

Memorandum

Date. JUL 1 2 2000

TO :	The Commission
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Sadye E. Dunn, Secretary

FROM: Michael S. Solender, General Counsel

Stephen Lemberg, Assistant General Counsel

Patricia M. Pollitzer, Attorney PFF

SUBJECT: Petition HP 00-1 requesting requirements for buckles on child-restraint systems

on various children's products

Attached is a briefing package from the staff concerning a petition submitted by John A. Galbreath. The petition requests that the Commission develop requirements for buckles used on child-restraint systems on such products as strollers, high chairs, changing stations and shopping carts. The staff recommends that the Commission deny the petition.

Please indicate your vote on the following options.

I.	Grant Petition HP 00-1 and direct the staf proposed rulemaking.	f to begin developing a draft advance notice of
	Signature	Date

II. Deny Petition HP 00-1 and direct the staff to prepare a letter of denial to the petitioner.

Signature	Date

Page 1 of 2

NOTE: This document has not been reviewed or accepted by the Commission.

ate 7//2/66 CPSC Hotline 1-800-638-CPSC(2772) * CPSC's Web Site http://

No Mirs/Prviloirs of

Firms Notified,

Child-Resistant Buckle Petition Briefing Package

July 2000

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No Mirs Prvilbirs or Products Identified Identified

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EXECUTIVE SUMMARY

In November 1999, John A. Galbreath petitioned the Consumer Product Safety Commission (CPSC) to "...initiate a new rule requiring that the buckles used to fasten child restraint systems in various products meet a child-resistance standard." The petition specifically requested that the buckle be required to have a double-action release mechanism, in which two separate and distinct actions are necessary for the release of the buckle. To support the claim that the requested action is necessary, the petitioner provided injury estimates and information on specific incidents from CPSC data files and a study on children and buckle release. The petitioner focused on high chairs, strollers, changing stations (tables) and grocery carts.

This briefing package provides the Commission with the available information about the hazards of falls from products with child restraint systems having buckles that are not designed to be child-resistant. A restraint system is provided on some juvenile products to secure children in the product in a recommended-use position. A fastener or buckle is often used on restraint systems to secure the child into the product. The primary issue to be considered is whether a mandatory standard may be reasonably necessary to eliminate or reduce the risk of injury associated with falls off products without child-resistant buckles on the restraint systems. Current ASTM voluntary standards for juvenile products with restraints do not require child-resistant buckles on the restraints.

CPSC staff estimates that in 1998, there were 30,800 children treated in U.S. hospital emergency rooms for fall-related injuries associated with high chairs, strollers and grocery carts. This estimate does not indicate the portion of injuries due to a child releasing the restraint system. However, CPSC received 25 consumer complaints from January 1997 to May 2000 involving children under 5 who allegedly released the buckle of a product's restraint system. The products involved in the incidents were shopping carts, high chairs and strollers. Information on the specific design of the buckles involved in these incidents is not known.

The most commonly used buckles on juvenile products employ center button- or siderelease mechanisms to disengage the restraint. These types of buckles require a single action to release the restraints. The petitioner states the need for a double-action release mechanism, such as his patented buckle, which requires both side- and center-button-release actions.

The staff recommends that the Commission deny the petition for lack of sufficient information to indicate that children releasing restraint system buckles represent a significant portion of fall injuries from juvenile products and shopping carts. Staff will continue its ongoing work on the CPSC Child Restraint Project to define areas of the restraint system that could require improvement, including the buckle.



Memorandum

Date: JUL 12 2000

TO : The Commission

Sadye E. Dunn, Secretary

Michael Solender, General Councel THROUGH:

Thomas Murr, Acting Executive Director

Ronald L. Medford, Assistant Executive Director, RLM FROM

Office of Hazard Identification & Reduction Debra L. Sweet, Project Manager,

Directorate for Epidemiology (301) 504-0470 ext. 1333

Child-Resistant Buckle Petition SUBJECT :

I. BACKGROUND

In November 1999, John A. Galbreath petitioned the Commission to "... initiate a new rule requiring that the buckles used to fasten child restraint systems in various products meet a child-resistance standard" (TAB A). The petition specifically requested that the buckle be required to have a double-action release mechanism, in which two separate and distinct actions are necessary for the release of the buckle. To support the claim that the requested action is necessary, the petitioner provided injury estimates, information on specific incidents from CPSC data files and a study on children and their ability to release a buckle. The petitioner focused on high chairs, strollers, changing stations (tables) and grocery carts.

A restraint system is provided on some juvenile products to secure children in the product in a recommended-use position. The restraint system is intended to prevent the child from coming out of the product, accidentally or intentionally. A fastener or buckle is often used on restraint systems to secure the child into the product. If a child were to release the buckle of the restraint, the child could fall from the product. The voluntary standards for juvenile products using restraint systems do not have child-resistance requirements. However, the voluntary standards for high chairs and strollers do specify requirements for buckle integrity.

The petitioner reported that his two daughters could "quickly and easily" release conventional side- and center button-release buckles on restraint systems. He added that personal acquaintances have had similar experiences.

The petitioner obtained incident summaries from three CPSC databases: the National Electronic Injury Surveillance System (NEISS), the Injury and Potential Injury Incident -(IPII) file and the In-Depth Investigation (INDP) file. From the NEISS database, the petitioner

-1-

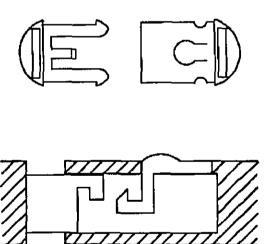
NOTE: This document has not been reviewed or accepted by the Commission. Initial fth-

estimated that 33,000 injuries per year occur as a result of children falling out of strollers, high chairs and shopping carts.

The petitioner recognized that these falls are not all the result of children releasing the restraint system buckle. He attributed some of the estimated injuries to the lack of a restraint system in the product and some to non-use of the restraint system provided. The petitioner claimed, "that a major reason for non-use of restraint systems is *ineffectiveness*, not inconvenience." The petitioner further claimed that children as young as 6 months-old can easily and frequently release the buckles on restraint systems.

The petitioner stated that buckles with double-action release mechanisms are currently available. On March 16, 2000 the petitioner met with CPSC staff to discuss the petition and his patented double-action buckle design (US Patent No 5991985). The illustration below (Figure 1) is an overview (top diagram) and cross-sectional view (bottom diagram) of the petitioner's buckle with a double-action release mechanism.

Figure 1. Petitioner's Buckle with Double-Action Release Mechanism (US Patent No. 5991985)



On January 5, 2000 the Commission published a <u>Federal Register</u> notice soliciting public comments on the petition (TAB B). The comment period closed March 6, 2000. The Commission received a total of 16 comments, including letters from a juvenile products trade organization, a national safety organization, a juvenile products manufacturer, a consumer safety advocate and consumers. Staff responses to issues raised by the commenters are provided in this briefing package at TABS C through I.

II. DISCUSSION

A. Incident Data (TAB C)

Staff reviewed data from January 1997 to May 2000 for incidents in which it was specifically stated in the narrative that a child unfastened the buckle of the product's restraint system. Eleven product codes¹ were searched, all of which are products that are known to have restraint systems and are intended for the use of children.

CPSC has received 25 consumer complaints since January 1997 involving children under age 5 who allegedly released the buckle of a product's restraint system. The products involved in the incidents were shopping carts (9), strollers (9) and high chairs (7). For a tabular description of the incidents, see TAB C, Appendix A. Information on the specific design of the buckles involved in these incidents is not known.

Shopping Cart Incidents

Nine children reportedly unbuckled the restraint systems of shopping carts. The children ranged in age from 11-months-old to 4-years-old (11-months-old (1), 21-months-old (1), 2-years-old (4), 3-years-old child (1) and 4-years-old (2)).

Six children were injured as a result of a fall when they unbuckled the restraint systems in their shopping cart. The injuries included contusions to the head and face, a hematoma on the head, an internal head injury, a dislocated jaw and loose teeth.

Of the remaining three incidents, two children were uninjured when they unbuckled the restraint system, since the release of the buckle was noticed before a fall occurred. In the final incident, a 2-year-old child unbuckled the restraint numerous times before her mother chose to remove the child from the seat and put her in the basket of the shopping cart. The child subsequently fell from the basket of the cart and received a hematoma on her brain, which required surgery.

Stroller Incidents

Nine children were able to release the restraint system buckle on strollers. The youngest child was 10-months-old and the oldest was 3-years-old (10-months old (1), 11-months-old (1), 12-months-old (3), 18-months-old (1), 19-months-old (1), 20-months-old (1) and 3-years-old (1).

Seven of the children fell out of the stroller once they released the buckle of the restraint system. Four of these children received minor injuries to the head and face. One child received a hematoma on the head, another child received bruises, and the other child was injured when

Product codes searched: baby changing tables, walkers and jumpers, strollers, infant backpack carriers, bike-mounted infant carriers, baby carriers (type not specified), baby bouncing seats, infant swings, high chairs, attachable high chairs and grocery or shopping carts.

hitting his head, but the extent of the injury is unknown. Two children released the buckles of the restraint system but were uninjured, as they did not fall from the stroller.

High Chair Incidents

High chairs were involved in seven incidents in which children were reported to have released the restraint system buckles. As high chairs are generally used for younger children, the children involved in these seven incidents ranged from 8-months-old to 18-months-old (8-months-old (1), 10-months-old (2), 11-months-old (1), 12-months-old (1), 17-months-old (1) and 18-months-old (1)).

Two of the seven children reportedly fell from the high chair after they released the buckle. One of these children received bruises. The other child hit his head on the floor during the incident but the extent of the injury is unknown. The remaining five children were uninjured in the incidents; they were only reported to have released the buckle.

Petitioner's Remarks

The petitioner stated that "almost 33,000 injuries/year in the U.S. result from children falling out of strollers, high chairs or shopping carts." This information was obtained from the National Electronic Injury Surveillance System (NEISS) database when the petitioner requested information from CPSC's clearinghouse. The petitioner added up the cases that he believed constituted falls from the products - not including falls resulting from children climbing on or into the products or product tipovers. The petitioner does not state what portion of these injuries are due to children releasing the buckles of restraint systems.

CPSC staff analyzed 1998 data from NEISS for children under age 5, involving high chairs, attachable high chairs, strollers and shopping carts for a comparison to the petitioner's estimate. Staff arrived at a similar estimate of 30,800 injuries to children under age 5 for these products in 1998. However, again, this does not provide any estimate of the portion of injuries due to the release of the restraint system buckles.

The petitioner included 23 incidents, which he obtained from CPSC databases, in a table of "Verbatim Comments." Source documents and investigations for the 23 incidents listed by the petitioner were reviewed for evidence that the child released the restraint system buckle. Eleven of the 23 incidents listed in the "Verbatim Comments" occurred when the child released the restraint system buckle. These incidents occurred between April 1997 and July 1999. The remaining incidents stated that the children 1) fell out after reportedly being buckled in, 2) loosened the restraint straps, 3) stood up in the product and fell out or 4) the child restraint system was easily unlocked. Nine of the 11 relevant incidents submitted with the petition are included in the staff's count of 25 incidents. The other two of the 11 incidents are from the NEISS database. The staff incident count is based on consumer complaint files, not including NEISS, since the NEISS data generally do not provide sufficient detail to indicate the role of buckles in fall-related incidents involving juvenile products.

B. Product Recalls (TAB D)

To date, restraint system buckles have been the subject of one recall announced by CPSC. In April 1997, Century Products Co. offered repair kits to prevent the stroller's restraint buckle from unlatching unexpectedly. However, the unlatching of the buckle was not attributed to a child releasing the buckle in any of the incidents reported.

C. Market Information (TAB E)

Juvenile Products with Child Restraints

Restraint systems are a part of many juvenile products. Table 1 provides estimates of the number of products in use for a variety of juvenile products that use child restraint systems and are intended for home use. Overall, there are more than 30 million of these products in use.

Table 1: Juvenile Products with Child Restraint Systems
Intended for Home Use

Product	Estimated Number of Products in Use (millions)
High Chairs	
- Regular	3.3
- Portable	0.6
- Reclining Multi-age	2.7
Changing Tables	2.1
Strollers	14.9
Infant Carriers	
- Frame (worn by parent)	0.7
- Plastic, with handle	2.8
Fabric Bouncer Seats	2.6
Baby swings	3.0
Products w/restraints	32.7

Source Based on information from the U.S. Bureau of the Census and the 1999 Baby Products Tracking Study for American Baby Group, In Draft, Bruno & Ridgeway

In addition to the juvenile products for home use, there may be as many as 3.5 million shopping carts equipped with child restraints. Other juvenile products found in public and commercial settings that are equipped with child restraints include diaper changing stations, high chairs, infant seats attached to grocery carts, and strollers.

Child Restraint Systems

Most juvenule products incorporate a plastic or a woven fabric strap in their child restraint systems. These straps go around the child in various configurations and are secured with one or more fasteners. The fasteners are usually made of hard plastic, but some may be made of metal.

Child restraint systems used on most juvenile products which use straps and fasteners have either a waist strap or a combination waist and crotch strap. Car seats, car seat carriers and some high chairs and strollers are equipped with shoulder, waist and crotch restraints.

Fasteners on child restraint systems have a variety of designs. Commonly used fasteners use either a center button-release mechanism or a side-release mechanism, as seen in the photos below.

Figure 2: Center button-release mechanism on a restraint system with both waist and crotch straps.

(Left picture is closed; right picture is open)

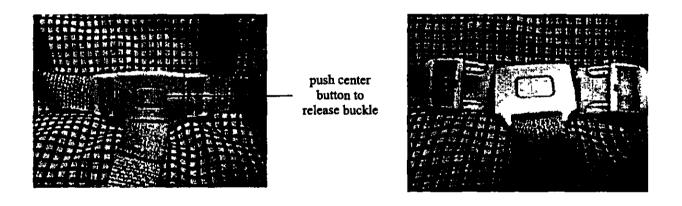
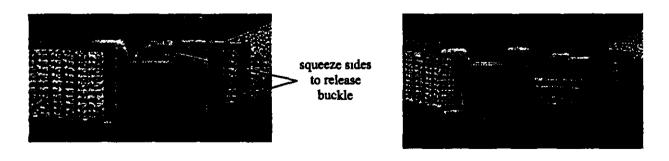


Figure 3: Side release mechanism on a restraint system with a waist strap only.

