the market sample failed the Zone 2 entrapment requirements. Samples failed Zone 2 requirements due to two issues. The first issue concerned a lack of internal structure to prevent the probe from entering a Zone 2 opening between the rail and the mattress, as seen in Figure 9.

Figure 9. A product without sufficient internal structure covering the Zone 2 opening.

The second issue related to the lack of specificity in the information manufacturers provide. Many manufacturers did not specify what mattress thickness to use with the product; nor did they describe how the consumer is to appropriately install and/or adjust the product to fit different size mattresses. An example of a product with installation instruction that allowed for a significant lateral gap between the mattress and the product is shown in Figure 10.

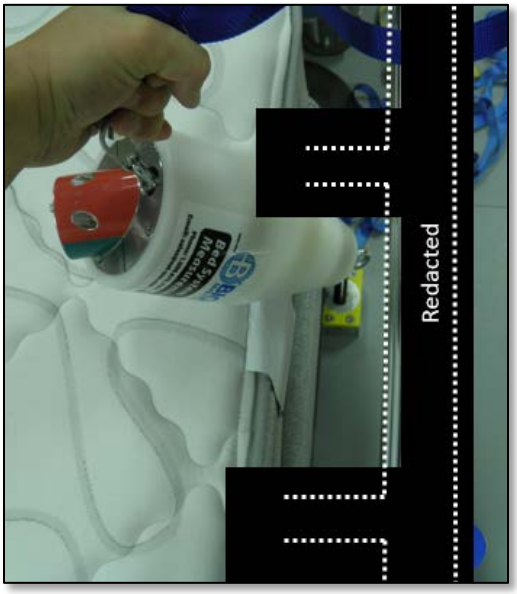


Figure 10. A product with a significant allowable lateral gap between mattress and product.

Approximately 31 percent of the market sample failed the Zone 3 entrapment requirements. The causes of the Zone 3 entrapment failures were similar to those listed for Zone 2. Most failures occurred due to a lack of adequate structure and issues with the lack of compatibility instructions, as noted earlier. In some cases, the gaps between the product's internal cross-beams were significant and allowed the probe to move laterally outward, partially into the gap between the cross-beams, which reduced the amount of mattress area supporting the probe, as seen in Figure 11. As the surface area supporting the probe decreases, the probe deflects more into the mattress, resulting in a failure related to the maximum allowable vertical deflection. One product used brackets that created a significant lateral space between the bed frame and the mattress and affected the distance between the product and a mattress. The significant gap between the product and the mattress allowed the probe to translate laterally outward, and reduced the amount of mattress supporting the probe, which reduced performance. As seen in Figure 12, the user manual also contributed to the lack of performance. Some user manuals do not explicitly state that the APBR should be installed against the mattress, and some of these include recommendations suggesting that this lateral gap can be as large as 2 inches. In addition, some user manuals that state that the APBR should be installed against the mattress also suggest that the distance between the product and the mattress could be as large as 2 inches, as large as 4¾ inches, or both. This issue is discussed in more detail in the Human Factors memorandum (Tab D).

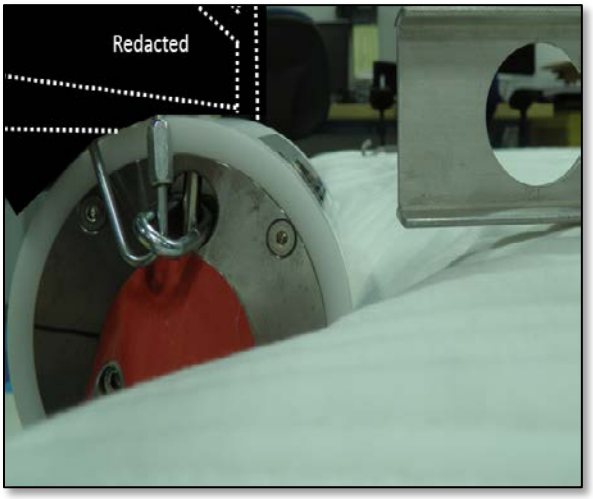


Figure 11. The large gaps between the cross-beams allowed the probe to translate outward, which reduced the amount of mattress supporting the probe.

