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**DATE:** June 11, 2014

# THIS MATTER IS NOT SCHEDULED FOR A BALLOT VOTE. A DECISIONAL MEETING FOR THIS MATTER IS SCHEDULED ON: [TBD]

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Todd A. Stevenson, Secretary

THROUGH: Stephanie Tsacoumis, General Counsel

Elliot F. Kaye, Executive Director

**FROM:** Patricia M. Pollitzer, Assistant General Counsel

Barbara E. Little, Attorney, OGC

**SUBJECT:** Proposed Rule: Safety Standard for Sling Carriers

The Office of the General Counsel is providing for Commission consideration the attached draft proposed rule for publication in the *Federal Register*. The proposed rule would establish a safety standard for sling carriers 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 dra			
	(Signatura)	(Data)		
	(Signature)	(Date)		

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC's Web Site: http://www.cpsc.gov

(Date)				
Do not approve publication of the attached document in the <i>Federal Register</i> .				
(Date)				

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Attachment: Draft Federal Register Notice: Proposed Rule to Establish a Safety Standard for Sling

Carriers

Billing Code 6355-01-P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Parts 1112 and 1228

Docket No. CPSC-2014-XXXX

**Safety Standard for Sling Carriers** 

**AGENCY:** Consumer Product Safety Commission.

**ACTION:** Notice of proposed rulemaking.

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 standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product. The Commission is proposing a safety standard for sling carriers in response to the direction under Section 104(b) of the CPSIA.

**DATES:** Submit comments by [INSERT DATE 75 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments related to the Paperwork Reduction Act (PRA) aspects of the marking, labeling, and instructional literature of the proposed rule to the Office of Information and Regulatory Affairs, OMB, Attn: CPSC Desk Officer, FAX: 202-395-6974, or e-mailed to: <a href="mailed:oira\_submission@omb.eop.gov">oira\_submission@omb.eop.gov</a>.

You may submit other comments, identified by Docket No.\_\_\_\_\_\_, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking

Portal at: <a href="http://www.regulations.gov">http://www.regulations.gov</a>. Follow the instructions for submitting comments. The

Commission does not accept comments submitted by electronic mail (e-mail), except through

www.regulations.gov. The Commission encourages you to submit electronic comments by using
the Federal eRulemaking Portal, as described above.

<u>Written Submissions</u>: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to:

<a href="http://www.regulations.gov">http://www.regulations.gov</a>. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

<u>Docket</u>: For access to the docket to read background documents or comments received, go to: <a href="http://www.regulations.gov">http://www.regulations.gov</a>, and insert the docket number\_\_\_\_\_\_, into the "Search" box, and follow the prompts.

**FOR FURTHER INFORMATION CONTACT:** Hope E J. Nesteruk, Project Manager, Division of Human Factors, Directorate for Engineering Sciences, Consumer Product Safety Commission, 5 Research Place, Rockville, MD 20850; telephone: 301-987-2579; e-mail: hnesteruk@cpsc.gov.

## **SUPPLEMENTARY INFORMATION:**

## I. Background and Statutory Authority

The Consumer Product Safety Improvement Act of 2008 (CPSIA, Pub. Law 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 standard if the Commission concludes that more stringent requirements would further reduce the risk of injury associated with the product.

Section 104(f) states:

As used in this section, the term "durable infant or toddler product"—

- (1) means a durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years; and
  - (2) includes-- ...(H) infant carriers.

Section 104 also requires manufacturers of durable infant or toddler products to comply with a registration program that the Commission establishes. Section 104(d).

In this document, the Commission is proposing a safety standard for sling carriers. Section 104(f)(2)(H) of the CPSIA lists "infant carriers" as one of the categories of durable infant or toddler products identified for purposes of section 104. As indicated by a review of ASTM's standards and retailers' websites, the category of "infant carriers" includes hand-held infant carriers, soft infant carriers, frame backpack carriers, and sling carriers. The Commission has issued final rules for hand-held infant carriers (78 Fed. Reg. 73415 (December 6, 2013)) and

soft infant carriers (78 Fed. Reg. 20511 (April 5, 2013)) and a proposed rule on frame backpack carriers (79 Fed. Reg. 28458 (May 16, 2014)). In the Commission's product registration card rule identifying additional products that the Commission considered durable infant or toddler products necessitating compliance with the product registration card requirements, the Commission specifically identified infant slings, or sling carriers, as a durable infant or toddler product. 76 Fed. Reg. 68668 (December 29, 2009). The durability of infant slings is discussed in section II.B. of this document.

Because the voluntary standard on infant slings, ASTM 2907-14a, "Standard Consumer Safety Specification for Sling Carriers," refers to "infant slings" as "sling carriers," the notice of proposed rulemaking refers to infant slings as "sling carriers." The terms are intended to be interchangeable and have the same meaning.

Pursuant to 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. CPSC staff participated in the ASTM sling carrier subcommittee meetings and task group meetings and worked with the ASTM sling carrier task groups to develop ballot language for revisions to the sling carrier voluntary standard. The proposed rule is based on the voluntary standard developed by ASTM International (formerly the American Society for Testing and Materials), ASTM F2907-14a, "Standard Consumer Safety Specification for Sling Carriers" (ASTM F2907-14a), without change.

The ASTM standard is copyrighted, but the standard is available as a read-only document during the comment period on this proposal only, at:

http://www.astm.org/Standards/F2907.htm, by permission of ASTM.

# **II.** Product Description

# A. Definition of Sling Carrier

ASTM F2907-14a "Standard Consumer Safety Specification for Sling Carriers" defines a "sling carrier" as "a product of fabric or sewn fabric construction, which is designed to contain a child in an upright or reclined position while being supported by the caregiver's torso." These products generally are intended for children starting at full-term birth until a weight of about 35 pounds. The designs of infant slings vary, but the designs generally range from unstructured hammock-shaped products that suspend from the caregiver's body, to long lengths of material or fabric that are wrapped around the caregiver's body. Infant slings normally are worn with the infant positioned on the front, hip, or back of the consumer, and with the infant facing toward or away from the consumer. As stated in the sling carrier definition, these products generally allow the infant to be placed in an upright or reclined position. However, the reclined position is intended to be used only when the infant is worn on the front of the consumer. The ability to carry the infant in a reclined position is the primary feature that distinguishes sling carriers from soft infant and toddler carriers, another subset of sling carriers.

The Commission identified three broad classes of sling carrier products available in the United States:

- Ring slings are hammock-shaped fabric products, in which one runs fabric through two rings to adjust and tighten the sling.
- Pouch slings are similar to ring slings but do not use rings for adjustment. Many pouch slings are sized rather than designed to be adjustable. Other pouch slings are more structured and use buckles or other fasteners to adjust the size.

• Wrap slings are generally composed of a long length of fabric, upwards of six yards long, and up to two feet wide. A wrap sling is completely unstructured with no fasteners or other means of structure; instead, the caregiver uses different methods of wrapping the material around the caregiver's body and the child's body to support the child. Wrap-like slings mimic the manner in which a wrap supports the child but use fabric in other manners, such as loops, to reduce the need for caregivers to learn wrapping methods.

Ring slings, modifications of wraps and pouch slings, and other products that meet the definition of a sling carrier contain parts that are also considered durable from an engineering perspective and suggest they were selected for long-term use. In addition, the test methods in ASTM F2907-14a combine to ensure that slings meet a minimum level of durability.

ASTM F2907 does not distinguish among the type of slings. The voluntary standard's requirements apply equally to all slings.

## **B.** Sling Carrier Use

ASTM F2907 – 14a states that sling carriers generally are intended for children starting at full-term birth, until a weight of about 35 pounds (15.9 kg). According to the data tables used to produce the 2000 Centers for Disease Control and Prevention (CDC) U.S. growth charts, the median (50<sup>th</sup> percentile) weight of a child does not exceed 35 pounds until about 46 months for boys and 49 months for girls (CDC, 2000). Moreover, the 5<sup>th</sup> percentile bodyweight of a child does not exceed 35 pounds until about 65 months for boys and 69 months for girls. This means that more than half of all 3-year-olds are likely to be at or below the maximum weight of 35 pounds, and that even some 5-year-olds are likely to be at or below this upper weight limit. Although the Commission believes that sling carriers are most likely to be used with infants, it

seems reasonably foreseeable that some portion of the user population will use these carriers with preschool-aged children.

Evidence suggests that sling carriers are often reused for multiple children. For example, according to a 2005 survey conducted by the American Baby Group (2006 *Baby Products Tracking Study*), nearly one-third (31 percent) of mothers who own slings had a sling that was handed down or purchased secondhand. Preliminary data from CPSC's Durable Nursery Products Exposure Survey found that 21 percent of sling owners acquired the sling used. The Survey also found that after the owner discontinued use of the sling, only 4 percent threw away the sling; 96 percent of owners stored the sling for future use, sold the sling, gave the sling away, or returned the sling to the original owner. These results suggest that most sling owners at least perceive sling carriers to have a future useful life, even if the sling had been used previously.

The Commission is aware of several online websites, forums, and "babywearing" groups dedicated to buying, selling, and trading previously used sling carriers. ("Babywearing" is commonly used to describe the wearing or carrying of a baby in a sling or similar carrier.) For example, a simple search of sold listings for a used "baby sling" on eBay resulted in more than 1,700 listings during a roughly 3-month period. Although some of the products in these ads do not meet the definition of a "sling carrier," a brief examination of the most recent 200 sales suggests that a very large percentage of these products would be considered a sling carrier. Thus, many consumers appear to be purchasing slings secondhand.

## C. Market Description

The Commission has identified 47 suppliers to the U.S. market, but there may be hundreds more suppliers that produce small quantities of slings. (The Commission made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as

firm websites.) Websites such as Etsy show thousands of listings for artisans producing slings and wraps (although each firm may have multiple listings), which accounts for additional suppliers who are not among the 47 suppliers identified. Sling carriers are distributed by a variety of methods, such as mass merchandisers, small specialty juvenile products stores, and Internet-only distributors.

Of the 47 sling carrier suppliers identified, 33 companies are based in the United States: 25 are manufacturers, and four are importers. Available information does not identify the supply source for four firms. There are also 14 foreign companies that export directly to the United States via Internet sales or directly to U.S. retailers.

A sling carrier is an uncomplicated product to produce, typically requiring only fabric, thread, rings (and in some cases, fasteners), and a sewing machine. A common scenario for a sling manufacturer starts with a mother using various slings or soft carriers and then deciding to make her own design in her home. Some of these home businesses grow into larger businesses that become more specialized and sophisticated, typically designing and marketing their own products but having the product manufactured overseas. However, the newer home businesses may be relatively unsophisticated and may not be aware of the sling carrier voluntary standard effort or know that sling carriers may be subject to existing federal regulations on children's products.

According to a the 2006 *Baby Products Tracking Study*, 17 percent of new mothers own sling carriers. As noted previously, approximately 31 percent of sling carriers were handed down or purchased secondhand. Thus, about 69 percent of sling carriers were acquired new. (The data collected for the *Baby Products Tracking Study* do not represent an unbiased statistical sample. American Baby Products surveyed potential respondents from its mailing lists to

generate a sample of 3,600 new and expectant mothers. Additionally, because the most recent survey information is from 2005, the data may not reflect the current market.) This information suggests annual sales of about 471,000 sling carriers (.17 x .69 x 4 million births per year), with prices ranging from \$30 to around \$150. (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 2009," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.)

However, this sales estimate may be a substantial underestimate for two reasons: (1) industry sources state that slings have increased in popularity since the survey was done in 2005; and (2) other products like wraps, pouches, and some soft carriers, which fall under the standard, may not have been included in the *Baby Products Tracking* study. Based on discussions with an industry representative, sales of these other products that fall under the proposed rule for sling carriers could increase the Commission's sales estimate to about 600,000 to 1 million units annually.

## III. Incident Data

The Commission is aware of a total of 122 incidents (16 fatal and 106 nonfatal) related to sling carriers, which were reported to have occurred from January 1, 2003 through October 27, 2013. Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Given that reporting is incomplete, the Commission strongly discourages drawing inferences based on the year-to-year increase or decrease shown in the reported data. (The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the

National Electronic Injury Surveillance System (NEISS). These reported deaths and incidents do not provide a complete count of all deaths and incidents that occurred during that 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 sling carriers.)

Among the incidents in which age was reported, all but one of the children were 12 months old or younger; the age of the oldest child was reported to be 3 years. Some incident reports did not indicate the age because there was no injury involved or age was unknown. Table 1 provides the age breakdown as reported in the 122 incidents.

Table 1: Age Distribution as Reported in Sling Carrier-Related Incidents 01/01/03-10/27/13

Age of Child	All Inc	cidents	Fatal and Nonfatal Injuries	
	Frequency	Percentage	Frequency	Percentage
Unreported*	31	25	1	1
One – Three Months	70	57	54	77
Four – Six Months	11	9	8	11
Seven – Nine Months	7	6	4	6
Ten – Twelve Months	2	2	2	3
Three Years	1	1	1	1
Total	122	100	70	100

Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

Note: Percentages do not add to 100 due to rounding.

#### A. Fatalities

CPSC received reports of 16 fatalities associated with the use of a sling carrier that occurred during the period from January 1, 2003 through October 27, 2013. Eleven of the 16 decedents were 1-month olds; the remaining five were between 3- and 5-months old. Nine of the decedents were described as having died of smothering, (also known as "suffocation," or "positional asphyxia.") Suffocation can occur when babies are contained entirely within the pouch of a sling. Infants who are placed with their heads below the rim of the sling are likely to

<sup>\*:</sup> Age was unknown or the incident reported no injury.

stay in the same position because they are surrounded by unyielding fabric under the tension of their weight, and are tightly confined within the product, typically with their faces directed towards or held against the parent's body. The highest risk of suffocation occurs when the infant's face (nose and mouth) is pressed against the mother's body, blocking the infant's breathing, and rapidly suffocating the baby within a few minutes. The cause of death was undetermined for the remaining decedents.

One fatal victim was 5 months old. The age range of the remaining 15 fatal victims was from birth to 3 months; 11 infants were ages 1 month and younger, and the remaining four were 3 months old. Infants younger than 4 months old are at a high risk for suffocation because they have relatively immature physiological systems controlling breathing and arousal.

## **B.** Nonfatalities

Of the 106 sling carrier-related nonfatal incidents that were reported to have occurred from January 1, 2003 through October 27, 2013, 54 reports reflected an injury to the infant during use of the product. Age was unreported for one of the injured, and one report stated that a 3-year-old was injured. For the rest of the incidents, the child's age ranged from 1 month to 11 months.

Among the 54 reported nonfatal injuries, nine were reported as involving hospitalizations. Among the hospitalizations, one injury was described as a permanent brain injury due to breathing difficulties suffered by the infant. The rest of the hospitalizations were serious head injuries, such as a fracture and/or brain hemorrhage, which resulted from infants falling from the carrier. Eleven additional skull/face/wrist fracture injuries were reported, but none of these incidents was reported to involve hospitalizations. The remaining non-hospitalized injuries included closed-head injuries, contusions/abrasions, lacerations/scratches, among others.

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(A closed head injury is a head injury where the skull remained intact. A closed head injury can range from a minor bump to the head to a severe life threatening traumatic brain injury.) A majority of the injuries resulted from falls from the carrier; most of these falls resulted from the caregiver slipping, tripping, or bending over while carrying the infant in the sling. The remaining injuries were due to miscellaneous product-related issues or other caregiver missteps, such as the caregiver not allowing enough safety clearance for the child in the sling carrier while the caregiver performed daily activities.

The remaining 52 incident reports stated that no injury had occurred or provided no information about any injury.

#### C. Hazard Pattern Identification

The Commission considered all 122 reported incidents (16 fatal and 106 nonfatal) to identify hazard patterns associated with sling carriers. In order of frequency of incident reports, the Commission grouped the hazard patterns into the following categories:

- 1. Problems with the *positioning* of the infant in the sling carrier: Thirty-one of the 122 reported incidents (25 percent) were in this category. Among them were nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood-circulation in the infant's leg. The rest of the incidents reported that the infant suffered breathing problems while in the carrier or that the caregiver had difficulty safely positioning the infant in the sling carrier to avoid the potential for suffocation.
- 2. *Caregiver missteps*: Twenty of the 28 incidents (23 percent) in this category were reported to have occurred when the caregiver slipped, tripped, or bent over, causing the infant in the sling to either fall with the caregiver or fall out of the carrier. Eight

additional incidents among the 28 reported in this category occurred when caregivers dropped the infant during placement into/removal out of the carrier or failed to provide enough safety clearance for the infant in the carrier as the caregivers conducted their daily activities. Examples of the latter scenario include an infant getting struck by a door or a falling object, or an infant hitting a wall. Although these 28 incidents did not involve any fatalities, all but one incident resulted in an injury to the infant. These incidents included 11 reports of skull fractures and one report of bleeding in the brain. Other injuries included closed-head injuries, contusions of the head/leg/back, and a finger laceration.

- 3. *Undetermined* or *unspecified* cause: Twenty five reported incidents (20 percent) included seven fatalities, two hospitalized injuries, and 13 non-hospitalized injuries, with very little information available on the circumstances leading to the incidents. The official reports did not indicate a specific cause of death. Among the injuries, which included fractures of the skull/wrist, as well as other serious head injuries, most were reported through hospital emergency departments with very little scenario-specific information.
- 4. Problems with *buckles*: Twelve of the 122 incidents (10 percent) reported buckles releasing, slipping, or breaking, causing infants to fall or nearly fall. There was one hospitalization for a skull fracture and two non-hospitalized injuries. There were no fatalities in this category.
- 5. *Miscellaneous product-related* issues: There were nine incident reports (seven percent) in which consumers complained of a design flaw posing a possible strangulation hazard, a broken component, rough fabric, or a sharp surface; or consumers indicated an

unspecified product failure. Although these reports did not include any fatalities, there were six injuries reported in this category, including one skull fracture.

6. *Consumer comments:* There were 17 non-event reports (14 percent) of consumer comments or observations of perceived safety hazards. In most of these cases, the consumer did not own the sling carrier in question. None of these reports indicates that any event actually occurred.

## **D. Product Recalls**

Since January 1, 2003, the CPSC has issued five consumer-level recalls involving sling carriers. All five recalls were for product defects that created a substantial product hazard and resulted in the recall of about 1.1 million sling carriers. Two of the recalled products posed a suffocation hazard, while three recalls were related to structural integrity and fall or potential fall hazards.

# IV. Other Standards

#### A. International Standards

The Commission identified one European standard that covers fabric carriers without rigid structure. In addition, a guideline for sling carriers is under development in Europe.

1. British Standard EN13209-2:2005, *Child Use and Care Articles – Baby Carriers – Safety Requirements and Test Methods – Part 2: Soft Carriers* (27 September 2005), is the European standard for soft, fabric carriers. However, EN13209 specifically states that the scope is intended for a "product [that] has holes designed to accommodate the child's legs." Sling carriers do not have holes through which a child's legs pass. Although some individual requirements in the EN13209 standard may be more stringent than those in F2907-14a, the reported incidents do not suggest

that these are prevalent hazard patterns associated with sling carriers. Therefore, the Commission does not believe that incorporating these more stringent requirements would further reduce the risk of injury associated with sling carriers.

2. CEN/TR 16512, Child use and care articles - Guidelines for the safety of children's slings, is a guideline that is under development in Europe. However, because this guideline, once completed would not be a standard, CEN/TR 16512 is not an option for consideration. The Commission expects that this guideline, when published, will contain recommendations similar to EN13209, but with recommendations adapted for the unique attributes of sling carriers.

The Commission notes that the ASTM F15.21 subcommittee has worked to make F2907 the most appropriate standard for the unique nature of sling carriers by harmonizing with other standards (*e.g.*, EN13209 and ASTM F2236), when appropriate, but also addressing the uniqueness of sling carriers, when needed. The Commission believes that ASTM F2907-14a is the most comprehensive standard that addresses the incident hazard patterns and that F2907-14a adequately addresses the hazards identified to date.

## **Voluntary Standard – ASTM F2907**

## 1. Description of Standard

ASTM F2907, "Standard Consumer Safety Performance Specification for Sling Carriers," establishes safety performance requirements, test methods, and labeling requirements to minimize the hazards to children presented by sling carriers. ASTM first published a consumer product safety standard for sling carriers in 2012. ASTM has revised the voluntary standard five times since then. The current version, ASTM F2907-14a, was approved on February 15, 2014, and published in March 2014. ASTM F15.21 subcommittee issued a ballot on May 16, 2014, that proposed a

modification in the occupant retention test pass/fail criteria. According to the ballot, "the current Occupant Retention test criteria (section 6.3) are not accurately separating good ring slings from poorly-constructed ring slings." The modification ASTM has proposed would increase from 1 inch to 3 inches the amount the ring sling attachment system may slip while still passing the standard. At the time of writing, the Commission does not have sufficient information to assess this change. Staff welcomes comments on the issue.

The current version of the sling carrier standard, ASTM F2907-14a, contains requirements to address the following issues:

- Laundering;
- Hazardous sharp points or edges;
- Small parts;
- Lead in paint;
- Wood parts;
- Locking and latching;
- Openings;
- Scissoring, shearing, and pinching;
- Monofilament threads;
- Flammability;
- Marking and labeling; and
- Instructional literature.

In addition, F2907-14a includes construction, quality, and durability test methods that are specific to sling carriers in the static, dynamic, occupant retention, and restraint system tests.

These test methods combine to ensure that slings meet a minimum level of durability.