(Left picture is closed; right picture is open)



Juvenile product manufacturers generally order parts for child restraints used in juvenile products from fastener and strap manufacturers and incorporate them into the product during assembly. The restraint assembly may be ordered as a unit or components may be purchased separately. Costs of buckles for restraints are a small part of the overall cost of the production of a juvenile product.

There are a number of fastener suppliers, both domestic and international. A search of the *Thomas Register* found 49 firms that supply strap buckles for a wide variety of applications. Staff does not know how many of these firms produce fasteners for juvenile products. Nor does staff know to what degree the fasteners currently being used on juvenile products are able to be opened by children who are using the products.

One juvenile product manufacturer, Peg Perego, a European company, uses a dual-action mechanism on its stroller and high chair buckles marketed for sale in the U.S.

Staff performed a limited review of juvenile products for sale at large retail stores in the Washington, D.C. area. Four firms, YKK, National Molding, ACW, and ITW Nexus, appeared to have produced the majority of the fasteners found on child restraints. However, it was not always possible to determine the identity of the fastener manufacturers.

D. Voluntary and Mandatory Standards (TAB F)

ASTM Standards

Staff reviewed the current ASTM standards and new standards development activities. There are four current standards with restraint requirements, none of which require child-resistant buckles on the restraints.

The ASTM standards for High Chairs (F404-99a) and Portable Hook-on Chairs (F1235-98) specify that the product must contain waist and crotch straps with mandatory use of the crotch restraint in conjunction with the waist strap. A performance requirement tests the restraint system's ability to hold an infant dummy in place. The standard also states that the buckle or fastening device must be a self-locking device and cannot separate or break when tested for the above conformance. In addition to the waist and crotch strap restraint system, the High Chair standard requires a passive crotch restraint, typically a vertical bar attached to the tray and extending to the seat, when the high chair is used with a tray. A performance requirement tests the passive restraint for conformance. This requirement is intended to prevent incidents of strangulation in which the child slides down between the tray and seat.

The ASTM standard for Carriages and Strollers (F833-99) specifies a waist strap restraint for strollers or carriages that convert to a stroller (carriages intended for use by infants do not require a restraint). The standard calls for a performance test on the waist strap in which the ability to restrain an infant dummy must be demonstrated. There is an additional test in this standard in which a force is applied on the restraint at the stroller attachment points. The strap, buckle and anchorage points must not slip, separate or break during, or upon completion of, the tests.

Staff reviewed the ASTM standard for Bicycle Child Carriers (F1625-95), since these products contain restraints and are intended for the use of children. The standard does not specify the type of restraint system and there is no performance specification for the buckle of the restraint system.

ASTM standards with specifications for restraint systems are currently being developed for hand-held infant carriers, infant swings, infant bouncers and soft and frame infant carriers. However, the performance requirements and tests have not been fully developed or finalized. The draft standards do not contain requirements for child resistant buckles on restraints.

E. Human Factors Analysis (TAB G)

The manual dexterity of a child is important in consideration of child-resistant buckles in order to determine the age at which a child has the physical ability to manipulate a restraint buckle. Manual dexterity skills begin to develop around 6 months. Children younger than 6 months have not acquired the skills to effectively release a buckling device. They may be attracted to buckles as general objects to manipulate, but they do not understand their function. Around 9 or 10 months, skills have developed to the point that children begin to poke and prod with some deliberation and begin to understand the function of objects and what to do with them.

Since children under 6 months of age lack the manual dexterity necessary to release a restraint buckle, child-resistant buckles may not be an issue for products intended for the use of very young children, such as infant swings, bouncer seats and infant carriers.

Consideration of other factors besides age and skill acquisition are important when determining if a child can open a buckle. The design, location and condition of a buckle are other factors that impact children's capability to open a buckle. Some buckles can be easily opened by children, others may be more complex and harder to open. Buckles can be located where they are easily reached by children or they can be positioned out of view or reach of a child. The release mechanisms of a buckle exposed to weather conditions or adverse use may cause deterioration and make the buckle easier to open.

F. Review of Ridenour Study (TAB H)

In support of his argument that current restraint system buckles are ineffective, the petitioner included a study by Marcella Ridenour (TAB A) in which the author reported a lack of child-resistance among three buckles tested.

In this study, three different stroller restraint buckle mechanisms were presented to 70 children, 24 to 36 months of age. The three buckle styles examined were the double D-ring variety with a flexible strap (Style 1), the center button-release mechanism (Style 2) and the side-release mechanism (Style 3). Children were randomly assigned to one of the three buckle groups and given 15 opportunities to attempt to open the same buckle mechanism. Ridenour concluded that the double D-ring buckle was the most difficult buckle for the children to open, followed by

the side-release mechanism. The easiest buckle for the children to open was the center-release mechanism.

It should be noted that the ASTM voluntary standard for high chairs prohibits the use of double D-ring fasteners on the restraint system. The standard requires a locking mechanism that is automatically engaged when the restraint system is enacted. A double D-ring requires manual manipulation to engage the buckle and tension to keep the buckle locked. The photos below illustrate a closed and an open double D-ring buckle.

Figure 4: Double D-Ring buckle (Left picture is closed; right picture is open)





Nineteen of the 70 children (27%) in the study were found to have been able to open one of the buckles. However, since 73% of the children were unable to unbuckle themselves, one could conclude that the buckles were relatively effective in the majority of cases even though they were not designed to be child resistant.

The majority of the incidents in the CPSC data, 17 of the 25, where the children were alleged to have unbuckled themselves involve children under 24 months of age. In contrast, the Ridenour study focused exclusively on children 24- to 36-months-old. Therefore, it would appear, based on CPSC data, that Ridenour focused on an age group that is not of primary concern. Looking specifically at the stroller incidents - the product involved in the Ridenour study - eight of the nine incidents reported to CPSC involved children under 24 months.

G. Comments Received in Response to the December 29, 1999, Federal Register Notice

The Commission received 16 comments in response to the <u>Federal Register</u> notice. Commenters included the petitioner; the attorneys for a juvenile products trade organization; a juvenile products manufacturer; two children's safety consultants; a national safety organization; eight consumers and one child safety advocate. Copies of the comments are available upon request from the Office of the Secretary.

The petitioner submitted additional data from CPSC to support his petition for child-resistant buckles. A safety consultant, four consumers and a national safety organization wrote in support of requiring shopping carts, strollers, high chairs, and similar products to have child-resistant buckles on the restraint system. In addition, four consumers and a child safety advocate

supported the petition and provided personal accounts of their children and grandchildren defeating the buckle on shopping carts, car seats, and high chairs.

Representatives of the juvenile products trade group and a manufacturer voiced opposition to the petition for mandatory rulemaking. One child safety consultant questioned the validity of the petitioner's data.

At a March 16, 2000 public meeting with the staff, the petitioner distributed copies of comments that he had solicited via the internet. Four of these solicited commenters did file a statement with the Commission and their comments are included. Below are the major issues raised by the commenters and the staff's responses.

1. A juvenile products trade organization stated that the "petitioner fails to extract from the data the circumstances surrounding the falls that occurred with each of these product categories and simply supposes that the falls were caused by the use of ineffective buckles."

Staff Response (TAB C):

The staff agrees that there is no estimate of the number of fall incidents that occur from juvenile products due to children releasing the restraint system buckle. However, the petitioner did not claim that his estimate of 33,000 injuries from falls are all due to ineffective buckles.

2. Subsequent to the submission of the petition, the petitioner provided an additional 33 "Verbatim Comments" from CPSC databases to support his petition for child-resistant buckles on restraint systems. The petitioner received these data from the CPSC Injury Information Clearinghouse for mid-year 1999 through the end of 1999.

Staff Response (TAB C):

Of the 33 incidents listed, six mentioned a child releasing the restraint system buckle. The remaining incidents listed reasons similar to those from the incidents submitted with the petition.

The 23 incidents originally submitted with the petition combined with these 33 additional incidents sums to 56 incidents submitted by the petitioner to support his claim for child-resistant buckles on restraint systems. Of the total 56 incidents submitted by the petitioner, 17 incidents actually state that a child unbuckled the restraint system (11 incidents from the original 23 and six from the additional 33 incidents). Fifteen of the 17 submitted incidents are included in staff's count of 25 incidents of child releasing restraint buckles from January 1997 through May 2000. The two incidents that staff did not include are the NEISS cases previously mentioned.

3. According to a consumer safety advocate, "most juvenile product restraints have easy to operate latching systems. This ease of use is designed primarily for parental convenience; however, if it is easy for parents to use, it is often easy for a child to figure out how to use it too. Because of ease of use, many children are easily able to defeat the restraint system. When the child repeatedly defeats the restraint system, many parents will simply stop using the restraint rather than continually battle with the child."

Staff Response:

Staff believes that the latching systems on juvenile products should be easy for adults to use, but difficult for children to defeat. However, in order for the Commission to mandate the use of child-resistant buckles it must have data to demonstrate that current restraint buckle design is resulting in children unbuckling the restraint and that as a result of doing so, children are sustaining injuries. The available data does not support this position. Further, there is no information provided by the petitioner or others that current buckle designs are difficult for consumers to use thereby causing them not to use restraints.

4. A national safety organization states that "falls are the leading cause of non-fatal injuries to children and, each year, more than 55 children age 4 and under die as a result of a fall-related injury."

Staff Response (TAB C):

Staff agrees that falls are the leading cause of non-fatal injuries to children. However, the role that buckles for restraint systems play in these injuries is unknown. The source of the commenter's statistic that more than 55 children under age 5 die as a result of fall-related injuries is unknown. According to the National Safety Council, 80 children under age 5 died as a result of a fall-related injury in 1998. Seventy children under age 5 died from the same cause in 1997, as cited by the National Safety Council. It is unknown how many, if any, of these fall deaths were the result of a child releasing a restraint system buckle.

5. A child safety advocate states that "since the early 1980's, the Commission's policy has been to defer to an industry's existing safety standard or allow the industry to make its own standard..." The commenter continues with a statement that there are no federal laws that require manufacturers to comply with voluntary standards.

Staff Response:

Section 3(i)(2) of the Federal Hazardous Substances Act states that if there is an applicable voluntary standard concerning a specific risk of injury the Commission is considering regulating, then before the Commission can issue a final regulation, it must find that either the voluntary standard is not likely to adequately reduce the risk of injury or compliance with the voluntary standard is not likely to be substantial.

By the nature of a *voluntary* standard, the government does not enforce compliance to the standard. However, CPSC's Office of Compliance may evaluate a children's product that fails to

comply with a voluntary standard to determine if it is defective and presents a substantial risk of injury to children. If so, the compliance staff may seek a recall of the product. Compliance to juvenile product ASTM voluntary standards is often determined by certification of the product by the Juvenile Product Manufacturers Association.

III. OPTIONS

1. Grant the petition.

If the Commission determines that falls due to children releasing child restraint system buckles may present an unreasonable risk of injury, and that mandatory action may be reasonably necessary to address the risk, the Commission may grant the petition and issue an ANPR to initiate rulemaking to require child-resistant release mechanisms on child restraint system buckles.

2. Deny the petition and direct the staff to work with industry.

The Commission may deny the petition and direct the staff to work with a voluntary standards organization, such as ASTM, to address the risk of fall-related injuries through the development of provisions for child-resistance of buckles on restraint systems.

3. Deny the petition.

If the Commission determines that the available information does not indicate that child restraint system buckles present an unreasonable risk of injury, or that mandatory requirements would not effectively reduce the risk of injury associated with child restraint system buckles, the Commission may deny the petition and take no further action to address the child-resistance of buckles on restraint systems.

IV. CONCLUSIONS AND STAFF RECOMMENDATION

The staff recommends that the Commission deny the petition. Although there is a risk of injury associated with falls from juvenile products and shopping carts, the available information does not indicate that child restraint buckles are responsible for a significant portion of these injuries.

The staff recognizes that each year a large number of children under 5-years-old receive hospital emergency room treatment for falls from juvenile products and shopping carts. Approximately 30,800 children were treated in emergency rooms for falls from high chairs, strollers and shopping carts in 1998. However, there is no estimate of the number of these fall injuries that are due to children defeating the buckle of the product's restraint system. Based on a search of CPSC consumer complaints over a three and a half year period, staff is aware of only 25 incidents on juvenile products and shopping carts in which a child was reported to have defeated the restraint buckle. Relative to the number of juvenile products and shopping carts with restraints in use in the U.S. at any given time, over 35 million, the number of reported incidents appears small.

In most falls from juvenile products or shopping carts with restraints, it is difficult to determine what role the buckle played in the incident. Therefore, the issue of the restraint's buckle, as well as the entire restraint system, should be explored more thoroughly. This is the subject of the CPSC Child Restraint Project, a two-year project started in FY 2000. The project will evaluate numerous aspects of the restraint system, including buckles, leg holes, anchorage points, seat measurements and adjustment mechanisms. The objective of this project is to define areas of the restraint system that require improvement, thus assuring that child restraints will effectively and safely secure children in juvenile products.

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TAB A

CPSC/OFFICE OF THE SECRETARY

1999 NOV 15 P 2: 04

John A Galbreath 2516 Chestnut Woods Ct Reisterstown, MD 21136 410-666-7273

November 15, 1999

Office of the Secretary
U.S Consumer Products Safety Commission
Washington, DC 20207

Subject: Petition For Rulemaking

Dear Sir or Madam:

This petition requests that the CPSC initiate a new rule requiring that the buckles used to fasten child restraint systems in various products meet a child-resistance standard. Specifically, this petition requests that these buckles be required to employ a double-action release mechanism, in which two separate and distinct actions are needed for release. Currently, there is no such standard, and the lack of one is a contributing factor in many injuries which occur when children fall out of these products. The products for which this new rule is requested include strollers, high chairs, changing stations, shopping carts, and the like.