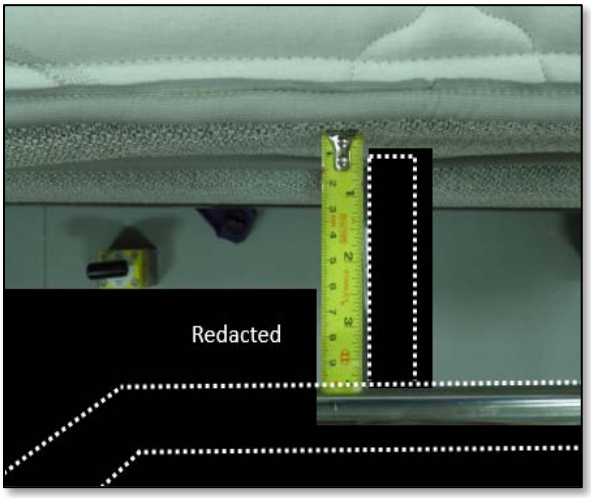


Figure 12. User manual allowed for a large lateral gap between the mattress and the product.

The Zone 4 entrapment failures were caused by overhanging structure at the ends of the rai being positioned too high relative to the mattress. Some products' geometry created large openings at the sides of the product, as seen in Figure 13. The test method for Zone 4 entrapment testing specifies that the product must be adjusted to the manufacturer's recommended height or heights above the mattress, for products that allow consumer adjustment (see section 8.4.6.3). In most cases, the manufacturer did not specify how to adjust or install the product for a given bed and mattress environment. As discussed in the Human Factors memorandum (Tab D), many instructions for products with consumer-adjustable heights simply tell consumers to adjust the product to their preferred or desired height; or, the instructions simply describe how to adjust the

height, without saying why consumers should do so. In the absence of clear instructions from the manufacturer, CPSC's technical staff chose to use a mattress available to the general public, with the product adjusted to any detent, as seen in Figure 14.

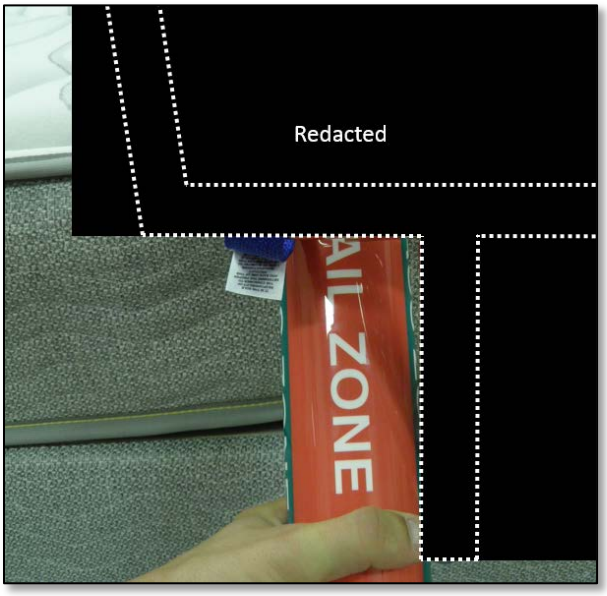


Figure 13. Structure created large opening under the rail at the ends of the rail.

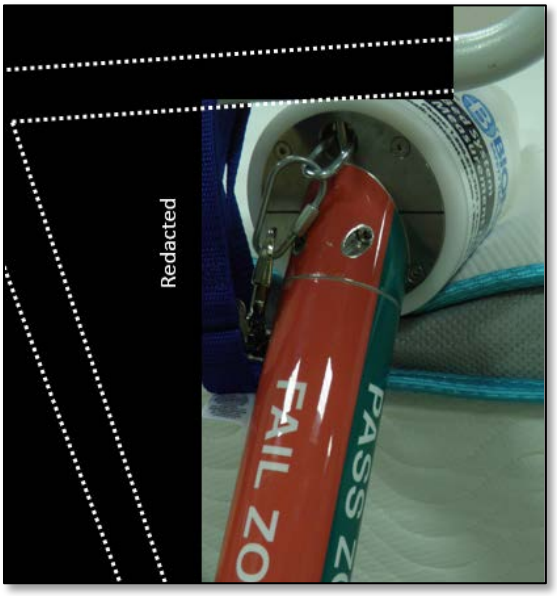


Figure 14. Overhanging structure too high relative to mattress.

The requirements of Section 6.5 *Misassembly* state that the product shall not be able to be misassembled. According to Section 6.5.2: "A product covered by this specification shall be considered [misassembled] if it appears to be functional under any condition and it does not meet the requirements of 6.1–6.4."[1] Within the 23 percent failure rate, most products failed because the retention strap could not be installed and still appear to be functional. Other products failed because they had user-installed structural beams, where not installing that beam reduced entrapment performance.

Section 9.1.2 *Label Permanency* required the warning labels to be permanent, irremovable without the use of solvents, tools or damaging the surface the label is on. In 54 percent of the market samples, CPSC staff removed a label without the aid of tools or solvents, and without damaging the substrate, as shown in Figure 15 below.

[1] The original standard misspelled the word "misassembled."

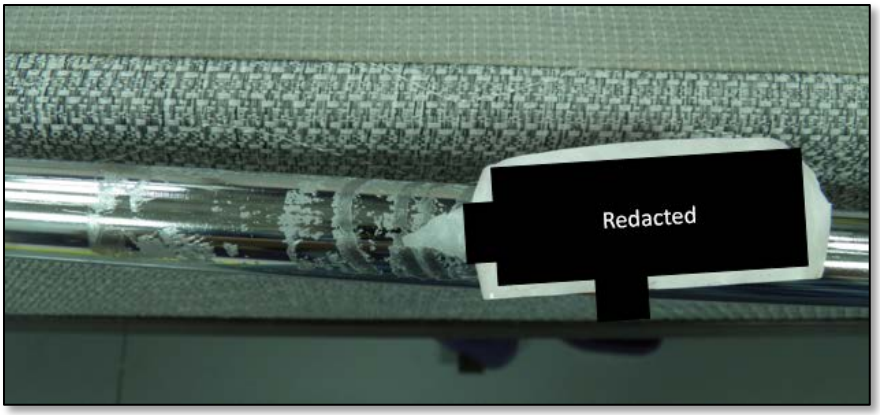


Figure 15. Label removed without damaging the substrate.

CONCLUSION

Staff reviewed ASTM F3186 – 17 and determined that the standard did address the risk of entrapment and strangulation injuries, but the standard also required significant interpretations to ensure data quality and test repeatability. CPSC staff communicated the issues to ASTM and recommended changes to revise the standard and clarify the standard's intent.

Staff physically tested 35 products, randomly selected to represent the market at large, to the requirements in ASTM F3186 – 17. The results indicate that there is 0 percent market compliance with the voluntary standard. All samples tested failed at least one requirement in the voluntary standard, with some products failing as many as five different sub-sections of the standard.

APPENDIX A:
CPSC LETTER TO ASTM SUBCOMMITTEE CHAIRMAN

U.S. CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

September 5, 2019

Dr. William A. Hyman
Subcommittee Chairman for ASTM F3186 Adult Portable Bed Rails
ASTM International
100 Barr Harbor Dr.
West Conshohocken, PA 19428-2959

Dear Dr. Hyman:

S.Consumer Product Safety Commission (CPSC) staff requests[1] that the subcommittee meet to discuss the issues identified below and potential solutions staff proposes in this letter. Staff is currently evaluating ASTM F3186-17 *Standard Specification for Adult Portable Bed Rails and Related Products*[2] and may raise additional issues later. CPSC staff is concerned about two requirements:

A. The zone 3 entrapment performance requirement (§ 6.3.3) is inconsistent with language in the zone 3 entrapment test method (§ 8.4.5.4).
B. The finger openings performance requirement (§ 6.4) is not clear because it references two different diameter ranges, uses two different systems of measurement, and is inconsistent with the figure referenced in the standard's text.

Regarding issue A, CPSC staff noticed that there are two sets of competing zone 3 entrapment performance requirements. Section 6.3.3 states that the highest point on the cylinder of the test probe must remain at or above the uncompressed mattress plane. In contrast, § 8.4.5.4(2) states that a product shall fail the zone 3 entrapment test when the probe's horizontal line is at or below the surface of the mattress. If the highest point on the cylinder remains above the

[1] The views expressed in this letter are those of CPSC technical staff and have not been reviewed or approved by, and may not reflect the views of, the Commission.
[2] ASTM F3186-17, Standard Specification for Adult Portable Bed Rails and Related Products, ASTM International, West Conshohocken, PA, 2017, www.astm.org

uncompressed mattress surface, and the horizontal line is at or below the surface of the mattress, then those two statements are fundamentally incompatible. Therefore, CPSC staff recommends changing the language in the performance requirement and test method, as detailed below:

> Proposed 6.3.3: Zone 3—~~The highest point on the cylinder of the test probe (see 7.2) shall not pass completely below the horizontal uncompressed plane of the mattress when tested according to 8.4.5.~~ If the line on the face of the 4.7 in. (120 mm) end of the cone is above the surface of the mattress, the space passes the test. If the line on the face of the 4.7 in. (120 mm) end of the cone is at or below the surface of the mattress, the space fails the test.
>
> Proposed 8.4.5.4: Turn the cone until the line on the face of the 4.7 in. (120 mm) end is horizontal, and let the cone sink into the space by its own weight. ~~(1) If the line on the face of the 4.7 in. (120 mm) end of the cone is above the surface of the mattress, the space passes the test. (2) If the line on the face of the 4.7 in. (120 mm) end of the cone is at or below the surface of the mattress, the space fails the test.~~

Issue B concerns the lack of clarity in the finger opening requirement listed in § 6.4.1. The requirement references two different sets of diameters in two different measurement systems. Since there are two different sets of diameters, CPSC staff is concerned that test labs will be unclear about which diameters are acceptable and which are not acceptable. In addition, the ¼-in. depth limitation is inconsistent with the dimension shown in ASTM F3186-17 Figure 2. CPSC staff proposes new language for the finger opening requirement to clarify and harmonize the language with other durable children's products, as detailed below:

> Proposed 6.4 Openings:
> ~~6.4.1 Holes or slots that extend entirely through a wall section of any rigid material less than 1/4 in. (6.35 mm) thick and admit a 5/8 in. (13 mm) diameter rod shall also admit a 1 in. (25.4 mm) diameter rod. Holes or slots that are between 8 mm and 25 mm and have a wall thickness less than 1/4 in. (6.35 mm) but are limited in depth to 1/4 in. (6.35 mm) maximum by another rigid surface shall be permissible (see Fig. 2).~~
> 6.4.1 Holes or slots that extend entirely through a wall section of any rigid material less than 0.25 in. (6.4 mm) thick and admit a 5/8 in. (15.9 mm) diameter rod shall also admit a 1.0 in. (25.4 mm) diameter rod. Holes or slots that are between 5/8 in. and 1.0 in. (15.9 and 25.4 mm) and have a wall thickness less than 0.25 in. (6.4 mm) but are limited in depth to 0.375 in. (9.5 mm) maximum by another rigid surface shall be permissible (see Fig. 2 for examples). The product shall be evaluated in all manufacturer's recommended use positions.

In addition to issues A and B, CPSC staff noted four minor issues:

C. There is a spelling error in § 6.5.2. In § 6.5.2, the word "misasssembled" is misspelled.
D. The hyperlink is invalid in § 7.2. CPSC staff assumes that the text was meant to reference the same web address as is listed in footnote #7. The footnote #7 hyperlink is active and works as intended.
E. The reference to NSA may be intended to reference "NST." The note in § 8.4 *Entrapment Tests* references an "NSA video." The rest of the standard does not reference "NSA" or an "NSA video," but the standard does reference an "NST video" in § 7.2 *Entrapment Test Probe*.
F. The zone 2 test method may not be intended to be pulled "in both directions." Applying a force "in both directions" appears to be inconsistent with how the probe is intended to be oriented in § 8.4.4.4.

I hope this information will be useful to the subcommittee. I look forward to arranging a time to discuss these issues.

Best Regards,

Ian B. Hall

Project Manager, Adult Portable Bed Rails
Mechanical Engineer
Division of Laboratory Science - Mechanical

cc:

Patricia Edwards, CPSC Voluntary Standards Coordinator
Molly Lynyak, ASTM F15 Manager

APPENDIX B:
MECHANICAL ENGINEERING TEST RESULTS OF APBR SAMPLES

Sample #	General Requirements			Performance Requirements					Label Permanency Requirements	Overall Result
	§ 5.1	§ 5.2	§ 5.3	§ 6.1	§ 6.2	§ 6.3	§ 6.4	§ 6.5	§ 9.1.2	
18-420-0003	M	M	NA	Not Met	M	Not Met	M	NA	M	Fail
18-420-0004	M	M	NA	Not Met	M	Not Met	M	NA	M	Fail
18-420-0005	M	M	NA	Not Met	M	Not Met	M	NA	Not Met	Fail
18-420-0006	M	M	NA	M	Not Met	Not Met	M	M	Not Met	Fail
18-420-0007	M	M	NA	Not Met	M	Not Met	M	M	Not Met	Fail
18-420-0008	M	M	NA	Not Met	M	Not Met	M	M	M	Fail
18-420-0009	M	M	NA	Not Met	M	Not Met	M	NA	M	Fail
18-420-0010	M	M	NA	M	Not Met	M	M	Not Met	Not Met	Fail
18-420-0011	M	M	NA	Not Met	Not Met	Not Met	M	NA	M	Fail
18-420-0012	M	Not Met	NA	Not Met	Not Met	Not Met	M	NA	Not Met	Fail
18-420-0013	M	M	NA	Not Met	Not Met	Not Met	M	NA	M	Fail
18-420-0014	M	M	NA	Not Met	Not Met	Not Met	M	M	Not Met	Fail
18-420-0015	M	M	NA	Not Met	Not Met	Not Met	M	M	Not Met	Fail
18-420-0016	M	M	NA	M	M	M	M	M	Not Met	Fail
18-420-0017	M	M	NA	Not Met	M	Not Met	M	Not Met	Not Met	Fail
18-420-0018	M	M	NA	Not Met	M	Not Met	M	NA	M	Fail
18-420-0019	M	M	NA	Not Met	M	Not Met	M	NT	NA	Fail
18-420-0020	M	M	NA	Not Met	M	Not Met	M	NA	Not Met	Fail
18-420-0021	M	M	NA	M	M	Not Met	M	NA	Not Met	Fail
18-420-0022	M	M	NA	Not Met	M	Not Met	M	NA	Not Met	Fail
18-420-0023	M	M	NA	Not Met	M	Not Met	M	Not Met	NA	Fail
18-420-0024	M	M	NA	Not Met	M	Not Met	M	NA	Not Met	Fail
18-420-0025	M	M	NA	Not Met	Not Met	Not Met	M	NA	Not Met	Fail
18-420-0026	M	M	NA	Not Met	Not Met	Not Met	NA	Not Met	Not Met	Fail
18-420-0027	M	M	NA	Not	M	Not	M	Not	Not	Fail

Sample #	General Requirements			Performance Requirements					Label Permanency Requirements	Overall Result
	§ 5.1	§ 5.2	§ 5.3	§ 6.1	§ 6.2	§ 6.3	§ 6.4	§ 6.5	§ 9.1.2	
				Met		Met		Met	Met	
18-420-0028	M	M	NA	M	Not Met	Not Met	M	NA	NA	Fail
18-420-0029	M	M	NA	M	Not Met	Not Met	M	NA	NA	Fail
18-420-0030	M	M	NA	Not Met	Not Met	Not Met	M	NA	NA	Fail
18-420-0031	M	M	NA	Not Met	M	Not Met	M	NA	NA	Fail
18-420-0032	M	M	NA	Not Met	Not Met	Not Met	M	Not Met	Not Met	Fail
18-420-0033	M	M	NA	Not Met	Not Met	Not Met	NA	NA	NA	Fail
18-420-0034	M	M	NA	Not Met	Not Met	Not Met	NA	Not Met	NA	Fail
18-420-0035	M	M	NA	Not Met	M	Not Met	NA	NA	Not Met	Fail
18-420-0036	M	M	NA	M	M	Not Met	NA	Not Met	Not Met	Fail
18-420-0037	M	M	NA	Not Met	M	Not Met	M	NA	M	Fail