- Static load test: This test checks that the sling can support the sling's maximum recommended weight with a safety factor of three, by gradually applying a weight of three times the manufacturer's maximum recommended weight, or 60 lbs., whichever is greater, in the support area of the sling, and maintain the weight for one minute.
- **Dynamic load test**: This test assesses the durability of the sling and proper functioning of the sling's fasteners by dropping a 35-lb. load into the sling's support area in each recommended carrying position every 4 seconds for up to 1,000 cycles.
- Occupant retention test: This test assesses whether the sling retains the occupant as the caregiver moves about. The test also assesses the sling's durability. The sling is attached to a test torso, and a test mass is placed in the sling. The test torso will move up and down at a rate of two times per second (approximately a brisk walking speed). The sling is tested to determine whether the adjustment mechanisms (e.g. rings, knots) release.
- **Restraint system test**: This test assesses whether any child restraints used by the sling are sufficient. Each restraint system is tested with a 45-lb. force on the restraint and again with a CAMI dummy. The anchorages for the restraint system are not to separate from their attachment points during or after testing.
  - 2. Adequacy of Requirements in Addressing Identifiable Hazard Patterns

**Positioning.** The Commission identified positioning as the primary hazard pattern in 31 cases. This includes nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood circulation in the infant's leg.

As noted previously, the Commission identified suffocation/asphyxia related to positioning as a risk associated with sling carriers. Suffocation can occur when babies are

contained entirely within the pouch of a sling. The highest risk of suffocation occurs when the infant's face (nose and mouth) is pressed against the mother's body, blocking the infant's breathing and rapidly suffocating a baby within a few minutes. Furthermore, because of its shape and lack of support, a sling carrier can facilitate an infant being positioned within the confines of the sling in a manner that causes acute neck hyper-flexion (chin touching the chest). Infants found in this compromised position are likely to stay in the position because infant neck muscles are too weak to support the weight of their head. Infants who stay for prolonged periods of time in this position can experience compromised airflow to the lungs, resulting in an inadequate supply of oxygen to the brain. Oxygen deprivation to the brain can lead to loss of consciousness and death.

Although there is no performance test for positioning in ASTM F2907-14a, ASTM F2907-14a requires statements in the warnings and instructions for sling carriers to caution against the hazards identified by the Commission through examination of the sling carrier incidents. Section 8.3.3 of F2907-14a specifies the warnings that must appear on each sling and addresses each of the hazard patterns the Commission found in the suffocation data. In short, all sling carriers must: (1) include a safety alert symbol ( $\triangle$ ) and the signal word "WARNING," (2) warn that failure to follow the manufacturer's instructions can result in "death or serious injury," (3) state the minimum and maximum recommended weights for the sling, and (4) warn about

the potential suffocation and fall hazards associated with sling carriers.

More specifically, according to ASTM F2097-14a, the warnings that pertain to

suffocation and positioning must address:

• the risk of suffocation to infants younger than 4 months if the infant's face is

pressed against the caregiver's body within the confines of the sling and the

increased risk of suffocation to infants born prematurely or those with respiratory problems;

- the need to check often to make sure that the infant's face remains uncovered,
   clearly visible to the caregiver, and away from the caregiver's body at all times;
- the importance of making sure that the infant does not curl into a position with the chin resting on or near the infant's chest, which can interfere with breathing even when nothing is covering the nose or mouth;
- the need to reposition the infant after nursing so the infant's face is not pressed against the caregiver's body; and
- the importance of never using the sling with infants smaller than 8 pounds,
   without seeking the advice of a healthcare professional.

Lastly, the warning label prescribed by ASTM F2907-14a must include a pictogram that illustrates proper and improper infant positioning within the sling. ASTM F2907-14a includes an example of the type of pictogram sought but does not specify a particular design.

Section 9 of ASTM F2907-14a specifies what instructional literature must be provided with the sling. This section requires that the instructions contain an image of each manufacturer's recommended carrying position, include all of the warning statements that are required to appear on the sling, and provide several additional instructions.

ASTM subcommittees for other durable nursery product standards have also tried to address positioning hazards related to a C-shaped curl in an infant's head, neck, and torso area; however, there has been no repeatable performance test identified. The Commission attempted to address the positioning hazard associated with sling carriers in a new manner, based on the recognition that a sling carrier is worn by the caregiver and involves direct contact with the

caregiver, thereby allowing for the possibility of the caregiver seeing a child who is in distress. Specifically, the Commission explored a "face exposure" test that, at a minimum, could keep a sling from preventing the caregiver from observing the infant's face. The Commission pursued this possible test with the ASTM task group but found that the available anthropomorphic mannequins, *e.g.*, CAMI dummies, do not accurately represent the manner in which a child sits in a sling, and that the variable nature of sling products makes the repeatability of a test questionable. Together with the ASTM task group, the Commission concluded that a test to address positioning hazards is technically infeasible at this point.

Ultimately, the Commission concluded that warning requirements about proper and improper infant positioning present in ASTM F2907-14a is the only feasible hazard-mitigation strategy at this time. The Commission will continue to consider possible performance requirements pertaining to this issue and will pursue such an approach with the ASTM Subcommittee in the future, if an approach becomes feasible. Because there is no feasible performance test and because the warning statements in ASTM F2907 were developed considering both known hazard patterns for sling carriers and established practices for warning labels, the Commission believes that the warnings and instructions published in ASTM F2907-14a are adequate to inform caregivers about how to reduce the likelihood of positioning incidents.

Caregiver Missteps. Incidents involving caregiver missteps included 11 reports of skull fractures and one episode of bleeding in the brain. Other injuries included closed head injuries, contusions of the head/leg/back, and a finger laceration. The Commission determined that these incidents were related directly to the actions, often accidental, of the caregiver. Examples include a caregiver slipping or tripping while wearing the sling carrier with the child inside, or

incidental contact occurring between the child and an object, such as a door or wall. Although these types of incidents cannot be addressed directly through a performance test, the standard addresses these incidents by alerting caregivers of the hazard and making sure that the sling contains the infant. ASTM F2907-14a requires the following statement to appear on the onproduct label to address the fall hazard to infants associated with "caregiver missteps," such as tripping or bending over:

FALL HAZARD – Leaning, bending over, or tripping can cause baby to fall.

Keep one hand on baby while moving.

In addition, the occupant retention test in ASTM F2907-14a is intended to reduce the likelihood that the child will fall out of the sling due to a caregiver misstep. ASTM F2907-14a requires the test mass to be contained within the sling for the duration of the test.

**Buckles.** Twelve of the incidents involved buckles releasing, slipping, or breaking, and included a hospitalization for a skull fracture and two non-hospitalized injuries. ASTM F2907-14a addresses this hazard in several ways, using the static, dynamic, occupant retention, and restraint system tests. For the reasons described previously, the Commission believes that the performance tests in F2907-14a adequately address hazards associated with buckle failure.

#### IV. Effective Date

The Administrative Procedure Act (APA) 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 Commission generally considers 6 months sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Six months is the period the Juvenile Products Manufacturers Association (JPMA) typically allows for products in JPMA's certification program to shift to a new voluntary standard once that new voluntary standard is published.

Therefore, juvenile product manufacturers are accustomed to adjusting to new standards with this time frame. However, in this instance, a large number of very small suppliers potentially will experience significant economic impacts complying with the rule. In addition, because ASTM F2907 has only been in existence for approximately 2 years, there is relatively little information regarding compliance with the voluntary standard. Thus, the Commission is proposing a 12-month effective date. The Commission invites comment on whether 12 months is an appropriate length of time for sling carrier manufacturers to come into compliance with the rule.

# V. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) requires agencies to review proposed rules for a rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency publishes a general notice of proposed rulemaking. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA must contain:

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small

entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and

- identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.
- 1. Reason for Agency Action and Legal Basis for the Proposed Rule

The Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are substantially the same as, or more stringent than, the voluntary standard. The Commission worked closely with ASTM to develop the new requirements and test procedures that have been incorporated into ASTM F2907-14a, which the Commission proposes to incorporate by reference.

## 2. Compliance Requirements of the Proposed Rule

The Commission is incorporating by reference the current voluntary standard, with no revision, to form the proposed rule. Some of the more significant requirements of the current voluntary standard for sling carriers (ASTM F2907–14a) include static and dynamic load testing to verify the structural integrity of the sling carriers and occupant retention testing to help ensure that the child is not ejected from the sling carrier. The ASTM standard requires that the buckles, fasteners, and knots that secure the sling carrier remain in position before and after these three performance tests. There is also a separate restraint system test to help ensure that any restraints used by the sling do not release while in use.

The voluntary standard also includes:

- requirements for several features to prevent cuts (hazardous sharp points or edges, and wood parts);
- small parts;

- marking and labeling requirements;
- flammability requirements;
- requirements for the permanency and adhesion of labels; and
- requirements for instructional literature.

The updated warning statements provide additional details of the fall and suffocation hazards and are intended to address the primary fatality risk associated with infant slings, suffocation.

## 3. Other Federal Rules

Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory, that the product complies with all applicable children's product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards by rule for, among other things, making sure that a children's product is tested periodically and when there has been a material change in the product, and safeguarding against the exercise of undue influence by a manufacturer or private labeler against a conformity assessment body. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, Testing and Labeling Pertaining to Product Certification (16 CFR part 1107), became effective on February 13, 2013 (the 1107) rule). When the sling carrier rule is finalized, sling carriers will be subject to a mandatory children's product safety rule. Accordingly, sling carriers will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule. Slings are already subject to lead and phthalates testing under the 1107 Rule. This rule adds certain mechanical tests and other requirements to the third party testing requirement.

In addition, the 1107 rule requires certifiers to use CPSC-accredited laboratories to conduct the third party testing of children's products. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformance assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. The NORs for existing rules are set forth in 16 CFR part 1112. Consequently the Commission is proposing an amendment to 16 CFR part 1112 that would establish the requirements for the accreditation of testing laboratories to test for compliance with the sling carrier final rule.

## 4. Impact on Small Businesses

Of the 47 identified suppliers of sling carriers to the U.S. market, 33 are domestic firms. (We limit our analysis to domestic firms because U.S. Small Business Administration (SBA) guidelines pertain to U.S.-based entities.) Under SBA guidelines, a manufacturer of sling carriers is small if it has 500 or fewer employees, and importers and wholesalers are small if the importers or wholesalers have 100 or fewer employees. Based on these guidelines, 31 of the domestic firms supplying sling carriers to the U.S. market appear to be small businesses. These businesses consist of 23 manufacturers, four importers, and four firms with unknown supply sources.

Additionally, as noted previously, an unquantified number of producers supply baby slings to the U.S. market via websites such as Etsy. Although we have no information on these suppliers, based on the general nature of suppliers selling products on Etsy and similar markets, we assume that these suppliers are well within SBA criteria for small business. For purposes of analysis, we refer to these suppliers as "very small manufacturers" to distinguish them from the more established manufacturers, but this is not an official SBA designation.

Before preparation of a regulatory flexibility analysis, the Commission conducts a screening analysis to determine whether a regulatory flexibility analysis or a certification statement of no significant impact on a substantial number of small entities is appropriate for a proposed rule. The SBA gives considerable flexibility in defining the threshold for "no significant economic impact." However, the Commission typically uses 1 percent of gross revenue as a threshold; unless the impact is expected to fall below the 1 percent threshold for the small businesses evaluated, the Commission prepares a regulatory flexibility analysis.

Because we were unable to demonstrate that the draft proposed rule would impose an economic impact less than 1 percent of gross revenue for the affected firms, the Commission did not prepare a certification statement, but conducted an IRFA.

## **Small Manufacturers**

JPMA and the Baby Carrier Industry Alliance (BCIA) have advised some manufacturers of F2907-12, F2907-13a, F2907-13b, and F2907-14. These organizations are offering assistance to member manufacturers on testing and compliance with the ASTM sling carrier standards. However, the ASTM sling carrier standards are relatively new, and there is no established history of compliance among manufacturers.

As of January 2014, only two of the 23 known small manufacturers of sling carriers are listed on the JPMA website as certified compliant. Based on our review of small firm websites and a conversation with a small ring sling manufacturer, we have identified three additional firms (not JPMA certified) that have conducted testing to some version of the ASTM standard, for a total of five firms that have conducted testing to some version of the ASTM standard. These firms may have already experienced the impacts of the proposed rule and may not

experience any additional impacts. The remaining firms are likely to incur some cost associated with the proposed rule.

Due to the nature of the product and the relative ease of production, the Commission believes that most of the physical changes needed to meet the standard, such as changing fabrics, changing stitching, adding reinforcements, changing buckles, changing rings, changing labels, and changing instructions, are unlikely to be costly. Because sling carriers are largely made of fabric, tooling costs are not usually a large factor.

Some manufacturers of ring slings are having difficulties with their products passing the occupant retention tests consistently. The problem appears to be variation in testing results based on how the sling is positioned on the test fixture. At this time, the precise cost of changes necessary to satisfy testing under the ASTM standard is unknown; and we cannot rule out the potential for costs high enough to lead to significant economic impacts, especially for the very small manufacturers.

According to one manufacturer, changes to warning labels required under the proposed rule may have an impact on very small suppliers. We do not have sufficient data to determine whether this impact is expected to be economically significant. For example, if the cost of printing and sewing in the labels is 30 cents per sling, then the impact would be 1 percent of the sales price for a \$30 sling. CPSC staff contacted a representative from the BCIA to obtain label prices but has no independent estimate at this time. An additional consideration is that the labels are relatively large and may reduce the appeal of the product if they cannot be readily concealed. However, this impact will apply to all sling manufacturers.

Another manufacturer also expressed concerns that minor deviations from the font sizes required by the standard on the labels could force manufacturers to redo portions of the testing.

This phenomenon may diminish as businesses become familiar with the requirements. Testing costs are discussed below.

The majority of the costs associated with the proposed standard will probably be related to testing. Few of the sling carrier manufacturers have the technical capability or the equipment to conduct any testing in house; and most small and very small manufacturers probably will have to rely on third party testing during product development. Some small and very small manufacturers could experience significant costs simply testing to find out initially whether their products comply with the proposed standard and with any additional testing necessary to develop complying products.

In addition, under section 14 of the CPSA, sling carriers are subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with the third party testing and certification requirements under the testing rule, Testing and Labeling Pertaining to Product Certification (16 CFR part 1107). This will include any physical and mechanical test requirements specified in the final rule; lead and phthalates testing, if applicable, are already required; hence, lead and phthalates testing are not included in this discussion.

According to a BCIA representative, third party testing to the ASTM sling carrier voluntary standard could cost around \$500–\$1,050 per model sample, with \$700 as an average cost. Third party testing consists of two costs: the testing costs unique to F2907 associated with the dynamic load test, the static load test, the occupant retention test, and the restraints test; and the general testing costs associated with testing for flammability, small parts, sharp edges, instructions, and labels. The testing costs unique to sling carriers vary widely, from \$210 to \$650, depending on whether the testing is done in China or the United States and whether a

discount, such as the discount negotiated by the BCIA for its members, is applied. The general testing costs may amount to \$300 to \$400. The very small firms that manufacture in the United States will probably also test in the United States to avoid logistical difficulties, thus incurring higher costs.

The \$700 estimate for average testing costs includes all the required testing, such as flammability, sharp edges, etc. If a very small manufacturer with one model only needed to conduct one third party test annually, the costs of testing would amount to \$700. A very small manufacturer producing 20 to 30 low-priced slings a month might have annual revenues of \$10,800 (30 slings per month x 12 months x \$30 per sling). Testing one sample at \$700 would amount to 6.5 percent (\$700/\$10,800) of annual revenue for this hypothetical very small manufacturer, which we would clearly classify as a significant economic impact. Even if this manufacturer could sell its slings for \$150, testing one sample at \$700 would amount to 1.3 percent of annual revenue of \$54,000 (360 slings\*\$150 per sling).

As a comparison, third party testing costs for soft infant and toddler carriers (SITCs) were estimated at \$500–\$600 per sample for the SITC standard, ASTM F2236-14. However, the higher testing costs for slings could reflect additional testing for occupant retention, which is not part of the SITC standard.

Based upon the previous example, even in the unlikely case that very small sling manufacturers are able to develop a complying product without incurring significant economic impacts, very small sling manufacturers are still likely to incur significant economic impacts complying with section 14 of the CPSA. These types of impacts would apply to the very small producers marketing their products primarily via Etsy and other websites.

Although information on sales revenue is limited to half of all manufacturers, we estimate that most of the 23 small domestic manufacturers have substantially larger sales volumes than the example above, with annual sales ranging between \$200,000 and \$16 million. Thus, product development and testing costs would be a lower percentage of sales revenue than the example above. At the lower range of \$200,000 in revenues, significant economic impacts would occur if the producer had to test three models per year. Firms with revenues closer to the upper end of the range, \$16 million, would need to test more than 200 models per year to experience significant economic impacts from testing. The number of tests needed for product development purposes or to meet the" high degree of assurance" criteria under section 14 of the CPSA is not known.

About a third of firms (8 of 23) also have other product lines, which may cushion the impact of design changes and increased testing costs for sling carriers. These other products may be similar products, such as mei tais (a traditional Asian unstructured soft carrier falling under the SITC standard) or SITCs, or these other products may be completely unrelated juvenile products.

# **Small Importers**

At this time, only one of the four importers identified is in compliance with F2907-12, F2907-13a or F2907-13b. Depending upon the costs of coming into compliance incurred by the importers' suppliers and whether the importers' suppliers are able to pass on the costs, the other three importers could experience a significant economic impact. Three of the four importers are owned by foreign parent companies that supply the importers' slings. These parent companies must make the business decision to comply or to discontinue U.S. operations. Two of the four

importers could respond by simply discontinuing their sling product line altogether because these importers have varied product lines.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements. Consequently, these importers will experience the associated costs of compliance. The resulting costs could have a significant impact on these small importers.

As mentioned previously, four of the small domestic firms have unknown supply sources, and none of these supply sources has claimed compliance with any version of F2907. However, two firms have varied product lines and may be in a better position to comply without incurring significant economic impacts. The other two appear to be small firms specializing in slings, and therefore, these small firms may be impacted more heavily by compliance and testing costs.

#### 5. Alternatives

Under the Danny Keysar Child Product Safety Notification Act, section 104 of the CPSIA, one alternative would be to set an effective date later than 12 months. Setting a later effective date would reduce the economic impact on firms in two ways. First, firms would be 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, thereby reducing their annual costs and the present value of their total costs. Given the large number of very small suppliers who potentially will experience significant economic impacts, a later effective date may warrant consideration. The Commission welcomes comments regarding an appropriate effective date.

#### VI. Environmental Considerations

The Commission's regulations address whether we are required to prepare an environmental assessment or an environmental impact statement. If our rule has "little or no

potential for affecting the human environment," our rule will be categorically exempted from this requirement. 16 CFR 1021.5(c)(1). The proposed rule falls within the categorical exemption.

# VII. Paperwork Reduction Act

This proposed 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). In this document, pursuant to 44 U.S.C. 3507(a)(1)(D), we set forth:

- a title for the collection of information;
- a summary of the collection of information;
- a brief description of the need for the information and the proposed use of the information;
- a description of the likely respondents and proposed frequency of response to the collection of information;
- an estimate of the burden that shall result from the collection of information; and
- notice that comments may be submitted to the OMB.

Title: Safety Standard for Sling Carriers

<u>Description:</u> The proposed rule would require each sling carrier to comply with ASTM F2907-14a, *Standard Consumer Safety Specification for Sling Carriers*. Sections 8 and 9 of ASTM F2907-14a 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).

<u>Description of Respondents:</u> Persons who manufacture or import sling carriers.

Estimated Burden: We estimate the burden of this collection of information as follows:

Table 1 – Estimated Annual Reporting Burden

16 CFR	Number of	Frequency	Total	Hours per	Total
Section	Respondents	of	Annual	Response	Burden
		Responses	Responses		Hours
1228	47	3	141	1	141

## Our estimates are based on the following:

Section 8.1.1 of ASTM F2907-14a requires that the name and the place of business (city, state, mailing address, including zip code, or telephone number) and website, if applicable, of the manufacturer, distributor, or seller be marked clearly and legibly on each product and its retail package. Section 8.1.2 of ASTM F2907-14a requires a code mark or other means that identifies the date (month and year, as a minimum) of manufacture.

There are 47 known entities supplying sling carriers to the U.S. market. All 47 firms are assumed to use labels already on both their products and their packaging, but the firms might need to make some modifications to their existing labels. The estimated time required to make these modifications is about 1 hour per model. Each entity supplies an average of three different models of sling carrier; therefore, the estimated burden associated with labels is 1 hour per model x 47 entities x 3 models per entity = 141 hours. We estimate the hourly compensation for the time required to create and update labels is \$27.71 (U.S. Bureau of Labor Statistics, "Employer Costs for Employee Compensation," September 2013, Table 9, total compensation for all sales and office workers in goods-producing private industries: <a href="http://www.bls.gov/ncs/">http://www.bls.gov/ncs/</a>). Therefore, the estimated annual cost to industry associated with the labeling requirements is \$3,907.11

(\$27.71 per hour x 141 hours = \$3,907.11). There are no operating, maintenance, or capital costs associated with the collection.

Section 9.1 of ASTM F2907-14a requires instructions to be supplied with the product. Sling carriers do not generally require assembly, but require instructions for proper use, fit, and adjustment on a caregiver's body, as well as maintenance, cleaning, and storage. Under the OMB's regulations (5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the "normal course of their activities" are excluded from a burden estimate, where an agency demonstrates that the disclosure activities required to comply are "usual and customary." Therefore, because we are unaware of sling carriers that generally require some instructions for use, but lack any instructions to the user, we estimate tentatively that there are no burden hours associated with section 9.1 of ASTM F803-13 because any burden associated with supplying instructions with sling carriers would be "usual and customary" and would not within the definition of "burden" under the OMB's regulations.

Based on this analysis, the proposed standard for sling carriers would impose a burden to industry of 141 hours, at an estimated cost of \$3,907.11 annually.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. § 3507(d)), we have submitted the information collection requirements of this rule to the OMB for review. Interested persons are requested to submit comments regarding information collection by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER], to the Office of Information and Regulatory Affairs, OMB (see the ADDRESSES section at the beginning of this notice).

Pursuant to 44 U.S.C. § 3506(c)(2)(A), we invite comments on:

- whether the collection of information is necessary for the proper performance of the
   CPSC's functions, including whether the information will have practical utility;
- the accuracy of the CPSC's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- ways to enhance the quality, utility, and clarity of the information to be collected;
- ways to reduce the burden of the collection of information on respondents, including the
  use of automated collection techniques, when appropriate, and other forms of information
  technology; and
- the estimated burden hours associated with label modification, including any alternative estimates.

### VIII. 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." Therefore, the preemption provision of section 26(a) of the CPSA would apply to a rule issued under section 104.

# IX. Certification and Notice of Requirements (NOR)

The CPSA establishes certain requirements for product certification and testing. 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). Certification of children's products subject to a children's product safety rule must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* 2063(a)(2). The Commission must publish a notice of requirements (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. *Id.* 2063(a)(3). Thus, the proposed rule for 16 CFR part 1228, "Safety Standard for Sling Carriers," when issued as a final rule, will be a children's product safety rule that requires the issuance of an NOR.

To meet the requirement that the Commission issue an NOR for the sling carrier standard, the Commission proposes to amend an existing rule. 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 took effect 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 Section14(a)(2) of the CPSA. The final rule also codifies all of the NORs that the CPSC had published to date. All new NORs, such as the sling carrier standard, require an amendment to part 1112. Accordingly, the proposed rule would amend part 1112 to include the sling carrier standard, along 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 sling carriers would be required to meet the third party conformity assessment body accreditation requirements in part 1112. 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 1228, *Safety Standard for Sling Carriers*, included in the laboratory's scope of accreditation of CPSC safety rules listed for the laboratory on the CPSC website at: <a href="www.cpsc.gov/labsearch">www.cpsc.gov/labsearch</a>.

As required by the RFA, staff conducted a final regulatory flexibility analysis (FRFA) when the Commission issued the part 1112 rule (78 FR 15836, 15855-58). 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. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending 16 CFR part 1112 rule to include the NOR for the sling carrier standard will not have a significant adverse impact on small laboratories. Moreover, 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 sling carrier 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 cost of adding the sling carrier standard to their scope of accreditation. As a consequence, the Commission certifies that the NOR for the sling carrier standard will not have a significant impact on a substantial number of small entities.

#### X. Request for Comments

This proposed rule begins a rulemaking proceeding under section 104(b) of the CPSIA to issue a consumer product safety standard for sling carriers. We invite all interested persons to submit comments on any aspect of the proposed rule.

Comments should be submitted in accordance with the instructions in the **ADDRESSES** section at the beginning of this notice.

# **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 1228

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

For the reasons discussed in the preamble, the Commission proposes to amend 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 Section 1112.15, by adding paragraph (b)(39) 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)(39) 16 CFR part 1228, Safety Standard for Sling Carriers.

#### PART 1228-SAFETY STANDARD FOR SLING CARRIERS

Sec.

1228.1 Scope.

1228.2 Requirements for Sling Carriers.

**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). § 1228.1 Scope.

This part establishes a consumer product safety standard for sling carriers.

# § 1228.2 Requirements for Sling Carriers.

(a) Each sling carrier must comply with all applicable provisions of ASTM F2907-14a, Standard Consumer Safety Specification for Sling Carriers, approved on February 15, 2014. 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; <a href="http://www.astm.org/cpsc.htm">http://www.astm.org/cpsc.htm</a>. 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) [Reserved]

Dated:			
	Todd A. Stevenson,		
Secretary, Consumer Product Safety Commission			



# **Staff Briefing Package**

Sling Carriers<sup>1</sup>
Notice of Proposed Rulemaking (NPR)

June 11, 2014

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

<sup>&</sup>lt;sup>1</sup> Also known as Infant Slings.

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# **Briefing Memorandum**



Memorandum

This document has been electronically approved and signed.

Date: May 28, 2014

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SUBJECT: Notice of Proposed Rulemaking for Sling Carriers, also Known as Infant Slings

#### I. INTRODUCTION

The Danny Keysar Child Product Safety Notification Act, section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires the U.S. Consumer Product Safety Commission (CPSC or the Commission) to: (1) examine and assess voluntary safety standards for durable infant or 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.

Section 104(f) of the CPSIA defines "durable infant or toddler products" as "durable products intended for use, or that may be reasonably expected to be used, by children under the age of 5 years" and identifies "infant carriers" as a durable infant or toddler product. The infant carrier category covers a variety of products, including hand-held infant carriers, soft infant and toddler carriers, and frame child carriers. For all types of infant carriers, the majority of children carried are under age 5.

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CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

<sup>&</sup>lt;sup>2</sup> Section 104(f)(2)(H).

The Commission has undertaken rulemaking for three different kinds of infant carriers: a final rule for hand-held infant carriers, <sup>3</sup> a final rule for soft infant carriers, <sup>4</sup> and a proposed rule for frame carriers.<sup>5</sup> The Commission specifically identified "infant slings" as a "durable infant or toddler product" in the Commission's product registration card rule under section 104(d).

Because the voluntary standard on infant slings, ASTM 2907-14, "Standard Consumer Safety Specification for Sling Carriers," refers to "infant slings" as "sling carriers," the briefing package refers to infant slings as "sling carriers." The terms are intended to be interchangeable and have the same meaning.

Section 104 of the CPSIA also requires 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 spring 2012 with staff participation in a task group within ASTM International (ASTM) Subcommittee F15.21 – Sling Carriers.

This briefing package assesses the effectiveness of voluntary standards for sling carriers and presents staff's recommendations for a draft proposed rule.

#### II. BACKGROUND

#### A. Product Review

The voluntary standard, ASTM F2907-14a, Standard Consumer Safety Specification for Sling Carriers, defines "sling carrier" as "a product of fabric or sewn fabric construction, which is designed to contain a child in an upright or reclined position while being supported by the caregiver's torso" (Section 1.3). These products generally are intended for children starting at full-term birth until a weight of about 35 pounds. The designs of slings vary, but they generally range from unstructured hammock-shaped products that suspend from the caregiver's body, to long lengths of material or fabric that are wrapped around the caregiver's body. Slings normally are worn with the infant positioned on the front, hip, or back of the caregiver, and with the infant facing toward or away from the caregiver. As stated in the sling carrier definition, these products generally allow the infant to be placed in an upright or reclined position. However, the reclined position is used only when the infant is carried on the front of the caregiver. The ability to carry the infant in a reclined position is the primary feature that distinguishes sling carriers from soft infant and toddler carriers.

<sup>&</sup>lt;sup>3</sup> 78 Fed. Reg. 73415 (December 6, 2013).

<sup>&</sup>lt;sup>4</sup> 78 Fed. Reg. 20511 (April 5, 2013). <sup>5</sup> 79 Fed. Reg. 28458 (May 16, 2013).

<sup>&</sup>lt;sup>6</sup> 76 Fed. Reg. 68668 (December 29, 2009).

Staff identified three broad classes of sling carrier products available in the United States. Figure 1 shows examples of each sling type. ASTM F2907 does not distinguish between the type of slings; and the voluntary standard's requirements apply to all slings, regardless of type.

- Ring slings are the quintessential "sling" one pictures when discussing this product group. This is a hammock-shaped fabric product, in which fabric is threaded through two rings that are used to adjust and tighten the sling.
- Pouch slings are similar to ring slings but do not use rings for adjustment. Many pouch slings are fixed in size and cannot be adjusted to fit different size caregivers. Other pouch slings are more structured and use buckles or other fasteners to adjust the size. The key features staff identified in pouch slings is the hammock-like attribute with the child contained in the pouch. Therefore, this is the broadest type that also includes products some may refer to as "bag slings."
- Wrap slings are generally composed of a long length of fabric, upwards of 6 yards long and up to 2 feet wide. A wrap sling is completely unstructured with no fasteners or other means of structure; instead, the caregiver uses different methods of wrapping the material around the caregiver's body and the child's body to support the child. Wrap-like slings mimic the manner in which a wrap sling supports the child but use fabric in other manners, such as loops, to reduce the need for caregivers to learn wrapping methods.







Pouch sling



Wrap and wrap-like slings

Figure 1. Examples of sling carrier types

The child shown in Figure 1 demonstrates the use of sling carriers with an upright child over the age of one. Each of the products shown can be used with younger infants, often by changing the position of the child. In addition, there are other sling carriers that, due to their design, are more appropriate for infants only. Figure 2 shows a wrap and other types of slings used in the reclined position for infants.



Figure 2: Reclined infant positions for slings

### B. Incident Data (Tab A)

As detailed in Tab A, staff is aware of a total of 122 incidents (16 fatal and 106 nonfatal) related to sling carriers that were reported to have occurred from January 1, 2003 through October 27, 2013. Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and noninjury incidents may change in the future. Specifically, data for 2011, 2012 and 2013 are not complete.

#### 1. Fatalities

CPSC received reports of 16 fatalities associated with the use of a sling carrier that were reported to have occurred during the period from January 1, 2003 through October 27, 2013. Eleven of the 16 decedents were 1-month olds; the rest were 3- and 5-month olds. Nine of the decedents were described as having died of smothering, while the cause of death was undetermined for the remaining decedents.

#### 2. Nonfatal Incidents

Of the 106 sling carrier-related nonfatal incidents that were reported to have occurred from January 1, 2003 through October 27, 2013, 54 reported an injury to the infant during use of the product. Almost all of the incident victims were between 1 month and 12 months old; one injury victim was 3 years old. For some incidents, age was not reported because there was no injury involved or age was unknown.

Among the 54 reported nonfatal injuries, nine were reported as hospitalizations. Among the hospitalizations, there was one injury described as a permanent brain injury due to breathing difficulties suffered by the infant. The rest were serious head injuries, such as a fracture and/or

brain hemorrhage, which resulted from infants falling from the carrier. There were 11 additional skull/face/wrist fracture injuries, but none of these incidents were reported as hospitalizations. The remaining non-hospitalized injuries included closed-head injuries, <sup>7</sup> contusions, abrasions, and scratches, among other injuries.

The remaining 52 incidents reported that no injury occurred or provided no information about any injury. However, many of the incident reports described scenarios that staff believes presented the potential for a serious injury or even death. For example, several incident reports indicate a child fell from the sling carrier, due to a buckle failure or for unknown reasons, but the child was either caught by the caregiver or otherwise did not sustain an injury.

#### 3. National Injury Estimates

The number of emergency department-treated injuries associated with slings for the time frame covered was insufficient to derive any reportable national estimates. Hence, reportable injury estimates cannot be calculated.

#### C. Hazard Pattern Identification (Tab A)

Staff considered all 122 reported incidents (16 fatal and 106 nonfatal) to identify hazard patterns associated with sling carriers. In order of frequency of incident reports, staff grouped the hazard patterns into the following categories:

- 1. Problems with the *positioning* of the infant in the sling carrier: Thirty-one of the 122 reported incidents (25 percent) were in this category. Among them were nine deaths due to smothering; one permanent brain impairment injury due to breathing difficulty; and two other injuries—one related to breathing difficulty and the other related to blood-circulation in the infant's leg. The rest of the incidents reported breathing problems suffered by the infant in the carrier or difficulty in safely positioning the infant in the sling carrier to avoid the potential for suffocation.
- 2. Caregiver missteps: Twenty-eight incidents (23 percent) were classified as related to caregiver missteps, e.g., slips, trips, or drops. Twenty of the 28 incidents in this category were reported to have occurred when the caregiver slipped, tripped, or bent over, causing the infant in the sling to either fall with the caregiver or fall out of the carrier. Eight additional incidents among the 28 reported in this category occurred when caregivers dropped the infant during placement into/removal out of the carrier

<sup>8</sup>According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller for the estimate to be reportable.

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<sup>&</sup>lt;sup>7</sup> According to Tab D from the Directorate for Health Sciences, a closed-head injury is a head injury where the skull remained intact but it can range in severity from a minor bump to a severe life-threatening traumatic brain injury.

or failed to provide enough safety clearance for the infant in the carrier as the caregivers conducted their daily activities. Examples of the latter scenario include an infant getting struck by a door or a falling object, or an infant hitting a wall. Although there were no fatalities in this category, all but one incident resulted in an injury to the infant. There were 11 reports of skull fractures and one of internal bleeding in the brain. Other injuries included closed head injuries, contusions of the head/leg/back, and a finger laceration.

- 3. Undetermined or unspecified cause: There were 25 reported incidents (20 percent), including seven fatalities, two hospitalized injuries, and 13 non-hospitalized injuries, with very little information available on the circumstances leading to the incidents. Among the fatalities, the official reports did not indicate a specific cause of death. Among the injuries, which included fractures of the skull/wrist, as well as other serious head injuries, most were reported through hospital emergency departments with very little scenario-specific information.
- 4. Problems with *buckles*: Twelve of the 122 incidents (10 percent) reported buckles releasing, slipping, or breaking, causing infants to fall or nearly fall. There was a hospitalization for a skull fracture and two non-hospitalized injuries. There were no fatalities in this category.
- 5. *Miscellaneous product-related* issues: There were nine incident reports (seven percent) in which consumers complained of a design flaw posing a possible strangulation hazard, a broken component, rough fabric or a sharp surface, or an unspecified product failure. Although there were no fatalities included in these reports, there were six injuries, including one skull fracture.
- 6. Consumer comments: There were 17 reports (14 percent) of consumer comments or observations of perceived safety hazards. In most of these cases, the consumer did not own or use the sling carrier in question. This pattern is listed last because none of these reports indicate that any event actually occurred.

#### D. Standards Overview (Tabs B and C)

1. ASTM Sling Carrier Standard F2907

A voluntary standard for sling carriers was first approved and published in 2012, as ASTM F2907-12, *Standard Consumer Safety Specification for Sling Carriers*. ASTM has revised the voluntary standard five times since then. The current version, ASTM F2907-14a, was approved on February 15, 2014 and published in March 2014.

ASTM F2907-12 established requirements to address the following issues:

- Sharp points and edges,
- Small parts,
- Lead in paints,
- , I 1XX
- Wood parts,
- Locking and latching,
- Flammability,
- Dynamic load testing,
- Static load testing,
- Occupant retention testing,
- Marking and labeling, and Instructional literature.
- a. Revisions to ASTM F2907

# ASTM F2907-13 (approved on April 15, 2013):

- Changed definition from 'manufacturer's use position" to 'manufacturer's carrying position" to add clarity for the test laboratories that the definition refers to the combined configuration of the carrier and the baby and to exclude positions shown as examples of unacceptable, unsafe or not recommended carrying positions.
- Changed static load requirement from "three times manufacturer's recommended
  weight" to "three times the manufacturer's recommended weight or 60 lbs.,
  whichever is greater" to ensure all slings were tested to a minimum load of 60 lbs.
- Added minimum and maximum manufacturer's recommended weight to onproduct labeling to ensure weight restrictions stay with the product if the sling is handed down or resold.

# ASTM F2907-13a (approved on August 1, 2013):

- Added the safety alert symbol (△) to on-product warning.
- Added language in instructional literature: "Always check to ensure that all knots, buckles, snaps, straps and adjustments are secure," to address the security of all
- attachment systems, including knots. The previous wording focused on damage only, but some slings use only knots tied by the caregiver to support the carrier.

  Accordingly, the task group felt it was important to remind the caregiver to ensure that the carrier is secure in addition to not damaged.
- Added language to the instructions to stop using product if damaged (in response
- to an earlier ballot comment).

  Removed specific language in the instructions that addressed suffocation after breastfeeding and included that warning on the on-product label. Section 9

contains requirements for supplemental instructions; however, the task group felt that the severity and prevalence of the hazard pattern suggest that the warning should be contained on the on-product label. A statement was added to the on-product label to address the suffocation hazard related to breastfeeding; and because the content of the on-product label is required in the instructions, the statement was no longer needed as an individual section number.

# ASTM F2907-13b (approved on October 1, 2013):

• Clarified scope and added a note under 1.3 to provide additional guidance in identifying slings. The note, intended as guidance only, was added out of concern that some unstructured soft infant and toddler carriers may be confused with slings, and vice-versa. The note states:

Slings consist of a variety of unstructured designs ranging from a hammock-shaped product suspended on the caregiver's upper torso to a long length of material wrapped around the caregiver's body.

- Corrected flammability test method references, added flammability requirements
  to 5.11, and added 16 C.F.R. part 1610 as a referenced document. The previous
  flammability requirement has an incorrect reference to a nonexistent C.F.R. While
  correcting the reference, the subcommittee felt the flammability requirements in
  the sling voluntary standard should harmonize with soft infant and toddler
  carriers.
- Reworked the suffocation warnings in 8.3.3 to prioritize the hazard patterns and to include a new warning about breastfeeding (see Tab C).

# ASTM F2907-14 (approved on January 1, 2014):

- Updated the example positioning figure (figure 5).
- Added a definition for "substantially similar carrying position."

# ASTM F2907-14a (approved on February 15, 2014):

- Clarified the test method to ensure testing consistency:
  - 1. That rips and tears in the fabric are failures;
  - 2. That not all of section 5 is applicable for assessing static and dynamic load testing;
  - 3. Defined the exact meaning of "shall support a static load" and "shall support a dynamic load";
  - 4. That the slings should retain the occupant (*i.e.*, test mass should not eject or otherwise pass below the bottom of the test torso during occupant retention testing);
  - 5. How to divide the test cycles evenly;

- 6. That substantially similar carrying positions can be counted as one position for testing; and
- 7. That slings with a large number of different carrying positions should still be tested to a minimum number of cycles (350) per carrying position. For example, without this, a sling with seven positions would only be tested to about 140 cycles ( $1000 \div 7 = 142.8$ ) in each position.

#### b. Open ballots for ASTM F2907

The ASTM F15.21 subcommittee issued a ballot on May 16, 2014 that proposed a modification in the occupant retention test pass/fail criteria. According to the ballot, "the current Occupant Retention test criteria (section 6.3) are not accurately separating good ring slings from poorly-constructed ring slings." The modification proposed would increase from 1 inch to 3 inches the amount the ring sling attachment system may slip while still passing the standard. At the time of writing, staff does not have sufficient information to assess this change. Staff welcomes comments on the issue.

#### 2. Other Fabric Carrier Standards

CPSC staff identified one European standard that covers fabric carriers without rigid structure. In addition, a guideline for sling carriers is under development in Europe.

- British Standard EN13209-2:2005, *Child Use and Care Articles Baby Carriers Safety Requirements and Test Methods Part 2: Soft Carriers*<sup>9</sup> is the European standard for soft, fabric carriers. However, EN13209 specifically states that the scope is intended for a "product [that] has holes designed to accommodate the child's legs." Sling carriers do not have holes through which a child's legs pass. Although some individual requirements in the EN13209 standard may be more stringent than those in F2907-14a, the reported incidents do not suggest that these are prevalent hazard patterns. Therefore, staff does not believe that incorporating these more stringent requirements would further reduce the risk of injury associated with sling carriers.
- CEN/TR 16512, Child use and care articles Guidelines for the safety of children's slings, is a guideline that currently is under development in Europe. However, because, once completed, this guideline would not be a standard, CEN/TR 16512 is not an available option for consideration. Staff expects that this guideline, when published, will contain recommendations similar to

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<sup>&</sup>lt;sup>9</sup> BS EN13209-2:2005 *Child use and care articles – Baby carriers – Safety requirements and test methods - Part 2: Soft carrier,* British Standards Institution (27 September 2005).

EN13209, but with recommendations adapted for the unique attributes of sling carries.

CPSC staff notes that the ASTM F15.21 subcommittee has worked to ensure that F2907 is the most appropriate standard for the unique nature of sling carriers by not only harmonizing with other standards (*e.g.*, EN13209 and ASTM F2236<sup>10</sup>), when appropriate, but also by addressing the uniqueness of sling carriers when needed. Therefore, ASTM F2907-14a is the only comprehensive standard that addresses the incident hazard patterns, and staff believes F2907-14a adequately addresses the hazards identified.

#### III. DISCUSSION

# A. Adequacy of F2907-14a Requirements (Tabs A, B, C, & D)

Staff believes that F2907 addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, small parts, wood part splinters, scissoring/shearing/pinching, openings/entrapments, and flammability. Specific requirements for labeling and instructions are also included, and these were developed and revised with staff participation. In addition, ASTM F2907 includes construction quality and durability test methods that are specific to sling carriers in the static, dynamic, occupant retention, and restraint tests described below:

- **Static load test**: This test assesses that the sling can support its maximum recommended weight with a safety factor of three by gradually applying a weight of three times the manufacturer's maximum recommended weight, or 60 lbs., whichever is greater, in the support area of the sling and maintaining for one minute.
- **Dynamic load test**: This test assesses the durability of the sling and proper functioning of the sling's fasteners by dropping a 35-lb. load into the sling's support area in each recommended carrying position every 4 seconds for up to 1,000 cycles.
- Occupant retention test: This test assesses that the sling retains the occupant while the caregiver is moving about and also functions as an additional durability test. The sling is attached to a test torso, and a test mass is placed in the sling. The test torso will move up and down at a rate of two times per second (approximately a brisk walking speed). The

<sup>11</sup> The restraint system and dynamic tests in F2907 are similar to those in F2236, and the occupant retention test in F2907 is based on the "Durability of attachment systems" test from BS EN13209.