Support for this request follows, drawn from 1) my personal experiences and those of my family, friends, and various other child caregivers; 2) injury data from the CPSC's NEISS and other databases; and 3) a recent research study which points up the lack of child-resistance in stroller restraint buckles.

Personal Experiences

While raising my two daughters, I had much personal experience with these restraint systems, and found them to be largely ineffective – primarily because my children, even while quite young, could quickly and easily release the conventional side or center-release buckles on the restraints. They then would stand up in the stroller, high chair, or shopping cart, and were often in danger of falling out. And in fact, they sometimes did fall out, incurring moderately severe injuries My friends and family have all had similar experiences.

In addition, I have since spoken with many other parents on this subject – primarily after seeing those parents encounter this problem themselves while pushing their children around malls, dining with them in restaurants, and shopping with them in grocery and other stores To a person, they were very aware of the problem, frustrated by it, and desirous of a more effective, more child-resistant buckle.

Injury Data

Methodology

I examined the NEISS database of stroller, high chair, and shopping cart injuries over the 7/31/98 to 7/31/99 timeframe (a year's worth of the latest available data). For each product, I isolated the injuries that were caused by children falling *out*, such as would occur when the restraint system was not used, or when it was used but was ineffective.

Falls which occurred from children climbing on or into the product were not counted as "falls", nor were falls which were a consequence of the product being first tipped over. More effective restraint systems would not necessarily prevent those types of falls, and thus it seemed prudent to not include them in my results. Said another way, the "children's injuries from falls" numbers shown in my results truly represent the number of injuries which could be prevented by more effective restraint systems

Once the injuries were tabulated for the NEISS sample of hospital emergency departments, national injury estimates were computed using the sample-to-national "gross-up" factors from calendar year 1998 (again, these were the latest available).

Results

The results are summarized in the attached table. A few highlights follow-

- Almost 33,000 injuries/year in the U.S. result from children falling out of strollers, high chairs, or shopping carts - that's two-thirds to three-quarters of the total children's injuries from these products.
- These injuries can be very severe skull fractures, concussions, head wounds, and broken bones
 often result, because the child usually falls head-first from a significant height to a hard-surface floor
- Moreover, these are just the reported injuries it's likely that many more injuries occur, but go unreported due to lack of medical insurance, parental embarrassment at their perceived inattention, etc.

Discussion

Certainly the magnitude of the injury numbers justifies further study of restraint system safety and effectiveness. Clearly, a significant number of injuries could be prevented if a more effective restraint system, which could not be defeated by a child, were a requirement on these products.

I recognize that some portion of these falls occur when a restraint system is not present, or when one is present but is not used. However, from my own personal experiences, those of my family and friends, and those of other parents I've spoken to, I can attest that a major reason for non-use of restraint systems is ineffectiveness, not inconvenience. Most people consider the conventional plastic snap buckle used in the restraints to be sufficiently convenient. These buckles are ineffective, though, and that leads to non-use. Children as young as 6 months can easily release the buckles, and they often do this repeatedly after an adult has strapped them in. After a while, the adult gives up – after all, why bother using the restraint system if the child can quickly and easily release the buckle and unstrap themselves? In sum, if these restraint systems were more effective, they would undoubtedly enjoy greater use.

I have attached actual verbatim comments, drawn from the NEISS, Accident Investigation, and Reported Incident databases, which vividly illustrate the problem of children unbuckling their restraint straps

It's interesting to note that the current ASTM standards for strollers, high chairs, and the like devote considerable attention to such matters as structural integrity, gaps between parts, etc. However, those things cause relatively few injuries, as evidenced by the NEISS injury data. Falls cause the great majority of injuries, yet there is relatively little in the standards concerning restraint systems, and nothing in them concerning the child-resistance of the restraint system's weak link – the buckle.

Recent Research Study

For further information and reference, I have also attached the results of a study on stroller buckles, done by Marcella Ridenour of Temple University's Biokinetics Research Laboratory. This study points up the lack of child-resistance in these buckles, and the ease with which even very young children can defeat them. The study also notes that safety features on other children's products, such as crib side rails, employ double-action mechanisms to prevent children from inadvertently or intentionally defeating them. The unferent child-resistance of double-action mechanisms is also well established in such devices as medicine bottles and cleaning solution containers.

Importantly, it would not be effective to merely increase the force needed to release a conventional side or center-release buckle. First, it would be difficult to determine just how much to increase the force by As Ms. Ridenour's study points out, children's automobile seat buckles currently have a force standard, but many children are still able to open those buckles. Second, taking such a "brute force" approach might make the buckles too difficult for older caregivers, or caregivers with reduced hand strength, to operate

Relevant Current & Upcoming CPSC Studies

Over the past few months, I have spoken informally with a number of CSPC people on the subject of child restraint system safety. The folks I've talked to have been very helpful and informative, and I was pleased to hear that this issue is already on your radar screen. In fact, the Division of Human Factors is about to undertake a comprehensive study of restraint system safety and effectiveness in children's products. Funding has been provided for this study in the current fiscal, and from my discussions with the people involved, it seems like the study will be given high priority when it comes to resources, scheduling, etc.

It seems appropriate that this upcoming study include an examination of two specific issues raised by this petition – first, the significant number of injuries which occur even when a restraint is used, because the restraint buckle is defeated by the child; and second, the degree to which ineffectiveness of the restraint contributes to non-use. A comprehensive examination of these two issues would provide a good basis for determining whether child restraint systems would benefit from having child-resistant buckles.

Separately, Hazard Analysis is currently conducting an update of their 1994 study on shopping cart safety. It also seems appropriate that this update include an examination of the two issues discussed above, with a view towards determining whether shopping cart restraint systems would benefit from having child-resistant buckles

Summary

Hopefully, your current and upcoming studies, and this petition, will drive a change in the restraint system standards for children's products, thus helping to reduce the large number of injuries caused by children falling out of them. Of note, buckle designs which require two distinct actions for release are already available, and could be quickly adopted by manufacturers in order to meet a child-resistance standard. If you have any questions about this petition, please feel free to contact me at my home number, shown at the top of this letter.

Sincerely,

ohn Galbreath

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STROLLER, HIGH CHAIR, AND SHOPPING CART INJURIES, 7/31/98 TO 7/31/99

	NEISS Sample of Hospital	of Hospital Eme	Emergency Depts.		Estimatec	Estimated Total U.S. *	
	Total <u>Ínjuries</u>	Children's <u>Injuries</u>	Children's Injuries <u>From Falls</u>	Total <u>Injuries</u>	Children's <u>Injuries</u>	Children's Injuries <u>From Falls</u>	% of Children's Injuries <u>From Falls</u>
Strollers	\$08	469	321	14,944	13,796	9,443	68.4%
High Chairs	263	254	188	8,432	8,143	6,027	. 74.0%
Shopping Carts	994	. 781	497	34,524	27,126	17,262	63.6%
Totals	1,765	1,504	900*1	57,900	49,115	32,732	%9.99

* Estimated using NEISS sample of hospital emergency depts. and CY98 sample-to-national "gross-up" factors

SAMPLE OF VERBATIM COMMENTS FROM STROLLER, HIGH CHAIR, & SHOPPING CART INJURIES

DATE	AGE	INJURY	VERBATIM COMMENTS
86/1/6	2 years	Head hematoma	A girl, age 2, was hospitalized for an epidural hematoma received in a fall from a shopping cart onto a tiled floor in a store. Victim was able to unbuckle the seatbelt in the shopping cart.
5/18/98	9 months	Head wound	A 9 month old female was placed in a high chair for feeding. Victim was able to unbuckle the seatbelt and slid out between the seat and tray. Victim landed feet first and fell into cupboard drawer. Victim lacerated forehead and was treated and released receiving 12 stitches
1/18/99	2 years	Dislocated jaw	A 2 year old female unbuckled seat belt of shopping cart twice in video store. After second time, she fell from shopping cart to floor.
96/7/	21 months	Facial hematoma	The 21 month old male victim was injured while on a shopping trip with his mother at a grocery store. The victim was seated in the seat of the basket when he undid his seat belt and fell out of the basket. He hit his forehead on the concrete floor and sustained a bump. He was transported to the hospital in an ambulance where he was treated for the hematoma and then released from the hospital.
3/17/99	7 months	Head cuts and scrapes	A 7 month old female sustained a minor contusion to her head While she was riding in her stroller, she was able to open the restraint straps and fell out of the stroller, striking her head on a concrete sidewalk.
10/6/98	9 months	Facial cuts and scrapes	Patient's 3 year old sibling unbuckled seatbelt in stroller, and child fell out onto street
8/25/97	6 months	None	The waist strap unlocked with ease on a baby stroller, during use by a 6 month old male.
6/25/98	17 months	Head injury	A 17 month old male hit his head on the floor after he unfastened one side of the harness on his high chair and tumbled out.
4/1/97	4 years	None	4 year old girl unbuckled safety seat belt in shopping cart. She has done this with other seat belts since she was I year old. Consumer feels seat belts should be redesigned.
11/5/98	5 months	Head bruise	A 5 month old female was bruised on her head in a fall from a high chair that has a restraint lock that is easily dislodged.

SAMPLE OF VERBATIM COMMENTS FROM STROLLER, HIGH CHAIR, & SHOPPING CART INJURIES

DATE	AGE	INJURY	VERBATIM COMMENTS
10/28/97	2 years	Head cuts and scrapes	Patient fell out of a shopping cart after unbuckling himself, and struck head on cement floor.
12/14/99	11 months	Internal head injury	The 11 month old male victim sustained a head injury after he fell out of a shopping cart. He unbuckled himself and stood up, losing his balance. He was taken to the hospital, examined, and released.
7122/99	2 years	Dental injury	The 2 year old female victim was injured while riding in a shopping cart at a grocery store. The victim unbuckled her seat belt and stood up in the seat of the cart. The victim fell to the floor, hitting her face and mouth. The victim was taken to the hospital where the victim was treated for the loose teeth and then released
66/9/5	3 years	Facial cuts and scrapes	The 3 year old male victim sustained a contusion to his face. The victim, who was seated in a shopping cart, unbuckled the seat belt and fell out, face down. The victim was taken to the hospital, examined and released
9/3/98	11 months	Head hematoma	An 11 month old male fell from a high chair when the restraining strap buckle released Although his head hit the floor and a hematoma formed on his forehead, no medical attention was sought.
8/1/98	2 months	None	A 2 month old female defeated the locking strap on her high chair and flipped over the tray, landing on her bottom on the tiled floor.
86/6/9	18 months	None	An 18 month old male is able to unbuckle the lock mechanism on straps in his stroller.
2/1/96	10 months	None	A 10 month old female nearly fell from her highchair after she loosened the strap buckle and stood up.
10/12/98	10 months	Internal head injury	Minor head trauma. Patient fell out of stroller at home. Reported to be buckled in
12/3/98	11 month	Head cuts and scrapes	An 11 month old male victim was buckled in a cart. While victim's mother and her slance were looking at something on an shelf in store, and the next they saw was the victim landed on his head on the shor. The victim was treated in the hospital.

SAMPLE OF VERBATIM COMMENTS FROM STROLLER, HIGH CHAIR, & SHOPPING CART INJURIES

DATE	AGE	INJURY	VERBATIM COMMENTS
5/10/99	10 months	Eye cut and scrape	10 month old male belted in stroller, stood up and fell out. Handle of stroller hit his eye. Corneal
			abrasion.
10/29/98	9 months	Head cuts and	The 9 month old victim sustained a contusion to his head when the belt from the cart he was
		scrapes	riding in came loose, he stood up and fell. He was taken to the hospital, treated, and released.
66/08/8	10 months	10 months Head cuts and	The 10 month old male victim was in a shopping cart seat, wearing a seat belt, when his mother
		scrapes	turned her back for a moment. The victim somehow got loose from the seat belt and fell out of
			the cart, landing on the floor and hitting his head. The victim's mother took him to the hospital
- -			where he was examined and diagnosed with a contusion to the head and released.

HOW CITED RESISTANT ARE STROLLER BELT BUCKLES?

MARCELLA V RIDENOUR

Biokineties Research Laboratory, Temple University

Summary —70 children, between the ages of 24 and 36 months, participated in the assessment of three different styles of stroller seat buckles representing difficulties for children to disconnect the buckle mechanism in the restraint system. None could prevent all the children from opening the restraint system. One was much easier for children to open than the other two styles. Stroller-restraint buckles provide false se curity to parents who use strollers, as there are no published standards regarding the use of children's stroller seat belt buckles as a safety device.

Most strollers for transporting young children have a restraint system to assure the children do not get out of the device at unpredictable times. An effective restraint system is necessary for safe use of a stroller because they may be used in hazardous locations such as streets with automobiles and bridges and docks over water. If the caretaker cannot maintain constant eye contact with the child, during a brief simultaneous event such as counting money, it is assumed the restraint system will prevent the child from escaping from the stroller during this momentary lapse of visual monitoring. Child safety experts recommend use of a seat belt but they do not warn about older children in the stroller who may quickly open the buckle and escape from the stroller (3)

Strollers come in a variety of sizes and styles. Those meeting the American Society of Testing and Materials Standard Consumer Safety Specification from for Carriages and Strollers must have a restraint system (1). This standard does not evaluate the child-resistance of the restraint-system buckle based on the problem solving and manipulative skills within the age range of the children using the stroller. Most caretakers assume, if the child meets the recommended age and physical size provided in the instructions, then the restraint system will hold the child until the caretaker decides to open the restraint system. Almost all stroller restraints are only activated when a parent or caretaker closes a belt with a buckle. If this belt buckle is part of the restraining system is ineffective. If these belt buckles can be opened by children within the recommended age range described in the instructions, then restraint systems will provide false security to parents who are transporting

The author expresses appreciation to Andrea Hoffman for essisting with data collection. Address enquirties to M. V. Kidenour, Biokinetics Research Laboratory, Pearson Hall, Temple University, Philadelphia, PA 1912.

M. V. KIDENOUR

left children in a stroiler through unsafe areas such as busy attects of hear

sting methods for the effectiveness of the stroller-restraint system involve ause the dummy cannot explore and manipulate the buckle. Testing of the entally fall out when the restraint is used according to manufacturer's inructions providing the child does not manipulate the closure device. All ne use of a CADI dummy This dummy is very different from a child bestraint system also unvolves a minimum force test to evaluate the attachard for infant and children's strollers since the late 1970s (1). This standard oes not address the child resistance of the belt buckles. The standard has a rocedure to evaluate the restraint system to assure the child cannot acci-American Society of Testing and Materials has published a safety stanent points between the restraint system and the stroller.

5% of the 2-yr.-old children and 26% of the 3-yr.-old children were able open the buckles on their car seats (4). Stroller standards do not have a ig devices used to secure dropside rails to open only if there is a minimum size of 10 pounds to activate the release mechanism or there is a double-acon release mechanism requiring two distinct actions for release (6, 7). The lany children are able to open the buckles on car seats. Hunter reported unimum requirement for child-resistance of the belt buckle in the restrain-Other juvenile product standards address the design of child-resistant itches and buckles. The mandatory crib standard requires locking or latchsandstory standard for buckles on children's automobile seats requires a ninimum of 9 pounds to release the buckle and a maximum of 14 pounds.

uirements, until 1992, there has been an extimated reduction of about 460 redicine containers requires testing with actual children and older adults to int packaging has reduced child mortality from the unintentional ingestion oral prescription drugs by children 5 years and younger. From 1974, the rat year oral prescription drugs were subject to child-resistant packaging reor children to open. The testing methods for child-resistance packaging for neet the requirements published by the federal government (1). Child-resis-There are other locking products intended for adult-use only such as redicine containers, and these products have standards to assure the latchig mechanisms are easily opened by adults and are designed to be difficult hild deaths (5). ig system.

etween 2.0 and 2.9 years old. The average age of children was 2.5 years All 70 children were enrolled in day-care situations which were the sites for The purpose of this study was to examine whether closing mechanism or restraint systems on strollers were effective and could not be opened by he oldest group of children who frequently use strollers, children who are ild. Both boys and girls were included in the study: 39 boys and 31 girls

ed the buckle device to provide a demonstration for each child This was to minutes during a session to open the buckle on the restraining system Each buckle required a different hand manipulation to open the device. The simulate opportunities for demonstrating release of the belt buckle within ating the buckle during the daily session. The child had a maximum of 5 to one of three style groups. The 15 observations were within a 3-wk pc. buckle devices since they typically use the same stroller over a long pertod of time For each session, the child was placed in the assigned stroller, and the experimenter attached the belt-buckle device and then immediately openthe child's environment. Then the child was asked to get out of the stroller. Each child had to attempt to get out of the stroller at least once by manipufaculty, staff, and students' children. These 70 children were divided into straining system. Three folding strollers were identical but for the buckle device on the belt of the restraint system. Each child was randomly assigned riod The maximum number of observations per day was two. When the child was observed for two sessions, one session was a morning and one session was in the afternoon These sessions provided repeated opportunities for each child to attempt to open the buckle device Children in homes and child care centers have many opportunities to manipulate the same styles of this study. All day-care centers were affiliated with a university and included three gloups, each group had 15 opportunities to attempt to open one of three closing mechanisms for the stroller waist-belt component of the rebuckles, Styles 1, 2, and 3, are illustrated in Fig. 1

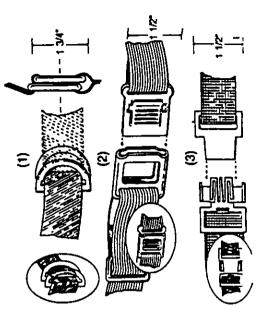


Fig. 1. Three styles of stroller buckles, with clasps at the (1) top. (2) middle, and (3) bottom

ere found among all comparisons between any two of three buckle styles =.05). Style 1, the D-rings and flexible strap, was opened less frequently tion sessions. The analysis indicated a significant main effect for device 23.16, pm 01). The style of buckle influenced the child's ability to in the buckle. Only 27% of the children, 12 boys and 9 girls, were able open any of the three buckles. The Newman-Keuls post boc test was used locate significant differences among the styles of buckles. Differences an Styles 2 and 3. Style 1 was opened during 12 (1%) of the 1050 test sesans. One child opened Style 1 in 10 of the 15 sessions, and two other ickle, were examined with a 3 by 15 analysis of variance. The nonrepeated ctor was the three styles of devices. The repeated factor was the 15 obser-The data, number of children successfully opening the stroller belt ildren opened Style 1 once in the 15 sessions.

iplied to the buckle. Style 2 required a push force in the center of the as opened during 54 (5%) of the 1050 test sessions. Four children, two asgned to Style 2 and two assigned to Style 3, were able to open these durg all 15 pessions. Eleven of the children were not able to open the Style 2 ackles during any of their 15 sessions Twenty children were not able to en assigned to Style 2 opened these buckles between 1 and 14 times durrur children assigned to Style 3 buckles opened the buckle between 1 and toward the center of the buckle, to separate the two components of the ickle. Style 2 was opened during 75 (7%) of the 1050 test sessions. Style 3 sen the Style 3 buckles during any of their 15 sessions. Eight of the chilg the 15 sessions, and most opened the buckles fewer than five times. ould not separate and release unless the required directional forces were yle 3 required two simultaneous push forces, from both sides of the buck-Both Styles 2 and 3 had two rigid overlapping components which ickle when the two overlapping components were in the correct alignment.

he ensiest buckle to open, Style 2, required only one pushing force when e buckles a few times during the early sessions and then were not able to e 15 sessions, caretakers of 2-yr.-old children must maintain visual contact all times because children may open these widely used styles of buckles cluded in this study at any time. Style 1, a strap threaded through two D. aped rings, appeared to be the most difficult to open. This buckle may we required more problem-solving skills to unthread the belt than the othtwo styles which required the execution of one or more directional forces. oth components of the buckle were in proper alignment. When the belt There was no significant difference for sessions; some children opened en them again. Other children opened the buckles a few times during the er sessions. Most children opened no buckles, and a few children opened ickles every session. Since there is no predictable pattern or trend among times during their 15 sessions.

STROLLER BELT BUCKLES

ing position and a child who is manipulating the buckle may accidentally formance which was not replicated in later sessions. If these openings are accidental rather than based on motor and cognitive skill, this unpredictable opening of buckle could result in the escape of a 2-yr-old. An extensive study (4) of cognitive skill-based child-resistant safety buckles showed the achievement of 100% child-resistant effectiveness for 3- to 5-yr.-old children, with adults being able to open the same buckle in less than 5 sec. One session was scheduled with each child or adult. Four different buckles were evaluated by the same child or adult. The testing of the buckles was in a laboratory environment in order not to encourage children to open car-seat apply the appropriate directional force. This may account for successful perdoes not have tension and is loose, the buckle alignment may be in the openrestraint buckles while traveling in an automobile.

ment and tightness of the restraint system each time the stroller is used. The chairs does not allow a double-D ring similar to the Style 1 buckle as the device to connect two components of the restraint system. According to American Society of Testing and Materials standards, all restraining systems on high chairs must have connecting and adjustment mechanisms which are the buckle. The unthreading process may be easier for larger children since the threading takes place closer to the end of the strap, making it easier to unthread the strap or for the strap to slip out of the threaded position. The double-D ring buckle requires the caretaker to select the appropriate adjustble-D ring buckle, should be interpreted cautiously because the resistance is not the only factor for establishing the adequacy of the restraint system. The normal movement of a child while restrained in a stroller may cause some slippage of straps through the double-D ring buckle which may loosen the restraint and allow the child to climb out of the restraint without opening American Society of Testing and Materials standard for restraints on high The favorable results obtained in the present study for Style 1, the douindependent (1)

Present results indicate some buckles on stroller restraint systems may ical stroller buckles have to meet any performance standard regarding child provide false security to parents and other caretakers. None of the three typ-

REFERENCES

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- 2 AMERICAN SOCIETY FOR TESTING AND MATERIALS (1993) F404-89, Standard consumer safety specification for high chairs. Annual Book of ASTM Standards, 15 07, 131-135
 3 BODMAR, J. & KAINER, B (1990) Upscale wheels for the disper set buying baby strollers. Changing Times, 44, 55
- 4 Huntin, R. M (1990) Cognitive skill based child remisant safety belt buckle Bozeman, MT Yellowstone Environmental Science

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6. U.S. Consumera Product Savety Commission (November 21, 1973) Requirements for full-size beloy cribs Federal Register, 38, 32129
7 U.S. Consumer Product Savety Commission (1994) Requirements for full size buby cribs Washington, DC U.S. Government Printing Office. (Code of Federal Regulations, Title 16, Commercial Practices, Part 3508)

Accepted January 8, 1997

TAB B

CONSUMER PRODUCT SAFETY COMMISSION

Petition Requesting Requirements for Buckles on Child-Restraint Systems on Various Children's Products

AGENCY: Consumer Product Safety Commission.
ACTION: Notice

SUMMARY: The Commission has received a petition (HP-00-1) requesting that the Commission develop requirements for buckles used on child-restraint systems on such products as strollers, high chairs, changing stations, and shopping carts. The Commission solicits written comments concerning the petition DATES: The Office of the Secretary must receive comments on the petition by March 6, 2000.

ADDRESSES: Comments, preferably in five copies, on the petition should be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-0800, or delivered to the Office of the Secretary, Room 501, 4330 East-West Highway, Bethesda, MD 20814. Comments may also be filed by telefacsimile to (301) 504-0127 or by email to cpsc-os@cpsc.gov. Comments should be captioned "Petition HP-00-1, Petition for Child-Restraint Systems "A copy of the petition is available for inspection at the Commission's Public Reading Room, Room 419, 4330 East-West Highway, Bethesda, MD. FOR FURTHER INFORMATION CONTACT: Rockelle Hammond, Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207. telephone (301) 504-0800, ext 1232. SUPPLEMENTARY INFORMATION: The Commission has received correspondence from John A. Galbreath requesting that the Commission issue a standard for buckles used on childrestraint systems on such products as strollers, high chairs, changing stations, and shopping carts. The petitioner relies on his own experience, CPSC's NEISS data, and a recent research study on stroller buckles to conclude that childrestraint systems on various children's products are ineffective. He states that these buckles are not sufficiently childresistant and can be defeated by children. The petitioner requests that the Commission issue a standard requiring that such buckles meet a test for child-resistance. The Commission is docketing the correspondence as a petition under provisions of the Federal Hazardous Substances Act, 15 U.S.C.

1261–1278.
Interested parties may obtain a copy of the petition by writing or calling the

Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, telephone (301) 504-0800 A copy of the petition is also available for inspection from 8 30 a m to 5 p m. Monday through Friday, in the Commission's Public Reading Room, Room 419, 4330 East-West Highway, Bethesda, Maryland

Dated December 29, 1999
Sadye E. Dunn,
Secretary, Consumer Product Safety
Commission
[FR Doc 00–190 Filed 1–4–00, 8 45 am]
BILLING CODE 6358-01-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)

AGENCY: Office of the Secretary, DoD
ACTION: Notice of Extension of Cancer
Treatment Clinical Trials Demonstration
Project

SUMMARY. This notice is to advise interested parties of an extension of a demonstration project in which the DoD provides CHAMPUS reimbursement for eligible beneficiaries who receive cancer treatment under approved National Institutes of Health, National Cancer Institute (NCI) clinical trials Participation in these clinical trials will improve access to promising cancer prevention and therapies for CHAMPUS eligible beneficiaries when their conditions meet protocol eligibility criteria DoD financing of these procedures will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of emerging therapies in the prevention and treatment of cancer. At this time, there is insufficient demonstration data for a full evaluation of costs associated with enrollment in clinical trials. Extending the demonstration until the termination of the NCI/DoD Interagency Agreement wall allow sufficient time for patient accrual to clinical trials and collection of data, which allows for comprehensive economic analysis. This demonstration also affects TRICARE, the managed health care program that includes CHAMPUS This demonstration project is under the authority of 10 U.S C., section 1092, and expires upon the termination of the NCI/DoD Interagency Agreement.

EFFECTIVE DATE: January 1, 2000. FOR FURTHER INFORMATION CONTACT: COL Karen Ferguson, Office of the Assistant

Secretary of Defense (Health Affairs), TRICARE Management Activity, (703) 681-3628

A Background

On January 24, 1996, the Department provided notice in the Federal Register (61 FR 1899) of an expansion of an existing demonstration for breast cancer treatment clinical trials to include all cancer treatment clinical trials under approved National Cancer Institute (NCI) clinical trials. The demonstration purpose is to improve beneficiary access to promising new therapies, assist in meeting the National Cancer Institute's clinical trial goals, and arrival at conclusions regarding the safety and efficacy of emerging therapies in the treatment of cancer. The January 24, 1996, notice anticipated the possibility of extending the demonstration

The NCI trials program is the principal means by which the oncology community has developed clinical evidence for the efficacy of various treatment approaches in cancer prevention and therapy Participating institutions include NCI's network of comprehensive and clinical cancer centers, university and community hospitals and practices, and military treatment facilities. Despite this extensive network which includes the nation's premier medical centers, cure rates for most types of cancer remain disappointing, highlighting the significant effort still required for improvement The principoal means by which advances in therapy will be realized is through application of research to victims of cancer In support of NCI's efforts to further the science of cancer prevention and treatment, the Department expended its breast cancer demonstration to include all NCIsponsored phase II and phase III clinical trials It further expanded the Interagency Agreement to cover cancer prevention clinical trials on June 21, 1999 This expanded demonstration will enhance current NCI efforts to determine safety and efficacy of promising cancer prevention and treatment therapies by expanding the patient population available for entry into clinical trials and stabilizing the referral base for these clinical activities While this demonstration provides an exception to current CHAMPUS benefit limitations, the Department hypothesizes that this increased access to innovative cancer prevention and cancer treatment therapies will occur at a cost comparable to that which the Department has experienced in paying for conventional therapies under the standard CHAMPUS program.

TAB C



Memorandum

Date:

June 27, 2000

TO

: Sue Ahmed, Ph.D.

Associate Executive Director, Directorate of Epidemiology

THROUGH:

Russ Roegner, Ph.D.

Division Director, Division of Hazard Analysis

FROM

Debra Sweet, Project Manager, EPHA

SUBJECT:

Child-Resistant Buckle Petition

This memorandum was prepared in response to Petition HP 00-1, a petition requesting requirements for child-resistant buckles on child restraint systems on various children's products.

The table below contains the search criteria used to identify reported incidents with restraint buckles. Please note that the maximum age searched was 4 years old. This is because juvenile products are generally targeted for children 4 years of age and younger.

Databases	Dates	Ages	Produ	ct Codes and Definitions*
IPII - Injury and Potential	1/1/1997	under age 5;	1502	Baby changing tables
Injury Incident File;	through	unknown age	1508	Walkers and jumpers
INDP - In-depth	5/12/2000		1522	Strollers
Investigation File	1		1527	Baby carners (backpacks)
	1		1531	Baby carriers (bike-mounted)
	1		1548	Baby carriers (not-specified)
			1549	Baby bouncing seats (other carriers)
	İ		1553	Baby swings
	1		1555	High chairs
	1		1556	Attachable high chairs
	1		1679	Grocery or shopping carts

^{*}All listed products are known to have restraints and are intended for the use of children

The data were reviewed for incidents containing - in the summary - an explanation of the incident in which it was specifically stated that a child unfastened the buckle of the product's restraint system.

The data found in the search is anecdotal data only and should not be used to produce estimates.

Incident Data

There were a total of 25 consumer complaints received since January 1997 involving children under 5 who allegedly released the buckle of a product's restraint system. The products involved in the incidents were shopping carts (9), strollers (9) and high chairs (7). See Appendix A for a table of the incidents. Information on the specific design of the buckles involved in these incidents is not known.

Shopping Cart Incidents

Nine children reportedly unbuckled the restraint systems of shopping carts. The children ranged in age from 11-months-old to 4-years-old (11-months-old (1), 21-months-old (1), 2-years-old (4), 3-years-old child (1) and 4-years-old (2)).

Six children were injured as a direct result of a fall when they unbuckled the restraint system in the shopping cart. The injuries incurred were less serious injuries such as a contusion to the head and a contusion to the face, and more serious injuries such as a hematoma on the head, an internal head injury, a dislocated jaw and loose teeth.

Of the remaining three incidents, two children were uninjured when they unbuckled the restraint system, since the release of the buckle was noticed before a fall occurred. In the final incident, a 2-year-old child unbuckled the restraint numerous times before her mother chose to remove the child from the seat and put her in the basket of the shopping cart. The child subsequently fell from the basket of the cart and received a hematoma on her brain, which required brain surgery.

Stroller Incidents

Nine children were able to release the restraint system buckle on strollers. The youngest child was 10-months-old and the oldest was 3-years-old (10-months old (1), 11-months-old (1), 12-months-old (3), 18-months-old (1), 19-months-old (1), 20-months-old (1) and 3-years-old (1)).

Seven of the children fell out of the stroller once they released the buckle of the restraint system. Four of these children received minor injuries to the head and face. One child received a hematoma on the head, another child received bruises to an unknown body part, and the other child was mildly injured when hitting his head, but the extent of the injury is unknown. Two children released the buckles of the restraint system but were uninjured, as they did not fall from the stroller.

High Chair Incidents

High chairs were involved in seven incidents in which children were reported to have released the restraint system buckles. As high chairs are generally used for younger children, the children involved in these seven incidents ranged from 8- months-old to 18-months-old (8-

months-old (1), 10-months-old (2), 11-months-old (1), 12-months-old (1), 17-months-old (1) and 18-months-old (1)).

Two of the seven children reportedly fell from the high chair after they released the buckle. One of these children received bruises. The injuries to the other child are unknown; however, the child hit his head on the floor during the incident. The remaining five children were uninjured in the incidents; they were only reported to have released the buckle.

Response to Comments

Petition from John Galbreath

Issue 1: Mr. Galbreath states that "almost 33,000 injuries/year in the U.S. result from children falling out of strollers, high chairs or shopping carts." This information was obtained from the NEISS database when the petitioner requested information from CPSC's clearinghouse. The petitioner added up the cases that he believed constituted falls from the products - not including falls resulting from children climbing on or into the products or product tipovers. The petitioner does not state what portion of these injuries are due to children releasing the buckles of restraint systems.

Response 1: In looking at the petitioner's "Verbatim Comments," he has recorded NEISS incidents dated 1997 through 1999. Hazard analysis staff analyzed 1998 data from the National Electronic Injury Surveillance System (NEISS) for children under 5, involving high chairs, attachable high chairs, strollers and shopping carts for a comparison to the petitioner's estimate. Staff arrived at a similar estimate of 30,800 injuries to children under 5 for these products in 1998. However, again, this does not indicate the portion of injuries due to releasing the restraint system buckles.

Issue 2: The petitioner submitted - with the original petition - 23 incidents in a table of "Verbatim Comments." The comments are taken from three CPSC databases (IPII, INDP and NEISS).

Response 2: Source documents and investigations for the 23 incidents listed by the petitioner were reviewed for evidence that the child released the restraint system buckle. Eleven of the 23 incidents listed in the "Verbatim Comments" occurred when the child released the restraint system buckle. These incidents occurred between April 1997 and July 1999. These incidents can be found in Appendix B. The remaining incidents cited that the children fell out after reportedly being buckled in, loosened the restraint straps, stood up in the product and fell out or the child restraint system was easily unlocked. Nine of the 11 relevant incidents submitted with the petition are included in the Hazard Analysis count of 25 incidents. The other two of the 11 submitted incidents are from the NEISS database. The Hazard Analysis incident count is based on IPII and INDP databases only, since the NEISS data generally don't provide sufficient detail to indicate the role of buckles in fall-related incidents involving juvenile products.

Additional Data from the Petitioner

Issue: Subsequent to the submission of the petition, the petitioner provides an additional 33 "Verbatim Comments" from CPSC databases to support his petition for child resistant buckles on restraint systems. The petitioner received these data from the CPSC clearinghouse for mid-year 1999 through the end of 1999.

The 23 incidents originally submitted with the petition combined with these 33 additional incidents sums to 56 incidents sent in by the petitioner to support his claim for child-resistant buckles on restraint systems.

Response: Of the 33 incidents listed, six mention a child releasing the restraint system buckle. The remaining incidents involve products where the restraint becomes unbuckled easily or without known cause.

Of the total 56 incidents submitted by the petitioner, 17 incidents actually state that a child unbuckled the restraint system (11 incidents from the original 23 and six from the additional 33 incidents). These 17 incidents can be found in Appendix B.

Letter from JPMA Attorney

Issue: "Petitioner fails to extract from the data the circumstances surrounding the falls that occurred with each of these product categories and simply supposes that the falls were caused by the use of ineffective buckles."

Response: It is difficult to get specific details about incidents reported through NEISS due to the small summary field in the data collection process. The IPII file can provide slightly more information about the incidents, but often the details are not clear. An in-depth investigation from INDP provides the greatest amount of data; however, few of the petitioner's reported incidents were investigated to get full details of the incidents. The petitioner does not have the fully detailed data to extract specific circumstances surrounding the falls due to the nature of the summary comments from the databases. However, the petitioner does not claim that his estimate of 33,000 injuries from falls are all due to ineffective buckles.

Letter from Consumer Advocate

Issue: The commenter reports 50,000 to 70,000 reported juvenile product injuries a year occur to children under 5 years of age. That number is then multiplied by a constant from which the commenter states "nearly half a million children nationally sustain injuries from juvenile products serious enough to warrant emergency room treatment."

Response: These calculations are a misrepresentation of CPSC's data on annual injuries from juvenile products. The 50,000 to 70,000 injuries are not the "reported" injuries per year to the NEISS hospitals, rather the national estimate of injuries projected from NEISS data. Therefore, this estimate stands alone for the nation and does not need to be expanded further. In 1998, there

were an estimated 71,000 children under age five treated in U.S. hospital emergency rooms for injuries associated with nursery products.

Letter from National Safe Kids Campaign

Issue: The commenter states that "falls are the leading cause of non-fatal injuries to children and, each year, more than 55 children age 4 and under die as a result of a fall-related injury."

Response: Staff agrees that falls are the leading cause of non-fatal injuries to children. However, the role that buckles for restraint systems play in these injuries is unknown. The source of the commenter's statistic that 55 children under age 5 die as a result of fall-related injuries is unknown. According to the National Safety Council, 80 children under age 5 died as a result of a fall-related injury in 1998. Seventy children under age 5 died from the same cause in 1997, as cited by the National Safety Council. It is unknown whether any of these fall deaths were the result of a child releasing a restraint system buckle.

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Appendix A

HAZARD ANALYSIS INCIDENT DATA

The following 25 incidents are consumer complaints that occurred since 1997 and involve children releasing the restraint system buckle.

Document No.	Date of	Age of	Scenario	Injury Diagnosis (injury from buckle release)
	THEORY	V ACCIONI	SHOBBUKGICARIUS	
H9750066A	4/1997	4 years	Child unbuckled safety belt in cart	
H9750026A	4/29/1997	4 years	Child unfastened safety belt on cart with ease	No injury
H00770063.A	9/1998	2 vears	Child was secured in the shopping cart's seat by the waist strap provided; the child unbuckled the seatbelt a total of four times before her mother moved her to the basket of the cart - no injury	No injury
		,	resulting While in the basket, the victim fell out, injuring her head, requiring surgery	
08131511806001	12/14/08	11 months	While mother turned briefly, child unbuckled his seatbelt, stood	Internal organ injury
76141911519001			landing on his head.	to the head
990119HEP2241	1/18/1999	2 years	Child unbuckled seat belt of shopping cart twice in a video store: after second time, child fell to floor	Dislocated jaw
990520HEP8213	8/6/1999	3 years	Child unbuckled the seat belt and fell out of cart face first	Contusion to face
990727HEP4641	7/22/1999	2 years	Child unbuckled seat belt, stood up in the seat of the shopping cart and fell to floor	Loose teeth
990707HEP8141	7/22/1999	21 months	Child unbuckled the seat belt in the cart and fell to the floor.	Hematoma to the head
991001HEP7522	10/01/1999	2 years	Child unded the seat belt in the seat of the cart, stood up and fell out of the cart landing on his head	Contusion to head
			(continued on next page)	

			(continued from previous page)	
			SHIROTOPINES:	the state of the s
980225CNE5092 N9820044A	11/01/1997	11 months	Child unbuckled seat belt on stroller, fell forward hitting head on the sidewalk.	Bruises
H98C0038A	6/9/1998	18 months	Child unbuckled the hard plastic locking mechanism of the restraint system. Consumer received a replacement stroller seat and restraint system and the child released the replacement restraint system, also.	No injury
H9870058A	6/21/1998	12 months	Child unhooked one side of the waist strap, bent forward and began to fall out of the stroller head first. The child's father caught her before she hit the ground	No mjury
990602HEP6401	\$/10/1999	19 months	Child unbuckled the seat belt and tried to climb out. The stroller began to tip and the child fell, striking her head.	Laceration to face
990526HEP5201	5/22/1999	12 months	Child unbuckled one side of his seat belt and tried to get out of the seat. The child fell and hit his forehead on a shelf	Abrasion to head
990713HEP8213	7/11/1999	10 months	Child unbuckled the restraint and stood up in the stroller. She fell through the stroller bottom landing on her forehead	Contusion to face
990818HEP1761	8/17/1999	3 years	Child unbuckled the seat belt, stood up and fell, striking his face on the stroller frame	Abrasion to face
990923HEP6983	6/166	20 months	Child unbuckled the restraint in his stroller and stood up, child fell sideways, striking his head on the floor.	Unknown/ treated and released from emergency room
990914HEP4241	9/13/1999	12 months	Child unhooked the straps of his stroller and stood up; stroller fell backwards; child hit head on sidewalk	Hematoma to the head
VO2400804	4/4/1007	12 months	HIGHERATION ON PROPERTY CALL CALL CALL CALL CALL CALL CALL CAL	Boriere
19960190A	6/25/1999	17 months	Child unfastened one side of the restraint on high chair and fell to floor, hitting head.	Unknown
H99A0030A	10/05/1999	8 months	Child was in metal, adjustable high chair and released the seat belt, fell out and was hanging on the chair frame.	No injury
H99B0277A	11/29/1999	10 months	Child was able to unhook the safety belt buckle on high chair.	No mjury
H0010234A	12/1999	11 months	Child is unable to fasten the seat belt on her high chair	No mjury
10030136A	2/2000	18 months	Child is able to open the restraint buckles on high chair	No mjury
000309HCC0484 10030069A	3/5/2000	10 months	Child disengaged the restraint buckle on high chair, restraint system was a replacement	No mjury
Source: CPSC databases: IPH and INDP	PIT and INDP			

Source: CPSC databases: IPII and INDP.

Appendix B

INCIDENT SUBMITTED BY THE PETITIONER

The following are incidents extracted from the petitioner's "Verbatim Comments." These incidents are the 17 of the 56 incidents that actually involve a child releasing the restraint system buckle.

Document No.	Date of	Age of Victim	Product	Scenario (verbatim)
	Incident			
H9750066A*	4/1/97	4 years	Shopping cart	girl unbuckled safety scatbelt in shopping cart.
NEISS - 730287	10/28/97	2 years	Shopping cart	fell out of shopping cart after unbuckling himself
N9820044A ^C 980225CNE5092	11/1/97	11 months	Stroller	female was able to unbuckle the scatbelt on her stroller
H98C0038A	86/6/9	18 months	Stroller	is able to unbuckle the lock mechanism on straps
H9970063A	86/1/6	2 years	Shopping cart	Victim was able to unbuckle the seatbelt in the shopping cart
NEISS - 812173	10/6/98	9 months	Stroller	Victim's 3 year-old sibling unbuckled scatbelt.
981216HEP6001	12/14/98	I I months	Shopping cart	He unbuckled himself and stood up
990119HEP2241P	1/18/99	2 years	Shopping cart	. female unbuckled seatbelt of shopping cart twice in video store.
990520HEP8213	66/9/5	3 years	Shopping cart	The victim unbuckled the seatbelt and fell out
19960190A ⁷	6/22/99	17 months	High chair	. he unfastened one side of the harness
990707HEP8141	96/2/1	21 months	Shopping cart	when he undid his seatbelt and fell out of the basket
990727HEP4641	96/22/J	2 years	Shopping cart	. victim unbuckled her seatbelt and stood up in seat of the cart.
990923HEP6983 ^C	6/1/6	2 years	Stroller	somehow unbuckled (restraint) and stood up
990914HEP4241 ^C	9/13/99	12 months	Stroller	. he unhooked the straps of his stroller and stood up .
991001HEP7522 ^C	10/1/99	2 years	Shopping cart	. In the seat portion of the shopping cart when he undid the seatbelt, stood up
H99A0030A ^C	10/5/99	8 months	High chair	. and managed to release button of seat belt.
H0010234A ^C	12/1/99	11 months	High chair	female is able to unfasten the scatbelt on her high chair.

⁻ Incident is found in the petition's "Verbatim Comments" table

Source: Incidents submitted by John Galbreath, petitioner. Original data from CPSC databases. NEISS, IPII and INDP.

c - Incident is found in the comment's "Verbatim Comments" table

TAB D



Memorandum

Date:

June 12, 2000

TO

: Debra Sweet, Project Manager

Hazard Analysis

THROUGH; Alan Schoem, Director Office of Compliance

Alan Schoem, Director
Office of Compliance
Terri Rogers, Associate Director
Children's Products

FROM

Dollie N. Manley, Compliance Office

Recalls and Compliance Division

Office of Compliance

SUBJECT:

Petition HP-00-1

Recalls From FY 1995 - 2000 (as of 4/7/2000)

I searched for recalled products for restraint system failures from fiscal years 1995 to 2000 (as of 4/7/2000), specifically failures associated directly with the buckle. Product areas searched include grocery or shopping carts, baby changing tables, baby carriers-bicycle mounted, baby bouncing seats, baby carriers (front and back), jumpers, strollers, high chairs, baby swings, and attachable high chairs. Only one recall, a stroller, was found.

Recalls From FY 1995 - 2000 (as of 4/7/2000)

Fiscal Year	Product	Defect	Іпјигу Туре	Corrective Action	Approximate # of Units
1997	Stroller	Restraint buckle unlatches and fold locks fail causing the stroller to collapse unexpectedly, and a child could fall out of the stroller and be injured.	Bumps and bruises	Free repair kit	166,000

A copy of the stroller press release is attached. Although this was not a product area of concern, a press release for the recall of children's swimming vests is attached; the buckles unlatched unexpectedly while in use.

Attachment(s)

News from CPSC

U.S. Consumer Product Safety Commission

Office of Information and Public Affairs

Washington, D.C. 20207

For Immediate Release April 16, 1997 Release # 97-102 Contact: Nychelle White (301) 504-0580 Ext. 1192

CPSC, Century Announce Recall to Repair TraveLite SPORT Strollers

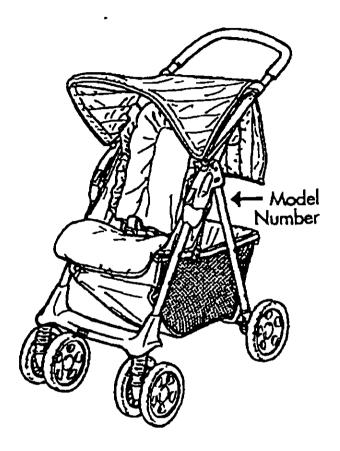
WASHINGTON, D.C. - In cooperation with the U.S. Consumer Product Safety Commission (CPSC), Century Products Co. of Macedonia, Ohio, is voluntarily providing a free repair kit for about 166,000 Century TraveLite SPORT strollers. Certain models of these strollers have restraint buckles that could unlatch and fold locks that could break causing the stroller to fold unexpectedly if the front wheels of the stroller hit a curb or other stationary object. If the restraint buckle unlatches or the fold locks fail, a child could fall out of the stroller and be injured.

Century has received approximately 1,400 reports from consumers about these problems, including 78 injuries, such as bumps and bruises.

Century is offering consumers a free repair kit to prevent strollers from folding unintentionally and to prevent the restraint buckle from unlatching. Consumers will receive instructions with the kit for making the repairs at home.

The strollers needing repair are Century TraveLite SPORT strollers with model numbers 11-171, 11-181, or 11-191. These strollers were made from February 1995 through October 1995. The model number and date manufactured are located on the side tubing of the stroller.

(stroller) -2-



Department, juvenile products, and discount stores nationwide sold these strollers beginning in February 1995 for about \$60 to \$80.

Consumers should immediately stop using these strollers and call Century toll-free at 1-800-944-0039 for a free repair kit with installation instructions. Consumers may also request the free repair kit by writing to Century Products Co., 9600 Valley View Rd., Macedonia, OH 44056.

The U.S. Consumer Product Safety Commission protects the public from unreasonable risks of injury or death from 15,000 types of consumer products under the agency's jurisdiction. To report a dangerous product or a product-related injury and for information on CPSC's fax-on-demand service, call CPSC's hotline at (800) 638-2772 or CPSC's teletypewriter at (800) 638-8270. To order a press release through fax-on-demand, call (301) 504-0051 from the handset of your fax machine and enter the release number. Consumers can obtain this release and recall information at CPSC's web tite at http://www.cpsc.gov.or.via Internet gopher services at epsc.gov. Consumers can report product hazards to info@opsc.gov.

News from CPSC

U.S. Consumer Product Safety Commission

Office of Information and Public Affairs

Washington, D.C 20207

For Immediate Release April 14, 1997 Release # 97-100 Contact: Nychelle White (301) 504-0580 Ext. 1192

CPSC, OddzOn Products Inc. Announce Recall of Children's "Starfish" Swimming Vests: Buckles Can Unlatch

WASHINGTON, D.C. - In cooperation with the U.S. Consumer Product Safety Commission (CPSC), OddzOn Products Inc. of Campbell, Calif., is recalling about 5,000 children's swimming vests manufactured in 1996 and sold under the brand name "Starfish." The vest's buckles can unlatch unexpectedly while in use, releasing a child into the water. Children could drown if they are released into the water without the aid of the swimming vest.

OddzOn Products Inc. has received one report of the buckles unlatching. No injuries have been reported.

The "Starfish" inflatable plastic swimming vest has a blue inner lining and collar and a yellow and pink body secured by two plastic buckles in the front. The "Starfish" logo and name appear on the front of the vest and on the buckles. The vest is available in sizes A through D and is intended for children between 1 and 8 years old.



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Toy, sporting goods, and gift stores nationwide sold the swimming vests from May 1996 through March 1997 for about \$14.

(vest) -2-

Consumers should take the "Starfish" swimming vests away from children immediately and return them to the store where purchased for a full refund. For more information about this recall, consumers should call OddzOn Products at (800) 755-6674.

The U.S. Consumer Product Safety Commission protects the public from unreasonable risks of injury or death from 15,000 types of consumer products under the agency's jurisdiction. To report a dangerous product or a product-related injury and for information on CPSC's fax-on-demand service, call CPSC's hotline at (800) 638-2772 or CPSC's teletypewriter at (800) 638-8270. To order a press release through fax-on-demand, call (301) 504-0051 from the handset of your fax machine and enter the release number. Consumers can obtain this release and recall information at CPSC's web site at http://www.epsc.gov.or.via.Internet.gopher services at epsc.gov. Consumers can report product hazards to info@epsc.gov.

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TAB E



Memorandum

Date: May 30, 2000

TO: Debra Sweet, Project Manager, Child-Resistant Buckle Petition

THROUGH: Warren J. Prunella, AED, EC 4/P

FROM: Mary F. Donaldson, EC

SUBJECT: Child-Resistant Buckle Petition, HP-00-1

Background

The Consumer Product Safety Commission is considering a petition from John Galbreath that would require the use of child resistant buckles in the restraint systems of juvenile products. The Petitioner specifically requests that buckles employ a double-action release mechanism. This paper presents an overview of juvenile products with restraint systems and some market information on the fastener market as it relates to this petition.

Juvenile Products with Child Restraints

Restraint systems are a part of many juvenile products. The petitioner specifically mentions strollers, high chairs, changing stations, and shopping carts as examples of products with child restraints. Other products with child restraints include various types of baby carriers (including bike mounted), baby swings, changing tables, and baby bouncer seats.

Table 1 provides estimates of numbers of products in use for a variety of juvenile products that use child restraints and are intended for home use. Overall, there are more than 30 million of these products in use. This includes about 7 million high chairs, 3.5 million infant carriers, 15 million strollers, 3 million baby swings, 2.6 million bouncer seats, and more than 2 million changing tables.

Table 1: Juvenile Products with Child Restraint Systems Intended for Home Use

Product	Estimated Products in Use (millions)
High Chairs	
- Regular	3.3
- Portable	.6
- Reclining Multi-age	2.7
Changing Tables	2.1
Strollers	14.9
Infant Carriers	
 Frame (worn by parent) 	.7
- Plastic, with handle	2.8
Fabric Bouncer Seats	2.6
Baby swings	3.0
Products w/restraints	32.7

Source: Based on information from the U.S. Bureau of the Census and the 1999 Baby Products Tracking Study for American Baby Group, In Draft, Bruno & Ridgeway.

In addition to the juvenile products for home use, there may be as many as 3.5 million shopping carts equipped with child restraints¹. Other juvenile products found in public and commercial settings that are equipped with child restraints include diaper changing stations, high chairs, infant seats attached to grocery carts, and strollers.

Child Restraint Systems

Most juvenile products incorporate a plastic or a woven fabric strap in their child restraint systems. These straps go around the child in various configurations and are secured with one or more fasteners. The fasteners are usually made of a hard plastic (PVC), but some may be made of metal.

Child restraint systems which use straps and fasteners generally may be described as two, three or five-point systems. The "points" refer to how many strap ends come together at a fastener.

Two-point systems typically have one long or two shorter straps, which encircle the child's waist and connect with a front fastener. Two point systems are used on changing tables and public diaper changing stations.

¹ U.S. CPSC Memorandum to Barbara Jacobson, HS, from William W. Zamula, ECSS, dated November 30, 1995, subject: Preliminary Cost Benefit Analysis of Shopping Cart Seat Belts.

Three-point restraint systems are often found on strollers, infant swings, and high chairs. This system has straps, which encircle a child's waist, or come down the sides of the chest from the shoulders and fasten to a crotch strap that comes up from the seat.

A five-point system adds a shoulder harness to a waist and crotch strap. In a five-point system, the shoulder harnesses usually use separate fasteners to attach to the waist strap and do not have to be disengaged to remove the child. This system may be found on some strollers.

Fasteners on child restraint systems have a variety of designs. Commonly used fasteners use either a center release mechanism or a side release mechanism. Some examples of the various fastener styles are shown in the attached appendix.

Sometimes, especially with high chairs, there is an added "passive-restraint" which may be an upright bar or strap which runs from the base of the seat to the bottom of the tray. This passive restraint is designed to prevent the child from exiting the product feet first, but does not keep the child from climbing out of the product.

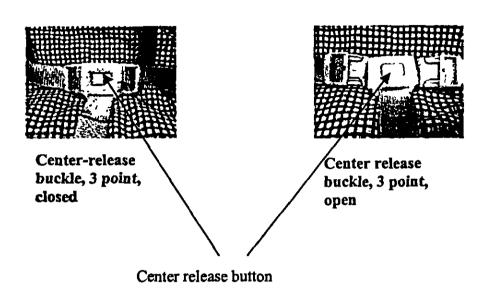
Juvenile product manufacturers generally order parts for child restraints from fastener and strap manufacturers and incorporate them into the product during assembly. The restraint assembly may be ordered as a unit or components may be purchased separately. Costs of buckles for restraints are a small part of the overall cost of the production of a juvenile product. According to one manufacturer, a 2-point side release buckle typically found on shopping carts costs about 10 cents for 25,000 and may drop in price about

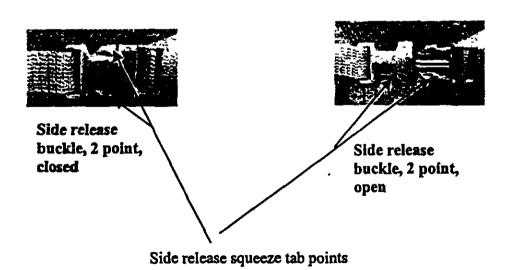
15 percent with large quantity orders of 100,000 or more. Their 5-point buckle ranged in price from 17.5 cents to 21 cents depending on quantity ordered.

There are a number of fastener suppliers, both domestic and international. A search of the *Thomas Register* found 49 firms that supply strap buckles for a wide variety of applications. It is not known how many of these firms produce fasteners for juvenile products. It also is not known to what degree the fasteners currently being used on juvenile products are able to be opened by children that are using the products.

Upon a review of juvenile products for sale at two large retail stores in the Washington, D.C. area, four firms appeared to have produced the majority of the fasteners found on child restraints. They were: YKK, National Molding, ACW, and ITW Nexus. However, it was not always possible to determine the identity of the fastener manufacturers. No fastener observed in the limited review of juvenile products for sale in the Washington, D.C. area had individual fasteners with a double-action release mechanism, as the petitioner requests. However, one firm, Peg Perego, a European manufacturer, utilizes a dual-action mechanism on its stroller buckles marketed for sale in the U.S.

Appendix





Photos provided by Directorate for Engineering Sciences.

TAB F



Memorandum

Date. June 22, 2000

TO: Debra Sweet, Project Manager, Child-Resistant Buckles Petition

THROUGH: Nick Marchica, ESME
THROUGH: Mark Kumagai, ESME
FROM: Caroleene Paul, ESME

SUBJECT: Industry standards with child restraint requirements

ASTM Standards

ESME reviewed the current ASTM Standards and recent new standards development activity. Table 1 shows the standards or draft standards with requirements for restraints. None of the standards or draft standards require child resistant buckles.

Table 1. ASTM standards and Draft standards with restraining strap requirements

Active ASTM Standard	Draft ASTM Standards
F404-99a High Chairs	Hand Held Infant Carriers
F1235-98 Portable Hook-on Chairs	Infant Swings
F833-99 Carriages and Strollers	Infant Bouncers
F1625-95 Bicycle Child Carriers	Soft and Frame Infant Carriers

Both the High Chair and Portable Hook-on Chair standards specify that a waist and crotch restraint be provided to secure a child in the seated position. The design of the restraint system must incorporate the mandatory use of the crotch restraint in conjunction with the waist strap. The intent of this requirement is to prevent the sole use of the waist strap, which is a potential strangulation hazard if the child slides down (submarines) out of the seat. The restraint system is tested by securing a Civil Aeromedical Institute (CAMI) infant dummy MK II into the high chair. A 45 lb force is applied to either leg of the dummy and a 45 lb upward force is applied on the dummy's torso. The restraint system must keep the CAMI dummy in the high chair or portable hook-on chair upon completion of the test. The buckle or fastening device must be a self locking device and cannot separate or break when tested as described above.

In addition to the waist and crotch strap restraint system, the High Chair standard requires a passive crotch restraint when the high chair is used with a tray. This requirement is typically met by attaching a vertical bar onto the tray that extends to the seating surface. This requirement is intended to address incidents of strangulation if the child submarines between the tray and the seating surface. The crotch restraint must be oriented less than 8.5 inches from the

seat back, and the leg openings can not allow the passage of a 3.0 x 5.5 inch probe. The probe simulates the torso of a 6-8 month old infant.

The Carriages and Strollers standard specifies a waist strap restraint for strollers or carriages that convert to a stroller (carriages intended for use by infants do not require a restraint). The waist strap is tested by securing a CAMI infant dummy MK II into the stroller and applying a 45 lb force on either leg. With the CAMI dummy in place, the stroller is lifted and rotated 360 degrees, along the front-back axis momentarily stopping at 90 degree increments. The stroller with the CAMI dummy in place is then rotated 360 degrees along the side-side axis, momentarily stopping at 90 degree increments. The final test on the waist strap is a 7 lb force applied on the restraint at the stroller attachment point. The waist strap must keep the CAMI dummy in the stroller during and upon completion of the tests. The strap, buckle and anchorage points must not slip, separate or break during and upon completion of the tests.

The Bicycle Child Carriers standard does not specify the type of restraint system. The standard requires restraint straps to maintain a 100 lb pull force without stretching or breaking.

Use of Age-Appropriate Models in Performance Requirements

Performance requirements in ASTM voluntary standards specify the use of an age-appropriate CAMI dummy to simulate the user of the product. The three CAMI dummies most commonly specified in the standards are a 7.5 lbm CAMI to simulate a new born child, an 18 lbm CAMI infant dummy MKII to simulate a 50% 6 month-old child and a CAMI MKII with a weighted vest to simulate a 28 lbm, 95% 12-15 month old child. If testing requires the simulation of an older child, an appropriate mass or force is often specified. These masses are based on anthropometric data.

CSU Study on Pushchairs

ESME reviewed a 1995 study on pushchairs (strollers) commissioned by Britain's Consumer Safety Unit (CSU) of the Department of Trade and Industry. The study was conducted in two phases: Phase 1 to identify appropriate forms of harnessing for pushchairs, conducted by the Research Institute for Consumer Ergonomics (RICE); Phase 2 to develop a performance based test method for pushchair harnesses, conducted by the Consumer's Association Research and Testing Centre (CARTC).

Phase 1 of the study assessed previous studies done in the UK, the USA, Australia, and the Netherlands. Discussion groups with parents were held in the UK, France, Portugal, Norway, and Sweden. The need for buckles "to be reasonably child-proof, but not adult-proof' was brought up by parents in the UK, France, and Portugal. The study also reviewed British and Australian/New Zealand standards that addressed child restraint systems as follows (some standards have since been superseded by revised standards as noted):

British Standards

BS 4792 Safety Requirements for Pushchairs
[superseded by BS 7409 Safety Requirements for Wheeled Child Conveyances]

Section 7 covers the safety harness:

Arrangements for the restraint of the child shall be provided:

- (a) by incorporating in the pushchair fittings suitable of the attachment of a child's safety harness that complies with BS 3785 (Specification for webbing safety harness for baby carriages and chairs and walking reins); and
- (b) by incorporating in the pushchair either:
 - (1) a crotch strap with a minimum width of 20 mm; or
 - (2) an integral, permanently attached harness assembly (waist straps and crotch strap with a minimum width of 20 mm and shoulder straps with a minimum width of 15 mm).

BS 3785 Webbing Safety Harness for Baby Carriages and Chairs and Walking Reins has been superseded by BS 6684 Safety Harnesses (Including Detachable Walking Reins) for Restraining Children When in Perambulators (Baby Carriages), Pushchairs and High Chairs and When Walking.

BS 7409, Safety Requirements for Wheeled Child Conveyances

In section 12 the safety harness is described as:

Seat and chassis assemblies shall be fitted with an integral 5-point harness assembly, comprising shoulder straps, waist straps and crotch strap, except in the case of seats complying with BS AU 202a (restraining devices for infants for use in road vehicles).

Australian/New Zealand Standards

AS/NZS 2088 Prams and strollers – safety requirements

In section 6, states that:

Strollers shall have incorporated an integral permanently attached 5-point harness assembly comprising shoulder straps, waist straps and crotch strap.

Phase 1 of the study was completed in February 1994. None of the above standards summarized in the study appear to have required child resistant buckles. Acquisition of all current standards is necessary to evaluate whether or not child resistant buckles are required.

Phase 1 of the study developed performance tests and design requirements intended to be simple, inexpensive and easy to perform. In the performance tests, restraining buckles are tested for strength and durability, and design requirements state "the opening mechanism must employ a double action, with at least one force requiring a 35-50N [7.9 – 11.2 lb] force to operate it." It further states that the force range "will prevent most children from opening the fastening, with the added complexity of a double action further reducing the number of children who could open it."

Phase 2 of the study focused on the research and testing performed to develop harness requirements for pushchairs that would stop a child from falling or climbing out of the pushchair. In an effort to develop a realistic test method, a literature search was performed to obtain as many current accident reports as possible. Of the incidents reported, some claimed that the harness either broke, became undone, or that it was undone by the child. Phase 2 continued with the test methodology in wooden dummy testing. No further mention of buckles was made.

TAB G



Memorandum

May 18, 2000

TO: Debra Sweet, Project Manager, Child-Resistant Buckles Petition

THROUGH: Jacqueline Elder, Deputy Assistant Executive Director

Office of Hazard Identification and Reduction

Robert B. Ochsman, Ph.D, CPE, Director

Division of Human Factors

FROM: Carolyn Meiers, Engineering Psychologist, Human Factors OM

SUBJECT: Human Factors Issues - Petition HP-00-1

The U.S. Consumer Product Safety Commission (CPSC) received a petition requesting that the Commission develop requirements for child-resistant buckles for use on products such as strollers, high chairs, changing stations, and shopping carts. This memorandum discusses Human Factors issues relating to this petition.

ISSUE: Buckles are Only One Part of a Restraint System

A systems approach to designing safe products means taking into consideration the characteristics of the product, the characteristics of the consumer, and the environment in which the product is used. When developing performance standards for child restraints, the effect of the interaction of these components must be considered. A systems approach shifts the development of performance requirements from a one-dimensional focus in which the mechanical features of a product take precedence, to a multidimensional focus that incorporates the issues of user acceptability and use of the product under real world conditions.

In the case of restraint systems, the restraints could have mechanical integrity and effectively secure a child in place yet present a strangulation hazard from straps when the child twists in the seat. Restraints could also have mechanical integrity and effective securing capability but be cumbersome for adults to use or be uncomfortable enough so a child will not tolerate it.

Buckles are only one part of a restraint system. For example, leg hole openings that are too large could cause a child to slip from the product onto the ground. Anchor point locations could determine the fit of restraint straps. The age range of children using the product is important to know because restraints must be adjustable to accommodate growing children. In the case of strollers, restraints must be effective when the stroller is going down a slope.

The CPSC Child Restraint Project plans to systematically analyze the range of variables impacting the restraint of children in juvenile products, as well as, the interaction of these variables. The results will be used to construct voluntary performance measures for child

restraints. The objective is to assure that child restraints will effectively and safely secure children in juvenile products with comfort, ease, and simplicity

Because of the merits of a systems approach described above, Human Factors staff believe that the issue of child-resistant buckles, that is the subject of this petition, should be considered concurrently with the other restraint variables in the Child Restraint Project rather than be treated as a separate entity.

ISSUE: Age At Which a Child Can Defeat a Buckle on a Juvenile Product

The table below charts the development of manual dexterity in children ages 6 to 12 months 1

AGE	SKILL	
6 Months	Very beginning of manual dexterity; primitive ability to reach out and take things. ²	
6-8 Months	Learns about objects by handling them. The greater the assortment of objects that are handled, the greater the amount of learning that takes place.	
6-12 Months	Beginning to become a tool user.	
9 Months	Difficulty in letting go of objects, pokes at objects with index finger instead of pushing them with hands Can pick up small items like a raisin with a pincer motion.	
10 Months		
11 Months	Learns to throw objects.	
By 12 months	Knows what to do with objects and what they are for.	

Manual dexterity skills begin to develop around 6 months. Children younger than 6 months have not acquired the skills to effectively undo a buckling device. They may be attracted to buckles as general objects to manipulate, but they do not understand their function. Around 9 or 10 months, skills have developed to the point that children begin to poke and prod with some deliberation and begins to understand the function of objects and what to do with them.

Consideration of other factors besides age and skill acquisition are important when determining if a child can open a buckle. Skill acquisition is necessary for without it a child cannot even begin to open a buckle. But design, location, condition and age of a buckle are just a few of the other factors that impact children's capability of opening a buckle. Juvenile products are equipped with a variety of buckle types that can change as manufacturers update product styles. Some of these may be easily opened by children, others may be more complex and harder to open. Buckles can be located where they are easily reached by children or they can be positioned out of view or reach of a child. If a buckle is exposed to weather conditions or everyday wear-and-tear, its mechanisms can deteriorate and make it easier to open. Simple use can wear down

^{1.} Behrman, Richard E., M.D. and Vaughan, Victor C., M.D. (1983) Nelson Textbook of Pediatrics, 12 ed. Philadelphia: W.B. Saunders Company

the efficacy of a buckle's securing power. Harness buckles on children's car seats were found to become easier to open after prolonged use.²

ISSUE: Effectiveness of Double-Action Buckling Mechanisms

The petitioner submitted a prototype of a double-action buckling mechanism as an example of a child-resistant buckle. Double-action implies that two actions are necessary to open the buckle. The buckle the petitioner submitted is opened by 1) squeezing the side-release mechanisms, and 2) pressing the center button. These two actions are to be performed simultaneously

The petitioner has not provided any test data for his buckle or suggested performance criteria against which it should be tested. Human Factors is not aware of any performance requirements, either mandatory or voluntary, for child-resistant buckles.

Testing should consider the ability of children in the appropriate age groups to defeat the proposed child-resistant as well as the ease with which adults can use it Untested designs can lead to poor performance and failure.

ISSUE: Attraction of Buckles to Children

Many juvenile products have restraint systems with some type of buckling mechanism. Children have many opportunities each day to observe these buckles in use. Because they are great imitators, children will try to manipulate these devices themselves. From early infancy on, children are exposed to toys, such as play gyms, activity boxes and pop-up toys, that encourage manipulations like reaching, grasping, shaking, pulling, pushing, poking, and twisting ³ Children's innate curiosity and the proximity and visibility of the buckles make them prime objects for inspection, exploration, and manipulation Therefore, if restraint buckles are in view and reach of the child, some children may be motivated to play with them for long periods. This persistence may increase the probability of children releasing the buckle.

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Hunter, R.M., Humter, M.M., Richards, D.D., Tombrello, S.M., and Boriskie, A. (1990). Cognitive Skill Based Child-Resistant Safety Belt Buckle Device. Yellowstone Environmental Science Bozeman, Montana
 Guidelines for Relating Children's Ages to Toy Characteristics. (1985). Contract No CPSC-85-1089

TAB H



Memorandum

Date May 30, 2000

TO Debra Sweet

> Project Manager, Restraint Petition Directorate for Epidemiology

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

Directorate for Health Sciences

Lori E Saltzman, M.S., Director,

FROM

Division of Health Sciences

Jason R Goldsmith, Ph.D., Physiologist, Division of Health Sciences, x-1387

SUBJECT: Petition HP 00-1 (Buckles on child-restraint systems)

This memorandum has been prepared in response to Petition HP 00-1 for the development of requirements for buckles to be used on child-restraint systems on such products as strollers, high chairs, changing stations, and shopping carts

The product that is the subject of this petition is any and all of a variety of buckles that are used to fasten children into various child-restraint systems commonly used in children's products. The petitioner asserts that the buckles currently used on these products are ineffective, and that a number of them are not sufficiently child resistant and therefore can be defeated by children The petitioner specifically requests that the buckles used on children's products be required to employ a double-action release mechanism.

Health Sciences' staff has been asked to. 1) assess the types of injuries that may occur as a result of falls out of products that employ child-restraint systems, but which possess buckles that were inoperative, missing or that had been circumvented; 2) provide a critical review of the research article that the petitioner presented to the Commission in the original petition, in which the child resistance of three buckle designs were examined; and 3) respond to a statement contained within a written comment on the petition that, "Of particular concern are head injuries to very fragile skulls and the fact that seemingly minor closed head injuries may not tell the whole story of the injury since children cannot be tested for neurological damage much before the age of 3." A discussion of these three issues is provided below.

DISCUSSION:

1) Injury assessment

The children's products under consideration in this discussion are the following—shopping carts, baby changing tables, baby carriers (bicycle mounted or other types), baby bouncing chairs, infant backpack carriers, jumpers, strollers, high chairs, and baby swings—The age group for which these products are intended is children 0 to 6 years of age (the upper range would be defined by those children still able and willing to ride in shopping carts)

The types and severity of injuries associated with falls from these products are dependent primarily on three factors: the distance the child falls (determined by the location of the product and/or height of the surface on which it was placed at the time the fall occurs), the surface(s) on to which the child may fall, and the anatomical region of the child's body that absorbs the energy of the impact.

Given that bouncing chairs are generally constructed in such a manner that the infant's body is no more than several inches above the surface that the chair is positioned on, this product will be discussed separately. Falls out of bouncing chairs that are positioned on carpeted flooring, or another soft surface, are likely to produce mild bruising or no injury at all. In contrast, falls onto more rigid surfaces, such as tile, cement or wood floors, may cause mild bruising of the infant's back and/or head. Falls out of bouncers that have been placed on elevated surfaces do not differ from falls out of other products and will be discussed below

Falls from strollers, swings, jumpers, and carriers, or from elevated surfaces, such as kitchen countertops (e.g., a bouncer chair placed upon such a surface), dresser or table tops (used as a changing surface), highchairs, shopping carts, or infant backpack carriers, have the potential to produce a variety of injuries, ranging from minor abrasions, contusions or lacerations to the more severe, such as long-bone fractures, ligamentous injuries, spinal fractures, skull fractures (see below), and concussions. Injuries to the head, such as intracranial injury, may occur when the child falls head first, making the head the point of impact of the fall. Head, neck and spine injuries are considered serious because they may require prolonged treatment and therapy. Incidents that result in internal bleeding and brain injury require professional medical treatment, and, due to their nature may result in permanent injuries or death ^{1,2}

In falls from bicycle carriers (i.e., a bicycle in motion), the weight of the child and velocity of the bicycle could also have some bearing on the extent and pattern of injuries. Falls of this type have the potential to produce internal organ injuries in addition to the injuries described above.

Whereas, many of these children's products are intended to be used by infants, it is important to consider the special characteristics of this age group. Fractures of the long bones and bruising of the extremities are common injuries in falls less than 10 feet involving infants. The relatively large size of the infant's head in proportion to its body, increases the chances of the head being involved in an impact after a fall. Impacts of the head are unlikely to lead to skull fractures since the bones of the infant's skull have yet to fuse. However, diffuse injury of the brain cells and/or hemorrhaging of the blood vessels that overlay the brain may still occur, and could potentially

cause permanent brain injury, coma or death ¹ Since the infant's scalp is soft and pliable, these injuries may occur without externally noticeable injury to the scalp ¹

The injuries enumerated above are similar to the injuries reported by the petitioner

2) Review of M. Ridenour article

In support of his contention that the buckles presently on the market are ineffective, the petitioner included as a reference a study by Marcella Ridenour³ in which the author reported a lack of child resistance amongst three buckles tested. In this study by the Temple University Biokinetics Research Laboratory investigator, three different stroller seat buckle mechanisms were presented to 70 children, 24 to 36 months of age. The three buckle styles examined were the D-ring variety with flexible strap (Style 1), the center-release mechanism (Style 2) and the type that requires simultaneous depression of plastic tabs on the top and bottom edge of the buckle (Style 3) Children were randomly assigned to one of the three buckle groups folding stroller utilized in all three groups was identical, with the exception of the buckle. Each child was given 15 opportunities within a three-week period (maximum of two sessions per day) to attempt to open the same buckle mechanism, for a total of 1050 trials (70 children x 15 trials each). During each session, the child was placed in the stroller, fastened in, and then shown how to unbuckle the restraint. The buckle was then fastened again and the child was asked to get out of the stroller. Five minutes were allowed for each session and the children were required to make at least one attempt per session to unbuckle themselves. Of additional concern is the fact that no indication was given as to whether the children possessed physical or mental handicaps or had prior exposure to the buckle style to which they were randomly assigned Either of these factors could significantly affect the children's ability to unbuckle themselves

The data, the number of successful openings, were examined by a 3 x 15 analysis of variance with repeated measures, which produced a significant main effect. Moreover, all post-hoc comparisons between buckle styles were reported to be significantly different. Unfortunately, all further discussion of the data and results were presented in a manner that made interpretation difficult. Specifically, the author does not openly state the number of children that were assigned to each of the three groups. Additionally, the study results were not presented as a proportion of the number of trials in each group, but rather as proportions of the total number of trials in the experiment. For example, the author states that, "Style 1 was opened during 12 (1%) of the 1050 test sessions". The author proceeds to state that Style 2 was opened in 7% of the trials and that Style 3 was opened in 5% of the trials. These descriptions are not useful and are extremely misleading, since they do not take into account the fact that only a subset of the 1050 trials were devoted to the testing of any particular buckle style.

Thus, despite the author leading the reader to believe that Syle 1 was the most difficult, Style 2 was the easiest, and Style 3 was of intermediate difficulty, for children to unbuckle, it is difficult to know if this is the correct interpretation since the author does not clearly describe how these conclusions are reached. However, if two assumptions are made, the number of children that were assigned to each of the three groups can be determined and the results further analyzed. The assumptions are that 1) the performance of all children in Style group 2 and 3 were accounted for in the narrative descriptions provided in the results section, and 2) no children

were uncooperative in any of the three style groups, each making at least one attempt in each test session (i e, 1050/1050 successful test sessions)

With the above assumptions in mind, it is possible to determine that 21 and 26 children were assigned to the Style 2 and Style 3 groups, respectively, and to deduce that 23 children were assigned to the Style 1 group. By this method, 19 children (i.e., 27% of 70) were found to have been able to open one of the buckles. This is in agreement with the author's statement that "only 27% of the children." were able to open any of the three buckles. The fact that the author goes on to describe these 27% as 12 boys and 9 girls (21 total) must be assumed to be an error. Based on these data, the author concludes that "some buckles in stroller restraint systems may provide false security to parents and adult caretakers." However, since 73% of the children were unable to unbuckle themselves, one could just as easily conclude that the buckles are effective in the majority of cases. Staff are concerned by the omission of the author's rationale used to derive these conclusions and made assumptions only for the purpose of trying to elucidate the findings in the report. It is particularly troubling that the consequences of not making at least one attempt to open a buckle was not addressed in the paper, and it is difficult to imagine that all 70 children were 100% cooperative.

Had the additional analysis been provided (i.e., the calculation of the proportion of children in each of the three groups that were unable to buckle themselves), a clearer picture of the three different buckle types would have emerged. Indeed, the reader would realize that Style 1, 2 and 3 were effective for 87, 52 and 77%, respectively, of the children tested. (The effectiveness could also be assessed by calculating the number of failures out of the total number of trials, but that may be incorrect given the use of repeated measures and the fact that the trials may not have been independent.) In tests designed to assess child resistance, Style 2 would be considered ineffective, Style 3 would be considered nearly effective (approaching the 80% criteria level with instructions provided) and Style 1 would be considered effective. Thus, in opposition to the Petitioner's argument, this paper can be taken to support the counter-argument, that effective buckles do exist.

3) Response to M. Cowan's statement regarding head injuries in children under age 3

In a comment received in response to the petition, a statement was made that, "Of particular concern are head injuries to very fragile skulls and the fact that seemingly minor closed head injuries may not tell the whole story of the injury since children cannot be tested for neurological damage much before the age of 3." Whereas minor closed head injuries may not tell the whole story of an injury, there are tests available that may reveal the existence of neurological damage in children three and under. In addition to the use of computed tomographic (CT) scans to directly visualize damage, or the monitoring of the cerebral metabolic rate for oxygen, which is an accurate indicator of the level of cerebral function, to ther assessment tools, such as the Glasgow Coma Scale, also exist. This scale is widely used and offers a roughly quantitative means of assessing the severity of head injury. It is typically used in adults presenting with head injuries and/or an altered level of consciousness. Many physicians also use the Glasgow Coma Scale in the treatment of children with head injuries. Since young children are both unable to obey commands or speak, the scale has been modified in several areas for use in this age group. 4.5.6

However, given that children's cognitive, social, and motor function change with age, it may take considerably longer (months or years) for the full effects of a head injury to manifest themselves ⁵ (This applies to both children under and over the age of three) For this reason, in all cases involving head injury of a child, follow-up visits with a physician should take place over the course of a child's development

Parents of children who do not display symptomology that would provoke a physician to use these tools, or who have no apparent injuries after examination, may be provided with a description of signs of neurologic deterioration and instructions to seek medical attention should such signs appear ⁴ Much as is the case with an adult who has received a head injury, it is incumbent upon a responsible individual (e.g., a parent or other guardian) to serve as a reliable observer of the child and look for noticeable changes in mood, behavior, or activity

Tibbs RE, Haines DE, Parent AD The child as a projectile Anat Rec 1998,253 167-75

² Tarantino CA, Dowd MD, Murdock TC Short vertical falls in infants Pediatric Emer Care 1999,15 5-8

³ Ridenour MV How child-resistant are stroller belt buckles? Percep Motor Skills 1997;84 611-6.

Ghajar J, Hariri RJ Management of pediatric head injury Ped Clin North Amer 1992,39 1093-1125.

⁵ Guthrie E, Mast J, Richards P, McQuaid M, Pavlakis S Traumatic brain injury in children and adolescents. Child Adolesc Psychiatr Clin North Am 1999,8.807-26

⁶ Mansfield RT. Head injuries in children and adults. Critical Care Clinics 1997,13 611-28.

TAB I



Memorandum

May 18, 2000

TO: Debra Sweet, Project Manager, Child-Resistant Buckle Petition

THROUGH: Jacqueline Elder, Deputy Assistant Executive Director

Office of Hazard Identification and Reduction

Robert B. Ochsman, Ph.D, CPE, Director

Division of Human Factors

FROM : Carolyn Meiers, Engineering Psychologist, Human Factors One

SUBJECT: Response to Comments on Petition HP-00-1

This memorandum responds to Human Factors issues raised by a commenter to Petition HP-00-1 regarding child-resistant buckles for juvenile products.

COMMENT: One commenter in favor of the petition stated the following:

- 1. "Most juvenile product restraints have easy to operate latching systems This ease of use is designed primarily for parental convenience; however, if it is easy for parents to use, it is often easy for a child to figure out how to use it too."
- 2. "Because of ease of use, many children are easily able to defeat the restraint system.."
- 3. "When the child repeatedly defeats the restraint system, many parents will simply stop using the restraint rather than continually battle with the child."
- 4. The effectiveness of child restraints on juvenile products involves several facets of the restraint design. These include double-locking mechanisms, buckle release pressure, restraint material and width, anchorage points, accessibility/visibility, and crotch strap adjustability.

RESPONSE:

1. Human Factors staff believe that the latching systems on juvenile products should be easy for adults to use, but difficult for children to defeat. This is the approach that is taken in regulations requiring child-resistant closures for medicines and hazardous household chemicals. In addition, cigarette lighters are required to resist operation by children under the age of 5. The products that meet these requirements demonstrate that when the differences in the cognitive and motor ability of adults and children are considered, and when appropriate testing is undertaken, effective

child-resistant mechanisms can be developed that are easy for adults to use and difficult for children to defeat. However, untested designs can lead to poor performance and failure

Testing should consider the ability of children in the appropriate age groups to defeat the proposed child-resistant mechanisms as well as the ease with which adults can use it. Experience with child-resistant closures and with cigarette lighters indicates that there is a potential for well-thought-out and tested buckle designs that will meet child-resistance and provide ease-of-use at the same time.

- 2. The commenter did not provide any details on how often children defeat restraint buckles or the types of buckles that are defeated. The CPSC receives anecdotal reports from consumers about children opening the buckles on restraint systems, but the extent of the problem is not known. We also do not know what types of buckles are being defeated and if there are types that do not fail.
- 3. Human Factors staff agree with the commenter that if consumers perceive that the use of safety features requires too much effort or are too inconvenient, they will circumvent the features or stop using them. Literature on compliance with safety instructions indicates that the less effort required by the user to comply with the safety instructions, the more substantial the compliance rates.

Because restraint systems encompass more than latching systems, the level of effort required to use other restraint features can also result in non compliance with the restraints. These other factors include the ease of securing the child into the restraint, the comfort of the child while secured, ease in adjusting the restraint for a snug fit, and how the restraint holds up with use

4. Human Factors staff agree with the commenter that a juvenile restraint system incorporates many variables. For instance, a child-resistant buckle can prevent a child from opening the buckle, but the system into which it is incorporated may not prevent a child from standing up in a stroller while secured in a restraint. Location of anchorage points can determine the efficacy of restraining straps. Depth of the seat can determine how easily a child can lean over a stroller. