



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MD 20814

The contents of this document will be
discussed at the Commission Meeting
(Briefing) scheduled for February 5, 2014.

This document has been electronically
approved and signed.

DATE: January 22, 2014

THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE.

A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: **TBD**

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director

FROM: Patricia M. Pollitzer, Assistant General Counsel
Hyun S. Kim, Attorney, OGC

SUBJECT: Final Rule: Safety Standard for Carriages and Strollers

The Office of the General Counsel is providing for Commission consideration the attached draft final rule for publication in the *Federal Register*. The final rule would establish a safety standard for carriages and strollers pursuant to the Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008.

Please indicate your vote on the following options:

I. Approve publication of the attached document in the *Federal Register*, as drafted.

(Signature)

(Date)

- II. Approve publication of the attached document in the *Federal Register*, with changes.
(Please specify.)

(Signature)

(Date)

- III. Do not approve publication of the attached document in the *Federal Register*.

(Signature)

(Date)

- IV. Take other action. (Please specify.)

(Signature)

(Date)

Attachment: Draft *Federal Register* Notice: Safety Standard for Carriages and Strollers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1227

Docket No. CPSC-2013-0019

Safety Standard for Carriages and Strollers

AGENCY: Consumer Product Safety Commission.

ACTION: Final rule.

SUMMARY: The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the United States Consumer Product Safety Commission (Commission or CPSC) to promulgate consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the products. The Commission is issuing a safety standard for carriages and strollers in response to the direction under Section 104(b) of the CPSIA.

DATES: The rule will become effective on [INSERT DATE 18 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.] The incorporation by reference of the publication listed in this rule is approved by the Director of the *Federal Register* as of [INSERT DATE 18 MONTHS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Mike Lee, Compliance Officer, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: 301-504-7737; e-mail: mlee@cpsc.gov.

SUPPLEMENTARY INFORMATION:

A. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub. L. 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA, part of the Danny Keysar Child Product Safety Notification Act, requires the Commission to: (1) examine and assess the effectiveness of voluntary consumer product safety standards for durable infant or toddler products, in consultation with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts; and (2) promulgate consumer product safety standards for durable infant and toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standards if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the products.

On May 20, 2013, the Commission issued a notice of proposed rulemaking (NPR) for carriages and strollers. 78 FR 29279. The NPR proposed to incorporate by reference the voluntary standard, ASTM 833-13, “Standard Consumer Safety Performance Specification for Carriages and Strollers,” with certain changes to provisions in the voluntary standard to strengthen the ASTM standard.

In this document, the Commission is issuing a safety standard for carriages and strollers. As required by Section 104(b)(1)(A), the Commission consulted with manufacturers, retailers, trade organizations, laboratories, consumer advocacy groups, consultants, and members of the public in the development of this proposed standard, largely through the ASTM process. The rule incorporates by reference the most recent voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F833-13b, “Standard Consumer Safety Performance Specification for Carriages and Strollers” (ASTM

F833-13b), with a modification to address head entrapment hazards associated with multi-positional/adjustable grab bars.

B. Product Description

The term “durable infant or toddler product” is defined in section 104(f)(1) of the CPSIA as a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years. “Strollers” are specifically identified in section 104(f)(2)(I) of the CPSIA as a durable infant or toddler product. ASTM F833-13b defines a “stroller” as a wheeled vehicle to transport children usually from infancy to 36 months of age. Children are transported generally in a sitting-up or semi-reclined position. The motive power is supplied by a person while pushing on a handle attached to the stroller. Carriages, on the other hand, are wheeled vehicles to transport an infant, usually in a lying down position. Thus, the principal difference between strollers and carriages is the position of the occupant. Both carriages and strollers may be capable of being folded for storage.

Umbrella strollers are lightweight, compact when folded, and may lack certain accessories, such as baskets underneath the seat, or cup holders for the caregiver. Strollers that fold in two dimensions, the height and length, are called “2D” strollers. Strollers that collapse in all three dimensions—height, length, and width—resulting in a smaller folded package than 2D strollers, are called “3D” strollers. Other types of strollers include travel systems that accommodate an infant car seat on a stroller. Strollers intended to be used at a jogging rate are called “jogging strollers.” Some products can be used as strollers and carriages (convertible carriages/strollers). Convertible carriages or strollers are intended to be converted by the owner to be used as a carriage or a stroller. Some strollers incorporate automatic or assisted folding and

unfolding mechanisms. All of these carriages and strollers fall within the scope of ASTM F833-13b.

C. Market Description

The majority of carriages/strollers are produced and/or marketed by juvenile product manufacturers and distributors. Currently, there are 85 known suppliers of carriages/strollers to the U.S. market. Thirty-four are domestic manufacturers, 36 are domestic importers, and four are domestic firms with unknown supply sources. In addition, 10 foreign firms supply strollers to the U.S. market: seven foreign manufacturers, one firm that imports products from foreign companies and distributes them from outside of the United States, one foreign retailer that ships directly to the United States, and one firm with an unknown supply source. There is an additional manufacturer whose size and location we could not determine.

According to a 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*), nearly all new mothers (99 percent) own at least one stroller. Applying this information to Centers for Disease Control and Prevention (CDC) birth data indicates that nearly 4 million strollers are owned by new mothers. Approximately 26 percent of those strollers were handed down or purchased secondhand, according to the *2006 Baby Products Tracking Study*. Thus, about 74 percent of strollers were acquired new, and approximately 3 million strollers are sold to households annually ($.99 \times .74 \times 4$ million births per year). Strollers can cost between \$20 to \$700, depending upon the type and brand of stroller. On average, umbrella strollers tend to be the least expensive (around \$25–\$50 for the least costly versions); and most other strollers cost around \$150–\$300, with many carriages, travel systems, and jogging stroller costs running in the \$500–700 range.

D. Incident Data

The preamble to the NPR summarized the incident data reported to the Commission from January 1, 2008 through December 31, 2012, involving strollers. 78 FR 29281. In the NPR CPSC's Directorate for Epidemiology staff identified four stroller-related fatalities. In addition, 1,203 stroller-related nonfatal incidents, 359 of which resulted in injuries, were reported during that time period.

The hazard patterns identified in the NPR included issues with wheels, parking brakes, lock mechanisms, restraints, hinges, structural integrity, stability/tip-over, clearance, car seat attachment, canopies, handlebars, seats, sharp points or edges, trays, and unspecified or miscellaneous problems. Since the NPR, 90 new incidents related to carriages and strollers were reported to the Commission between January 1, 2013 and June 30, 2013; these incidents reportedly occurred between January 1, 2008 and June 30, 2013. There were no new fatal incidents reported. Out of the 90 new incidents, 32 stroller-related, nonfatal injuries were reported. Thus, the total number of incidents reported from January 1, 2008 through June 30, 2013, increased to 1,297 incidents, including 4 fatalities, and 391 injuries.

The hazard patterns identified among the 90 new incidents were similar to the ones identified in the NPR. Wheel problems accounted for 25 of the 90 new incidents, which resulted in six injuries. Lock mechanical failures resulted in 11 incidents, causing five injuries. Ten incidents, resulting in three injuries, arose from stability issues. Restraints were associated with two injuries and eight noninjury incidents.

Of the 90 new incidents, four incidents required hospitalization. Two incidents resulted in finger amputations, one that occurred when a child's finger got caught in the folding hinge; the second finger amputation occurred when a stroller collapsed. The third hospitalization involved a child unbuckling the restraints, attempting to leave the stroller, and getting caught on

the extended rivet used to latch the folded stroller; this incident caused a laceration to the crotch area. The fourth hospitalization resulted from a stroller rolling off a train platform and falling onto the tracks with the child in the stroller, causing a cut on the child's forehead.

The NPR also noted 78 reported stroller incidents that involved children older than 4 years of age and adults. Out of the 78 incidents, 72 involved victims between 17 and 64 years of age. Almost all of the incidents (74 out of 78) resulted in injuries, mostly to the fingers. Six new incidents were reported from January 1, 2013 to June 30, 2013, for a total of 84 stroller incidents. Based on the narratives provided, all six new incidents involved children older than 4 years of age or adults, and the six incidents each resulted in finger injuries.

E. Overview of ASTM F833

ASTM first published a consumer product safety standard for carriages and strollers in 1983. ASTM F833, "Standard Consumer Safety Performance Specification for Carriages and Strollers," established safety performance requirements, test methods, and labeling requirements to minimize the hazards to children presented by carriages and strollers. ASTM F833 has been revised more than 20 times. The current standard, ASTM F833-13b, was approved on November 1, 2013.

1. Proposed Rule

In the NPR, the Commission proposed to incorporate ASTM F833-13, which addressed many of the hazards patterns identified for strollers. Among other requirements, ASTM F833-13 provided:

- an improved test method for the parking brake requirement;
- a new requirement and test method to address head entrapment hazards associated with car seats on a stroller (combination unit);

- a new requirement, test method, and warnings to address wheel and swivel assemblies' detachments;
- an improved test method for latching and locking mechanisms;
- a new requirement and test method to address the scenario of the child releasing the buckle of the restraint system and a clarification on the buckle closing system;
- a new requirement and test method to address pinching, shearing, and scissoring at the saddle hinge link on 3D fold strollers;
- a new requirement and test method to address pinching, shearing, and scissoring at the canopy hinges;
- an improved requirement and test method to address stability issues by taking into account multiple seats facing different directions, such as rotating seats;
- a new requirement and test method to address a strangulation hazard associated with cords and straps within the occupant space; and
- warning label clarifications.

In the NPR, the Commission also proposed a performance requirement and test method to address scissoring, shearing, and pinching hazards associated with 2D fold strollers, which were already required for 3D fold strollers. The Commission noted that hinge issues caused the highest injury rate of any stroller hazard category (75 incidents, resulting in 72 injuries). Most of the hinge-related injuries resulted from scissoring, pinching, or shearing at the hinge link of 2D and 3D fold strollers. Most of the incidents occurred when a caregiver was unfolding the stroller for use and the child was climbing into the stroller. Reported injuries involved pinched, lacerated, or amputated fingers or arms, including one hospitalization for reattachment of a finger. For testing of the 2D fold stroller and convertible carriage/strollers, the Commission

proposed a test within an access zone based on the incident data and the anthropometric dimensions of a child occupant. The Commission also proposed a test method to test the frame folding action of a stroller while the stroller is moved from the completely folded to the completely erect position and from the partially folded position to the fully erect and locked position (travel distance calculation).

2. Current ASTM Standard for Carriages and Strollers (ASTM F833-13b)

ASTM adopted the performance requirement and test method proposed by the Commission in a subsequent version of the ASTM standard, ASTM F833-13a, to address scissoring, shearing, and pinching hazards associated with 2D fold strollers. ASTM approved ASTM F833-13a on September 15, 2013. On November 1, 2013, ASTM approved the current version of the standard, ASTM F833-13b, which adopts the performance requirement and test method for 2D fold strollers, with a modification to the travel distance calculation to test for scissoring, shearing, and pinching.

In this rule, the Commission incorporates by reference ASTM F833-13b because the Commission's proposed modifications in the NPR have been adopted in ASTM F833-13b, including the requirements and test methods for 2D fold strollers to address hazards associated with scissoring, shearing, and pinching. Specifically, ASTM F833-13b provides a definition of a "2D fold stroller" as a stroller that folds the handlebars and leg tubes only in the front-to-back (or back-to-front) direction. To address the 2D fold stroller hazards, ASTM F833-13b requires the frame folding action of a 2D fold stroller and convertible carriage/stroller to be designed and constructed to prevent injury from scissoring, shearing, or pinching. Scissoring, shearing, or pinching that may cause injury exists when the edges of the rigid parts admit a 0.210-in (5.33-mm) diameter probe but do not admit a 0.375-in (9.53-mm) diameter probe when tested.

However, units with a removable seat that prevents the complete folding of unit when still attached are exempt from this requirement.

ASTM F833-13b also provides a test method for 2D frame strollers to address folding scissoring, shearing, and pinching. In the NPR, the Commission proposed a test method for scissoring, shearing, and pinching hazards that may occur while moving the stroller from a completely folded and partially folded position to the fully erect and locked position. The test proposed in the NPR calculated the travel distance based on the distance between front and rear wheels in an open position and in a closed position. ASTM F833-13b modified the travel distance calculation for the test. The modified test shows the travel distance based on the distance between front and rear wheels only in an open position. ASTM's rationale for the test explains that products are evaluated for the last 1/3 of travel for a predefined access zone because the last 1/3 of travel is considered the most hazardous condition, where a seated child's hand may be vulnerable to scissoring, shearing, and pinching within the access zone while the caregiver is preoccupied with the final stages of erecting the stroller.

CPSC staff compared both methods of the calculation, using various strollers, including strollers involved in incidents. Although in certain strollers the total amount of travel distance to be tested would be less than the travel distance proposed in the NPR, CPSC staff's review showed that the revised test method would be less burdensome and would provide an equal degree of safety as the travel distance calculation proposed in the NPR. According to CPSC staff, under the revised travel distance calculation, the most critical part of the frame folding associated with the incidents will be tested for scissoring, shearing, or pinching. Because the revised test is simpler to use, and because the reduction in travel distance does not make the test

less effective, the Commission incorporates by reference ASTM F833-13b with the revised travel distance calculation.

F. Response to Comments

The Commission received six comments from manufacturers, consumer advocacy groups, and trade associations in response to the NPR. A summary of each comment topic and response is provided. In general, all of the commenters support the mandatory standard for carriages and strollers.

1. 2D Fold Stroller Test

Comment: One manufacturer recommended simplifying the test method that was included in the NPR, as outlined in section 7.18.2 *for units where the front and rear wheels move toward each other during folding*, to address scissoring, shearing, and pinching hazards for 2D frame fold strollers. The commenter proposed determining the starting point for the stroller test by beginning at 2/3 the distance between the front and rear wheel axles in an open position of the stroller. The commenter stated that the ASTM subcommittee was working to include this starting point definition in the next revision and requested that the Commission review and adopt the change to the test method once the requirement is approved by the ASTM subcommittee.

Response: ASTM has revised the travel distance calculation in ASTM F833-13b. CPSC staff compared the travel distance calculation test proposed in the NPR and the modified test in ASTM F833-13b, using various strollers, including certain incident strollers. CPSC staff's review showed that the revised test is simpler, but the revised test will still test the most critical part of the frame folding associated with the incidents. Accordingly, the Commission will adopt ASTM F833-13b with the revised travel distance calculation because the hazards identified by

CPSC staff (scissoring, shearing, and pinching hazards in 2D fold strollers) will be addressed adequately by the test in ASTM F833-13b.

2. 2D Fold Stroller Access Zone

Comment: A commenter suggested an exemption to the 2D fold stroller test procedure, if there is a cover over the hinge that is within the access zone; for example, a stroller hinge that has a cover over the top and sides of the hinge, but the bottom is left open to allow the frame members to rotate during folding. The only way to access the hinge would be to come up from underneath or behind through the rear of the stroller, which would not be possible if a child is sitting in the stroller or standing on the side of the stroller. According to the commenter, the ASTM subcommittee is currently reviewing an additional requirement to assess at what point a covering on a hinge is sufficient protection from the 2D frame fold pinch hazard. The commenter requested that the Commission review and adopt the additional requirement once the additional requirement is approved by the ASTM subcommittee.

Response: As discussed in the preamble, ASTM 833-13b now addresses hazards associated with frame fold hinges for both 2D fold strollers and 3D fold strollers, regardless of the direction of entry, to reduce the risk of finger injury to a child who is sitting or is about to sit in a stroller. CPSC staff believes that there are many factors, including the size, shape, and material properties of the cover that may hinder the cover's effectiveness. Without more information about protective covers and how they would be used, the Commission will not provide an exemption for such covers without further review and testing. However, if ASTM subsequently publishes a standard to include a protective cover exemption, ASTM can notify the Commission of the revision, and the Commission would consider the revision at that time.

3. Combined Braking and Stability Test

Comment: A commenter suggested that the Commission adopt the combined braking and stability test that Consumer Reports uses in its testing. The commenter stated that the test evaluates both brake efficacy and stability in various orientations on an incline of 20°—as opposed to 12°. In addition, the commenter states that the brake standard should assess how easy it is to engage the brake, and reliably tell if the brake is engaged.

Response: The parking brake requirements were improved significantly in the ASTM F833-13 version of the standard to approximate the force that is applied to the parking brake, if the 12° inclined plane was increased to 20°. ASTM F833-13 also included an improved requirement and test method for multiple seats facing different directions, such as rotating seats, to address stability issues. These requirements are included in ASTM F833-13b. Therefore, the Commission finds that the requirements in ASTM F833-13b are adequate to address the hazards associated with parking brakes and stability issues and do not require additional requirements at this time.

4. Irregular Surface Test

Comment: Two commenters suggested that the Commission adopt the Irregular Surface Test in EN 1888:2012. The commenters stated that the irregular surface test is a durability test that evaluates the strollers for the expected lifetime of the product.

Response: ASTM F833-13 included improved parking brake, stability, wheel detachment, and locking mechanism requirements that address the hazards associated with the structural issues identified in the incident data. These requirements are included in ASTM F833-13b. CPSC staff's review of fatigue tests, such as the irregular surface test, indicates that such tests are time-consuming (and costly) and that tests with lower repetitions and higher weights/forces yield

substantially similar results. Accordingly, the Commission will not require the irregular surface test at this time.

5. Passive Containment/Clearance

Comment: One commenter recommended that the standard's passive containment/foot opening test method be augmented with a requirement that any adjustable part, such as an adjustable grab bar or a car seat adapter that remains in the stroller, be tested in all possible use positions.

Response: The Commission agrees that the test for passive containment/foot opening should be improved. An adjustable (or multi-positional) grab bar can adjust to suit the height of the child to increase comfort while holding the bar. However, adjustable grab bars may be left in an unsafe position, resulting in a potentially fatal head entrapment between the grab bar and the seat because the consumer may have difficulty discerning visually the difference between certain positions of the grab bar, such as the car seat position and the occupant-use position. CPSC staff is aware of earlier model year strollers that had adjustable grab bars, as described by the commenter. Of the four stroller-related fatalities from January 1, 2008 through December 31, 2012, one incident involved a 5-month-old infant whose head became entrapped between the seat and tray. Therefore, the Commission believes that the opening between the seat and the tray or the seat and grab bar could lead to a potentially fatal head entrapment hazard.

Currently, the test method for passive containment/foot opening in ASTM F833-13b provides under 7.12 Passive Containment/Foot Opening Test Method the following steps: Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). Per the manufacturer's instructions, position any adjustable features (that is, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create the minimum opening(s) size.

If the head probe fails to pass completely through the bounded opening, the following steps are required: If necessary, reattach/reposition tray(s) grab bar(s) to the manufacturer's recommended use position, then perform the torso probe test per 7.12.4. Per the manufacturer's instructions, position any adjustable features (that is, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the maximum opening(s) size.

To prevent head entrapment hazards, the current test under ASTM F833-13b requires the trays or grab bar to be in the manufacturer-recommended use position. This requirement specifies a minimum opening created by the grab bar or tray and foot rest. However, this test may not always capture a hazardous head entrapment opening between an adjustable grab bar and seat that could occur if the grab bar were improperly positioned. For example, a hazardous opening that is larger than the minimum opening may be created by the grab bar and foot rest configuration.

Accordingly, the Commission revises the test method for passive containment/foot opening as follows: Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create an opening(s) size that is most likely to cause failure.

If the head probe fails to pass completely through the bounded opening, the following steps are required: If necessary, reattach/reposition tray(s) grab bar(s), then perform the torso probe test per 7.12.4. Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the opening(s) size that is most likely to cause failure.

The revised wording: “most likely to cause failure” requires the tester to place the adjustable feature, such as a grab bar, if possible, in a position that creates a hazardous opening, thereby causing the stroller to fail, irrespective of the manufacturer’s instructions or the manufacturer’s use position. The test is based on an evaluation of the bounded opening(s) that is/are most likely to create an entrapment hazard and should address the potential for entrapment hazards for multi-positional or adjustable grab bars in strollers.

The commenter also recommended that a car seat adapter that can remain in the stroller be tested for head entrapment. Currently, the Commission is not aware of a car seat adapter that is intended to remain installed in the stroller when the car seat is not used; and the Commission does not have any additional information or data to recommend additional requirements for car seat adapters at this time. However, this issue may be raised in an ASTM subcommittee meeting for further review and discussion.

6. Effective Date

Comment: Several comments addressed the effective date of the proposed rule. One commenter supported the proposed 18-month effective date. A second commenter asked the Commission to take a careful look at how much time is needed to bring carriages and strollers into compliance and to make the new rule effective on the earliest practicable date. A third commenter suggested a 12-month effective date. The commenter stated that, given the extended length of time that it took for both the voluntary standard and the proposed rule to reach this point, consumers should not have to wait until late 2015 to see products that meet the standard.

Response: In the NPR, the Commission noted that there were significant revisions to the ASTM standard in ASTM F833-13 requiring many modifications to carriages and strollers. Due to the complexity of stroller designs, and to allow time for manufacturers to come into compliance, the

Commission proposed an 18-month effective date. The new performance requirements and test methods adopted in ASTM 833-13 and ASTM 833-13b are extensive and require manufacturers to make fundamental changes to carriages and strollers (*i.e.*, latching mechanism, parking brakes, static load, restraining system, passive containment/foot openings, wheel and swivel assemblies, hinges, and stability/tip over.) Although these requirements were approved in ASTM 833-13 in April, 2013, after the NPR was published, ASTM revised the standard, ASTM 833-13b, on November 1, 2013, to address the scissoring, shearing, and pinching hazards in 2D fold strollers. Now, in the final rule, the Commission requires an additional modification to address head entrapment issues. All of these requirements warrant additional time to allow manufacturers to come into full compliance with the mandatory standard. The Commission believes that 18 months is a reasonable amount of time for manufacturers who will need to redesign products, test new prototype products, and then retool their production processes to meet the considerable modifications that were made in ASTM F833-13 and ASTM F833-13b, plus the additional modification to the passive containment/foot opening test method in the final rule. Moreover, 18 months will reduce the impact on the firms that have product lines that largely or exclusively focus on strollers and stroller accessories. A longer effective date reduces the impact on firms in two ways. First, firms are less likely to experience a lapse in production, which could result if they are unable to comply within the required timeframe. Second, firms could spread costs over a longer time period. For these reasons, the standard for carriages and strollers will become effective 18 months after publication of the final rule.

7. Effective Date Marking

Comment: Two commenters stated that products that are manufactured after the effective date of the rule should be marked clearly so that consumers can easily identify products that meet the mandatory standard.

Response: A code mark or other means that identifies the date (month and year at a minimum) of manufacture is already required to be on the product under ASTM F833-13b. In addition, a final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 CFR part 1107 (the 1107 rule), became effective on February 13, 2013. Under the 1107 rule, a manufacturer or importer may voluntarily label a certified compliant product: “Meets CPSC Safety Requirements.” At this time, the Commission will not require additional markings because ASTM F833-13b already requires the date of manufacture on each product and retail package, and producers may label compliant products as such under the 1107 rule.

8. Restraining System/Harness

Comment: One commenter suggested that the Commission require a five-point harness for all strollers and carriages for improved protection to ensure that the child does not move into an unsafe position on his own or due to the stroller being jarred. This commenter also suggested that the Commission look for feasible means of requiring an alert mechanism to indicate whether the harness restraint system is secured properly.

Response: Although a five-point harness system may provide extra protection if a stroller tips over, CPSC staff’s review of incident data did not demonstrate that such a system would result in a significant improvement in occupant safety beyond a three-point harness. Moreover, the recent changes to prevent stroller tip over that have been added to ASTM F833-13 and adopted in ASTM F833-13b, such as the new wheel-detachment requirements, should mitigate the

likelihood of tip-over incidents. Accordingly, at this time, the Commission will not require a five-point harness in the standard. In addition, the Commission has insufficient information regarding whether an alert mechanism could be implemented without significantly raising the cost of a stroller, or whether such a system would be effective in reducing incidents involving restraints. However, this issue may be raised for further review and discussion in an ASTM subcommittee meeting.

9. Warnings

Comment: To emphasize the risk of entrapment or suffocation to children falling asleep in strollers and other infant products not intended for overnight sleep (but where children often fall asleep), one commenter recommended changing the wording in section 8.2.2 of the standard, which currently states: “Do not leave child unattended” to state instead: “Children have become entrapped or suffocated while sleeping in strollers. Never leave a sleeping child unattended. Move to a crib or safe sleep surface.”

Response: The current wording advises the caregiver to attend to the child whether or not he/she is sleeping, thus providing a more generic warning. In most of the incidents where children were reportedly sleeping, the caregiver was also present. CPSC staff’s review of the incident data shows that in one of the fatal incidents, a child was left sleeping in the stroller and was later found entrapped between the seat and tray. In another fatal incident, a child was left sleeping in the infant carrier that was attached to the stroller and found entrapped between the stroller handlebar and foot end of the car seat. The Commission reiterates that children should not be left unattended whether they are sleeping or not. However, the Commission believes that products in which children often fall asleep, such as strollers and hand-held carriers, could benefit from a harmonized and well-designed warning label on the product to educate consumers

to take proper action. Accordingly, the Commission would support CPSC staff's participation in a cross-product ad hoc working group; and should the need arise, the Commission will consider future action, once such a warning label is developed.

Comment: Another commenter recommended changing the current wording in section 8.2.2 of ASTM F833-13 from: "The product shall have the following warning statements . . ." to: "The product shall have the following warning statements that address . . ." to provide additional flexibility for manufacturers to alter warnings.

Response: The warning statements in sections 8.2.2.2, 8.2.2.3, and 8.2.2.4 already include a provision for manufacturers to insert their own words to describe their restraint system or product-specific instructions. The suggestion would only affect section 8.2.2.1, which includes the warning statement: "Never leave child unattended." The commenter stated that a simple change in wording to: "Never leave *your* child unattended" would not be allowed under 8.2.2. The Commission does not believe that a change to the warnings is warranted, given that the requested word changes would not necessarily increase the effectiveness of the warning. However, this issue may be raised for further review and discussion in a future ASTM subcommittee meeting.

G. Final Rule

The CPSC is incorporating by reference ASTM F833-13b because the Commission's proposed modifications in the NPR have been adopted in ASTM F833-13b, including requirements and test methods to address scissoring, shearing, and pinching hazards associated with 2D fold strollers. However, the Commission is requiring an additional modification to the passive containment/foot opening test method in ASTM F833-13b, to address head entrapment

hazards associated with multi-positional/adjustable grab bars. Specifically, the test method for passive containment/foot opening is revised as follows:

(a) 7.12.1 Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create an opening(s) size that is most likely to cause failure; and

(b) 7.12.3 If necessary, reattach/reposition tray(s) grab bar(s), then perform the torso probe test per 7.12.4. Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the opening(s) size that is most likely to cause failure.

H. Effective Date

The Administrative Procedure Act (APA) generally requires that the effective date of the rule be at least 30 days after publication of the final rule. 5 U.S.C. 553(d). The safety standard for carriages and strollers will become effective 18 months after publication of a final rule in the *Federal Register*.

I. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612, requires agencies to consider the impact of proposed and final rules on small entities, including small businesses. Section 604 of the RFA requires that the Commission prepare a final regulatory flexibility analysis when promulgating final rules, unless the head of the agency certifies that the rule will not have a significant impact on a substantial number of small entities. The final regulatory flexibility

analysis must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

- a succinct statement of the objectives of, and legal basis for, the rule;
- a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
- a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
- a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

2. Reason for Agency Action

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards that are substantially the same as, or more stringent than, the voluntary standard for a durable infant or toddler product. CPSC staff worked closely with ASTM stakeholders to develop the new requirements and test procedures that have

been incorporated into ASTM F833-13b, which together form the basis for the mandatory standard.

3. Other Federal Rules

There are two federal rules that would impact the stroller mandatory standard: (1) Testing and Labeling Pertaining to Product Certification (16 CFR part 1107); and (2) Requirements Pertaining to Third Party Conformity Assessment Bodies (16 CFR part 1112).

The testing and labeling rule (16 CFR part 1107) requires that manufacturers of children's products subject to product safety rules, certify, based on third party testing, that their children's products comply with all applicable safety rules. Because strollers will be subject to a mandatory rule, they will also be subject to the third party testing requirements when the stroller rule becomes effective.

In addition, the 1107 rule requires the third party testing of children's products to be conducted by CPSC-accredited laboratories. Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. These NORs are set forth in 16 CFR part 1112.

4. Impact on Small Business

There are approximately 85 firms that currently supply carriages/strollers in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of strollers is considered small if the manufacturer has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, about 55 are small firms—26 domestic manufacturers, 26 domestic importers, and

three firms with unknown supply sources. There may be additional unknown small stroller suppliers operating in the U.S. market.

Small Manufacturers

The expected impact of the final rule will differ based on whether a firm's strollers are already compliant with ASTM F833-11, the voluntary standard in effect prior to ASTM F833-13. In general, firms whose strollers meet the requirements of ASTM F833-11 are likely to continue to comply with the voluntary standard as new versions are published. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. Firms supplying strollers that comply with ASTM F833-11 likely would also comply with F833-13b before the final rule becomes effective.

ASTM F833-13b requirements could require product redesign for at least some strollers that are not compliant with ASTM F833-11 (eight of 26 small domestic manufacturers). Most of the redesign and retooling costs are associated with meeting the requirements of the standard. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric. However, a redesign could be more significant if changes to the frame are required. Due to the complexity of carriages and strollers, a complete redesign of these products, including engineering time, prototype development, tooling, and other incidental costs, could exceed \$1 million for the most complex stroller models. Industry sources, including the Juvenile Products Manufacturers Association (JPMA) note that new tooling alone could exceed \$300,000 per product model. However, costs and development time are likely to vary widely across firms. Companies with substantial experience in manufacturing strollers should be able to complete redesigns more cost effectively than firms with less experience. Additionally, firms

with numerous stroller models may experience lower costs because stroller models could be redesigned as a group.

The modification to the passive containment/foot opening test method may or may not have any impact on small manufacturers because CPSC staff could not identify any strollers on the U.S. market that have adjustable grab bars. Therefore, the direct impact on manufacturers whose products are expected to meet the requirements of ASTM F833-13b (18 of 26 small domestic manufacturers) is not expected to be significant, although it is possible that there are unknown stroller suppliers with products that might be affected.

The 18-month effective date may mitigate the impact on small manufacturers because such firms are less likely to experience a lapse in production, which could result if these firms are unable to comply within the required timeframe, and costs may be spread over a longer period.

In addition, there are indirect impacts. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with third party testing and certification requirements triggered by the final rule. Those additional third party testing costs will pertain to any physical and mechanical test requirements specified in the stroller final rule; lead and phthalates testing is already required. Third party testing costs could as much as \$800–\$1,000 per model sample.

On average, each small domestic manufacturer supplies seven different models of strollers to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$5,600–\$7,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F833-13b is unlikely to be significant if only one stroller sample per model is

required. However, the economic impact could be significant for some small firms, if as few as two or three samples per model are required to meet the testing requirements.

Small Importers

In the absence of regulation, small importers of strollers currently in compliance with F833-11 (13 of 26 small domestic importers) would likely continue to comply with the standard as it evolves, including the final mandatory standard. Any increase in production costs experienced by their suppliers may be passed on to them. However, these costs are not likely to be significant, given that CPSC staff could not identify any strollers on the U.S. market that have adjustable grab bars requiring modification.

Small importers of strollers would need to find an alternate source if their existing supplier does not come into compliance with the requirements of ASTM F833-13b. Thirteen importers of strollers currently may not be in compliance with ASTM F833-11. Some importers may discontinue the carriage/stroller product line altogether. The impact of such a decision could be mitigated by replacing the noncompliant stroller with a compliant stroller or by deciding to import an alternative product. However, some of these firms have few or no other products in their product line. Because many of these firms have low sales revenues and limited product lines apart from strollers and stroller accessories, it is possible that the final rule could have a significant impact on one or more importers. The 18-month effective date may mitigate the impact because such firms are less likely to experience a lapse in obtaining compliant strollers, which could result if they are unable to comply within the required timeframe; and costs may be spread over a longer time period.

All importers are also subject to third party testing and certification requirements. Consequently, importers will experience costs similar to those for manufacturers, if their

supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves, even if only one sample per model were required.

5. Alternatives

One alternative that could reduce the impact on small entities would be to make the voluntary standard mandatory, with no further modifications. However, given that CPSC staff could not identify any strollers on the U.S. market that currently would be impacted by the modification to the passive containment/foot opening test method, this reduction may be insignificant. In addition, incorporating the voluntary standard without modifications would not substantially benefit firms with noncompliant products because their strollers might still require redesign. The 18-month effective date may mitigate the impact because suppliers will have additional time to modify and/or develop compliant strollers and spread the associated costs over a longer period of time. However, the Commission could opt to set a later effective date, which may reduce further the impact on affected firms. A third alternative would be to set an earlier effective date. However, setting an earlier effective date could increase the impact of the rule on small entities, particularly those with limited product lines and low sales revenues.

J. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. These regulations provide a categorical exclusion for certain CPSC actions that normally have "little or no potential for affecting the human environment." Among those actions are rules or safety standards for consumer products. 16 CFR 1021.5(c)(1). The rule falls within the categorical exclusion.

K. Paperwork Reduction Act

This rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The preamble to the proposed rule (77 FR 29286) discussed the information collection burden of the proposed rule and specifically requested comments on the accuracy of our estimates. Sections 8 and 9 of ASTM F833-13b contain requirements for marking, labeling, and instructional literature. These requirements fall within the definition of “collection of information,” as defined in 44 U.S.C. 3502(3).

OMB has assigned control number 3041-0164 to this information collection. The Commission did not receive any comments regarding the information collection burden of this proposal. However, the final rule makes modifications regarding the information collection burden because the number of estimated manufacturers subject to the information collection burden is now estimated at 85 manufacturers rather than the 86 manufacturers initially estimated in the proposed rule due to firms entering and exiting the U.S. stroller market. Additionally, the average number of stroller models supplied by all of the firms has increased from six to eight models.

Accordingly, the estimated burden of this collection of information is modified, as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR Section	Number of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Burden Hours
1227	85	8	680	1	680

L. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the Commission for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA refers to the rules to be issued under that section as “consumer product safety rules,” thus, implying that the preemptive effect of section 26(a) of the CPSA would apply. Therefore, a rule issued under section 104 of the CPSIA will invoke the preemptive effect of section 26(a) of the CPSA when it becomes effective.

M. Certification and Notice of Requirements (NOR)

Section 14(a) of the CPSA imposes the requirement that products subject to a consumer product safety rule under the CPSA, or to a similar rule, ban, standard or regulation under any other Act enforced by the Commission, must be certified as complying with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). Section 14(a)(2) of the CPSA requires that certification of children’s products subject to a children’s product safety rule be based on testing conducted by a CPSC-accepted third party conformity assessment body. Section 14(a)(3) of the CPSA requires the Commission to publish a NOR for the accreditation of third party conformity assessment bodies (or laboratories) to assess conformity with a children’s product safety rule to which a children’s product is subject. The “Safety Standard for Carriages and Strollers,” to be codified at 16 CFR part 1227, is a children’s product safety rule that requires the issuance of an NOR.

The Commission published a final rule, *Requirements Pertaining to Third Party Conformity Assessment Bodies*, 78 FR 15836 (March 12, 2013), which is codified at 16 CFR part 1112 (referred to here as part 1112). This rule became effective on June 10, 2013. Part 1112 establishes requirements for accreditation of third party conformity assessment bodies (or laboratories) to test for conformance with a children's product safety rule in accordance with Section 14(a)(2) of the CPSA. Part 1112 also codifies a list of all of the NORs that the CPSC had published at the time part 1112 was issued. All NORs issued after the Commission published part 1112, such as the standard for carriages and strollers, require the Commission to amend part 1112. Accordingly, this rule amends part 1112 to include the standard for carriages and strollers in the list with the other children's product safety rules for which the CPSC has issued NORs.

Laboratories applying for acceptance as a CPSC-accepted third party conformity assessment body to test to the new standard for carriages and strollers would be required to meet the third party conformity assessment body accreditation requirements in 16 CFR part 1112, *Requirements Pertaining to Third Party Conformity Assessment Bodies*. When a laboratory meets the requirements as a CPSC-accepted third party conformity assessment body, the laboratory can apply to the CPSC to have 16 CFR part 1227, *Safety Standard for Carriages and Strollers*, included in its scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: www.cpsc.gov/labsearch.

CPSC staff conducted an analysis of the potential impacts on small entities of the proposed rule establishing accreditation requirements, as required by the Regulatory Flexibility Act, and the agency prepared an Initial Regulatory Flexibility Analysis (IRFA). *Requirements Pertaining to Third Party Conformity Assessment Bodies*. 77 FR 31086, 31123-26. Specifically,

the NOR for the standard for carriages and strollers would not have a significant adverse impact on small laboratories. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the standard for carriages and strollers. Most of these laboratories already will have been accredited to test for conformance to other juvenile product standards, and the only cost to them would be the cost of adding the standard for carriages and strollers to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the standard for carriages and strollers will not have a significant impact on a substantial number of small entities.

List of Subjects

16 CFR Part 1112

Administrative practice and procedure, Audit, Consumer protection, Reporting and recordkeeping requirements, Third party conformity assessment body.

16 CFR Part 1227

Consumer protection, Imports, Incorporation by reference, Infants and children, Labeling, Law enforcement, and Toys.

For the reasons discussed in the preamble, the Commission amends Title 16 of the Code of Federal Regulations as follows:

PART 1112—REQUIREMENTS PERTAINING TO THIRD PARTY CONFORMITY ASSESSMENT BODIES

1. The authority citation for part 1112 continues to read as follows:

Authority: 15 U.S.C. 2063; Pub. L. 110-314, section 3, 122 Stat. 3016, 3017 (2008).

2. Amend Part 1112.15 by adding paragraph (b)(36) to read as follows:

§ 1112.15 When can a third party conformity assessment body apply for CPSC acceptance for a particular CPSC rule and/or test method?

* * * * *

(b) (36) 16 CFR part 1227, Safety Standard for Carriages and Strollers.

* * * * *

3. Add part 1227 to read as follows:

PART 1227-SAFETY STANDARD FOR CARRIAGES AND STROLLERS

Sec.

1227.1 Scope.

1227.2 Requirements for Carriages and Strollers.

Authority: The Consumer Product Safety Improvement Act of 2008, Pub. L. 110-314, § 104, 122 Stat. 3016 (August 14, 2008); Pub. L. 112-28, 125 Stat. 273 (August 12, 2011).

§ 1227.1 Scope.

This part establishes a consumer product safety standard for carriages and strollers.

§ 1227.2 Requirements for Carriages and Strollers.

(a) Except as provided in paragraph (b) of this section, each carriage and stroller must comply with all applicable provisions of ASTM F833-13b, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, approved on November 1, 2013. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy from ASTM International, 100 Bar Harbor Drive, P.O. Box 0700, West Conshohocken, PA 19428; <http://www.astm.org/cpsc.htm>. You may inspect a copy at the Office of the Secretary, U.S. Consumer Product Safety

Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814, telephone 301-504-7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(b) Comply with ASTM F833-13b standard with the following changes:

(1) Instead of complying with section 7.12.1 of ASTM F833-13b, comply with the following:

(i) 7.12.1 Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create an opening(s) size that is most likely to cause failure.

(ii) [Reserved]

(2) Instead of complying with section 7.12.3 of ASTM F833-13b, comply with the following:

(i) 7.12.3 If necessary, reattach/reposition tray(s) grab bar(s), then perform the torso probe test per 7.12.4. Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the opening(s) size that is most likely to cause failure.

(ii) [Reserved]

Dated: _____

Todd A. Stevenson,
Secretary, Consumer Product Safety Commission



Staff Briefing Package

Draft Final Rule for Carriages and Strollers under the Danny
Keysar Child Product Safety Notification Act

January 22, 2014

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Briefing Memorandum



**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814**

This document has been electronically
approved and signed.

Memorandum

January 3, 2014

TO: The Commission
Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel
Elliot F. Kaye, Executive Director
Robert J. Howell, Deputy Executive Director for Safety Operations

FROM: George A. Borlase Ph.D., P.E., Assistant Executive Director,
Office of Hazard Identification and Reduction

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

SUBJECT: Staff's Draft Final Rule for Carriages and Strollers under the Danny
Keysar Child Product Safety Notification Act

I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act of the Consumer Product Safety Improvement Act (CPSIA) of 2008 requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to (1) assess the effectiveness of voluntary standards for durable infant or toddler products, and (2) develop mandatory safety standards for those products. Strollers are one of the product categories specifically identified as a durable infant or toddler product in section 104(f) (2) of the CPSIA. The Commission is charged with promulgating a consumer product safety standard that is substantially the same as the voluntary standard for strollers, or more stringent than the voluntary standard, if the Commission determines that a more stringent standard would further reduce the risk of injury associated with strollers.

Section 104 of the CPSIA directs the Commission to consult with representatives of consumer groups, juvenile product manufacturers, and independent child product engineers and experts to examine and assess the effectiveness of the voluntary standards. This consultation process commenced in January 2011, with staff participation in a task group within ASTM International (ASTM) Subcommittee F15.17 – Carriages, Strollers, Walkers, and Stationary Activity Centers.

The Commission published a notice of proposed rulemaking (NPR) in the *Federal Register* on May 20, 2013. (78 Federal Register 29279). This briefing package includes staff's responses to comments received in response to the NPR. This briefing package also presents staff's draft final rule to address the potential hazards associated with the use of strollers.

II. BACKGROUND

A. Rulemaking History

As noted above, the Commission issued an NPR for carriages and strollers (78 Federal Register 29279) on May 20, 2013. The NPR proposed incorporating by reference the voluntary standard, ASTM F833-13, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, with one modification relating to scissoring, shearing, and pinching hazards associated with 2D fold strollers.¹

B. ASTM Voluntary Standard Overview

ASTM F833, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, is the voluntary standard that addresses the identified hazard patterns associated with the use of carriages and strollers. The standard was first approved in 1983, with more than 20 revisions made over the ensuing 30 years. ASTM F833-13 is the version that was published in April 2013, and the version that the Commission proposed incorporating by reference in the NPR. The 2013 version of the standard includes the following 10 changes and additions to the earlier version of the standard:

1. an improved test method for the parking brake requirement;
2. a new requirement and test method to address head entrapment hazards associated with car seats on a stroller (combination unit);
3. a new requirement, test method, and warnings to address wheel and swivel assemblies' detachments;
4. an improved test method for latching and locking mechanisms;
5. a new requirement and test method to address the scenario of the child releasing the buckle of the restraint system and a clarification on the buckle closing system;
6. a new requirement and test method to address pinching, shearing, and scissoring at the saddle hinge link on 3D fold strollers;
7. a new requirement and test method to address pinching, shearing, and scissoring at the canopy hinges;
8. an improved requirement and test method to address stability issues by taking into account multiple seats facing different directions, such as rotating seats;
9. a new requirement and test method to address a strangulation hazard associated with cords and straps within the occupant space; and
10. clarifications in warning label contents.

¹ A "2D" stroller folds the handlebars and leg tubes only in the front-to-back (or back-to-front) direction. A "3D" stroller collapses in all three dimensions—height, length and width—resulting in a smaller folded package than 2D strollers.

On September 15, 2013, ASTM approved a revised version of the standard, ASTM F833-13a, which included the modification that the Commission proposed in the NPR. After ASTM F833-13a was published, ASTM balloted another item related to strollers; *i.e.*, a change in the calculation of the travel distance for certain 2D strollers. The ballot received no negatives, and a revised version of the standard, which included the balloted language, was subsequently published as ASTM F833-13b. Staff recommends that the Commission incorporate by reference ASTM F833-13b, with one modification, to address head entrapment hazards that may result from openings between the stroller seat and the tray, or the stroller seat and grab bar.

III. DISCUSSION

A. Overview of New Incident Data

For the NPR, CPSC staff reviewed incident data involving carriages and strollers. The NPR stated that staff was aware of 1,207 incidents related to strollers and carriages that were reported to have occurred from January 1, 2008 through December 31, 2012. A search of the CPSC epidemiological databases showed that 90 new incidents related to carriages and strollers were reported to the Commission between January 1, 2013 and June 30, 2013; these incidents reportedly occurred between January 1, 2008 and June 30, 2013. Reporting is ongoing, however; so the incident totals are subject to change, particularly for more recent years. This brings the total number of incidents to 1,297, including four fatalities and 391 injuries that reportedly occurred between January 1, 2008 and June 30, 2013. The hazard patterns identified among the 90 new incidents were similar to the patterns identified among the incidents considered for the NPR and that are detailed in Tab A of this briefing package.

There were no new fatal incidents reported between January 1, 2013 and June 30, 2013. A total of 32 stroller-related, nonfatal injuries were reported from January 1, 2013 through June 30, 2013. Six of the 32 injuries were a result of wheel problems. This category also had the highest number of incidents (25) among the 90 new incidents. Lock mechanical failures resulted in 11 incidents, including five injuries. Ten incidents, including three injuries, were a result of stability issues. Restraints were associated with two injuries and eight noninjury incidents.

Of the 90 new incidents, there were four incidents where hospitalization was required. Two incidents were due to finger amputations, one of which occurred when a child's finger got caught in the folding hinge; the second finger amputation occurred when a stroller collapsed. The third hospitalization involved a child unbuckling the restraints, attempting to leave the stroller, and getting caught on the extended rivet that is used to latch the folded stroller, resulting in a laceration to the crotch area. The fourth hospitalization was due to a stroller rolling off a train platform and falling onto the tracks with the child in the stroller, resulting in a cut on the child's forehead.

The NPR also noted 78 reported stroller incidents that involved children older than 4 years of age and adults. Out of the 78 incidents, 72 involved victims between 17 and 64 years of age. Almost all of the incidents (74 out of 78) resulted in injuries, mostly to the fingers. Six new incidents were reported from January 1, 2013 to June 30, 2013, for a total of 84 stroller incidents involving

children older than 4 years of age or adults. All six new incidents involved finger injuries, and the users' ages were unreported or unknown, with the exception of one consumer, who was 29 years old.

B. Staff Response to NPR Comments

There were six comments received in response to the NPR. Two of these comments were submitted by the same individual, who is a manufacturer. The remaining four comments were submitted together, by a manufacturer, the American Academy of Pediatrics, Consumers Union, and by Kids in Danger and the Consumer Federation of America. All commenters supported the overall purpose of the proposed rule. The comments can be viewed at: www.regulations.gov, by searching under the docket number of the rulemaking, CPSC-2013-0019. Staff's responses to the comments can be found in Tabs B–D. Table 1 lists the main topics and location of staff's response.

Table 1: Comment Topics and Location of Staff's Response

Topic	Tab
2D Frame Fold Travel Distance Calculation	B
2D Frame Fold Protective Cover	B
Combined Braking and Stability Test	B
Effective Date	D
Irregular Surface Test	B
Marking on Products	C
Passive Containment/Clearance	B, C
Restraints	C
Warnings	C

Below are summaries of the comments and staff's responses to the specific issues the commenters raised.

Starting Point for 2D Frame Fold Stroller Test

Comment:

One manufacturer recommended simplifying the test method included in the NPR modification, as outlined in section 7.18.2 *for units where the front and rear wheels move toward each other during folding*, to address scissoring, shearing, and pinching hazards for 2D frame fold strollers. The commenter suggested determining the starting point for the stroller test by beginning at 2/3 the distance between the front and rear wheel axles in an open position of the stroller. The commenter stated that the ASTM subcommittee is working to include this starting point definition in the next revision and requested that the Commission review and adopt the change to the test method once the requirement is approved by the ASTM subcommittee.

Response:

The commenter's request was balloted by ASTM (ASTM F15 (13-07) (Item Number: 001)) and incorporated into the latest revision of the ASTM standard (F833-13b), published in November 2013. This calculation method equals the distance between front and rear wheels in an open position to the overall travel distance, while the method in the NPR also takes into account the distance between wheels in a closed position. Staff compared both methods of the calculation, using various strollers, including certain incident strollers. Although in certain strollers, the total amount of travel to be tested would be less than the NPR-proposed calculation, staff believes that the new calculation included in ASTM F833-13b still incorporates the most critical part of the frame folding associated with the incidents. Staff agrees with this change because the new method is less burdensome and appears to provide an equal degree of safety given that the reduction in travel distance does not make the test less effective.

2D Frame Fold Hinges Access Zone

Comment:

A commenter suggested an exemption to the 2D fold test procedure if there is a cover over the hinge that is within the access zone. An example of this suggested exemption is a stroller hinge that has a cover over the top and sides of the hinge, but the bottom is left open to allow the frame members to rotate during folding. The only way to access the hinge would be to come up from underneath or behind through the rear of the stroller, which would not be possible if a child is sitting in the stroller or standing on the side of the stroller. According to the commenter, the ASTM subcommittee is currently reviewing an additional requirement to assess at what point a covering on a hinge is sufficient protection from the 2D frame fold pinch hazard. The commenter requested that the Commission review and adopt the additional requirement once the additional requirement is approved by the ASTM subcommittee.

Response:

Because the frame fold hinge is a significant hazard, staff is cautious about providing an exemption for a protective cover without thoroughly reviewing and analyzing the protective cover. Staff believes that there are many factors, including the size, shape, and material properties of the cover that may hinder the cover's effectiveness. Staff believes hinges that are within the access zone should not allow finger entrapment, regardless of direction of entry, to reduce the risk of finger injury to a child who is either sitting or about to sit in a stroller. However, if ASTM publishes a standard to include a protective cover exemption, ASTM can notify the Commission of the revised ASTM standard for the Commission's consideration under Pub. L. No. 112-28.²

Combined Braking and Stability Test

² Section 3 of the revision to the Consumer Product Safety Improvement Act of 2008 (Pub. L. No. 112-28; H.R. 2715) instructs ASTM to notify the CPSC of revisions to voluntary standards that are a basis for a consumer product safety standard promulgated by the Commission.

Comment:

A commenter suggested that the Commission adopt the combined braking and stability test that Consumer Reports uses in its testing. The commenter stated that the test evaluates both brake efficacy and stability in various orientations on an incline of 20°—as opposed to 12°. In addition, the commenter states that the brake standard should assess how easy it is to engage the brake, and reliably tell if the brake is engaged.

Response:

The parking brake requirements were improved significantly in the ASTM F833-13 version of the standard to approximate the force that is applied to the parking brake, if the 12° inclined plane was increased to 20°. Therefore, staff believes that the new requirement is adequate to address the hazards associated with parking brakes and do not require additional requirements at this time. ASTM F833-13 also included an improved requirement and test method for multiple seats facing different directions, such as rotating seats, to address stability issues.

Irregular Surface Test

Comment:

Two commenters suggested that the Commission adopt the Irregular Surface Test in EN 1888:2012. The commenters stated that the irregular surface test is a durability test that evaluates the strollers for expected lifetime of the product.

Response:

Staff believes the ASTM standard that has been updated with improved parking brake, stability, wheel detachment, and locking mechanism requirements is sufficient to address the structural issues that the incident data demonstrate. Due to the time-consuming (and therefore, costly) nature of fatigue tests, CPSC staff typically favors tests with lower repetitions and higher weights/forces that yield substantially similar results. At this time, staff does not recommend adding the irregular surface test to the proposed rule.

Passive Containment/Clearance

Comment:

A commenter suggested augmenting the passive containment requirement and test with a requirement that any adjustable part, such as an adjustable grab bar,³ or a car seat adapter that remains in the stroller, be tested in all possible positions.

Response:

³ Grab bars that can adjust to suit the height of the child to increase comfort while holding the bar.

Staff agrees with the commenter's recommendation for adjustable grab bars because of the likelihood that the grab bar can be left in an unsafe position, resulting in a potentially fatal head entrapment between the grab bar and the seat. ASTM F833-13b has requirements for strollers with a tray or grab bar, to prevent a head entrapment hazard. The standard requires the grab bar to be in the manufacturer-recommended use position. CPSC staff is aware of earlier model year strollers that had adjustable grab bars, as described by the commenter. Staff believes that it could be difficult for the consumer to discern visually the difference between certain positions of the grab bar, such as the car seat position and the occupant-use position.

Four stroller-related fatalities from January 1, 2008 through June 30, 2013, were reported to CPSC and discussed in the NPR briefing package. One incident involved a 5-month-old infant whose head became entrapped between the seat and tray. Staff considers the opening between the seat and the tray or the seat and grab bar to be a potentially fatal head entrapment hazard if the stroller fails ASTM F833-13b, Section 7.12, *Passive Containment/Foot Opening Test Method*. On April 20, 2012, CPSC staff requested that the ASTM subcommittee consider developing head entrapment requirements for products with a multi-positional grab bar. A task group was formed; however, staff is not aware of any progress on this issue. Due to the potential for a fatal entrapment between an adjustable grab bar and seat, CPSC staff recommends the following addition (strikeouts reflect deleted language; underline reflects added language) to section 7.12.1 and 7.12.3 of ASTM F833-13b:

7.12 Passive Containment/Foot Opening Test Method:

7.12.1 Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). ~~Per the manufacturer's instructions,~~ Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create an the minimum opening(s) size that is most likely to cause failure.

7.12.2 Place the head probe (Fig. 10) adjacent to the opening(s) most likely to allow the head probe to pass through. With the harness restraint system unbuckled, place the buckle portion of the crotch belt beneath the head probe. Gradually rotate the unit 90° with the front wheels as a stationary pivot within a period of 5 s and maintain for an additional 10 s. The head probe shall remain in contact with seat during the test. If the head probe passes completely through the bounded opening (a) without detaching the tray(s) or grab bar(s), or (b) by completely detaching the tray(s) or grab bar(s), or (c) by moving the tray(s) or grab bar(s) out of the manufacturer's recommended use position, then the stroller meets the criteria of 6.8. If the sample does not meet any of the criteria listed in (a), (b), or (c) above, then proceed to 7.12.3.

7.12.3 If necessary, reattach/reposition tray(s) grab bar(s) ~~to the manufacturer's recommended use position,~~ then perform the torso probe test per 7.12.4. ~~Per the manufacturer's instructions,~~ Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the ~~maximum~~ opening(s) size that is most likely to cause failure.

The original requirement specifies a minimum opening created by the grab bar or tray and foot rest. This test may not capture a hazardous opening that is larger than the minimum opening created by the grab bar and foot rest configuration. The revised wording: "most likely to cause failure," requires the tester to position the grab bar, if possible, in a position that creates a

hazardous opening, and thereby, causes the stroller to fail, irrespective of the manufacturer's instructions or manufacturer's recommended use position. This addition should address the entrapment hazard for multi-positional or adjustable grab bars in strollers.

The commenter also recommended that a car seat adapter that can remain in the stroller be tested for head entrapment. Staff is not aware of a car seat adapter that is intended to remain installed in the stroller when the car seat is not used. Staff has not sufficiently evaluated this issue to recommend additional requirements for car seat adapters. Staff intends to discuss the issue with ASTM for consideration in the voluntary standard.

Effective Date

Comment:

Several commenters weighed in on the appropriate effective date for the proposed rule. One commenter supported the proposed 18-month effective date. A second commenter asked the Commission to take a careful look at how much time is needed to bring carriages and strollers into compliance and to make the new rule effective on the earliest practicable date. A third commenter suggested a 12-month effective date. The commenter stated that, given the extended length of time that it took for both the voluntary standard and the proposed rule to reach this point, consumers should not have to wait until late 2015 to see products that meet the standard.

Response:

CPSC staff considers 18 months to be a reasonable time for manufacturers who will redesign, test new prototype products, and then retool their production process to meet the considerable modifications that were made to the standard and the additional requirements proposed in the final rule. In addition, 18 months will reduce the economic impact on the firms that have product lines that largely or exclusively focus on strollers and stroller accessories. A longer effective date, such as the proposed 18-month period, reduces the economic impact on firms in two ways. One, they are less likely to experience a lapse in production, which could result if they are unable to comply within the required timeframe. Two, they could spread costs over a longer time period.

Staff notes that ongoing compliance activities can still be used to pull unsafe strollers from the market. Given these factors, staff continues to recommend that the Commission provide an effective date of 18 months after publication of the final rule.

Product Marking to Indicate Compliance with Mandatory Rule

Comment:

Two commenters recommended that products be marked clearly to allow a consumer to determine if the carriage or stroller was manufactured after the mandatory standard became effective.

Response:

A code mark or other means to identify the date (month and year as a minimum) of manufacture is already required to be on the product under section 8.1.2 of ASTM F833-13b.

A final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, *Testing and Labeling Pertaining to Product Certification*, 16 C.F.R. part 1107 (the 1107 rule), became effective on February 13, 2013. Under the 1107 rule, a manufacturer or importer may voluntarily label a certified compliant product as “Meets CPSC Safety Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, at this time, staff does not recommend requiring additional markings.

Restraining System/Harness

Comment:

One commenter suggested that the Commission require a five-point harness for all strollers and carriages for improved protection to ensure that the child does not move into an unsafe position on his own or due to the stroller being jarred. The commenter also suggested that the Commission look for feasible means of requiring an alert mechanism that would clearly signal or indicate whether the harness restraint system is properly secured.

Response:

Staff agrees that a five-point harness system may provide extra protection if a stroller tips over. However, because the incident data do not clearly demonstrate a significant improvement in occupant safety beyond a three-point harness, staff is not convinced that the addition of a requirement of a five-point harness is warranted. Furthermore, the recent changes that have been added to the standard to prevent the root causes of strollers tipping over, such as the new wheel-detachment requirements, should mitigate the likelihood of tip-over incidents.

Regarding the alert mechanism, staff is uncertain whether alarm systems could be accomplished without significantly increasing the cost of a stroller or whether such a system would be effective in reducing restraint issues. However, staff will raise this issue in an ASTM subcommittee meeting for review and discussion.

Warnings

Comment:

One commenter mentioned the risk of entrapment or suffocation to children falling asleep in strollers and other infant products not intended for overnight sleep (but where children often fall asleep). The commenter suggested changing the wording in section 8.2.2 of the standard, which currently states: “Do not leave child unattended” to state instead: “Children have become

entrapped or suffocated while sleeping in strollers. Never leave a sleeping child unattended. Move to a crib or safe sleep surface.”

Response:

The current wording advises the caregiver to attend to the child whether or not he/she is sleeping, thus providing a more generic warning. In most of the incidents where children were reportedly sleeping, the caregiver was also present. Staff notes that in one of the fatal incidents, a child was left sleeping in the stroller and was later found entrapped between the seat and tray. In another fatal incident, the child was left sleeping in the infant carrier that was attached to the stroller and found entrapped between the stroller handlebar and foot end of the car seat. Children should not be left unattended whether they are sleeping or not. Staff believes that products in which children often fall asleep, such as strollers and hand-held carriers could benefit from a harmonized and well-designed warning label on the product, to educate consumers to take proper action. Staff will raise this issue with the ASTM F15 subcommittee, rather than recommend that a revised label be included in the final rule.

Comment:

One commenter suggested changing the wording in section 8.2.2 to make the language more flexible, without affecting the purpose or effectiveness of the warning. The commenter suggested changing the current wording in 8.2.2 from: “The product shall have the following warning statements” to: “The product shall have the following warning statements that address.”

Response:

The warning statements in 8.2.2.2, 8.2.2.3, and 8.2.2.4 already include a provision for the manufacturer to insert their own words to describe their restraint system or product-specific instructions. The suggestion would only affect section 8.2.2.1, which includes the warning statement: “Never leave child unattended.” The commenter stated that a simple change in wording to: “Never leave *your* child unattended” would not be allowed under 8.2.2. The warnings were developed by the ASTM subcommittee, and staff does not believe that the word changes would increase the effectiveness of the warning. Staff believes that such edits to warnings are more appropriately addressed by the ASTM subcommittee for any necessary revisions in a future standard.

C. Potential Small Business Impact

The majority of strollers and carriages are produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff estimates that there are about 55 domestic suppliers of strollers and carriages that would be considered small businesses under U.S. Small Business Administration guidelines—26 manufacturers, 26 importers, and three firms with unknown supply sources. The potential impact on these firms of the staff-recommended final rule is presented in the Directorate for Economic Analysis memorandum (Tab D).

The impact on the 18 small domestic manufacturers whose strollers meet the voluntary standard is not expected to be significant because staff could not identify any strollers on the U.S. market that have adjustable grab bars that would be affected by the modification to the passive containment test procedure in the final standard. However, the impact could be significant for some of the eight small domestic manufacturers whose strollers do not meet the voluntary standard, as well as some of the 26 small domestic importers of strollers. This would be particularly true for firms with low revenues and/or limited product lines beyond strollers and stroller accessories. However, the staff-recommended 18-month effective date will help mitigate the impact, allowing these firms to spread their costs over a longer time period.

D. Effective Date of Final Rule

The Administrative Procedure Act (APA) generally requires that the effective date of a rule be at least 30 days after publication of the final rule (5 U.S.C. § 553(d)). In the NPR, the Commission proposed an 18-month effective date, which staff believes is justified based on input from stroller manufacturers at the time of the NPR. Staff continues to recommend an 18-month-effective date after publication of the final rule, particularly to accommodate suppliers who might be unfamiliar with the ASTM standard, as well as to reduce the economic impact on suppliers with product lines focusing largely or exclusively on strollers. A longer effective date reduces the economic impact on firms in two ways. First, firms are less likely to experience a lapse in production, which could result if firms are unable to comply within the required timeframe. Second, firms could spread costs over a longer time period.

IV. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission publish a final rule that incorporates by reference the voluntary standard, ASTM F833-13b, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, with a modification to address head entrapment hazards associated with multi-positional/adjustable grab bars. Specifically, staff recommends that section 7.12.1 and 7.12.3 of ASTM F833-13b be amended to test for hazardous openings created by the grab bar and foot rest configurations in the position most likely to cause failure. The original requirement specified a minimum opening created by the grab bar or tray and foot rest. This test may not capture a hazardous opening that is larger than the minimum opening created by the grab bar and foot rest configuration. The revised wording: “most likely to cause failure.” requires the tester to position the grab bar, if possible, in a position that creates a hazardous opening, and thereby, causes the stroller to fail, irrespective of the manufacturer’s instructions or manufacturer’s recommended use position. This addition should address the entrapment hazard for multi-positional or adjustable grab bars in strollers.

Staff also recommends that the standard take effect 18 months after publication of the final rule in the *Federal Register*.

TAB A: Carriage and Stroller-Related Deaths, Injuries, and Potential Injuries between January 1, 2013 and June 30, 2013, and 2012 NEISS Estimates

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

November 22, 2013

TO : Rana Balci-Sinha, Ph.D.
Stroller Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH : Kathleen Stralka
Associate Executive Director
Directorate for Epidemiology

Stephen Hanway
Director, Division of Hazard Analysis
Directorate for Epidemiology

FROM : Angie Qin
Division of Hazard Analysis
Directorate for Epidemiology

SUBJECT : Carriage and Stroller-Related Deaths, Injuries, and Potential Injuries;
January 2008–June 2013, and January 2008–December 2012 NEISS
Estimates⁴

I. Introduction

This memorandum provides statistics on deaths and injuries, as well as a summary of the types of hazards related to strollers and carriages (products coded 1522 and 1505), for incidents that reportedly occurred from January 2008 through June 2013.⁵ The counts are based on reports received by U.S. Consumer Product Safety Commission (CPSC) staff. The memorandum also includes the estimated number of emergency department-treated injuries from January 2008 through December 2012. The data provided in this memorandum include additional data that were received by CPSC after the notice of proposed rulemaking (NPR) published on May 20, 2013.

⁴ This analysis was prepared by CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

⁵ Not all of these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this memorandum to evaluate the addressability of the incidents, but rather to quantify the number of fatalities and injuries reported to CPSC staff and to provide estimates of emergency department-treated injuries when available. If the date of incident or injury is not reported, the date of entry into the CPSC database is used.

CPSC staff reviewed the data for incidents reported for users 4 years old or younger. Incidents in which the user's age was unreported or unknown also were included. Incidents related to a travel system, which includes a stroller, an infant car seat, and a car seat base, were also included.

II. Incident Data⁶

CPSC staff received 1,297 reported incidents (4 fatal and 1,293 nonfatal incidents) related to strollers that reportedly occurred from January 1, 2008 through June 30, 2013, and which involved children 4 years old or younger (or whose age was unreported/unknown). Of those, 1,207 incidents were presented in the NPR, and 90 newly reported incidents were entered from January 1, 2013 to June 30, 2013. The reporting is ongoing. Therefore, the number of reported fatalities, nonfatal injuries, and noninjury incidents may change in the future. Table 1 shows the breakdown of the incidents by severity of injury and age of the victim. Table 2 categorizes incidents by severity and incident year.

Table 1: Distribution of Stroller-Related Incidents, by Severity of Injury and Victim's Age (1/1/2008–6/30/2013)

Age	Fatalities	Injuries	Non-injuries or injury not reported	Total
Less than 1 year	2	97	156	255
12 to 23 months	1	116	74	191
2 years	0	70	41	111
3 years	0	24	19	43
4 years	1	9	4	14
Not reported*	0	75	608	683
Total	4	391	902	1,297

Source: CPSC epidemiological database CPRMS.

* Includes incidents where user's age was unreported or unknown.

⁶ The CPSC database searched was the Consumer Product Safety Risk Management System (CPSRMS). These reported deaths and incidents are not a complete count of all incidents that may have occurred during this time period. However, they do provide a minimum number of deaths and incidents occurring during this time period and illustrate the circumstances involved in the incidents related to strollers.

All data coded under product codes 1522 and 1505 were extracted from CPRMS. Upon careful joint review with Engineering Sciences staff, some cases were considered out of scope for the purposes of this memorandum. Cases involving adults or older children who were not the intended users of the stroller are excluded. Examples of such excluded cases are incidental cases, such as falls or strains while pushing or carrying a stroller, tripping over the stroller, and motor vehicle accidents. With the exception of incidents occurring at U.S. military bases in foreign countries, all incidents occurring outside of the United States have been excluded. All incidents where a hazardous environment in and around the stroller/baby carriage resulted in fatalities, injuries, or near-injuries were considered to be in scope.

Table 2: Distribution of Stroller-Related Incidents by Severity of Injury and Year
(1/1/2008–6/30/2013)

Year of incident**	Fatalities	Injuries	Non-injuries or injury not reported	Total
2008	1	59	161	221
2009	0	120	207	327
2010	1	95	142	238
2011	2	41	266	309
2012	0	54	97	151
2013	0	22	29	51
Total	4	391	902	1,297

Source: CPSC epidemiological databases CPSRMS.

** If the date of incident or injury is not reported, the date of entry into CPSRMS is used.

Note: Year in italics indicates reporting is ongoing.

A. Fatalities

There were four stroller-related fatal incidents that reportedly occurred between January 1, 2008 and June 30, 2013. They were all presented in the May, 20, 2013 stroller NPR; no new fatal incidents were reported from January 1, 2013 to June 30, 2013.

B. Nonfatal Incidents

There were 1,293 stroller-related nonfatal incidents that reportedly occurred between January 1, 2008 and June 30, 2013. Of those, 1,203 incidents were presented in the NPR, and 90 new incidents were reported from January 1, 2013 to June 30, 2013.

Of the 90 new nonfatal incidents, there were 32 injury incidents and 58 noninjury or injury-not-reported incidents. There were four incidents where hospitalization was required. Two incidents were related to finger amputation. One incident happened when the child's finger was caught in the hinge of a stroller. The other one happened when the stroller collapsed. In addition, one incident occurred when the child was caught on a round rivet after unbuckling the restraint, resulting in a laceration to the crotch area. One incident involved a stroller rolling off a train platform and falling onto the tracks, resulting in a cut to the forehead. The incident could be related to brake failure or an inactivated brake; the definite cause was unclear.

III. Hazard Patterns in the New Incidents (Reported January 2013–June 2013)

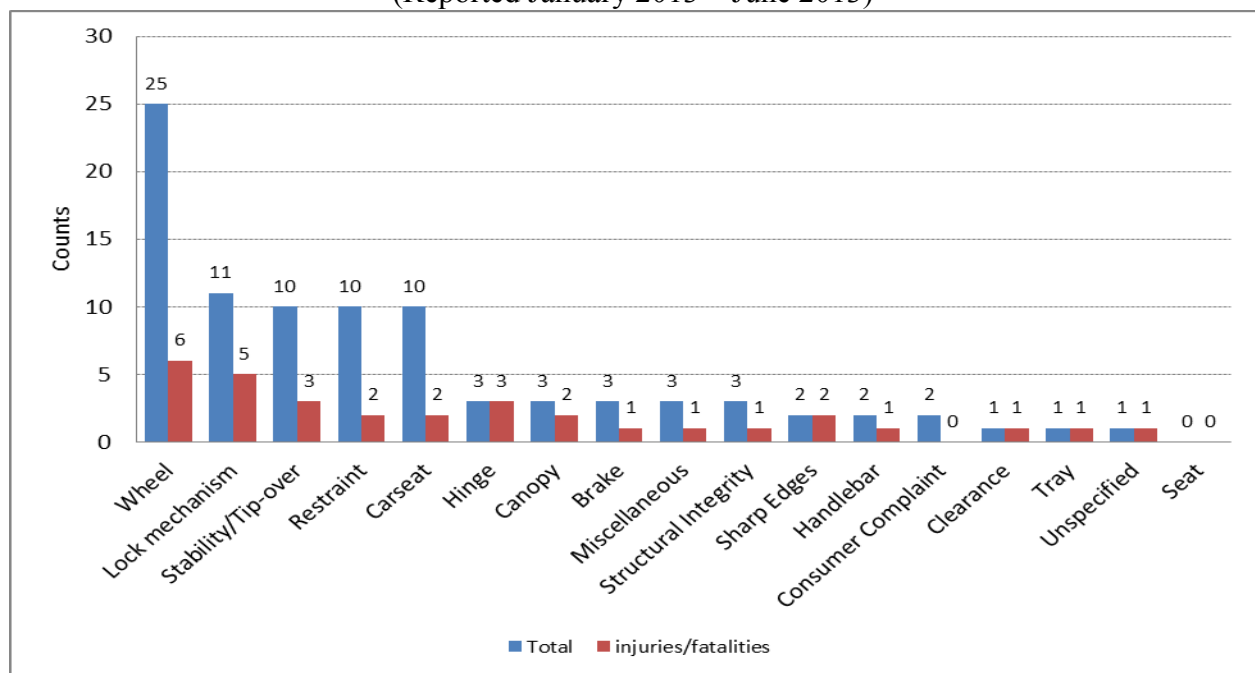
No new hazard pattern was observed in the incident data that were received after preparation of information for the NPR. The 90 new stroller-related incidents can be grouped into the same 17 categories that were described in the NPR; these categories are based on the stroller component that was involved in the incident. The categories and the number of new incidents that fall into the categories are listed below:

- A. *Wheel:* There were 25 new incidents related to wheel problems. This category included: cases in which the wheel/rim broke; issues with wheel detachment/attachment, wheel lock or wheel stability issues; and cases in which a tire or tube burst. There were six injuries reported in this category.
- B. *Lock mechanism:* There were 11 new incidents related to lock mechanical failure, which resulted in the stroller folding up or collapsing unexpectedly. There were five injuries reported, including one hospitalization for an amputated finger.
- C. *Stability/tip-over:* There were 10 new incidents related to stability/tip over. Three injuries were reported in this category.
- D. *Restraint:* There were 10 new incidents related to a restraint problem. This category included: restraint failure; breakage or detachment; cases in which the restraint was unbuckled by the child; and cases in which the restraint was too loose, too long, or not used. There were two injuries reported, including one that led to a hospitalization for a laceration to the crotch area.
- E. *Car seat attachment:* There were 10 new incidents, two resulting in injuries, involving a stroller with a car seat adapter, including: car seat detachment; inability to lock; and tip over.
- F. *Hinge:* There were three new incidents related to hinge problems. All three involved finger injuries, including one hospitalization for an amputated finger.
- G. *Canopy:* There were three new incidents involving canopy-related problems, such as finger injuries involving canopy hinges, seams falling apart, or the canopy fogging up. There were two injuries reported in this category.
- H. *Parking brake:* There were three new incidents related to parking brake failure or parking brake assembly problems. This category included one minor injury.
- I. *Structural integrity:* There were three new incidents related to structural integrity problems. This category included the failure or malfunction of various structural components (such as the seat and frame). This category included one injury.
- J. *Sharp points or edges:* Two new incident reports, both resulting in injuries, in this category involved sharp points or edges of various structural components of the stroller.
- K. *Handlebar:* This category included two new incidents where breakage, detachment, or malfunction of the handlebar occurred: one incident involved an injury and one had no injury reported.
- L. *Clearance:* There was one new incident related to a clearance issue. The victim's head was stuck between the seat back and the canopy, resulting in a bruise on his neck.
- M. *Tray:* There was one incident related to sharp points on the tray, resulting in an injury.

- N. Seat:* This category included seat or seat fabric problems. No new incident was found in this category.
- O. Consumer complaint:* This category included consumers requesting a repair kit after a recall and complaining that the product resembled a recalled product. There are two new non-injury reports in this category.
- P. Miscellaneous:* There were three incidents with miscellaneous problems, one of which involved a reported injury. This category includes two cases involving a child chewing on the front bar or handlebar, and one case involving a stroller falling into the water because of strong wind.
- Q. Unspecified:* There was one new report that lacks sufficient information to determine the cause of the incident. This incident involved a stroller rolling off the train platform and falling onto the tracks. The victim was taken to the hospital for treatment of a cut on the forehead. The incident could be related to brake failure or inactivated brakes; the cause was unclear.

The distribution of the 90 newly reported incidents by the hazardous components described above is shown in Figure 1.

Figure 1: Distribution of Reported Stroller-Related Incidents by Components Presenting the Hazard
(Reported January 2013 – June 2013)



Source: CPSC epidemiological database CPSRMS.

IV. National Injury Estimates⁷

No new trend was observed in the data that CPSC received since the preparation of the data for the stroller NPR was completed. There were an estimated 56,600 stroller-related injuries (sample size=2,269, coefficient of variation=0.16) that were treated in U.S. hospital emergency departments from January 2008 to December 2012. There were an estimated 10,400 stroller-related injuries for year 2012. The age of the patients in these incidents ranged between one-month and four years old. More than 98 percent of the patients were reported to be three years old or younger. Partial estimates for 2013 are not available until NEISS data for 2013 is finalized in spring 2014. There was no statistically significant increase or decrease observed in the estimated injuries from one complete year to the next (p-value > 0.1), nor was there any statistically significant trend observed over the 5-year period 2008–2012 (p-value = 0.45).

No deaths were reported through NEISS. Based on the narratives, most of the new incidents were related to falls (*e.g.*, unspecified falls from the stroller, falls from climbing on the stroller, falls from stroller tip over, stroller falling down steps). Most of the injuries (91%) were treated and released. The following injury characteristics occurred most frequently:

- Injured body part – head (54%), face (29%).
- Injury type – internal organ injury (39%), contusions/abrasions (26%), laceration (16%).

V. Incidents Among Older Children and Adults

There were 84 incidents from CPSRMS related to strollers that were reported to have occurred from January 1, 2008 through June 30, 2013, and involved children older than four years and adults. Of those, 78 incidents were included in the stroller NPR, and six new incidents were entered from January 1, 2013 to June 30, 2013. All six new incidents involved finger injuries and the users' ages were unreported or unknown, with the exception of one consumer (age=29).

There were 47 injuries from NEISS related to strollers that were reported to have occurred from January 1, 2008 through June 30, 2013, and involved children older than 4 years and adults. Of those, 17 were new incidents that were received by CPSC after preparation of information for the May 20, 2013 stroller NPR was completed. Of the new incidents, nine involved a child between 5 and 10 years old and the rest involved victims between 13 and 72 years old. Seven out of the 17 incidents (41%) involved finger or hand injuries.

⁷ 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 the 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 CPSC staff to make national estimates of the number of injuries associated with specific consumer products.

All data coded under product codes 1522 and 1505 for patients aged 4 years and younger was extracted. Certain records were considered out-of-scope for the purposes of this memo. Cases involving adults or children older than age 4 who were not riding in the stroller are excluded. Cases involving tripping over a stroller, having cardiac arrest in a stroller, or motor vehicle accidents were also excluded. These records were excluded prior to deriving the statistical injury estimates.

**TAB B: Division of Mechanical Engineering
Recommendations for the Final Carriage and Stroller
Standard**

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

November 25, 2013

TO : Rana Balci-Sinha, Ph.D.
Strollers Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: George A. Borlase, Ph.D., P.E.
Assistant Executive Director
Office of Hazard Identification and Reduction

FROM : Mark E. Kumagai, P.E.
Director Division of Mechanical Engineering
Directorate for Engineering Sciences

SUBJECT : Recommendations for the Final Rule on
Carriages and Strollers

I. Background/Overview

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act (CPSIA), requires CPSC staff to: (1) examine and assess voluntary safety standards for certain infant and toddler products, and (2) promulgate mandatory consumer product safety standards that are substantially the same as the voluntary standards or more stringent than the voluntary standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. The list of products in section 104 includes strollers.

In the notice of proposed rulemaking (NPR),⁸ staff recommended adding a new performance requirement to the ASTM voluntary standard F833-13, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, to address scissoring, shearing, and pinching hazards associated with 2D fold strollers.

This memorandum includes staff's responses to related public comments received on the NPR and staff's recommended changes to ASTM F833-13b, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, which is the most recent published version of ASTM F833.)

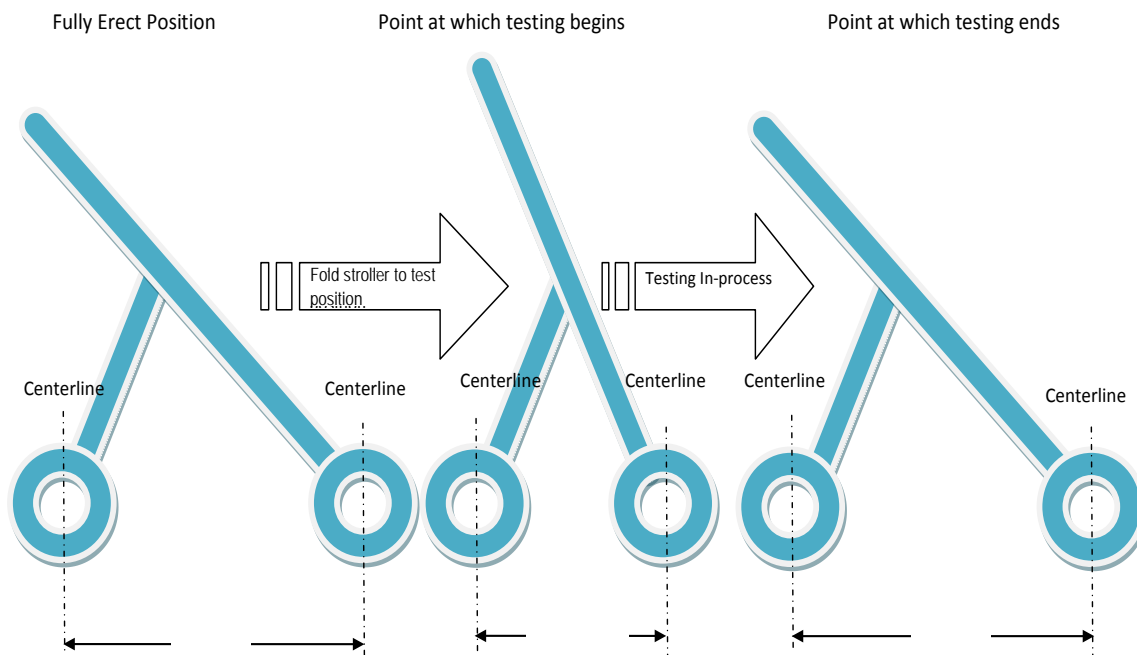
⁸ The NPR was published in the *Federal Register* on May 20, 2013. (78 Federal Register 29279).

II. Public Comments and Staff Responses

Starting Point for 2D Frame Fold Stroller Test

Comment: One commenter recommended a simplified test method for section 7.18.2, *For units where the front and rear wheels move toward each other during folding*, to address scissoring, shearing, and pinching hazards for 2D frame fold strollers. The commenter suggested determining the starting point for the stroller test by beginning at 2/3 the distance between the front and rear wheel axles, as shown in the figure below. The commenter stated that the ASTM subcommittee is working to include this starting point definition in the next revision and requested that the Commission review and adopt the change to the test method once the requirement is approved by the ASTM subcommittee.

Figure Y



Response: The commenter's request was balloted by ASTM (ASTM F15 (13-07) Item Number: 001) in September 2013, and incorporated into the latest revision of the ASTM standard (F833-13b) and published in November 2013. Staff compared the new method of calculation with the one proposed in the NPR, using various strollers, including certain incident strollers. Staff believes that the new calculation still includes the most critical part of the frame folding that is associated with the incidents, even though in certain strollers the total amount of travel to be tested would be less than with the NPR-proposed calculation. Staff agrees with this change because it is simpler and appears to provide an equal degree of safety.

2D Frame Fold Hinges Access Zone

Comment: A commenter suggested an exemption to the 2D fold test procedure if there is a cover over the hinge that is within the access zone. An example of this exemption is a cover for a

stroller hinge that covers the top and sides of the hinge, but leaves the bottom open to allow the frame members to rotate during folding. The only way to access the hinge would be to come up from underneath or behind through the rear of the stroller, which would not be possible if a child is sitting in the stroller or standing on the side of the stroller. According to the commenter, ASTM subcommittee is currently reviewing an additional requirement to assess at what point a covering on a hinge is sufficient protection from the 2D frame fold pinch hazard. The commenter requested that the Commission review and adopt the additional requirement once it is approved by the ASTM subcommittee.

Response: Considering that the frame fold hinge is a significant hazard, staff is cautious about providing an exemption for a protective cover without thorough review and analysis of the exemption. Staff believes that there are many factors, including the size, shape, and material properties of the cover that may hinder the cover's effectiveness. Staff believes that hinges that are within the access zone should not allow finger entrapment, regardless of direction of entry, to reduce the risk of finger injury to a child who is either sitting or about to sit in a stroller. However, if ASTM publishes a revised standard to include a protective cover exemption, ASTM could notify the Commission of the revised ASTM standard and the Commission would consider the revision.⁹

Combined Braking and Stability Test

Comment: A commenter suggested that the Commission adopt the combined braking and stability test that Consumer Reports uses in its testing. The commenter stated that the test evaluates both brake efficacy and stability in various orientations on an incline of 20°—as opposed to 12° which was used in the previous versions of the ASTM standard, including that the version proposed in the NPR. In addition, the commenter states that the brake standard should assess how easy it is to engage the brake, and reliably tell if the brake is engaged.

Response: The parking brake requirements were significantly improved in the ASTM F833-13 version of the standard to approximate the force that is applied to the parking brake if the 12° inclined plane were increased to 20°. Therefore, staff believes that the new requirement is adequate to address the hazards associated with parking brakes and do not require additional requirements at this time. ASTM F833-13 also included an improved requirement and test method for multiple seats facing different directions, such as rotating seats, to address stability issues.

Passive Containment/Clearance

Comment: A commenter suggested augmenting the passive containment requirement and test with a requirement that any adjustable parts, such as an adjustable grab bar or a car seat adapter that remains in the stroller, be tested in all possible positions.

⁹ Section 3 of the revision to the Consumer Product Safety Improvement Act of 2008 (Pub. L. No. 112-28; H.R. 2715) instructs ASTM to notify the CPSC of revisions to voluntary standards that are a basis for the CPSC's safety standards for consideration for a revised safety standard.

Response: Staff agrees with the commenter's recommendation for adjustable grab bars for the following reason:

ASTM F833-13b has requirements for strollers with a tray or grab bar to prevent a head entrapment hazard. The standard requires the grab bar to be in the manufacturer-recommended use position. CPSC staff is aware of earlier model year strollers that had adjustable grab bars, as described by the commenter. Figures 1 and 2 below show a stroller grab bar that can be used in multiple positions. Figure 1 shows the manufacturer's recommended position when carrying a child. The opening created between the grab bar and seat shown in Figure 1 does not present a head entrapment hazard. Figure 2 shows the position of the grab bar for use as a car seat attachment. This position would be considered a head entrapment hazard because the opening permits the passage of a 3.0-in. x 5.5-in. torso probe but does not allow the passage of an 8.0-in. diameter head probe. Staff is concerned that a consumer would not be able to discern the difference between the car seat position, Figure 2, and the occupant-use position, Figure 1.



Figure 1. Grab bar in manufacturer-use position for an occupant. The opening between the grab bar and seat PASSES ASTM F833-13b, Section 7.12, *Passive Containment/Foot Opening Test Method*.



Figure 2. Grab bar in the car seat attachment position. The opening between the grab bar and seat FAILS ASTM F833-13b, Section 7.12, *Passive Containment/Foot Opening Test Method*.

Four stroller-related fatalities were reported to CPSC from January 1, 2008 through June 30, 2013. One incident involved a 5-month-old infant whose head became entrapped between the seat and tray. Staff considers the opening between the seat and the tray or the seat and grab bar to be a potentially fatal head entrapment hazard if it fails ASTM F833-13b, Section 7.12, *Passive Containment/Foot Opening Test Method*.

On April 20, 2012, CPSC staff requested that the ASTM subcommittee consider developing head entrapment requirements for products with a multi-positional grab bar. A task group was formed; however, staff is not aware of any progress on this issue. Due to the potential for a fatal entrapment between an adjustable grab bar and seat, CPSC staff recommends the following modification (strikeouts reflect deleted language; underline reflects added language) to section 7.12.1 and 7.12.3 of ASTM F833-13b:

7.12 Passive Containment/Foot Opening Test Method:

7.12.1 Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). ~~Per the manufacturer's instructions,~~ Position any adjustable features (that is., grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create ~~an~~the ~~minimum~~ opening(s) size that is most likely to cause failure.

7.12.2 Place the head probe (Fig. 10) adjacent to the opening(s) most likely to allow the head probe to pass through. With the harness restraint system unbuckled, place the buckle portion of the crotch belt beneath the head probe. Gradually rotate the unit 90° with the front wheels as a stationary pivot within a period of 5 s and maintain for an additional 10 s. The head probe shall remain in contact with seat during the test. If the head probe passes completely through the bounded opening (a) without detaching the tray(s) or grab bar(s), or (b) by completely detaching the tray(s) or grab bar(s), or (c) by moving the tray(s) or grab bar(s) out of the manufacturer's recommended use position, then the stroller meets the criteria of 6.8. If the sample does not meet any of the criteria listed in (a), (b), or (c) above, then proceed to 7.12.3.

7.12.3 If necessary, reattach/reposition tray(s) grab bar(s) ~~to the manufacturer's recommended use position,~~ then perform the torso probe test per 7.12.4. ~~Per the manufacturer's instructions,~~ Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the ~~maximum~~ opening(s) size that is most likely to cause failure.

The original requirement specifies a minimum opening created by the grab bar or tray and foot rest. This test may not capture a hazardous opening that is larger than the minimum opening created by the grab bar and foot rest configuration. The revised wording: “**most likely to cause failure**” requires the tester to position the grab bar, if possible, in a position that creates a hazardous opening, and thereby, causes the stroller to fail, irrespective of the manufacturer's instructions or manufacturer's recommended use position. This addition should address the entrapment hazard for multi-positional or adjustable grab bars in strollers.

The commenter also recommended that a car seat adapter that can remain in the stroller be tested for head entrapment. Staff is not aware of a car seat adapter that is intended to remain installed in the stroller when the car seat is not used. Staff has not sufficiently evaluated this issue to recommend additional requirements for car seat adapters. Staff believes that ASTM should work with staff to investigate this issue further and develop requirements, if needed.

Irregular Surface Test

Comment: Two commenters suggested that the Irregular Surface Test in EN 1888:2012 be adopted. The commenters stated that the irregular surface test is a durability test that evaluates the strollers for expected lifetime of the product.

Response: Staff believes that the ASTM standard that has been updated with improved parking brake, stability, wheel detachment, and locking mechanism requirements is sufficient to address the structural issues that the incident data demonstrate. Due to the time consuming (and therefore, costly) nature of fatigue tests, CPSC staff typically favors tests with lower repetitions

and higher weights/forces that yield substantially similar results. At this time, staff does not recommend adding the irregular surface test to the proposed rule.

III. Staff-Recommended Change to F833-13b

Staff is recommending that the Commission adopt the ASTM voluntary standard F833-13b for carriages and strollers, with one addition, to address head entrapment hazards associated with multi-positional/adjustable grab bars.

CPSC staff recommends that the Commission publish a final rule that incorporates by reference the voluntary standard, ASTM F833-13b, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, with revisions as written in the appendix to this memorandum.

Appendix

CPSC Staff-Recommended Revisions to the Voluntary Standard, ASTM F833-13b (underline reflects added language; strike-out reflects deleted language)

7.12 *Passive Containment/Foot Opening Test Method:*

7.12.1 Secure the front wheels of the unit in their normal standing position so that the unit cannot move forward. Attach the tray(s) or grab bar(s) in the position that creates the bounded opening(s). ~~Per the manufacturer's instructions,~~ Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s) to create an the minimum opening(s) size that is most likely to cause failure.

7.12.2 Place the head probe (Fig. 10) adjacent to the opening(s) most likely to allow the head probe to pass through. With the harness restraint system unbuckled, place the buckle portion of the crotch belt beneath the head probe. Gradually rotate the unit 90° with the front wheels as a stationary pivot within a period of 5 s and maintain for an additional 10 s. The head probe shall remain in contact with seat during the test. If the head probe passes completely through the bounded opening (a) without detaching the tray(s) or grab bar(s), or (b) by completely detaching the tray(s) or grab bar(s), or (c) by moving the tray(s) or grab bar(s) out of the manufacturer's recommended use position, then the stroller meets the criteria of 6.8. If the sample does not meet any of the criteria listed in (a), (b), or (c) above, then proceed to 7.12.3.

7.12.3 If necessary, reattach/reposition tray(s) grab bar(s) ~~to the manufacturer's recommended use position,~~ then perform the torso probe test per 7.12.4. ~~Per the manufacturer's instructions,~~ Position any adjustable features (that is, grab bar, calf supports, foot rests, etc.) that may affect the bounded opening(s), to create the ~~maximum~~ opening(s) size that is most likely to cause failure.

TAB C: Carriages and Strollers, Human Factors Staff Responses to Comments

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UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
4330 EAST WEST HIGHWAY
BETHESDA, MARYLAND 20814

Memorandum

Date: November 25, 2013

TO: Rana Balci-Sinha, Ph.D.
Project Manager
Division of Human Factors
Directorate for Engineering Sciences

THROUGH: Bonnie B. Novak
Director
Division of Human Factors
Directorate for Engineering Sciences

FROM: Jonathan D. Midgett, Ph.D.
Engineering Psychologist
Office of Hazard Identification and Reduction

SUBJECT: Carriages and Strollers: Human Factors Staff Responses to Comments

I. Introduction

The Consumer Product Safety Improvement Act of 2008, Public Law 110–314 (CPSIA) was enacted on August 14, 2008. Section 104, the Danny Keysar Child Product Safety Notification Act, requires the Commission to promulgate mandatory consumer product safety standards for durable infant or toddler products. These standards are to be “substantially the same as” applicable voluntary standards or more stringent than the voluntary standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

The Commission proposed a safety standard for carriages and strollers in the *Federal Register* (78 Federal Register 29279, May 20, 2013), based on the voluntary standard, ASTM F833-13, “Standard Consumer Safety Performance Specification for Carriages and Strollers.”

This memorandum responds to the major human factors issues raised in the comments submitted in response to the May 20, 2013 NPR and that pertain to the final rule on carriages and strollers.

II. Public Comments

Product Marking to Indicate Compliance with Mandatory Rule

Comment

Two commenters recommended that products be marked clearly to allow a consumer to determine if the carriage or stroller was manufactured after the mandatory standard became effective.

Response

A code mark or other means that identifies the date (month and year as a minimum) of manufacture is already required to be on the product, under section 8.1.2 of ASTM F833-13b.

A final rule implementing sections 14(a)(2) and 14(i)(2) of the Consumer Product Safety Act (CPSA), as amended by the CPSIA, Testing and Labeling Pertaining to Product Certification, 16 C.F.R. part 1107 (the 1107 rule), became effective on February 13, 2013. Under the 1107 rule, a manufacturer or importer may voluntarily label a certified compliant product as “Meets CPSC Safety Requirements.” Because producers are already allowed to label compliant products as such under the 1107 rule, staff does not recommend requiring additional markings at this time.

Warnings

Comment

One commenter suggested changing the wording in section 8.2.2 of the standard, which currently states: “Do not leave child unattended.” The commenter’s proposed language says: “Children have become entrapped or suffocated while sleeping in strollers. Never leave a sleeping child unattended. Move to a crib or safe sleep surface.”

Response

The current wording advises the caregiver to attend to the child, whether or not he/she is sleeping, thus, providing a more generic warning. In most of the incidents where the children were reportedly sleeping in the stroller, the caregiver was also present. Staff notes that in one of the fatal incidents, a child was left sleeping in the stroller and was later found entrapped between the seat and tray. In another fatal incident, the child was left sleeping in the infant carrier that was attached to the stroller and found entrapped between the stroller handlebar and foot end of the car seat. Children should not be left unattended whether they are sleeping or not. However, staff believes that products in which children often sleep, even if not intended for sleep, such as strollers and hand-held carriers, can incorporate a harmonized and well-designed warning label to educate consumers to take proper action. Staff believes a cross-product ad hoc working group may be the best choice to develop such a warning label, and staff would support participation in such a group. Staff will raise this issue with the ASTM F15 subcommittee, rather than recommend that a revised label be included in the final rule.

Comment

One commenter suggested changing the wording in section 8.2.2 to make the language more flexible, without affecting the purpose or effectiveness of the warning. The commenter suggested changing the current wording in 8.2.2 from: “The product shall have the following warning statements. . .” to: “The product shall have the following warning statements that address. . .”

Response

The warning statements in 8.2.2.2, 8.2.2.3, and 8.2.2.4 already include a provision for the manufacturer to insert other words to describe their restraint system or add product-specific instructions to the current language.

The suggestion would only affect section 8.2.2.1, which includes the warning statement: “Never leave child unattended.” The commenter stated that a simple change in wording to: “Never leave *your* child unattended” would not be allowed under 8.2.2. The warnings were developed by the ASTM subcommittee, and staff does not recommend word changes that would not increase the effectiveness of the warning. Staff believes that such edits to warnings are more appropriately addressed by the ASTM subcommittee for any necessary revisions in a future standard.

Restraining System/Harness

Comment

One commenter suggested that the Commission require a five-point harness for all strollers and carriages for improved protection. In addition, the commenter suggested that the Commission look for feasible means of requiring an alert mechanism that would clearly signal or indicate whether the harness restraint system is properly secured.

Response

Staff agrees that a five-point harness system may provide extra protection if a stroller tips over. However, because the incident data do not clearly demonstrate a significant improvement in occupant safety beyond a three-point harness, staff is not convinced that the addition of a requirement of a five-point harness is warranted. Furthermore, the recent changes that have been added to the standard to prevent the root causes of strollers tipping over, such as the new wheel-detachment requirements, should mitigate the likelihood of tip-over incidents.

Regarding the alert mechanism, staff is uncertain whether alarm systems could be accomplished without significantly raising the cost of a stroller; nor is staff certain that such a system would be effective in reducing restraint issues. Visual feedback is unlikely to get the attention of the caregiver because an unsecured, loose, or excessively tight restraint would already be noticed by the caregiver. An auditory signal would be a significant technical addition to a stroller, requiring a power source, signaling device, and switches. However, this issue may be raised in an ASTM subcommittee meeting for review and discussion.

Passive Containment/Clearance

Comment

A commenter suggested augmenting the passive containment requirement and test with a requirement that any adjustable parts, such as an adjustable grab bar or a car seat adapter that remains in the stroller, be tested in all possible positions.

Response

Staff agrees with the commenter's recommendation for adjustable grab bars. A grab bar can give the appearance of being useful to the child occupant when it is adjusted in the position intended to hold a car seat. This appearance will increase the likelihood that consumers will leave a grab bar in a position that could create a hazardous, bounded opening. Car seat adapters could also give this appearance, but staff will raise this issue with the ASTM subcommittee for further analysis. Therefore, staff recommends that the passive containment/foot opening test method be modified so that adjustable grab bars are tested in the most onerous position.

TAB D: Final Regulatory Flexibility Analysis of Staff-Recommended Final Rule for Carriages and Strollers

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**UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
BETHESDA, MD 20814**

Memorandum

Date: November 30, 2013

TO : Rana Balci-Sinha, Ph.D.
Stroller Project Manager
Division of Human Factors
Directorate for Engineering Sciences

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

Deborah V. Aiken, Ph.D.
Senior Staff Coordinator
Directorate for Economic Analysis

FROM : Jill L. Jenkins, Ph.D.
Economist
Directorate for Economic Analysis

SUBJECT : Final Regulatory Flexibility Analysis of the Staff-Recommended Final Rule for
Carriages and Strollers and the Accreditation Requirements for Conformity
Assessment Bodies for Testing Conformance to the Stroller Standard

Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to evaluate the existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as the applicable voluntary standard, or more stringent than the voluntary standard if the Commission determines that more stringent standards would further reduce the risk of injury. Strollers are among the durable products specifically named in section 104.

On May 20, 2013, the CPSC published a notice of proposed rulemaking (NPR) in the *Federal Register* (FR) (78 FR 29279). The proposed rule incorporated by reference the voluntary ASTM International (ASTM) standard for carriages and strollers (F833-13), with the addition of frame folding requirements for 2D strollers. Since the NPR, ASTM has published F833-13b, which incorporates the 2D frame folding requirements from the NPR, with a clarification to the travel distance calculation that was raised in the public comments received in response to the NPR. Therefore, staff recommends adopting ASTM F833-13b by reference.

Additionally, Engineering Sciences (ES) staff recommends modifying the passive containment/foot opening test method to require that adjustable grab bars are tested in the most onerous position, based on a comment received in response to the strollers NPR.

The Regulatory Flexibility Act (RFA) requires that final rules be reviewed for their potential economic impact on small entities, including small businesses. Section 604 of the RFA requires that agencies prepare a final regulatory flexibility analysis when promulgating a final rule, unless the head of the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The final regulatory flexibility analysis must describe the impact of the rule on small entities and identify any alternatives that may reduce the impact. Specifically, the final regulatory flexibility analysis must contain:

1. a succinct statement of the objectives of, and legal basis for, the rule;
2. a summary of the significant issues raised by public comments in response to the initial regulatory flexibility analysis, a summary of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments;
3. a description of, and, where feasible, an estimate of, the number of small entities to which the rule will apply;
4. a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities subject to the requirements and the type of professional skills necessary for the preparation of reports or records; and
5. a description of the steps the agency has taken to reduce the significant economic impact on small entities, consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the rule, and why each one of the other significant alternatives to the rule considered by the agency, which affect the impact on small entities, was rejected.

The Product

ASTM F833-13b, *Standard Consumer Safety Performance Specification for Carriages and Strollers*, defines “carriages” and “strollers” as wheeled vehicles used for the transport of children. Mobility is supplied by a walking non-occupant pushing or pulling on the handle. Carriages and strollers differ primarily by the intended age and position of the occupant. Infants lie flat in carriages, while both infants and older children use strollers in a seated or semi-reclined position. Strollers can generally be folded for storage, while most carriages cannot.

The staff-recommended final rule includes jogging strollers, which typically have thicker, more robust wheels so that they can be moved at a rapid pace. This includes strollers intended for use in public locations, such as malls and airports, as well as strollers used for multiple occupants. Multiple-occupant strollers, which are often used in day care situations, are also available for private consumer use and can accommodate up to 10 occupants. Wheeled products

that can be self-propelled by a child are specifically excluded, as are shopping cart-style strollers used in grocery stores.

The Market for Strollers

The majority of strollers are produced and/or marketed by juvenile product manufacturers and distributors. CPSC staff believes that there are currently at least 85 suppliers of strollers to the U.S. market. Thirty-four are domestic manufacturers, 36 are domestic importers, and four are domestic firms with unknown supply sources. There are also 10 foreign firms—seven foreign manufacturers, one firm that imports products from foreign companies and distributes them from outside of the United States, one foreign retailer that ships directly to the United States, and one firm with an unknown supply source. There is an additional manufacturer whose size and location could not be determined.¹⁰ Staff expects that the products of 49 of the 85 stroller suppliers will be compliant with ASTM F833-13b because 20 firms have strollers that are certified by the Juvenile Products Manufacturers Association (JPMA) to F833-11, and 29 firms have strollers that claim compliance with F833.¹¹

Staff estimated the annual sales of strollers using information from the 2005 survey conducted by the American Baby Group (*2006 Baby Products Tracking Study*).¹² Nearly all new mothers (99 percent) own at least one stroller. Approximately 26 percent of strollers were handed down or purchased secondhand.¹³ Thus, about 74 percent of strollers were acquired new. This suggests annual sales of about 3 million strollers ($.99 \times .74 \times 4$ million births per year).¹⁴ Strollers generally cost from \$20 to \$700, depending upon the type and brand.¹⁵ On average, umbrella strollers tend to be the least expensive (around \$25–\$50 for the least costly versions); most other strollers cost around \$150–\$300. However, some carriages, travel systems, and jogging strollers may be priced in the \$500–\$700 range.

¹⁰ Determinations were made using information from Dun & Bradstreet and ReferenceUSAGov, as well as firm websites.

¹¹ JPMA typically allows 6 months for products in JPMA's certification program to shift to a new standard once the new standard is published. ASTM F833-13b, the voluntary standard upon which the staff-recommended final rule is based, is expected to become effective for JPMA certification purposes prior to the staff-recommended effective date of 18 months after final rule publication.

¹² The data collected for the *Baby Products Tracking Study* does not represent an unbiased statistical sample. The sample of 3,600 new and expectant mothers is drawn from American Baby magazine's mailing lists. Additionally, because the most recent survey information is from 2005, the survey may not reflect the current market.

¹³ The data on secondhand products for new mothers was not presented in the *Baby Products Tracking Study*. Instead, the secondhand product data for new mothers and expectant mothers were combined by staff and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers were averaged by CPSC staff to calculate the approximate percentage of products that were handed down or purchased secondhand.

¹⁴ U.S. Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), National Center for Health Statistics, National Vital Statistics System, "Births: Final Data for 2010," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. The number of births in 2010 is rounded from 3,999,386.

¹⁵ Higher-end models can cost up to \$4,000 but are less common.

According to ASTM, strollers are intended to be used during a child's first 36 months.¹⁶ Staff assumes that strollers are used during a child's first two years with some caregivers continuing use of their stroller into the third year. Staff does not know the proportion of consumers who continue to use strollers into the third year, so we estimate risk under the assumption that approximately 25–75 percent will do so. Based on data from the *2006 Baby Products Tracking Study*, nearly 4 million strollers are owned by new mothers. Therefore, there would be approximately 8.9–10.9 million households with strollers available for use annually (4 million x .99 x 2.25 to 4 million x .99 x 2.75). According to Epidemiology (EPI) staff, there were an annual average of 11,320 emergency department-treated injuries to children under age 5 related to strollers between January 2008 and December 2012.¹⁷ Therefore, there may have been about 10.4–12.7 emergency department-treated injuries annually for every 10,000 strollers available for use in the households of new, second-year, and third-year mothers.

Reason for Agency Action and Legal Basis for the Staff-Recommended Final Rule

The Danny Keysar Child Product Safety Notification Act requires the CPSC to promulgate a mandatory standard for strollers that is substantially the same as, or more stringent than, the voluntary standard. CPSC staff worked closely with ASTM to develop the new requirements and test procedures that have been added to ASTM F833-13b, which forms the basis of the staff-recommended final rule. The modification to the passive containment/foot opening test method recommended by ES staff to require that adjustable grab bars are tested in the most onerous position is based on an NPR public comment.

Requirements of the Staff-Recommended Final Rule

CPSC staff recommends that the Commission incorporate by reference the voluntary ASTM standard for strollers (F833-13b), with an ES staff-recommended modification to the passive containment/foot opening test method to require that adjustable grab bars are tested in the most onerous position.

ASTM F833-13b

Some of the more significant requirements of ASTM F833-13b are listed below. Requirements that ASTM added or modified since the NPR are in italics.

- latching mechanisms—intended to prevent unintentional folding while in use;
- brakes—intended to limit movement with the braking mechanism engaged and prevent the occupant from releasing the brake while in the stroller;

¹⁶ ASTM F833-13b.

¹⁷ Memorandum from Angie Qin, Division of Hazard Analysis, Directorate for Epidemiology, dated August 20, 2013, Subject: Stroller-Related Deaths, Injuries, and Potential Injuries; January 2008 – June 2013. NOTE: There were an estimated 11,550 annual emergency department-treated injuries based on EPI data provided for the NPR, hence, the drop in risk estimates between the initial and final regulatory flexibility analyses.

- static load testing on seating area—intended to keep the child fully supported while the stroller is stationary;
- stability test for preventing tip over— prevents strollers from tipping over in “worst case scenario” situations, such as the child attempting to climb in while the stroller is on an inclined surface;
- restraints—intended to maintain the integrity and effectiveness of restraint systems that are required in all strollers, except carriages that are intended to be used only for infants in a lying down position;
- occupant retention—carriages and other strollers with reclined positions must have walls on all sides of the occupant seat to prevent the child from falling out;
- impact test—requires that car seats used in conjunction with a stroller or carriage remain attached at all points when repeatedly run into a rigid barrier;
- passive containment/foot opening—intended to prevent entrapments in strollers with trays or grab bars;
- wheel detachment—intended to maintain the integrity of stroller wheels and their assemblies;
- cord/strap extensions and loops in occupant spaces—intended to prevent entanglements and choking hazards;
- 3D fold and canopy—intended to prevent scissoring, shearing, pinching, and, in some cases, amputation in the joints of 3D-folding strollers;
- *2D frame folding—intended to address scissoring, shearing, and pinching in the joints of 2D-folding strollers. ASTM adopted the NPR proposal with a clarification to how travel distance should be calculated that addresses public comments received in response to the strollers NPR;*
- head entrapment—intended to address incidents, including one fatality, where children’s heads were caught in openings created when a stroller/carriage was combined with a rearward-facing car seat;
- buckle release—intended to prevent children from releasing themselves from their stroller.

The voluntary standard also includes: (1) torque and tension tests to prevent removal of components; (2) requirements for several stroller features to prevent entrapment and cuts (minimum and maximum opening size, coverage of exposed coil springs, small parts, hazardous sharp edges or points, smoothness of wood parts, and edges that can scissor, shear, or pinch); (3) marking and labeling requirements; (4) requirements for the permanency and adhesion of labels; (5) requirements for instructional literature; and (6) toy accessory requirements.

Staff-Recommended Change

In the past, entrapments have occurred in strollers with grab bars. Staff has been unable to identify any current strollers on the U.S. market that have adjustable grab bars, and EPI staff found no entrapments due to this feature over the period from January 2008 to June 2013. However, there have been incidents related to the clearance between the seat and the tray. In response to the NPR, one commenter recommended that the Commission “augment the passive containment requirement and test with a requirement that any adjustable parts . . . should be

tested in all possible use positions.” After reviewing the comment, ES staff recommends that the adjustable tray or grab bar be tested in the most onerous position (*i.e.*, the one most likely to fail the products).

Although staff is not aware of any current strollers on the U.S. market that would be affected by this modification, it is possible that such strollers are on the market. If so, these products might require modifications to meet the staff-recommended requirement and test procedure. It is likely that changes to hard tools might be required (*i.e.*, molds of desired stroller components that are injected with plastic or another material during the production process). Hard tools are often modified by an outside firm, which means that production would cease, and unless the firm maintains an alternating production schedule, this could result in significant downtime for the firm’s production process. Product redevelopment could potentially be necessary as well.

Issues Raised by Public Comments

There was one public comment submitted in response to the NPR that resulted in a change to the 2D frame folding test procedure as adopted by ASTM. A second commenter recommended testing strollers with adjustable parts in all possible use positions. As a result, ES staff developed a modification to the passive containment test procedure that tests these products in the most onerous adjustable position.

Additionally, there were several comments that addressed the rule’s effective date. One requested a maximum 12-month effective date, while others requested that we reevaluate the 18-month effective date and definitely not allow longer than 18 months. Commenters were concerned about the length of time consumers would need to wait for products that would meet the final rule. Staff generally considers 6 months to be an appropriate effective date. However, based on input from stroller manufacturers at the time of the NPR, staff believes that an 18-month effective date is justified, particularly to accommodate suppliers who might be unfamiliar with the ASTM standard. Additionally, many suppliers have product lines that largely or exclusively focus on strollers and stroller accessories. A shorter effective date would likely have a more significant economic impact on these firms and could potentially drive some firms out of the market for strollers. Ongoing compliance activities would still be used to pull unsafe strollers from the market. Given these factors, staff continues to recommend an 18-month effective date.

Other Federal or State Rules

There are two federal rules that would interact with the stroller mandatory standard: (1) *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107); and (2) *Requirements Pertaining to Third Party Conformity Assessment Bodies* (16 C.F.R. part 1112).

The testing and labeling rule (16 C.F.R. part 1107) requires that manufacturers of children’s products subject to product safety rules, certify, based on third party testing, that their children’s products comply with all applicable safety rules. Because strollers will be subject to a

mandatory rule, they will also be subject to the third party testing requirements when the stroller rule becomes effective.

In addition, the 1107 rule requires the third party testing of children's products to be conducted by CPSC-accredited laboratories. Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformity assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. These NORs are set forth in 16 C.F.R. part 1112. Consequently, staff recommends amending 16 C.F.R. part 1112 to establish the requirements for the accreditation of testing laboratories to test for compliance with the stroller final rule. The Commission proposed this amendment as part of the stroller NPR.

Impact on Small Businesses

There are approximately 85 firms currently known to be marketing strollers in the United States. Under U.S. Small Business Administration (SBA) guidelines, a manufacturer of strollers is considered small if the manufacturer has 500 or fewer employees, and importers and wholesalers are considered small if they have 100 or fewer employees. Based on these guidelines, about 55 are small firms—26 domestic manufacturers, 26 domestic importers, and three firms with unknown supply sources. There may be additional unknown small stroller suppliers operating in the U.S. market.

Small Manufacturers

The expected impact of the staff-recommended final rule on small manufacturers will differ based on whether a firm's strollers are already compliant with F833-11. In general, firms whose strollers meet the requirements of F833-11 are likely to continue to comply with the voluntary standard as new versions are published. Many of these firms are active in the ASTM standard development process, and compliance with the voluntary standard is part of an established business practice. It is likely that firms supplying strollers that comply with ASTM F833-11 would also comply with F833-13b before the final stroller rule becomes effective.

Meeting ASTM F833-13b's requirements could necessitate product redesign for at least some strollers not believed to be compliant with F833-11 (eight of 26 small domestic manufacturers), even without the passive containment modification. A redesign would be minor if most of the changes involve adding straps and fasteners or using different mesh or fabric. However, a redesign could be more significant if changes to the frame are required. Due to the complexity of carriages and strollers, a complete redesign of these products, including engineering time, prototype development, tooling, and other incidental costs, could exceed \$1 million for the most complex stroller models. Industry sources, including JPMA,¹⁸ note that new tooling alone could exceed \$300,000 per product model. However, costs and development time are likely to vary widely across firms. Companies with substantial experience in manufacturing strollers should be able to complete redesigns more cost effectively than firms with less

¹⁸ Dwyer, 2012.

experience. Additionally, firms with numerous stroller models may experience lower costs because stroller models could be redesigned as a group.

At this time, staff is not aware if the ES staff-recommended modification to the passive containment test procedure would have any impact on small manufacturers because staff could not identify any strollers on the U.S. market that have adjustable grab bars. Therefore, the direct impact on manufacturers whose products are expected to meet the requirements of ASTM F833-13b (18 of 26 small domestic manufacturers) is not expected to be significant; although it is possible that there are unknown stroller suppliers with products that might be affected.

The staff-recommended 18-month effective date should help reduce the impact of the staff-recommended final rule. This would give firms additional time to develop new/modified products and spread costs over a longer time frame.

In addition to the direct impact of the staff-recommended final rule described above, there are indirect impacts. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with third party testing and certification requirements triggered by the final rule. Those additional third party testing costs will pertain to any physical and mechanical test requirements specified in the stroller final rule; lead and phthalates testing is already required. Based on industry input and confidential business information supplied for the development of the third party testing rule, testing to the ASTM voluntary standard could cost about \$800–\$1,000 per model sample.¹⁹

On average, each small domestic manufacturer supplies seven different models of strollers to the U.S. market annually. Therefore, if third party testing were conducted every year on a single sample for each model, third party testing costs for each manufacturer would be about \$5,600–\$7,000 annually. Based on a review of firm revenues, the impact of third party testing to ASTM F833-13b is unlikely to be significant, if only one stroller sample per model is required. However, the economic impact could be significant for some small firms, if as few as two or three samples per model are required to meet the testing requirements.

Small Importers

In the absence of regulation, small importers of strollers currently in compliance with F833-11 (13 of 26 small domestic importers) would likely continue to comply with the voluntary standard as it evolves, as well as comply with the final mandatory standard. Any increase in production costs experienced by their suppliers may be passed on to them. However, staff does not expect these costs to be significant, given that we were not able to identify any strollers with adjustable grab bars in the U.S. market.

Importers of strollers would need to find an alternate source if their existing supplier does not come into compliance with the requirements of the staff-recommended final rule, which could potentially be the case with the 13 importers of strollers not believed to be in compliance with

¹⁹ One firm said that complete CPSIA testing for one stroller model is greater than \$5,000, primarily due to the high cost of chemical evaluations and the number of coatings and substrates involved.

F833-11. Some importers could respond to the rule by discontinuing the import of noncomplying strollers, possibly discontinuing the product line altogether. The impact of such a decision could be mitigated by replacing the noncompliant stroller with a compliant stroller, or by deciding to import an alternative product to replace the stroller. However, some of these firms have few or no other products in their product line.

Because many of these firms have low sales revenues and limited product lines apart from strollers and stroller accessories, it is possible that the staff-recommended final rule could have a significant impact on one or more importers, even without the passive containment modification. The staff-recommended 18-month effective date would spread the costs of compliance over a longer period of time, mitigating the impact on all importers.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements. Consequently, importers will experience costs similar to those for manufacturers, if their supplying foreign firm(s) does not perform third party testing. The resulting costs could have a significant impact on a few small importers who must perform the testing themselves, even if only one sample per model were required.

Alternatives

One alternative that could reduce the impact on small entities is to make the voluntary standard mandatory, with no modifications. However, given that staff could not identify any strollers on the U.S. market that would be impacted by the recommended passive containment modification, it is unclear how significant this reduction might be. And adopting the voluntary standard with no modifications would not substantially benefit firms with noncompliant products because their strollers might still require redesign.

Staff continues to recommend an 18-month effective date, which will allow suppliers additional time to modify and/or develop compliant strollers and spread the associated costs over a longer period of time. However, the Commission could opt to set a later effective date. Doing so would further reduce the impact on affected firms. A third alternative would be to set an earlier effective date. However, setting an earlier effective date could increase the impact of the staff-recommended rule on small entities, particularly those with limited product lines and low sales revenues.

Small Business Impacts of the Accreditation Requirements for Testing Laboratories

In accordance with section 14 of the CPSA, all children's products that are subject to a children's product safety rule must be tested by accredited conformity assessment bodies (*i.e.*, testing laboratories) for compliance with applicable product safety rules. These accreditation requirements have been codified for existing rules at 16 C.F.R. part 1112. Consequently, staff recommends amending 16 C.F.R. part 1112 to establish the accreditation requirements for testing laboratories that wish to test for compliance with the stroller final rule. This section assesses the impact of the amendment on the small laboratories.

CPSC conducted a final regulatory flexibility analysis (FRFA) as part of the process of promulgating the original 1112 rule (78 FR 15836, 15855-58), as required by the RFA. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. Based upon the number of laboratories in the United States that have applied for CPSC acceptance of the accreditation to test for conformance to other juvenile product standards, we expect that only a few laboratories will seek CPSC acceptance of their accreditation to test for conformance with the stroller standard. Most of these laboratories will have already been accredited to test for conformance to other juvenile product standards, and the only costs to them would be the costs of adding the stroller standard to their scope of accreditation. As a consequence, the Commission could certify that the NOR for the stroller standard will not have a significant impact on a substantial number of small entities.