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<sup>&</sup>lt;sup>10</sup> Standard Consumer Safety Specification for Soft Infant and Toddler Carriers, a type of infant carrier that is somewhat similar to sling carriers.

sling is tested to determine if fasteners and adjustment mechanisms (*e.g.*, rings, knots) release.

• **Restraint system test**: The test assesses that any child restraints used in the sling are sufficient. Each restraint system is tested with a 45-lb. force on the restraint and again with a CAMI<sup>12</sup> dummy. The anchorages for the restraint system shall not separate from their attachment points during or after testing.

Section C, above, lists hazard patterns by frequency of incident reports but not necessarily by severity of the hazard. The listing below identifies hazard patterns in order of severity, starting with fatalities and injuries requiring hospitalization, followed by injuries not requiring hospitalization (**bold font** indicates a hazard where fatalities have been reported). The following list discusses each hazard and how it relates to the current voluntary standard, ASTM F2907-14a:

### 1. Positioning (31 reports, 9 fatalities, 3 injuries)

Staff identified positioning as the primary hazard pattern in 31 cases. In Tab D, CPSC Health Sciences staff identified suffocation/asphyxia related to positioning as a risk associated with sling carriers. Suffocation can occur when babies are contained entirely within the pouch of a sling. The highest risk of suffocation occurs when the infant's face (nose and mouth) is pressed against the caregiver's body, blocking the infant's breathing and rapidly suffocating a baby within a few minutes. Furthermore, there is a concern that the product, because of its shape and lack of support, can facilitate an infant being positioned within the confines of the sling in a manner that causes acute neck hyperflexion (chin touching the chest). Infants found in this compromised position are likely to stay in the position because infant neck muscles are too weak to support the weight of their head. Infants who stay for prolonged periods of time in this position can experience compromised airflow to the lungs, resulting in an inadequate supply of oxygen to the brain. Oxygen deprivation to the brain can lead to loss of consciousness and death.

Although there is no performance test for positioning in the F2907, statements in the required warnings and instructions are directly related to the hazards identified by Health Sciences staff and observed in the incidents. Section 8.3.3 of F2907 describes the onproduct warning and addresses each of the hazard patterns staff found in the suffocation data. In short, all sling carriers must: (1) warn that failure to follow the manufacturer's instructions can result in death or serious injury, (2) state the minimum and maximum recommended weights for the sling, and (3) warn about the potential suffocation and fall

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<sup>&</sup>lt;sup>12</sup> The CAMI (Civil Aeronautical Medical Institute) Newborn Infant and 6-month-old Infant test dummies are used in testing of many juvenile products by ASTM standards. These anthropomorphic test devices were originally developed by the Civil Aeronautical Medical Institute and have been used by the National Highway Traffic Safety Administration for the evaluation of child restraint systems (49 C.F.R. part 572 subparts D and K). The dummies consist of steel and aluminum blocks attached to leather skeletons wrapped in layers of foam padding and covered with a stitched cloth outer shell. ASTM F2907 uses the CAMI infant dummy, which represents a 50th percentile 6-month-old infant (17.5 lbs.).

hazards associated with sling carriers. In addition, F2907 requires all products to contain an on-product pictogram that compares proper and improper infant positioning.

More specifically, the warnings in F2907 that pertain to suffocation and positioning must address:

- the risk of suffocation to infants younger than 4 months if the infant's face is pressed against the caregiver's body within the confines of the sling and the increased risk of suffocation to infants born prematurely or with respiratory problems;
- the need to check often to make sure that that the infant's face remains uncovered, clearly visible to the caregiver, and away from the caregiver's body at all times;
- the importance of making sure that the infant does not curl into a position with the chin resting on or near the infant's chest, which can interfere with breathing even when nothing is covering the nose or mouth;<sup>13</sup>
- the need to reposition the infant after nursing so the infant's face is not pressed against the caregiver's body; and
- the importance of never using the sling with infants smaller than eight pounds without seeking the advice of a healthcare professional.

Other durable nursery voluntary standards subcommittees have tried to address positioning hazards related to a C-shaped curl in an infant's head, neck, and torso area; however, a repeatable performance test has not yet been identified. Staff attempted to address the hazard differently, by recognizing that a sling carrier is worn by the caregiver and involves direct contact with the caregiver, thereby allowing for the possibility of the caregiver seeing a child who is in distress. Therefore, staff explored a "face exposure" test that could, at a minimum, keep a sling from preventing the caregiver from observing the infant's face. Staff pursued this possible test with the ASTM task group, but, as explained in detail in Tab C, found that the available anthropomorphic mannequins (*e.g.*, CAMI dummy) do not accurately represent the manner in which a child sits in a sling, and that the variable nature of sling products makes the repeatability of a test questionable. Together with the ASTM task group, staff concluded that a test is technically infeasible at this point.

Ultimately, staff concluded that warning requirements about proper and improper infant positioning is the only feasible hazard-mitigation strategy at this time. Staff will continue to consider possible performance requirements pertaining to this issue and can pursue such an approach with the ASTM Subcommittee in the future, if feasible. Because there

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UNDER CPSA 6(b)(1)

<sup>&</sup>lt;sup>13</sup> Commonly referred to as positional asphyxia.

is no feasible performance test and because the warning statements in ASTM F2907 have been developed considering both known hazard patterns and established practices for warning labels, staff believes that the warnings and instructions published in ASTM F2907-14a are adequate to inform caregivers about how to reduce the likelihood of positioning incidents. Further discussion of the warnings and positioning issues can be found in Tab C.

# 2. Undetermined or unspecified (25 reports, 7 fatalities, 15 injuries)

The fatalities in these cases did not list a cause of death because the injuries were reported mostly through hospital emergency departments with very little scenario-specific information. Although this category includes fatalities and serious head injuries, such as skull fractures, staff is unable to address these cases without knowing the details of the hazard scenarios. However, the dynamic, static, occupant retention, and restraint tests address a variety of ways the sling could fail or an infant could fall.

Staff worked extensively with the ASTM subcommittee to verify the test methods. During testing and verification of ASTM F2907, CPSC staff noted several items in the dynamic and occupant retention tests that needed clarification. CPSC staff brought these items to the attention of the subcommittee in an August 2013 letter. <sup>14</sup> Subsequent task group and subcommittee work resulted in two rounds of balloting and culminated in the most recent version of the voluntary standard, F2907-14a. Staff believes the modifications in the test methods that were incorporated into ASTM 2907-14a, as discussed above, will help to improve consistency among test laboratories.

### 3. Caregiver Missteps (28 reports, 27 injuries)

Caregiver missteps included 11 reports of skull fractures and one episode of internal bleeding in the brain. Other injuries included closed head injuries, contusions of the head/leg/back, and a finger laceration. Staff determined that these incidents were related directly to the actions, often accidental, of the caregiver. For example, a caregiver slips or trips while wearing the sling carrier that is holding the child, or incidental contact occurs between the child and an object, such as a door or wall. These types of incidents cannot be addressed directly through a performance test, but these incidents are addressed by alerting caregivers of the hazard and testing that the sling retains the occupant. ASTM F2907-14a requires a statement on the on-product label to address the fall hazard to infants associated with "caregiver missteps," such as tripping or bending over:

FALL HAZARD – Leaning, bending over, or tripping can cause baby to fall. Keep one hand on baby while moving.

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 $<sup>14 \\</sup> http://www.cpsc.gov/Global/Regulations-Laws-and-Standards/Voluntary-Standards/Draft-Voluntary-Standards-Proposals/SlingCarriersOnTestMethods.pdf$ 

In addition, the occupant retention test in ASTM F2907, discussed in detail in Tab B, requires the test mass to be contained within the sling for the duration of the test and will reduce the likelihood that the child will fall out of the sling due to a misstep.

# 4. Buckles (12 reports, 3 injuries)

Twelve of the incidents involved buckles releasing, slipping, or breaking and included a hospitalization for a skull fracture and two non-hospitalized injuries. ASTM F2907 addresses this hazard in several ways, using the static, dynamic, occupant retention, and restraint system tests, described above and in Tab B. For the reasons described above and in Tab B, staff believes that the performance tests in F2907 adequately address hazards resulting from buckle failure.

# 5. *Miscellaneous product-related issues (9 reports, 6 injuries)*

The nine incidents included under "miscellaneous product-related issues" did not have enough information to place them clearly in another category; but the nine incidents included reports of a design flaw posing a strangulation hazard, a broken component, fabric shrinkage, rough fabric or a sharp surface, a small part being liberated, or an unspecified product failure. Many of these hazards, such as small parts and sharp edges, are covered by the "general hazards," section 5, of ASTM F2907, which also includes laundering the sling. In addition, the reports that indicated the child fell because the sling "broke" or "opened up," without additional detail, most likely would be addressed by the dynamic test, the occupant retention tests, or both, as discussed above and in Tab B.

#### 6. Consumer Comments (17 reports, no incidents)

These reports were consumer comments or observations of perceived safety hazards. In most of these cases, the consumer did not own the product in question. For example, a consumer saw a sling for sale that was similar to a recalled product; a consumer came across a website that sells a product that "looks extremely unsafe"; or a consumer found a product for sale that does not contain CPSIA-required tracking labels. Although these concerns generally cannot be addressed by a standard, staff believes that the improvements in instructions and labeling that have come about by the first publication of F2907 in 2012, and the modifications since then, will help educate consumers about proper sling usage. In addition, concerns such as missing CPSIA-required tracking labels are enforceable through means other than this proposed rule.

#### **B.** Recent Compliance Activity (Tab E)

Since January 1, 2003, the CPSC has issued five consumer-level recalls and two informative press releases involving sling carriers. All five of these recalls were for product defects that created a substantial product hazard and resulted in the recall of about 1.1 million sling carriers.

Two of the recalled products posed a suffocation hazard, while three recalls were related to structural integrity and fall or potential fall hazards. The recalls are listed below <sup>15</sup>:

# Structural Integrity

Zolo, 2005: Stitching, CPSC Link.

Ellaroo, 2008: Rings bending/breaking, CPSC link.

Infantino, 2007: Plastic breaking, CPSC link.

#### Suffocation

Infantino, 2010: Suffocation, <u>CPSC link</u>. This recall was updated by a safety alert on <u>March 6, 2012</u> due to reselling of recalled product.

Sprout Stuff, 2010: Suffocation, CPSC link.

In addition to the five recalls, CPSC issued the following two informational press releases in 2010:

March 2010 – This informational press release provided general warnings regarding the risk of suffocation in preemies, low-birth weight, or otherwise fragile, young infants due to positioning hazards in slings. Parents were warned of two potential hazards: the sling fabric pressing again the child's face and the potential for a child's chin to curl toward his or her chest, restricting the airways and limiting the oxygen supply. CPSC recommended that parents and caregivers make sure that the infant's face is not covered or blocked and is clear from the sling and the parent or caregiver's body.

<u>November 2010</u> – This informational press release recommended that parents with infants younger than 4 months old, premature, low-birth weight, or with colds and respiratory problems should take extra care in using a sling carrier. In addition, the press release provided guidance for positioning the infant within the sling carrier.

# C. Potential Small Business Impact (Tab F)

Of the 47 identified suppliers of sling carriers to the U.S. market, 33 are domestic firms. Of these 33 domestic suppliers, CPSC staff has identified 31 domestic suppliers that would be classified as small businesses under U.S Small Business Administration guidelines: 23 manufacturers, 4 importers and 4 firms with unknown supply sources. In addition, there are a large, but unquantified, number of producers supplying baby slings to the U.S. market via websites such as Etsy, referred to as "very small" manufacturers.

As of January 2014, only 2 of the 23 known small manufacturers of sling carriers are listed on the Juvenile Products Manufacturers Association (JPMA) website as certified compliant. Based on our review of small firm websites, a conversation with a small ring sling manufacturer, and a

UNDER CPSA 6(b)(1)

<sup>&</sup>lt;sup>15</sup> Details of each of these recalls can be found in the Recall section on the CPSC.gov website by clicking on the links provided.

draft magazine article by a small nursing wrap producer, we have identified three additional firms (not JPMA certified) that have conducted testing to some version of the ASTM standard, for a total of 5 firms that have conducted testing to some version of the ASTM standard. These firms may have already experienced the impacts of staff's draft proposed rule and may not experience any additional impacts. The remaining firms are likely to incur some cost associated with the proposed rule.

Due to the nature of the product and the relative ease of production, staff believes that most of the physical changes needed to meet the standard, such as changing fabrics, changing stitching, adding reinforcements, changing buckles, changing rings, changing labels, and changing instructions, are unlikely to be costly. The majority of the costs associated with the draft proposed standard likely will be related to testing. Some small and very small manufacturers could experience significant testing costs simply determining initially whether their products comply with the draft proposed standard and with any additional testing necessary to develop complying products. After developing complying products, very small firms are still likely to incur significant economic impacts complying with the third party testing and certification requirements of section 14 of the CPSA. An effective date longer than the 12-month date recommended by the staff could mitigate the impact on small businesses.

Some manufacturers of ring slings have reported difficulty passing the occupant retention tests consistently. At this time, the precise cost of product changes necessary to satisfy testing under the ASTM standard is unknown; additionally, staff cannot rule out the potential for costs to be high enough to lead to significant economic impacts, especially for very small manufacturers. However, the ASTM F15.21 subcommittee, including members of CPSC technical staff, is working to address this issue. Once complete, this may mitigate the impact on ring sling manufacturers.

# D. Sling Carriers as a durable infant carrier (Tabs A, B, C, E, F, and G)

Section 104(f) of the CPSIA defines a "durable infant or toddler product" as a "durable product intended for use, or that may be reasonably expected to be used, by children under the age of 5 years" and "includes ... infant carriers." For all types of infant carriers, the majority of children carried are under the age of 5 years. Sling carriers are one specific type of infant carrier, a product category that also includes hand-held infant carriers, soft infant and toddler carriers, and frame child carriers.

As discussed in Tab G, the U.S. Department of Commerce defines durable products as "[t]angible products that can be stored or inventoried and that have an average life of at least three years." CPSC's Directorate for Economic Analysis identified two other definitions of

<sup>18</sup> Section 104(f)(2)(H)

<sup>&</sup>lt;sup>16</sup> Durable infant and toddler products are specifically excluded from small batch exemptions for product safety rules promulgated under Section 104 of the CPSIA (http://www.cpsc.gov/en/Business--Manufacturing/Small-Business-Resources/Small-Batch-Manufacturers-and-Third-Party-/).

17 Section 104(f)(1)

durable product, and interpreted the three together to mean that a durable product should have an expected life of at least 3 years. Although it is difficult to assess whether sling carriers reach the 3-year life expectancy, staff believes that there is sufficient evidence to support sling carriers as "durable" products because sling carriers can be used for children up through 3 years old, have durable parts, are stored for later use, are used for more than one child, and consumers believe them to be usable for more than one child. The evidence is outlined below:

- Age of children carried in sling carriers
  - One reported incident victim was 3 years old (Tab A), which demonstrates these products are used past the first year of life.
  - The voluntary standard (F2907) defines a sling carrier for use up to 35 pounds. Three-year-old children are likely to still be within this weight limit, and some 4-and 5-year-old children may be under 35 pounds (Tab C).
- Durability of sling carrier parts
  - Although wraps and pouch slings are all-fabric products, ring slings, modifications of wraps and pouch slings, and other products that meet the definition of a sling carrier also contain parts that are considered durable from an engineering perspective and suggest they were selected for long-term use. In addition, the test methods in ASTM F2907-14a combine to ensure that slings meet a minimum level of durability (Tab B).
- Reuse of sling carriers
  - Two incidents involved a hand-me-down sling carrier. One sling was reported to have been received from a relative and the other sling carrier was reported to have been used for the infant's older sibling (Tab A).
  - Preliminary data from CPSC's durable nursery product survey indicate that only 4 percent of respondents throw used sling carriers away, and that 96 percent of respondents save the sling carrier for later use, sell the sling carrier, or give the sling carrier away. In addition, the 2006 Baby Products Tracking Study indicated around one-quarter of sling carrier users obtain their sling carrier second hand (Tab F).
  - With 96 percent of survey respondents to CPSC's durable nursery product survey indicating that the sling carrier was saved or otherwise passed on to another caregiver, it is foreseeable that some sling carriers are likely to be used by more than one child. In addition, sling carriers appear to be bought and sold on resale markets (Tabs C and G).
- Recalls of sling carriers
  - CPSC issued a recall in March 2008 regarding a certain sling carrier that was manufactured in March and April 2007<sup>19</sup> (Tab E). CPSC received reports of incidents involving sling carriers subject to the recall more than 5 years after the recall announcement.

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<sup>&</sup>lt;sup>19</sup> Lot numbers 03/07 and 07/04 per recall notice

• CPSC issued a recall in March 2010 regarding a different sling carrier that was sold from 2003 to 2010. That recall was reissued as a safety alert 2 years later (March 2012) because the sling carriers subject to the recall were found in the marketplace (Tab E).

In sum, sling carriers are a type of infant carrier, a product specifically identified as a "durable infant or toddler product" in section 104(f)(2)(H) of the CPSIA. The test methods in ASTM F2907-14a are designed to ensure that slings meet a minimum level of durability. Data on sling usage indicate (1) sling carriers can be stored or inventoried with a useable life of 3 years or more from the manufacture or sales date and (2) consumers perceive sling carriers to have a useable life spanning more than one child. For these reasons, staff believes a sling carrier is a "durable infant or toddler product" under section 104 of the CPSIA.

#### E. Effective Date

Unless there are specific reasons justifying a longer effective date, staff generally considers six months sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule. Six months is the period JPMA typically allows for products in their certification program to shift to a new voluntary standard once that new voluntary standard is published. Therefore, juvenile product manufacturers are accustomed to adjusting to new voluntary standards with this time frame, and staff typically recommends a 6-month effective date for durable nursery product rules.

However, a longer effective date could reduce the impact on small firms. Setting a later effective date would reduce the economic impact on firms in two ways. First, firms would be 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, thereby reducing their annual costs and the present value of their total costs. Given the large number of very small suppliers who will potentially experience significant economic impacts, in addition to the lack of established history of compliance with the voluntary standard, staff is recommending a 12-month effective date. CPSC staff welcomes comments regarding this proposed effective date.

#### IV. STAFF RECOMMENDATIONS

CPSC staff recommends that the Commission publish an NPR that incorporates by reference the voluntary standard, ASTM F2907-14a, *Standard Consumer Safety Specification for Sling Carriers*. Staff is also recommending an effective date of 12 months after publication of the final rule.

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<sup>&</sup>lt;sup>20</sup> Per recall notice

TAB A: Sling Carriers-Related Deaths, Injuries, and Potential Injuries; January 1, 2003–October 27, 2013

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A B

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#### Memorandum

Date: November 22, 2013

TO: Hope Nesteruk

Sling Carriers Project Manager Division of Human Factors Directorate for Engineering

THROUGH: Kathleen Stralka

Associate Executive Director Directorate for Epidemiology

Stephen Hanway

Division Director, Division of Hazard Analysis

Directorate for Epidemiology

FROM : Risana Chowdhury

Division of Hazard Analysis Directorate for Epidemiology

SUBJECT: Sling Carriers-Related Deaths, Injuries, and Potential Injuries; January 1, 2003

to October 27, 2013<sup>21</sup>

#### I. Introduction

This memorandum characterizes the number of deaths and injuries and the types of hazards related to sling carriers over a period of more than 10 years, from January 1, 2003 through October 27, 2013.<sup>22</sup> These characterizations are based on incident reports received by CPSC staff. The number of emergency department-treated injuries associated with slings, for the time

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

<sup>&</sup>lt;sup>21</sup> 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.

Not all of these incidents are addressable by an action the CPSC could take. It is not the purpose of this memorandum, however, to evaluate the addressability of the incidents, but rather, to quantify the number of fatalities and injuries reported to CPSC staff and to provide, when feasible, estimates of emergency department-treated injuries.

frame covered, was insufficient to derive any reportable national estimates.<sup>23</sup> Hence, injury estimates are not presented in this memorandum. However, the emergency department-treated injuries are included in the total count of reported incidents presented here.

The ASTM voluntary standard for Sling Carriers, F2907, addresses safety issues related to sling carriers. According to the ASTM definition, "a sling carrier is a product of fabric or sewn fabric construction, which is designed to contain a child from birth (full term infant weighing 8 lb. (3.6 kg) or more) through 35 lb. (15.9 kg), in an upright or reclined position, while being supported by the caregiver's torso. The sling carrier is normally "worn" by the caregiver, and thus the child is supported from one or both shoulders of the caregiver. These products are worn on the front, hip, or back of the caregiver, with the child either facing towards or away from the caregiver or reclined on the front only of the caregiver."

ASTM F2907-12 is the first voluntary standard on sling carriers and was developed primarily based on incident data provided by CPSC staff from the year 2003. This memorandum discusses the data from the year 2003 through October 2013.

# II. Incident Data<sup>24</sup>

CPSC staff is aware of a total of 122 incidents (16 fatal and 106 nonfatal) related to sling carriers that were reported to have occurred from January 1, 2003 through October 27, 2013. Because reporting is ongoing, the number of reported fatalities, nonfatal injuries, and non-injury incidents may change in the future. Table 1 provides the breakdown of the incidents by year. Given that many of these reports are anecdotal, and reporting is incomplete, CPSC staff strongly discourages drawing any inferences from the year-to-year increase or decrease shown in the reported data.

 <sup>&</sup>lt;sup>23</sup>According to the NEISS publication criteria, an estimate must be 1,200 or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller before the estimate can be published.
 <sup>24</sup> The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death

<sup>&</sup>lt;sup>24</sup> The CPSC databases searched were the In-Depth Investigation (INDP) file, the Injury or Potential Injury Incident (IPII) file, the Death Certificate (DTHS) file, and the National Electronic Injury Surveillance System (NEISS). These reports do not provide a complete count of all the incidents and deaths that 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 sling carriers.

The date of extraction for reported incident data was 10/28/13. The incident reports involving carriers do not always clearly specify the type of the carrier involved. As such, all data coded under product codes 1527/1548/1549 and age range 0–4 years was extracted, yielding a very large initial data pool. Upon careful joint review with CPSC's Directorates for Engineering Sciences, Economic Analysis, and Health Sciences staff, many cases were considered out of scope for this memorandum. For example, cases where SIDS or other pre-existing medical condition was listed as official cause of death, or cases where a child was outside a carrier at the time of injury, were excluded. However, all incidents where a hazardous environment in and around the sling carrier resulted in a fatality, injury, or a near-injury incident were retained. With the exception of incidents occurring on United States military bases, all incidents that occurred outside of the United States have been excluded. To prevent any double-counting, when multiple reports of the same incident were identified, they were consolidated and counted as one incident.

Table 1: Sling Carrier-Related Reported Incidents January 01, 2003–October 27, 20013

Incident Year		Number of Reported Incidents			
	Total	Injuries (hospitalizations)	Fatal		
2003	4	3 (1)	0		
2004	6	6	0		
2005	8	4 (2)	2		
2006	13	7 (2)	1		
2007	13	5 (1)	1		
2008	10	3	3		
2009	17	7	4		
2010	23	7 (2)	1		
2011*	7	3	1		
2012*	6	0	2		
2013*	15	9 (1)	1		
Total	122	54 (9)	16		

Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

Note: \* indicates data collection is ongoing.

Among the incidents where age was reported, all but one of the children were 12 months old or younger. One incident involved a 3-year-old child. Age was not reported in 31 incidents because no injury was involved or age was unknown. Table 2 provides the age breakdown as reported in the 122 incidents.

Table 2: Age Distribution as Reported in Sling Carrier-Related Incidents January 01, 2003–October 27, 20013

Age of Child	All Incidents		Fatal and Nonfatal Injuries	
	Frequency	Percentage	Frequency	Percentage
Unreported*	31	25	1	1
One – Three Months	70	57	54	77
Four – Six Months	11	9	8	11
Seven – Nine Months	7	6	4	6
Ten – Twelve Months	2	2	2	3
Three Years	1	1	1	1
Total	122	100	70	100

Source: CPSC epidemiological databases IPII, INDP, DTHS, and NEISS.

Note: Percentages do not add to 100 due to rounding.

<sup>\*</sup> Age was unknown or the incident reported no injury.

To ascertain whether the involved sling carrier was bought new and was used by a caregiver for one infant, staff reviewed all available information provided in the incident reports pertaining to the product acquisition history. For 59 of the 122 incident reports, information was unavailable; in an additional six reports, the consumer reported not owning any sling carriers. In 55 of the remaining 57 incident reports, the sling carrier was reported to have been purchased new and used by a caregiver for only a single infant; in the remaining two cases, the hand-me-down sling carrier was reported to have been received from a relative, or the infant's older sibling was reported to have used the sling carrier before. In both incidents, the sling carrier was being reused by a different infant than had previously used it.

#### A. Fatalities

Sixteen fatalities were associated with the use of a sling carrier that were reported to have occurred during the period from January 1, 2003 through October 27, 2013. Eleven of the 16 decedents were 1-month olds; the remaining five were between 3 and 5 months old. Nine of the decedents were described as having died of smothering, while the cause of death was undetermined for the remaining decedents.

# B. Nonfatal Incidents

Of the 106 sling carrier-related nonfatal incidents that were reported to have occurred from January 1, 2003 through October 27, 2013, 54 reports reflected an injury to the infant during use of the product. Age was unreported for one of the injured, and one report stated that a 3-year-old was injured. For the rest, the ages ranged from 1 month to 12 months.

Among the 54 reported nonfatal injuries, nine were reported as involving hospitalizations. Among the hospitalizations, one injury was described as a permanent brain injury due to breathing difficulties suffered by the infant. The rest were serious head injuries, such as a fracture and/or brain hemorrhage, resulting from infants falling from the carrier. Eleven additional skull/face/wrist fracture injuries were reported, but none of them reportedly required hospitalization. The remaining non-hospitalized injuries included closed-head injuries, <sup>25</sup> contusions/abrasions, and lacerations/scratches, among others. A majority of the injuries resulted from falls from the carrier; most of these falls resulted from the caregiver slipping, tripping, or bending over while carrying the infant in the sling. The remaining injuries were due to miscellaneous product-related issues or other caregiver missteps, such as not allowing enough safety clearance for the child in the sling carrier while proceeding with daily activities.

<sup>&</sup>lt;sup>25</sup> According to Tab D from the Directorate for Health Sciences, a closed-head injury is a head injury where the skull remained intact but it can range in severity from a minor bump to a severe life-threatening traumatic brain injury.

The remaining 52 incident reports stated that no injury had occurred or provided no information about any injury. However, many of the incident reports described scenarios that staff believes presented the potential for a serious injury or even death.

#### III. Hazard Patterns

CPSC staff considered all 122 reported incidents (16 fatal and 106 nonfatal) to identify hazard patterns associated with sling carriers. In order of frequency of incident reports, staff grouped the hazard patterns into the following categories:

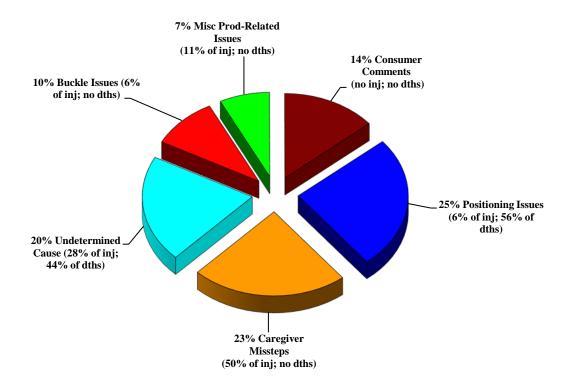
- 1. Problems with *positioning* the infant in the sling carrier: Thirty-one of the 122 reported incidents (25 percent) were in this category. Among them were nine deaths due to smothering, one permanent brain impairment injury due to breathing difficulty, and two other injuries—one related to breathing difficulty and the other related to blood-circulation in the infant's leg. The rest of the incidents reported breathing problems suffered by the infant in the carrier or difficulty in safely positioning the infant in the sling carrier to avoid the potential for suffocation.
- 2. Caregiver missteps: Twenty-eight incidents (23 percent) were in this category. Twenty of these 28 incidents reportedly occurred when the caregiver slipped, tripped, or bent over, causing the infant in the sling to fall with the caregiver or fall out of the carrier. Eight additional incidents among the 28 reported in this category occurred when caregivers dropped the infant during placement into/removal out of the carrier or failed to provide enough safety clearance for the infant in the carrier as caregivers conducted their daily activities. Examples of the latter scenario included an infant striking a door or a falling object, or an infant hitting a wall. Although these 20 incidents did not involve any fatalities, all but one incident resulted in an injury to the infant. These incidents included 11 reports of skull fractures and one report of bleeding in the brain. Other injuries included closed head injuries, contusions of the head/leg/back, and a finger laceration.
- 3. Undetermined or unspecified cause: Twenty-five reported incidents (20 percent) included seven fatalities, two hospitalized injuries, and 13 non-hospitalized injuries, with very little information available on the circumstances leading up to the incidents. The official reports did not indicate a specific cause of death. Among the injuries, which included fractures of the skull and wrist, as well as other serious head injuries, most were reported through hospital emergency departments with very little scenario-specific information.

- 4. Problems with *buckles*: Twelve of the 122 incidents (10 percent) reported buckles releasing, slipping, or breaking, causing infants to fall or nearly fall. One incident required hospitalization for a skull fracture, and two non-hospitalized injuries reportedly occurred. No fatalities were reported in this category.
- 5. *Miscellaneous product-related* issues: In nine incident reports (seven percent), consumers complained of a design flaw posing a strangulation hazard, a broken component, rough fabric, or a sharp surface, or consumers indicated an unspecified product failure. Although there were no fatalities included in these reports, six injuries and one skull fracture reportedly occurred.
- 6. *Consumer comments:* Seventeen non-event reports (14 percent) involved consumer comments or observations of perceived safety hazards. In most of these cases, the consumer did not own the sling carrier in question. None of these reports indicate that any event actually occurred.

The distribution of the 122 reported incidents by hazard pattern described above is shown in Figure 1.

Figure 1: Distribution of Repored Incidents, Injuries, and Fatalities Associated with Sling Carriers by Hazard Pattern Characterizations

January 1, 2013 - October 27, 2013



Source: CPSC epidemiological databases IPH, INDP, DTHS, and NEISS. Note: Percentages do not always add to 100 due to rounding. Also, "inj" = "injury" and "dths" = "deaths."

T A B

# **TAB B: Engineering Assessment of ASTM F2907 Requirements for Sling Carriers (CPSIA Section 104)**



#### Memorandum

April 21, 2014

To: Hope E. J. Nesteruk, Project Manager, Infant Slings Rulemaking

Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Gregory K. Rea, Director,

Division of Mechanical Engineering, Directorate for Laboratory Sciences

From: Maxwell Sanborn, Mechanical Engineer,

Division of Mechanical Engineering, Directorate for Laboratory Sciences

SUBJECT: Engineering Assessment of ASTM F2907 Requirements for Sling Carriers (CPSIA

Section 104)

#### I. INTRODUCTION

This memorandum assesses the effectiveness of ASTM F2907-14a, *Standard Consumer Safety Specification for Sling Carriers*, and recommends that the Commission propose to incorporate by reference the voluntary standard ASTM F2907-14a, *Standard Consumer Safety Specification for Sling Carriers* as the mandatory standard, without modification. We provide this assessment in accordance with the Danny Keysar Child Product Safety Notification Act, Section 104 of the Consumer Product Safety Improvement Act (CPSIA), *Standards and Consumer Registration of Durable Nursery Products*.

F2907-14a defines a "sling carrier" as a "product of fabric or sewn fabric construction, which is designed to contain a child, in an upright or reclined position while being supported by the caregiver's torso. In general, the child will be between full term birth and 35 lb. (15.9 kg)." The sling carrier is normally "worn" by the caregiver, and thus, the child is supported from one or both shoulders of the caregiver. Slings consist of a variety of unstructured designs, ranging from a hammock-shaped product suspended on the caregiver's upper torso, to a long length of material wrapped around the caregiver's body. These products are worn on the front, hip, or back of the caregiver, with the child facing towards or away from the caregiver or reclined on the front only of the caregiver. Figure 1 shows typical sling carriers.

# Slings as Durable Children's Products

CPSC Hotline: 1-800-638-CPSC(2772) CPSC's Web Site: http://www.cpsc.gov

Although all slings are intended to contain a child in an upright or reclined position, the design and construction of slings varies widely. Of the 14 different sling products in CPSC's possession, four are wraps or wrap-like, four are ring slings, four are pouch-style slings, and the remaining two are "bag" <sup>26</sup>style. The wrap and wrap-like products are all or mostly fabric, with few or no fasteners. The ring slings all have similar construction and fastener hardware. Two models have plastic rings, and the other two have metal rings. Of the pouch slings, two have fasteners, and two have no fasteners. Finally, both "bag" style slings have fasteners (in this case, plastic buckles), but they also have rigid plastic support boards under the child support area. Thus, eight of the 14 samples use rigid fasteners.

The use of rigid machine components (in this case, fasteners), especially metals, suggests that these products are not intended for short-term use.

Additionally, 10 of the 14 samples have a maximum recommended weight limit of at least 35 pounds (including one with a weight limit of 40 pounds).







Figure 1. Example Sling Carriers (pouch, wrap, ring)

# History of ASTM F2907, Standard Consumer Safety Specification for Sling Carriers

The voluntary standard for sling carriers was first approved and published in 2012, as ASTM F2907-12, *Standard Consumer Safety Specification for Sling Carriers*. ASTM has revised the voluntary standard five times since then. The current version, ASTM F2907-14a, was approved on February 15, 2014 and published in February 2014.

ASTM F2907-12 established requirements to address the following issues:

- Sharp points and edges,
- Small parts,
- Lead in paints,

<sup>26</sup> A "bag" sling a less common sling type that is similar to the one in recall 10-177 (http://www.cpsc.gov/en/Recalls/2010/Infantino-Recalls-to-Replace-SlingRider-Baby-Slings-Three-Infant-Deaths-Reported/)

- Wood parts,
- Locking and latching,
- Flammability,
- Dynamic load testing,
- Static load testing,
- Occupant retention testing,
- Marking and labeling, and
- Instructional literature.

# ASTM F2907-13 (approved on 4/15/13):

- Changed "manufacturer's use position" to "manufacturer's carrying position";
- Changed static load requirement from three times manufacturer's recommended weight to three times the manufacturer's recommended weight or 60 lbs. (27.2 kg), whichever is greater; and
- Added minimum and maximum manufacturer's recommended weight to on-product labeling.

# ASTM F2907-13a (approved on 8/1/13):

- Added safety alert symbol to warning in 8.3.2;
- Added language in instructional literature: "Always check to ensure that all knots, buckles, snaps, straps and adjustments are secure";
- Added language to the instructions to stop using product if it is damaged; and
- Removed instruction language in 9.3.6 that addressed suffocation after breastfeeding.

# ASTM F2907-13b (approved on 10/1/13):

- Clarified scope and added a note under 1.3 providing additional guidance defining a sling;
  - Corrected flammability test method references and added flammability requirements to 5.11 and added 16 C.F.R. part 1610 as a referenced document; and
- Reworked suffocation warnings in 8.3.3 to address hazard patterns, including adding a warning about breastfeeding.

# ASTM F2907-14 (approved on 1/1/14):

- Updated the example positioning figure (Figure 5); and
- Add a definition for "substantially similar carrying position."

#### ASTM F2907-14a (approved on 2/15/14):

- Clarified the static, dynamic, restraint and occupant retention test methods and criteria as follows:
  - 1. That rips and tears in the fabric are failures;
  - 2. That not all of section 5 is applicable for assessing static and dynamic load testing;

- 3. What "shall support a static load" and "shall support a dynamic load" mean;
- 4. That the slings should retain the occupant (*i.e.*, test mass should not eject or otherwise pass below the bottom of the test torso during occupant retention testing);
- 5. How to divide the test cycles evenly;
- 6. That substantially similar carrying positions can be counted as one position for testing; and
- 7. That slings with a large number of different carrying positions should still be tested to a minimum number of cycles (350) per carrying position. For example, without this requirement, a sling with seven positions would only be tested to 140 cycles in each position.

# **Description of ASTM F2907 Performance Requirements**

In addition to the general requirements typically found in children's products, such as prohibition of sharp points/edges, small parts, and lead in paints, Section 6 of ASTM F2907-14a also has four performance requirements that are specific to sling carriers. These requirements include the static load test, dynamic load test, occupant retention test, and restraint system test. A brief description of each follows:

- Static load test: This test assesses whether the sling can support its maximum recommended weight with a safety factor of three by gradually applying a weight of three times the manufacturer's maximum recommended weight, or 60 lbs. (27.2 kg), whichever is greater, in the support area of the sling and maintaining for one minute. This test is repeated for all manufacturer-recommended carrying positions.
- Dynamic load test: This test assesses the durability of the sling and proper functioning of its fasteners by dropping a weighted bag (35 lbs. [15.9 kg], 6 to 8 inches [150 to 200 mm] in diameter) from 1-inch above the sling's support area every 4 seconds for 1,000 cycles. If the sling has more than one carrying position, the cycles are divided among the different carrying positions, with a minimum of 350 cycles per position.

For both the static and dynamic tests, the sling is fastened to a test torso, as directed in the instruction manual accompanying the sling. At test conclusion, there shall be no seam separation, breakage, or disengagement of attachment systems, or any hazardous condition. Adjustable attachment systems of the sling carrier shall not slip more than 1-inch.

• Occupant retention test: This test assesses whether the sling retains the occupant while the caregiver is moving about and also functions as an additional durability test. A test mass (a bag filled with sand, 20 or 35 lbs. [9.9 or 15.9 kg], depending on the manufacturer's weight limit) is placed in the sling. The test torso will move up and down 4.75 inches (12 cm) at a rate of two times per second (2 Hz). After 100 cycles, no adjustable attachment systems shall slip more than 1 inch. After 1,000 cycles, the attachment system and restraint system (if applicable) shall not be released. If the sling has more than one carrying position, the cycles are divided among the different carrying positions, with a minimum of 350 cycles per position.

• Restraint system test: The test assesses whether any child restraints used by the sling are sufficient. The sling is secured to a horizontal test plane. A force of 45 lbs. (200 N) is applied to a single attachment point of the restraint system in the normal use direction, and maintained for 10 seconds, and repeated five times. A standard CAMI, Mark II 6-month infant dummy is placed in the carrier with the restraint system adjusted according to the manufacturer's instructions. A force of 45 lbs. (200 N) is applied horizontally on the centerline of one of the dummy's leg, by the ankle, held for 10 seconds, and repeated five times. The anchorages for the restraint system shall not separate from their attachment points after testing.

# II. ADEQUACY OF THE CURRENT ASTM F2907-14a REQUIREMENTS

This section discusses how each hazard pattern relates to the current voluntary standard; F2907-14a. LSM staff believes that F2907-14a addresses many of the general hazards associated with durable nursery products, such as lead in paints, sharp edges/sharp points, and small parts. F2907-14a also includes specific requirements for restraint systems.

#### Hazard Pattern 1- Positioning

Thirty-one of the 122 reported incidents (25 percent) were in this category. Among them were nine deaths due to smothering, one injury resulting in permanent brain impairment due to breathing difficulty, and two injuries, one related to breathing difficulty and the other related to blood circulation in the infant's leg. The rest of the incidents reported breathing problems suffered by the infant in the carrier or difficulty in positioning the infant in the sling carrier in a manner that would avoid the potential for suffocation. The current version of ASTM F2907 includes requirements for marking and labeling and instructional literature to warn consumers of the dangers of suffocation due to improper positioning. This is discussed in the Human Factors technical memorandum (see Tab C). Currently, no technically feasible method exists to test for this most prevalent hazard pattern. However, staff will continue to monitor hazard patterns and recommend future changes, if necessary or appropriate.

#### *Hazard pattern 2 - Caregiver missteps*

Twenty of the 28 incidents in this category occurred when the caregiver slipped, tripped, or bent over, causing the infant in the sling to fall with the caregiver or fall out of the carrier. F2907 addresses this hazard pattern in two ways: labeling and the occupant retention test. Labeling is addressed in the HF technical memorandum (see Tab C).

The occupant retention test addresses fall hazards resulting from attachment and restraint system slippage and release. While this test does not directly address caregiver missteps, a child in a well-secured sling carrier will fare better during a caregiver's fall than a child in a poorly secured

<sup>27</sup> CAMI, Mark II 6-month infant dummy represents a 50<sup>th</sup> percentile, 6-month-old infant, with a weight of approximately 17 pounds, and a sitting height of approximately 17.5 inches, in accordance with FMVSS No. 213 Standard, specified in 49 C.F.R., part 572, Subpart D.

carrier. Additionally, during occupant retention testing, when the test mass falls out of the sling, the result is considered a failure.

The remaining eight incidents in this hazard pattern occurred when caregivers were hit by a door or the caregiver bumped into a wall.

#### *Hazard Pattern 4 – Buckles*

Twelve of the incidents involved buckles releasing, slipping, or breaking. Incidents included one hospitalization for a skull fracture and two non-hospitalized injuries. No fatalities were reported in this category. ASTM F2907 addresses this hazard in several ways, using the static, dynamic, occupant retention, and restraint system tests.

During the static load test, a load of three times the manufacturer's maximum recommended weight is applied to the sling carrier for one minute. This load would be borne by the sling fabric, load bearing straps and buckles or other fasteners. A factor of safety of three is typical for many similar load bearing durable children's products. Staff tested 14 slings currently on the market and all passed the static load test.

The dynamic and occupant retention test both subject the test sling to 1,000 cycles of cyclic loading. These tests not only test the fasteners' durability but also their ability to resist slippage. Four of the fourteen samples tested failed the dynamic test, all due to fasteners slipping more than 1 inch. Six of the fourteen (including the four that failed the dynamic test) samples tested in the occupant retention also allowed its fastener to slip more than 1 inch. These types of failures are not catastrophic but gradual, so a caregiver should be able to notice the slippage and adjust the product accordingly.

The restraint system test in F2907-14a tests fasteners in sling carrier restraint systems. The restraint systems in slings are used to secure the occupant in one of the manufacturer's recommended carrying positions. These systems are not load bearing, and only two of the 14 samples tested even had restraint systems. One of the two failed because it allowed the waist restraint to be used without the mandatory use of the crotch restraint, not because of a fastener failure.

Staff believes that these performance tests adequately address hazards resulting from fastener failure.

# *Hazard Pattern 5 – Miscellaneous product-related issues*

The nine incidents included under "miscellaneous product-related issues" did not have enough information to place them clearly in another category, but the incidents included reports of a design flaw posing a strangulation hazard, a broken component, fabric shrinkage, rough fabric or a sharp surface, a small part being liberated, or the scenarios indicated an unspecified product failure. Many of these hazards, such as small parts and sharp edges, are covered by "general hazards" section 5, of ASTM F2907. In addition, the reports that indicated the child fell because the sling "broke" or "opened up," without additional detail, most likely would be addressed by the dynamic and occupant retention tests.

Hazard Patterns 3 and 6 – Unspecified issues and consumer comments

This category of hazard patterns included 25 reported incidents (20 percent), including seven fatalities, two hospitalized injuries, and 13 non-hospitalized injuries, with very little information available on the circumstances leading up to the incidents. Seventeen reports (14 percent) consisted of consumer complaints about recalled sling carriers being sold by retailers or observing perceived safety hazards related to the product. At this time, insufficient information exists on the "Unspecified" and "Consumer Comments" hazard patterns to enable staff to recommend performance changes to the existing voluntary standard.

#### III. OTHER STANDARDS

LSM staff compared the performance requirements of ASTM F2907-14a to the performance requirements of other standards. LSM staff found one international standard, British Standard EN13209 *Child Use and Care Articles – Baby Carriers – Safety Requirements and Test Methods – Part 2: Soft Carrier*, which for a similar product category; however, BS EN13209 specifically states that it is intended for a "product [that] has holes designed to accommodate the child's legs." Therefore, BS EN13209 is not applicable to sling carriers. Some individual requirements in the BS EN13209 standard are more stringent than F2907-14a. BS EN13209 includes requirements for surface chemicals (besides lead), cords/ribbons, graspable components, filling material and packaging film. However, because BS EN13209 specifically excludes products, such as sling carriers, from its bounded leg opening requirement, and we do not have incidents to suggest that these are prevalent hazard patterns, staff does not believe incorporating these more stringent requirements would appreciably increase safety in slings.

For the reasons described previously, staff believes that the current ASTM F2907-14a standard is the appropriate standard to address the incident hazards because there are no other standards that apply to this product.

T A B

# **TAB C:** Human Factors Assessment of ASTM F2907 Requirements for Sling Carriers (CPSIA Section 104)



**MEMORANDUM** 

DATE: April 15, 2014

To: Hope E. J. Nesteruk, Project Manager, Sling Carriers Rulemaking

Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Bonnie B. Novak, Director,

Division of Human Factors, Directorate for Engineering Sciences

FROM: Timothy P. Smith, Senior Human Factors Engineer,

Division of Human Factors, Directorate for Engineering Sciences

SUBJECT: Human Factors Assessment of ASTM F2907 Requirements for Sling Carriers

(CPSIA Section 104)

#### **BACKGROUND**

Section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA), commonly known as the Danny Keysar Child Product Safety Notification Act, requires the U.S. Consumer Product Safety Commission (CPSC or Commission) to promulgate consumer product safety standards for durable infant or toddler products. These standards must be "substantially the same as" applicable voluntary standards or more stringent than such standards if the Commission determines that more stringent standards would further reduce the risk of injury associated with these products. Section 104(f) of the CPSIA defines a "durable infant or toddler product" as a durable product intended for use by, or that may be reasonably expected to be used by, children younger than 5 years old, and includes sling carriers. <sup>1</sup>

The ASTM International<sup>2</sup> (ASTM) voluntary standard ASTM F2907, *Consumer Safety Specification for Sling Carriers*, establishes requirements for sling carriers. ASTM developed this voluntary standard in response to incident data supplied by CPSC staff. The voluntary standard is intended to minimize the hazards associated with sling carriers from the reasonably foreseeable use and misuse of these products. This standard was first published in 2012, and the most current, approved version of the voluntary standard is ASTM F2907 – 14a. Section 8 of the voluntary standard specifies marking and labeling requirements, which include warning statements that must appear on each sling. Section 9 specifies the instructional literature that must be provided with the sling. This memorandum, prepared by staff of the CPSC Division of Human Factors (HF), assesses the adequacy of these sections of ASTM F2907 – 14a in addressing the risk of injuries and deaths associated with the use of sling carriers. This

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<sup>&</sup>lt;sup>1</sup> See, for example, 16 C.F.R. part 1130, *Requirements for Consumer Registration of Durable Infant or Toddler Products*, which includes sling carriers among those products considered a durable infant or toddler product (16 C.F.R. § 1130.2(a)(18)).

<sup>&</sup>lt;sup>2</sup> Formerly known as the American Society for Testing and Materials.

memorandum also discusses the likelihood of consumers reusing sling carriers for multiple children.

#### DISCUSSION

ASTM F2907 – 14a defines a "sling carrier" as "a product of fabric or sewn fabric construction, which is designed to contain a child in an upright or reclined position while being supported by the caregiver's torso" (Section 1.3). These products generally are intended for children starting at full-term birth until a weight of about 35 pounds (15.9 kg). The designs of slings vary, but they generally range from unstructured hammock-shaped products that suspend from the caregiver's body, to long lengths of material or fabric that are wrapped around the caregiver's body. Slings normally are worn with the infant positioned on the front, hip, or back of the caregiver, and facing toward or away from the caregiver. Additionally, as stated in the "sling carrier" definition, slings generally allow the infant to be placed in an upright or reclined position. However, the reclined position is intended to be used only when the infant is worn on the front of the consumer. The ability to carry an infant in a reclined position is the primary feature that distinguishes sling carriers from soft infant and toddler carriers.<sup>3</sup>

#### HAZARD PATTERNS FOR SLING CARRIERS

Staff of the CPSC Division of Hazard Analysis, Directorate for Epidemiology (EPHA), identified 122 incidents associated with sling carriers from January 1, 2003 through October 27, 2013 (Chowdhury, 2013; see Tab A). Of these incidents, 16 resulted in a fatality and 54 resulted in injury. Ninety-one of the 122 incident reports included the victim's age, and in all but one of these cases, the victim was 12 months old or younger. Most of the victims were younger than 4 months old.

EPHA staff identified six general hazard patterns associated with sling carriers. Two of these hazard patterns were: (1) undetermined or unspecified causes, and (2) consumer comments or complaints of perceived safety hazards that did not involve an actual incident. The four remaining hazard patterns were the following:

• Infant positioning problems: Problems with the positioning of the infant in the sling was the most common hazard pattern, accounting for 31 (25 percent) of the 122 available incidents and 9 of the 16 fatalities. This pattern primarily involved cases in which the position of the infant in the sling led to breathing problems, resulted in suffocation, or was believed to place the infant at risk of suffocation. These at-risk positions included positions that might pose a risk of mechanical asphyxia (e.g., with the infant's face against the caregiver's body or the sling fabric) or positional asphyxia (i.e., with the chin on or near the infant's chest). Some incidents occurred after the infant had been nursing in the sling, and some incidents involved complaints of difficulties keeping the infant positioned in the sling so that the infant was visible and not covered by the sling fabric.

<sup>&</sup>lt;sup>3</sup> Soft infant and toddler carriers only carry children in an upright position and are covered under ASTM F2236, *Standard Consumer Safety Specification for Soft Infant and Toddler Carriers*.

<sup>&</sup>lt;sup>4</sup> The single outlier was reported to be 3 years old.

- Caregiver missteps: Caregiver "missteps" accounted for 28 (23 percent) of the reported incidents. The majority of these incidents (16) involved cases of the caregiver tripping, alipping, or otherwise falling while wearing the infant in the carrier. Another four incidents involved the infant falling from the sling as a result of the caregiver bending over, and two incidents involved the infant falling from the sling while being put into or removed from the sling. Six incidents involved the caregiver failing to provide enough clearance for the worn infant, such as cases in which the infant was struck by a door or was struck against a wall while being worn.
- Buckle and hardware problems: Twelve (10 percent) of the reported incidents involved a buckle or similar hardware (e.g., a ring on a ring sling) breaking, bending, failing to breaking or bending, and six cases involved the sling material slipping through or loosening at the site of the hardware. Two of these latter cases appear to have been caused by the hardware (in these cases, rings) bending.
- Miscellaneous product-related issues: Nine (7 percent) of the reported incidents involved other product-related issues that did not fall neatly into one of the other categories. Two of these incidents involved the sling apparently opening up and allowing the infant to fall, and one involved the sling breaking in some unspecified way, causing the infant to fall.

# CURRENT ASTM WARNING AND INSTRUCTIONAL REQUIREMENTS

Section 8 of ASTM F2907 – 14a specifies marking and labeling requirements for sling carriers, and Section 8.3 specifies the warnings that must appear on each sling. In short, all sling carriers must include a safety alert symbol  $(\triangle)$  and the signal word "WARNING," must warn that failure to follow the manufacturer's instructions can result in "death or serious injury," must state the minimum and maximum recommended weights for the sling, and must warn about the potential suffocation and fall hazards associated with sling carriers.

More specifically, according to ASTM F2907 -14a, the warnings that pertain to suffocation must address

- the risk of suffocation to infants younger than 4 months if the infant's face is pressed against the caregiver's body, and the increased risk to infants born prematurely or with respiratory problems;
- the need to check often to make sure the infant's face remains uncovered, clearly visible to the caregiver, and away from the caregiver's body at all times;

- the importance of making sure that the infant does not curl into a position with the chin resting on or near the infant's chest, which can interfere with breathing even when nothing is covering the nose or mouth;<sup>5</sup>
- the need to reposition the infant after nursing so that the infant's face is not pressed against the caregiver's body; and
- the importance of never using the sling with infants smaller than 8 pounds, without seeking the advice of a healthcare professional.

The warnings that pertain to the fall hazard must alert consumers to the risk of infant falls due to the caregiver leaning, bending over, or tripping while wearing the product and must instruct caregivers to keep one hand on the infant while moving. Lastly, the warning label must include a pictogram that illustrates proper and improper infant positioning within the sling. The voluntary standard includes an example of the type of pictogram sought but does not specify a particular design.

Section 9 of the ASTM standard specifies the instructional literature that must be provided with the sling. This section requires that the instructions contain an image of each manufacturer's recommended carrying position, include all of the warning statements that are required to appear on the sling, and provide several additional instructions. A detailed list of the additional instructions that must be addressed can be found in Section 9.3 of the voluntary standard.

#### HF STAFF ASSESSMENT OF WARNING AND INSTRUCTIONAL REQUIREMENTS

Warnings literature and guidelines generally suggest that on-product warnings include four textual components: (1) a signal word, such as "WARNING," to indicate the seriousness of the hazards; <sup>6</sup> (2) a hazard statement that specifies the nature of the hazard; (3) a description of the consequence of exposure to the hazard; and (4) instructions regarding appropriate hazard-avoidance behaviors (Wogalter & Laughery, 2005). Overall, HF staff believes that the current ASTM F2907 warning and instructional requirements adequately address these warning elements, and staff does not believe that revisions to these requirements are necessary for the proposed rule. HF staff worked extensively with the ASTM Subcommittee on Sling Carriers to improve these requirements from the original 2012 version of the voluntary standard so that the requirements clearly address the primary sling hazards that the performance requirements could not address.

As noted earlier, the primary hazard associated with sling carriers concerns infant positioning and the risk of suffocation. The required warnings place particular emphasis on the suffocation hazard to infants younger than 4 months old and the increased risk to those born prematurely or with respiratory problems. Moreover, the suffocation warning emphasizes the importance of checking often to make sure the infant's face is uncovered, clearly visible, and away from the

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<sup>&</sup>lt;sup>5</sup> Commonly referred to as positional asphyxia.

<sup>&</sup>lt;sup>6</sup> For hazards involving the potential for personal injury, a safety alert symbol typically precedes the signal word.

caregiver's body. The incident data revealed that some suffocation fatalities occurred soon after the infant had been nursing in the sling. Thus, language was added to the suffocation warning about the importance of repositioning the infant after feeding so that the infant's face is not pressed against the caregiver's body. To reinforce and clarify the warning text about infant positioning, manufacturers must include a pictogram in the warning label that illustrates proper and improper infant positioning within the sling. Given the substantial variability among sling carrier designs, however, staff doubts that a single, generic positioning pictogram can be created and applied to all sling carriers. Thus, HF staff agrees with limiting the pictogram requirement to not specify a particular design beyond stating that the pictogram must compare proper infant positioning with improper infant positioning.

The warnings describe the fall hazard for infants associated with the common hazard pattern of "caregiver missteps," such as tripping or bending over, and explicitly instruct caregivers to keep one hand on the infant at all times while moving. In addition, this warning might partially address the three "miscellaneous" incidents in which the infant fell from the sling when the sling apparently broke or opened up unexpectedly. Lastly, HF staff worked with the ASTM Subcommittee to require that each sling and its retail package be labeled permanently with the manufacturer's minimum- and maximum-recommended weight.<sup>8</sup>

The primary addition to the instructional requirements since the 2012 version of the voluntary standard was an instruction emphasizing the importance of checking that all knots, buckles, snaps, straps, and adjustments are secure. As noted earlier, six incidents involved the sling material loosening at the hardware. An additional incident involved a buckle suddenly releasing during use. Although staff of the CPSC's Division of Mechanical Engineering, Directorate for Laboratory Sciences (LSM) believes that the ASTM F2907 performance requirements adequately address these and other incidents of buckle failure (Sanborn, 2014; see Tab B), these requirements assume that the hardware has been adjusted and secured properly before use. Thus, HF staff worked with the Subcommittee to add an instructional requirement that tells consumers to check that all knots, buckles, and other hardware used to secure and adjust the sling are secure. Staff believes that this requirement also might address the two "miscellaneous" incidents in which the infant fell after the sling opened up unexpectedly.

#### FEASIBILITY OF PERFORMANCE REQUIREMENTS FOR INFANT POSITIONING

As noted earlier, problems with the positioning of the infant in the sling was the most common hazard pattern and accounted for the majority of fatalities with sling carriers. Thus, HF and other CPSC staff attempted to develop possible performance tests or requirements that could address the infant positioning hazard. In addition, CPSC staff held an ASTM task group meeting at the CPSC to discuss possible performance-based solutions.

<sup>8</sup> In the original standard, the warnings instructed consumers to: "Follow the manufacturer's recommended weight range." However, neither the product, nor its retail package, was required to include the specific weight range.

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<sup>&</sup>lt;sup>7</sup> In addition, research suggests that safety symbols and graphics can increase the noticeability of a warning (Wogalter, Silver, Leonard, & Zaikina, 2006; Wogalter & Vigilante, 2006).

One possibility staff developed and considered was a "face exposure" test to assess the extent to which an infant's face would remain uncovered and visible to the caregiver when the infant is in the sling, thereby enabling the caregiver to see an infant who is in distress. The envisioned performance test involved the use of a cylindrical probe, a newborn CAMI dummy, the sling to be tested, and the test torso specified in the voluntary standard. The sling would be fastened to the test torso as directed in the product instructions, and the CAMI would be positioned within the sling in a manufacturer's recommended carrying position. The cylindrical probe would represent the sight line of the caregiver, and its cross-section would approximate the facial dimensions of a newborn infant. The probe would be directed toward the face of the newborn CAMI, along the likely line-of-sight of the caregiver, and any contact between the probe and the sling material would constitute a failure.

The ability to assess reliably whether an infant might be clearly visible in a sling, however, depends on the extent to which the mannequin or dummy truly represents how the infant would be positioned within the sling. Staff found it very difficult to position the CAMI realistically within the slings because the joints of the CAMI were not designed to mimic accurately the movements or range of motion of a real infant. For example, an infant will tend to curl its legs in front of the infant's torso when carried in a sling; yet the legs of a CAMI are very inflexible, thereby preventing one from positioning the CAMI within the sling in a way that reflects the real-life position of an infant. Staff is not aware of any readily available newborn-representative mannequins or dummies with realistic ranges of motion that could be used as a substitute for the CAMI in such testing. In addition, there is substantial variability among sling carrier designs, and certain products offer an enormous degree of adjustability that makes a repeatable test for face exposure highly challenging. <sup>10</sup>

Ultimately, staff has concluded that warning about proper and improper infant positioning is the only feasible hazard-mitigation strategy at this time. Staff will continue to consider possible performance requirements concerning this issue. If additional or revised infant-positioning performance requirements become feasible, staff can pursue such requirements with the ASTM Subcommittee in the future.

# FORESEEABLE REUSE OF SLING CARRIERS

As noted earlier, ASTM F2907 – 14a states that sling carriers generally are intended for children starting at full-term birth until a weight of about 35 pounds (15.9 kg). <sup>11</sup> According to the data tables used to produce the 2000 Centers for Disease Control and Prevention (CDC) U.S. growth charts, the median (50<sup>th</sup> percentile) weight of a child does not exceed 35 pounds until about 46

<sup>&</sup>lt;sup>9</sup> The test torso is specified in Section 7.1.1 and Figure 2 of ASTM F2907 – 14a.

<sup>&</sup>lt;sup>10</sup> Sling carriers that consist solely of a long length of material that must be tied or knotted, commonly referred to as "wraps," can be wrapped and tied around the caregiver's body in myriad ways, and even small adjustments could make the same sling switch from passing the requirement to failing the requirement. Moreover, staff found that the same sling could be made to pass or fail, depending on how the sling was positioned on and fitted to the test torso. <sup>11</sup> Furthermore, the dynamic load test of the voluntary standard (see sections 6.1.2 and 7.2 of ASTM F2907 – 14a) uses a 35-pound weight to test for structural integrity. Thus, the voluntary standard recognizes that children weighing up to 35 pounds may be carried in a sling carrier.

months for boys and 49 months for girls (CDC, 2000). Moreover, the 5<sup>th</sup> percentile bodyweight of a child does not exceed 35 pounds until about 65 months for boys and 69 months for girls. This means that more than half of all 3-year-olds are likely to be at or below the maximum weight of 35 pounds, and that even some 5-year-olds are likely to be at or below this upper weight limit. Although HF staff believes that sling carriers are most likely to be used with infants, it seems reasonably foreseeable that some portion of the user population will use these carriers with preschool-aged children.

In addition, evidence suggests that sling carriers are often reused for multiple children. For example, according to the 2006 Baby Products Tracking Study, as reported by staff of CPSC's Directorate for Economic Analysis (EC), nearly one-third (31 percent) of mothers who own slings had a sling that was handed down or purchased secondhand (Aiken, 2014; see Tab G). EC staff also reported that preliminary data from CPSC's Durable Nursery Products Exposure Survey found that 21 percent of sling owners acquired the sling used. The Survey also found that after the owner discontinued use of the sling, only 4 percent threw away the sling; 96 percent of owners stored the sling for future use, sold the sling, gave the sling away, or returned the sling to the original owner. These results suggest that most sling owners at least perceive sling carriers to have a future useful life, even if the sling had been used previously. Furthermore, staff is aware of several online websites, forums, and "babywearing" 121 groups dedicated to buying, selling, and trading previously used sling carriers. For example, a simple search of sold listings for a used "baby sling" on eBay resulted in more than 1,700 listings during a roughly 3-month period. 13 Although some of the products in these ads do not meet the definition of a "sling carrier," a brief examination of the most recent 200 sales suggests that a very large percentage of these products would be considered a sling carrier. Thus, many consumers appear to be purchasing slings secondhand, presumably for use.

#### **CONCLUSIONS**

HF staff believes that the current ASTM F2907 marking, labeling, and instructional requirements are reasonable and does not believe that revisions to these requirements are necessary for the proposed rule. Staff will continue to consider possible performance tests or requirements to address infant positioning and visibility and can pursue this strategy further with the ASTM Sling Carriers Subcommittee if such a strategy becomes feasible.

Staff also believes that it is reasonably foreseeable that consumers will reuse sling carriers with multiple children. In addition, slings generally are intended for children from birth until a weight of 35 pounds, and children do not reach this upper weight limit until they are at least 3 years old, on average. Thus, some consumers—albeit a small number—are likely to use slings with children 3 years old and older.

<sup>&</sup>lt;sup>12</sup> "Babywearing" is commonly used to describe the wearing or carrying of a baby in a sling or similar carrier. <sup>13</sup> A search using the phrase "baby sling" was completed at 15:05 on April 15, 2014, with the results filtered to include only items in "used" condition and to show only "sold listings." The search resulted in 1,745 listings dated January 15, 2014 (12:49) to April 14, 2014 (21:38).

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TAB D: Health Sciences staff review of the mechanisms of injury and death associated with sling carriers.

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#### Memorandum

Date: March 27, 2014

TO: Hope E. J. Nesteruk, Project Manager, Sling Carriers Rulemaking

Division of Human Factors, Directorate for Engineering Sciences

THROUGH: Mary Ann Danello, Ph.D., Associate Executive Director

Directorate for Health Sciences

Jacqueline Ferrante, Ph.D., Director

Division of Pharmacology and Physiology Assessment

FROM : Suad Wanna-Nakamura, Ph.D. Physiologist

Division of Pharmacology and Physiology Assessment

SUBJECT: Health Sciences staff review of the mechanisms of injury and death associated

with sling carriers.

#### INTRODUCTION

The Danny Keysar Child Product Safety Notification Act (Section 104(b) of the Consumer Product Safety Improvement Act or CPSIA) <sup>41</sup> directs 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. The Act also requires that these standards be substantially the same as 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.

A sling carrier is a type of infant carrier. Infant carriers are specifically identified as a durable infant or toddler product in section 104(f) of the CPSIA. The ASTM standard for sling carriers defines a "sling carrier" as a "product of fabric or sewn fabric construction, which is designed to contain a child, in an upright or reclined position while being supported by the caregiver's torso" (F2907-14a, ASTM standard). This memorandum reviews the mechanisms and severity of injuries associated with sling carrier incidents from January 1, 2003 through October 27, 2013.

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<sup>&</sup>lt;sup>41</sup> CPSIA, Pub Law 110-314) was enacted on August 14, 2008. Section 104(b) of the CPSIA. http://www.cpsc.gov//PageFiles/113865/cpsia.pdf.

#### ANALYSIS OF INJURIES AND DEATHS

CPSC staff received 122 reports of incidents related to sling carriers during a10-year period (January 1, 2003 through October 27, 2013). Of those, 16 were fatalities and 106 were injuries. About half of the injuries (54/106) that were reported as hospitalizations were fall related. The severity of injury ranged from serious head injuries (skull fractures and brain hemorrhage) to minor soft tissue injuries (contusions, lacerations and abrasions). The injuries also included closed-head injuries (CHI), which are commonly caused by falls and direct head impact with an object. CHIs are types of traumatic head injuries in which the skull is not penetrated and the dura mater (a sac like membrane that covers the brain) remains intact, making these injuries more difficult to detect because the injury is not visible. The severity of CHI injuries can range from minor to severe. Trauma to the brain in a closed-head injury can be very serious if it results in brain swelling. When there is no place to expand within an intact skull, the brain cells can generate extreme pressure within the skull, causing various neurological complications, affecting verbal learning and memory function for at a least 1 year after the injury and persistent residual memory deficit in adolescence (Levin et. al., 1988). The remaining 52 incidents reported that no injury had occurred or did not report an injury. Most of the falls were due to the caregiver tripping, slipping and falling, or bending while carrying the infant in the sling (Chowdhury, 2014). The injury potential of any fall is dependent upon several factors, including height of the fall, nature of the impact surface, and orientation of the body at impact (Chalmers and Langley 1996; MacKay, 2003). The orientation of the body at impact is one of the most important factors in determining the type and severity of injury (Snyder et al., 1977).

In nine of the 16 fatal incidents, the cause of death was classified by the medical examiner as "suffocation," "positional asphyxia," or "smothering." In the remaining seven incidents, the cause of death was listed as "undetermined." Suffocation deaths cannot be determined by autopsy alone because there are no specific physiological markers. A thorough investigation of the circumstances leading to the death, as well as the exclusion of other causes, is necessary. When the details surrounding the death are limited, the medical examiner is likely to list the cause of death as "undetermined."

With the exception of a 5-month-old infant, the age range of the 15 remaining fatal victims was from birth to 3 months; 11 infants were ages 1 month and younger, and the remaining four were 3 months old. Infants younger than 4 months old are at high risk of suffocation because they have relatively immature physiological systems controlling breathing and arousal. Limited physical and developmental capabilities of these infants render them susceptible to dangers from suffocation in certain settings. Young infants are unlikely to have developed the arousal and cardiovascular control mechanisms that would wake them in life-threatening circumstances. As such, a very young sleeping infant is unable to arouse itself when air supply to the lungs is compromised (Blair *et al.*, 2006; Kattwinkel et al., 2000; Nakamura et al., 1999; and Wanna-Nakamura, 2008, 2010).

HS staff has identified mechanical suffocation/asphyxia as a risk associated with sling carriers. Asphyxia via smothering is caused by mechanical obstruction or occlusion of the airways (DiMaio, 2001; Gordon and Shapiro, 1982; and Azmack, 2006). The physiological sequence of

events that follows smothering is a decrease in heart rate, followed by gasps that eventually lead to cessation of breathing. In infants, a decrease in heart rate can occur within 30 seconds after the airways are blocked (Rosen et al., 1984). Suffocation can occur when babies are contained entirely within the pouch of a sling. Infants who are placed with their heads below the rim of the sling are likely to stay in the same position because they are surrounded by unyielding fabric under the tension of their weight and are tightly confined within the product, typically with their faces directed towards or held against the parent's body. The highest risk of suffocation occurs when the infant's face (nose and mouth) is pressed against the mother's body, blocking its breathing, and rapidly suffocating the baby within a few minutes.

Furthermore, HS believes that there is also concern that sling-type carriers can cause infants who are placed with their head below the rim of the sling to assume a curled posture. This position can cause acute neck hyperflexion (chin touching the chest). Infants found in this compromised position are likely to stay in this position because they are tightly enclosed within the product, and their neck muscles are too weak to support the weight of the head. Infants who stay for prolonged periods of time in this position can experience compromised airflow to the lungs (Bass and Bull, 2009), resulting in an inadequate supply of oxygen to the brain. Oxygen deprivation to the brain can lead to loss of consciousness and death.

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TAB E: Durable Nursery Products: Summary of Sling
Carriers Product Safety Recalls and Associated Injuries
from January 1, 2003 to October 27, 2013



#### Memorandum

Date: January 15, 2014

TO : Hope Nesteruk, Sling Carriers Project Manager

Division of Human Factors, Directorate of Engineering

THROUGH: Ray M. Aragon, Assistant Executive Director, EXC

Mary F. Toro, Director of Regulatory Enforcement, CRE

Troy Whitfield, Lead Compliance Officer, Mechanical Hazards Team

FROM : Julio Alvarado, Compliance Officer, Mechanical Hazards Team

SUBJECT: Durable Nursery Products: Summary of Sling Carriers Product Safety Recalls

and Associated Injuries from January 1, 2003 to October 27, 2013

# **Purpose**

This memorandum provides compliance information relevant to the drafting of a safety standard for sling carriers. Section 104 of the Consumer Product Safety Improvement Act of 2008, Public Law No. 110-314, 122 Stat. 3016 (August 14, 2008) (CPSIA), also known as the Danny Keysar Child Product Safety Notification Act, requires the Commission to assess voluntary safety standards for infant and toddler products and develop mandatory standards that are substantially the same as, or more stringent than, the voluntary standard. CPSC staff is drafting a proposed rule for a sling carrier standard for Commission consideration. The proposed rule addresses the hazards associated with sling carriers through performance requirements focusing on positioning, improvements in restraint systems, and enhancements to the clarity and effectiveness of warning labels. This memorandum summarizes the product safety recalls conducted by the Office of Compliance and Field Operations (Compliance) and the reported injuries involving sling carriers.

# **Compliance Investigation Information**

Compliance staff reviewed the recalls and informative press releases on sling carriers dated January 1, 2003 to October 27, 2013. <sup>42</sup> During that time, there have been a total of five consumer-level recalls and two informative press releases involving about 1.1 million sling carriers.

CPSC Hotline: 1-800-638-CPSC(2772) ★ CPSC Web Site: http://www.cpsc.gov

<sup>&</sup>lt;sup>42</sup> January 1 2003 to October 27. 2013 was selected to align with the incident data search (tab A).

On August 23, 2005, a recall conducted by ZoloWear, Inc., involved about 165 ZoloWear Infant Carriers/Slings, sold from May 2005 through August 2005. The stitching that attaches the webbing to the carrier/sling can break and pose a fall hazard, potentially injuring the infant. One incident was reported to ZoloWear and CPSC, in which the webbing from the carrier/sling started to come apart, but the infant was not in the sling at the time. Consumers were to call ZoloWear, Inc., for instructions on having the carriers/slings repaired.

A recall conducted by Infantino, LLC, on March 22, 2007, involved about 100,000 SlingRider Infant Carriers sold from July 2006 through February 2007. The plastic slider that adjusts the strap could break, causing the strap supporting the carrier to release, posing a fall hazard for the infant. Infantino received 10 reports of the plastic sliders breaking and asked consumers to stop using the sling carriers. Consumers were instructed to contact Infantino to return the carriers and receive a free replacement product.

A recall conducted by Ellaroo, LLC, on March 11, 2008, involved about 1,200 Ellaroo Ring Sling Baby Carriers that were sold from June 2007 through February 2008. The recall involved the sling carrier aluminum rings' ability to bend or break, which can cause the sling to slide through the ring and pose a fall hazard to the infant. The aluminum rings are designed to be positioned in front of the parent or caregiver's body, supporting the child from one of the shoulders. There were four incidents reported to Ellaroo, which included the rings bending and two incidents of rings breaking. Consumers were instructed to contact Ellaroo for instructions on returning the sling carriers for a repair or replacement Ring Sling.

On March 12, 2010, CPSC announced an informational press release, advising parents and caregivers to be cautious when using infant sling carriers. CPSC had identified and investigated at least 14 deaths <sup>43</sup> associated with sling carriers. The press release explained the two types of suffocations associated with sling carriers. The sling's fabric can press against an infant's nose and mouth, blocking the child's ability to breathe. Additionally the nonstructured design of the sling can keep the infant in a curled position, bending the chin toward the chest, restricting the airways, and limiting the oxygen supply. CPSC recommended that parents and caregivers make sure that the infant's face is not covered or blocked while in the sling and is clear from the sling and the parent's or caregiver's body. In addition, CPSC urged parents of preemies, twins, babies in fragile health, and babies with low weight to use extra care and consult their pediatricians about using slings.

On March 24, 2010, Infantino announced a second recall after receiving three reports of deaths in 2009, due to suffocation. Infantino instituted a replacement program that affected 1 million infant slings sold in the United States from January 2003 through March 2010. The announcement encouraged consumers to stop using their sling carrier immediately and to contact Infantino to receive one of three replacement products and a baby rattle. A recall alert released on March 6, 2012, informed consumers of the recalled SlingRider Sling and Wendy Bellissimo models being resold in error after the recall date, in violation of applicable law.

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<sup>&</sup>lt;sup>43</sup> 12 of these 14 deaths are included in the incident data in Tab A. The remaining 2 incidents occurred outside the timeframe of the analysis in Tab A, but within the 20-year time frame referenced in the press release.

On June 2, 2010, Sprout Stuff conducted a recall of about 40 Sprout Stuff Infant Ring Slings. Sprout Stuff Infant Ring Slings were sold directly to consumers from October 2006 to May 2007. Sprout Stuff and CPSC learned of one death that occurred in 2007, when a 10-day-old boy suffocated. Consumers were instructed to contact Sprout Stuff to return the sling carriers for a full refund.

On November 19, 2010, CPSC announced an informational press release for new parents about safe baby wearing. After reviewing numerous cases, CPSC recommended that parents with infants who were younger than 4 months old, premature, of low-birth weight, or with colds and respiratory problems to take extra care in using a sling carrier. In addition, the document provided guidance for positioning the infant within the sling carrier.

# TAB F: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed Standard for Sling Carriers

T A B

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#### Memorandum

Date: April 17, 2014

TO: Hope Nesteruk

Project Manager, Sling Carriers 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 : William W. Zamula

**Economist** 

Directorate for Economic Analysis

SUBJECT: Initial Regulatory Flexibility Analysis of Staff-Recommended Proposed

Standard for Sling Carriers

#### Introduction

On August 14, 2008, the Consumer Product Safety Improvement Act (CPSIA) was enacted. Among its provisions, section 104, the Danny Keysar Child Product Safety Notification Act, requires that the U.S. Consumer Product Safety Commission (CPSC) evaluate the existing voluntary standards for durable infant or toddler products and promulgate a mandatory standard substantially the same as, or more stringent than, the applicable voluntary standard. Upon review, CPSC staff recommends that the Commission adopt the voluntary ASTM International (or ASTM, formerly known as the American Society for Testing and Materials) standard for sling carriers (F2907–14a), *Standard Consumer Safety Specification for Sling Carriers*, with no modifications.

The Regulatory Flexibility Act (RFA) requires that proposed rules be reviewed for their potential economic impact on small entities, including small businesses. Section 603 of the RFA requires that CPSC staff prepare an initial regulatory flexibility analysis (IRFA) and make it available to

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the public for comment when the general notice of proposed rulemaking is published. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives that may reduce the impact. Specifically, the IRFA must contain:

- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
- identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

#### The Product

As specified in the current ASTM standard (F2907-14a), a sling carrier is a product, normally of sewn fabric construction, that is designed to contain an infant/toddler in an upright or reclined position, while being supported by the caregiver's torso. These products are intended for infants and toddlers between full-term birth (with a weight of about 8 lbs.) and 35 lbs. The principal difference between a sling carrier and a soft infant and toddler carrier (SITC) is that a SITC is not intended to contain an infant or toddler in a reclined position. Products that fall under the sling carrier standard may be called slings, wraps, infant carriers, or pouches.

# **The Market for Sling Carriers**

CPSC staff has identified 47 suppliers to the U.S. market, 44 but there may be hundreds more suppliers that produce small quantities of slings. Websites such as Etsy show thousands of listings for artisans producing slings and wraps (although each firm may have multiple listings), which accounts for additional suppliers who are not among the 47 suppliers identified. Sling carriers are distributed by a variety of methods, such as mass merchandisers, small specialty juvenile products stores, and Internet-only distributors.

Of the 47 sling carrier suppliers identified, 33 companies are based in the United States: 25 are manufacturers and four are importers. Available information does not identify the supply source for four firms. There are also 14 foreign companies that export directly to the United States via Internet sales or directly to U.S. retailers.

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<sup>&</sup>lt;sup>44</sup> Staff made these determinations using information from Dun & Bradstreet and Reference USAGov, as well as firm websites.

A sling carrier is not a complicated product to produce; typically, only fabric, thread, rings, (and in some cases, fasteners) and a sewing machine are required to produce sling carriers. A common scenario for a sling manufacturer starts with a mother using various slings or soft carriers and then deciding to make her own design in her home. Some of these home businesses grow into larger businesses that become more specialized and sophisticated, typically designing and marketing their own products, but having the product manufactured overseas. However, the newer home businesses generally are unsophisticated and may not be aware of the sling carrier voluntary standard or are not aware that they may be subject to existing federal regulations on children's products.

According to a 2005 survey conducted by the American Baby Group (2006 *Baby Products Tracking Study*), 17 percent of new mothers own sling carriers. Approximately 31 percent of sling carriers were handed down or purchased secondhand. Thus, about 69 percent of sling carriers are acquired new. This suggests annual sales of about 471,000 sling carriers (0.17 x 0.69 x 4 million births per year), with prices ranging from \$30 to around \$150. However, this sales estimate may be a substantial underestimate for two reasons: (1) industry sources state that slings have increased in popularity since the survey was done in 2005; and (2) other products like wraps, pouches, and some soft carriers, which fall under the standard, may not have been included in the *Baby Products Tracking* study. Based on discussions with an industry representative, sales of these other products that fall under the proposed rule for sling carriers could increase the sales estimate we derived to about 600,000 to 1 million units annually.

To meet the NEISS publication criteria, an estimate must be 1,200 emergency department (ED) injuries or greater, the sample size must be 20 or greater, and the coefficient of variation must be 33 percent or smaller. The NEISS ED injury estimate for sling carriers was less than 1,200 over the 10 years considered by Epidemiology staff; hence, our estimate did not meet the publication criteria. However, because the estimate was less than 1,200, there presumably would be, on average, fewer than 120 ED injuries annually during the 10-year period.

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<sup>&</sup>lt;sup>45</sup> Personal communication with Vesta Garcia, former Executive Director of the Baby Carrier Industry Alliance, current chairman of the ASTM F2907 Standard Committee, November 19, 2013.

<sup>&</sup>lt;sup>46</sup> The data on secondhand products for new mothers were not available. Instead, data for new mothers and expectant mothers were combined and broken into first-time mothers and experienced mothers. Data for first-time mothers and experienced mothers have been averaged to calculate the approximate percentage of sling carriers that were handed down or purchased secondhand.

<sup>&</sup>lt;sup>47</sup> The data collected for the *Baby Products Tracking Study* do not represent an unbiased statistical sample. American Baby Products surveyed potential respondents from its mailing lists to generate a sample of 3,600 new and expectant mothers. Additionally, because the most recent survey information is from 2005, the survey information may not reflect the current market.

<sup>&</sup>lt;sup>48</sup> 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 2009," *National Vital Statistics Reports* Volume 61, Number 1 (August 28, 2012): Table I. Number of births in 2010 is rounded from 3,999,386.

<sup>49</sup> Ibid 45

<sup>&</sup>lt;sup>50</sup> Memorandum from Risana Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, *Sling Carriers-Related Deaths, Injuries, and Potential Injuries: January 1, 2003 – October 27, 2013*, dated November 22, 2013.

Sling carriers are typically used in the first year of a child's life. Based on data from the 2006 *Baby Products Tracking Study*, and assuming that each new mother owns only one sling carrier, approximately 680,000 sling carriers are owned by new mothers (0.17 ownership x 4 million/births per year). Therefore, the injury rate would be less than 1.76 emergency department-treated injuries per 10,000 sling carriers available for use in the households of new mothers ((120 injuries ÷ 680,000 sling carriers in households of new mothers) x 10,000). If ownership is higher than estimated by the *Baby Products Tracking Study*, as suggested in discussion with industry sources, then the injury rate would be even lower. The annual sales estimate of 600,000 to 1 million units, reported earlier, implies a higher ownership rate and suggests that the injury rate is substantially lower than 1.76 per 10,000 sling carriers.

# Reason for Agency Action and Legal Basis for the Draft Proposed Rule

Section 104 of the CPSIA, requires the CPSC to promulgate mandatory standards for nursery products that are 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 incorporated into ASTM F2907-14a, which forms the basis of the draft proposed rule.

#### **Compliance Requirements of the Draft Proposed Rule**

Staff recommends that the Commission adopt the current voluntary standard, with no revisions, as the Commission's proposed rule. Some of the more significant requirements of the current voluntary standard for sling carriers (ASTM F2907–14a) include static and dynamic load testing to check structural integrity of the sling carriers and occupant retention testing to check that the child is not ejected from the sling carrier. The standard requires that the buckles, fasteners, and knots that secure the sling carrier remain in position before and after these three performance tests. There is also a separate restraint system test to help ensure that any restraints used by the sling do not release while in use.

The voluntary standard also includes:

- requirements for several features to prevent cuts (hazardous sharp points or edges, and wood parts);
- small parts;
- marking and labeling requirements;
- flammability requirements;
- requirements for the permanency and adhesion of labels; and
- requirements for instructional literature.

The updated warning statements provide additional details of the fall and suffocation hazards. The primary fatality risk associated with sling carriers is suffocation, and this hazard is intended to be addressed with these additional requirements for labeling and instructions.

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<sup>&</sup>lt;sup>51</sup> Memorandum from Maxwell Sanborn, Division of Mechanical Engineering, Directorate for Laboratory Sciences dated February 18, 2014.

#### **Other Federal Rules**

Section 14(a)(2) of the Consumer Product Safety Act (CPSA) requires every manufacturer and private labeler of a children's product that is subject to a children's product safety rule to certify, based on third party testing conducted by a CPSC-accepted laboratory that the product complies with all applicable children's product safety rules. Section 14(i)(2) of the CPSA requires the Commission to establish protocols and standards by rule for, among other things, ensuring that a children's product is tested periodically and where there has been a material change in the product, and safeguarding against the exercise of undue influence on a conformity assessment body by a manufacturer or private labeler. A final rule implementing sections 14(a)(2) and 14(i)(2) of CPSA, *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107), became effective on February 13, 2013 (the 1107 rule). Sling carriers will be subject to a mandatory children's product safety rule, so they will also be subject to the third party testing requirements of section 14 of the CPSA and the 1107 rule.

In addition, the 1107 rule requires the third party testing of children's products to be conducted by CPSC-accredited laboratories. Section 14(a)(3) of the CPSA required the Commission to publish a notice of requirements (NOR) for the accreditation of third party conformance assessment bodies (*i.e.*, testing laboratories) to test for conformance with each children's product safety rule. The NORs for existing rules are set forth in 16 C.F.R. part 1112. Consequently, staff recommends that the Commission propose an amendment to 16 C.F.R. part 1112 that would establish the requirements for the accreditation of testing laboratories to test for compliance with the sling carrier final rule.

# **Impact on Small Businesses**

Of the 47 identified suppliers of sling carriers to the U.S. market, 33 are domestic firms. We limit our analysis to domestic firms because U.S. Small Business Administration (SBA) guidelines pertain to U.S.-based entities. Under SBA guidelines, a manufacturer of sling carriers is small if it has 500 or fewer employees, and importers and wholesalers are small if they have 100 or fewer employees. Based on these guidelines, 31 of the domestic firms supplying sling carriers to the U.S. market appear to be small businesses. These businesses consist of 23 manufacturers, four importers, and four firms with unknown supply sources.

Additionally, as noted above, there are a large but unquantified number of producers supplying baby slings to the U.S. market via websites such as Etsy. Although we have no information on these suppliers, based on the general nature of suppliers selling products on Etsy and similar markets, we assume that these suppliers are well within SBA criteria for small business. For purposes of analysis, we term these suppliers "very small" manufacturers to distinguish them from the more established manufacturers, but this is not an official SBA designation.

Prior to the preparation of a regulatory flexibility analysis, staff conducts a screening analysis in order to determine whether a regulatory flexibility analysis or a certification statement of no significant impact on a substantial number of small entities is appropriate for a proposed rule. The SBA gives considerable flexibility in defining the threshold for "no significant economic impact." However, staff typically uses 1 percent of gross revenue as a threshold; unless the

impact is expected to fall below the 1 percent threshold for the small businesses evaluated, staff prepares a regulatory flexibility analysis. <sup>52</sup> Because we were unable to demonstrate that the draft proposed rule would impose an economic impact less than 1 percent of gross revenue for the affected firms, staff does not recommend certification for this rule. <sup>53</sup> Instead, we conduct an Initial Regulatory Flexibility Analysis.

#### **Small Manufacturers**

The Juvenile Products Manufacturers Association (JPMA) and the Baby Carrier Industry Alliance (BCIA) are offering assistance to member manufacturers on testing and compliance with the ASTM sling carrier standards. However, the ASTM sling carrier standards are relatively new, and there is no established history of compliance among manufacturers.

As of January 2014, only two of the 23 known small manufacturers of sling carriers are listed on the JPMA website as certified compliant. Some manufacturers claim to be "CPSIA compliant," but that may refer only to requirements for flammability, labeling, instructions, small parts, and sharp edges and not necessarily the ASTM standard. Based on our review of small firm websites, a conversation with a small ring sling manufacturer, and a draft magazine article by a small nursing wrap producer, we have identified three additional firms that have conducted testing to some version of the ASTM standard, for a total of five firms. These five firms may have already experienced the impacts of staff's draft proposed rule and may not experience any additional impacts.

Due to the nature of the product and the relative ease of production, staff believes that most of the physical changes needed to meet the standard are unlikely to be costly. Because sling carriers are largely made of fabric, tooling costs are not usually a large cost factor. Rather, changes required may involve changing fabrics, adding reinforcements, changing stitching, changing rings (for ring slings), changing buckles or other types of fasteners or hardware, changing labels, and changing instruction manuals.

Some manufacturers of ring slings are having difficulty passing the occupant retention tests consistently. At this time, the precise cost of product changes necessary to satisfy testing under the ASTM standard is unknown; additionally, we cannot rule out the potential for costs to be high enough to lead to significant economic impacts, especially for very small manufacturers.

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<sup>&</sup>lt;sup>52</sup> The SBA provides several examples of screening measures, including the one percent of gross revenue measure. (see U.S. Small Business Administration, Office of Advocacy. *A Guide for Government Agencies: How to Comply with the Regulatory Flexibility Act and Implementing the President's Small Business Agenda and Executive Order 13272*. May, 2012, pp. 18–20. http://www.sba.gov/sites/default/files/rfaguide 0512 0.pdf.)

Staff has chosen the gross revenue measure because we generally have data to support its calculation. In addition, we use one percent rather than a higher threshold because we believe that it is cautious in the sense that we err on the side of preparing a regulatory flexibility analysis rather than incorrectly recommending certification. However, we note that firms in some industries could experience significant economic impacts beneath the one percent threshold.

However, the ASTM F15.21 subcommittee is working to address this issue. Once complete, this may mitigate the impact on ring sling manufacturers.

According to one manufacturer, changes to warning labels required under the draft proposed rule may have an impact on very small suppliers.<sup>54</sup> We do not have sufficient data to determine whether or not this impact is expected to be economically significant. For example, if the cost of printing and sewing in the labels is 30 cents per sling, then the impact would be 1 percent of the sales price for a \$30 sling. Staff has contacted a BCIA representative to obtain label prices, but has no independent estimate at this time. We welcome comments on the price of the labels and the costs for applying them. An additional consideration is that the labels are relatively large and may reduce the appeal of the product if they cannot be readily concealed, but this impact will apply to all sling manufacturers.

The majority of the costs associated with the draft proposed standard will probably be related to testing. Few of the sling carrier manufacturers have the technical capability or the equipment to conduct any testing in-house; and most small and very small manufacturers probably will have to rely on third party testing during product development. Some small and very small manufacturers could experience significant costs simply testing to find out initially whether their products comply with the draft proposed standard and with any additional testing necessary to develop complying products.

In addition, under section 14 of the CPSA, sling carriers will be subject to third party testing and certification. Once the new requirements become effective, all manufacturers will be subject to the additional costs associated with third party testing and certification requirements under the testing rule, *Testing and Labeling Pertaining to Product Certification* (16 C.F.R. part 1107). This will include any physical and mechanical test requirements specified in the final rule. Lead and phthalates testing, if applicable, are already required; hence, lead and phthalates testing are not included in this discussion. Moreover, very small manufacturers are ineligible to seek relief through a small batch exemption because durable infant and toddler products are specifically excluded from small batch exemptions as product safety rules are promulgated for such products under Section 104 of the CPSIA.<sup>55</sup>

According to a Baby Carrier Industry Association (BCIA) representative, third party testing to the ASTM sling carrier voluntary standard could cost around \$510–\$1,050 per model sample. Third party testing costs consists of two parts: the testing costs unique to F2907 associated with the dynamic load test, the static load test, the occupant retention test, and the restraints test; and the general testing costs associated with testing for flammability, small parts, sharp edges, instructions, and labels. The testing costs unique to sling carriers vary widely, from \$210 to \$650, depending on whether the testing is done in China or the U.S. and on whether a discount, such as those negotiated by the BCIA for its members, is applied. The general testing costs may

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<sup>&</sup>lt;sup>54</sup> Personal communication with a small ring sling manufacturer, December 6, 2013.

<sup>&</sup>lt;sup>55</sup> See a description of exclusions from the small batch exemption on CPSC's website: <a href="http://www.cpsc.gov/en/Business--Manufacturing/Small-Business-Resources/Small-Batch-Manufacturers-and-Third-Party-/">http://www.cpsc.gov/en/Business--Manufacturing/Small-Business-Resources/Small-Batch-Manufacturers-and-Third-Party-/</a>.

amount to \$300 to \$400. The very small firms that manufacture in the U.S. will probably also test in the U.S. to avoid logistical difficulties, thus incurring higher costs.  $^{56}$ 

As noted above, testing costs will vary widely. Because very small firms will probably have their products tested in the U.S., their costs will be higher than the minimum testing cost of \$510 per model sample. We will assume that a fee of \$700 per sample covers all the required testing, including flammability, small parts, sharp edges, instructions, and labels. If a very small manufacturer with one model needed to test only one sample annually, the costs of testing would amount to \$700. A very small manufacturer producing 20 to 30 low-priced slings a month might have annual revenues of \$10,800 (30 slings per month x 12 months x \$30 per sling). Testing only one sample at \$700 would amount to 6.5 percent (\$700/\$10,800) of annual revenue for this hypothetical very small manufacturer, which we would classify to be clearly a significant economic impact. Even if this manufacturer could sell its slings for \$150, testing one sample at \$700 would amount to 1.3 percent of annual revenue of \$54,000 (360 slings\*\$150 per sling).

Based upon the example above, even in the unlikely case that very small sling manufacturers (such as those that market their products via websites like Etsy) are able to develop a complying product without incurring significant economic impacts, most are still likely to incur significant economic impacts complying with section 14 of the CPSA.

Although information on sales revenue is limited to half of the known 23 domestic manufacturers, we estimate that most have substantially larger sales volumes than the example above, with annual sales ranging from \$200,000 to \$16 million. Thus, product development and testing costs would be a lower percentage of sales revenue than the example above. At the lower range of \$200,000 in revenues, significant economic impacts would occur if the producer had to test three samples per year. Firms with revenues closer to the upper end of the range, \$16 million, would need to test more than 200 samples per year to experience significant economic impacts from testing. Staff does not know the number of samples needed for product development or to meet the "high degree of assurance" criteria under section 14 of the CPSA.

About one-third of firms (8 of 23) also have other product lines, which may cushion the impact of design changes and increased testing costs for sling carriers. These other products may be similar products, such as mei tais (a traditional Asian unstructured soft carrier falling under the SITC standard) or SITCs, or they may be completely unrelated juvenile products.

# **Small Importers**

At this time, only one of the four importers identified is in compliance with F2907-12, F2907-13a or F2907-13b. Depending upon the costs of coming into compliance incurred by their suppliers, and whether their suppliers pass on the costs, the other three importers could experience a significant economic impact. Three of the four importers are owned by foreign parent companies that supply their slings. These parent companies must make the business decision to comply or to discontinue U.S. operations. Two of the four importers could respond

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<sup>&</sup>lt;sup>56</sup> Personal communication with Linnea Catalan, Executive Director of the BCIA, March 13, 2014.

by simply discontinuing their sling product line altogether because these importers have varied product lines.

As is the case with manufacturers, all importers will be subject to third party testing and certification requirements. Consequently, importers will experience the associated testing costs. The resulting costs could have a significant impact on these small importers.

As mentioned above, four of the small domestic firms have unknown supply sources, and none of these have claimed compliance with any version of F2907. However, two firms have varied product lines and may be in a better position to comply, without incurring significant economic impacts. The other two appear to be small firms specializing in slings that may be impacted more heavily by compliance and testing costs.

#### **Alternatives**

Typically, staff recommends a 6-month effective date for durable nursery product rules. Six months is generally considered sufficient time for suppliers to come into compliance with a proposed durable infant and toddler product rule, unless there are specific reasons for a longer effective date. For this rule, staff is recommending a 12-month effective date.

However, one alternative that could reduce the impact on small firms would be to set an effective date later than 12 months. Setting a later effective date would reduce the economic impact on firms in two ways. First, firms would be less likely to experience a lapse in production, which could result if firms are unable to comply within the required timeframe. Second, they could spread costs over a longer time period, thereby reducing their annual costs, as well as the present value of their total costs. Given the large number of very small suppliers who will potentially experience significant economic impacts, a later effective date may warrant consideration. CPSC staff welcomes comments regarding an appropriate effective date.

Finally, the Commission could determine that sling carriers do not constitute a durable children's product. As noted above, sling carriers are generally used for a brief period of time, less than a year in most cases, but the *Baby Products Tracking Study* found that 31 percent of baby sling carriers were handed down or obtained second hand (though not necessarily used). The definitions of what constitutes a durable product, and the degree to which other empirical and anecdotal evidence on sling carriers conforms to these definitions is discussed in greater detail in a separate memorandum. <sup>57</sup> If sling carriers are determined not to be a durable children's product, sling carriers would not be subject to section 104 of the CPSIA, and the Commission would have the option not to regulate.

#### The 1112 Rule and the Impact on Small Conformity Assessment Bodies

In accordance with section 14 of the CPSA, children's products that are subject to a children's product safety rule must be tested by one of the accredited conformity assessment bodies (*i.e.*,

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<sup>&</sup>lt;sup>57</sup> Memorandum from Deborah V. Aiken, Directorate for Economic Analysis, dated March 27, 2014,

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 that the Commission propose an amendment to 16 C.F.R. part 1112 that would establish the accreditation requirements for the testing laboratories that want to test for compliance with the sling carriers final rule. This section assesses the impact of the amendment on small laboratories.

A final regulatory flexibility analysis (FRFA) was conducted as part of the original 1112 rule (78FR15836, 15855-58), as required by the Regulatory Flexibility Act. Briefly, the FRFA concluded that the accreditation requirements would not have a significant adverse impact on a substantial number of small testing laboratories because no requirements were imposed on laboratories that did not intend to provide third party testing services. The only laboratories that were expected to provide such services were those that anticipated receiving sufficient revenue from the mandated testing to justify accepting the requirements as a business decision.

Based on similar reasoning, amending the rule to include the NOR for the sling carrier standard would not have a significant adverse impact on small laboratories. Additionally, based on 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, the only cost to them would be the cost of adding the sling carrier standard to their accreditation. As a consequence, the Commission could certify that the NOR for the sling carrier standard will not have a significant impact on a substantial number of small entities.

# TAB G: Sling Carriers as Durable Products

T A B

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# Memorandum

Date: March 27, 2014

TO : Hope Nesteruk

Project Manager, Sling Carriers Division of Human Factors Directorate for Engineering

Sciences

THROUGH: Gregory B. Rodgers, Ph.D.

Associate Executive Director Directorate for Economic Analysis

FROM: Deborah V. Aiken, Ph.D.

Senior Staff Coordinator

Directorate for Economic Analysis

SUBJECT: Sling Carriers as Durable Products

The purpose of this memorandum is to provide information regarding the durability of sling carriers and whether they can be defined appropriately as a "durable nursery product." The memorandum examines various definitions for "durable goods" and discusses attributes of sling carriers that may provide some insight into the durability of the product.

# **Definition of "Durable Goods" or "Consumer Durables"**

There is no single definition of a "durable good" or "consumer durable." For this exercise, we compare three alternatives: (1) a "common" definition, (2) a "technical" definition, and (3) an "official" definition from the U.S. Department of Commerce.

For a "common" definition, we consult the dictionary. According to Webster's New World Dictionary, Second College Edition, "durable goods" are "goods that remain usable for a relatively long period of time, such as machinery, automobiles, or household appliances." The key characteristic of a durable good, according to the common definition, is the length of the product's useful life. The comparison to machinery, automobiles, and household appliances

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implies a somewhat lengthy useful life, perhaps closer to 5 or 10 years (or more), rather than just 1 or 2 years; but obviously the boundary is not precise.

A source of a "technical" definition is the MIT Dictionary of Modern Economics (fourth edition).<sup>58</sup> which defines "consumer durables" as:

Any consumer good which has a significant 'life' and which is not immediately consumed (like food). Consumer durables have some characteristics of capital goods in that they tend to yield a flow of services over their lifetime rather than one immediate 'service' in one act of consumption. Nonetheless, the dividing line between consumer goods, consumer durables and capital goods is a hazy one in practice.

In this "technical" definition, the key attribute appears to be the length of time during which the product is used. This definition seems generally unrestricted in the sense that many or even most consumer goods aside from food (as mentioned), medications, or entertainment activities are consumed over a period of time. However, a key consideration is whether the period of time over which the good is used (i.e., the product life of the good) is long enough to be considered "significant."

Finally, we look to a government agency for an "official" definition. The U.S. Commerce Department's Bureau of Economic Analysis (BEA) defines "durable goods" as "[t]angible products that can be stored or inventoried and that have an average life of at least three years."59 In this definition, durable goods are nonperishable and are used over a period of time as in the "common" and "technical" definitions. However, the BEA definition is specific in that the useful life must be at least 3 years. 60 The 3-year useful life seems at least roughly consistent with the "common" definition, but it is unclear how the 3 years would relate to "significant" life in the "technical" definition.<sup>61</sup>

In sum, it appears, at a minimum, that a "durable product" can be defined as a product that (1) is nonperishable, and (2) provides the user with a flow of services over a period of time rather than during a discrete consumption event. If we follow the MIT Dictionary of Modern Economics, the period of time that a product generates services over its useful life should be "significant," for the product to be classified as "durable." Although the term "significant" does not imply any particular length of useful life, it is probably safe to consider anything with an expected useful

<sup>&</sup>lt;sup>58</sup> Pearce, David W. The MIT Dictionary of Modern Economics, 1992.

<sup>&</sup>lt;sup>59</sup> See: https://www.<u>bea.gov/glossary\_d.htm</u>

<sup>&</sup>lt;sup>60</sup> The fact that durable goods are tangible products that can be "stored or inventoried" does not provide a distinction between "durable goods" from "nondurable goods" in the BEA definition. Nondurable goods are defined as "[t]angible products that can be stored or inventoried and have an average product life of less than three years." (See https://www.bea.gov/glossary/glossary\_n.htm#Non\_FI.) Hence, the only difference in the BEA definition is whether the average life of the product is "at least three years" or "less than three years."

The 3-year useful life criterion appears in various other definitions for durable goods (see, for example,

http://dictionary.reference.com/). Online examples of consumer durable goods include cars, household goods (home appliances, consumer electronics, furniture, etc.), sports equipment, firearms, and toys. Online examples of nondurable consumer goods include cosmetics, cleaning products, food, fuel, beer, cigarettes, medication, office supplies, packaging and containers, paper and paper products, personal products, rubber, plastics, textiles, clothing, and footwear.

life of 3 years or more as durable because that would be consistent with the BEA's practice. For products with useful lives less than 3 years, the appropriate default classification is probably that they are nondurable goods. However, extenuating circumstances (such as the existence of a well-organized and large secondary market) could blur the distinction between durable and nondurable, making it more difficult to classify a particular product.

# **Durability Characteristics of Infant Slings**

# Information from Manufacturers

In advertising, safety, and instructional materials accompanying slings, the maximum weights typically suggested for use of infant slings is up to 35 lbs. for infants and toddlers. 62 According to Human Factors, the median (50<sup>th</sup> percentile) weight of a child does not exceed 35 pounds until about 46 months for boys and 49 months for girls. Moreover, the 5<sup>th</sup> percentile bodyweight of a child does not exceed 35 pounds until about 65 months for boys and 69 months for girls. Therefore, based on a maximum weight of 35 pounds, the products could be used with a child over the age of 3 years.

We were able to obtain feedback regarding beliefs about sling usage and durability from two sling manufacturers. According to one sling manufacturer, the typical length of sling use is less than 1 year and ends before the child reaches age 1 year. The manufacturer acknowledged that some mothers may re-use slings through multiple children but said that this is neither commonplace, nor desirable because the slings wear out after repeated washings and other ordinary wear and tear. A second manufacturer stated that the bulk of users tend to discontinue sling use when the child reaches about 18 months of age but a small portion of users ("lifestyle" users) may continue use with a child as old as 5 years and as heavy as 45 pounds.

The second sling producer said that the length of time during which any particular sling would be used would vary from person to person, depending on the user's habits. For some brands, use of the sling for 4 years was definitely possible, depending upon the quality of the product's construction.

It is interesting to note that the second producer's product sells at the higher end of the price range for slings in the market, while the first producer's product is priced toward the lower end of that range. As reported in the Initial Regulatory Flexibility Analysis, the observed market prices for slings ranged from \$30 to \$150.63 If product price correlates with the quality of materials used in construction, we might expect that slings priced at the higher end of the range would tend to have a longer expected useful life.

Hazard Data

<sup>&</sup>lt;sup>62</sup> Some slings have maximum recommended weights of 20 pounds, but 35 pounds is more common.

<sup>&</sup>lt;sup>63</sup> Memorandum from William Zamula, Directorate of Economic Analysis, *Initial Regulatory Flexibility Analysis of* Staff-Recommended Proposed Standard for Sling Carriers, dated February 18, 2013.

The evaluation of sling injuries and deaths conducted by the Directorate for Epidemiology may provide some support that sling use is somewhat rare in children over the age of 1 year.<sup>64</sup> In that study, there was only one case in which the victim was more than a year old. However, the lack of cases involving older children could also reflect a lower risk of injury or death from sling use in children over the age of one year.

#### Survey Data

The useful life of sling carriers may be extended through secondhand use. The results of the 2006 Baby Products Tracking Study suggest that there is some secondhand use of slings. Overall, for mothers who own slings, 31 percent of slings were either handed down or purchased secondhand. Experienced mothers were twice as likely to own used slings (44 percent) as first-time mothers (22 percent). However, the Tracking Study does not provide any information on how often or for how many years they are used.

Preliminary, unweighted data from CPSC's Durable Nursery Products Exposure Survey suggest that the majority of parents (73 percent) stop using slings before the baby's first birthday, with roughly 35 percent stopping within the baby's first 6 months of life. Another 19 percent continued using the sling through the second year of life, stopping by the time the child reached age 2. Eight percent continued to use the sling in the third year, but all had stopped by the child's third birthday. No respondents indicated that they used a sling for a child older than 3 years. Again, this data are preliminary and should be regarded with caution.

CPSC's nursery products survey also collected information on how sling owners acquired their slings and what they did with their used slings once they were done using them. Most owners (79 percent) acquired their slings new, while 21 percent acquired them used. After they discontinued use, 4 percent threw them away, 54 percent stored them for future use, and 42 percent sold them, gave them away, or gave them back to the owner. Thus, there appears to be a substantial proportion of used slings available for future use. However, we do not know the extent to which used slings are actually re-used.

#### **Summary**

EC staff cannot come to any firm conclusions regarding the durability of sling carriers. There are a number of factors that indicate the expected product life for infant slings is less than 3 years; and thus, infant slings would not meet the BEA "durable product" definition. Manufacturers we contacted indicated that most users discontinue use after the child is approximately 18 months old. This appears to be supported by CPSC's nursery products exposure study, which found in preliminary results that approximately 73 percent of parents stop using slings before the baby's first birthday. Additionally, approximately 79 percent of parents

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<sup>&</sup>lt;sup>64</sup> Memorandum from Risana Chowdhury, Division of Hazard Analysis, Directorate for Epidemiology, *Sling Carriers-Related Deaths, Injuries, and Potential Injuries: January 1, 2003 – October 27, 2013*, dated November 22, 2013.

acquired their slings new, which may indicate a high purchase rate of new products usually used by children under 1 year old.

On the other hand, there are a number of other factors that may support using a different definition of "durable product" than BEA's definition, or that suggest that some slings last for 3 years. Most slings are not thrown away after their use with a child; in fact, CPSC survey data indicate that only 4 percent of infant slings are discarded after use. Moreover, 21 percent to 31 percent of slings are acquired secondhand. According to one sling manufacturer, there are slings in the market that are apparently constructed to last for more than 3 years, and a small percentage of users who use them until a child reaches age 3 or older. 65

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<sup>&</sup>lt;sup>65</sup>All respondents in CPSC's survey reported they discontinued sling use by the child's third birthday.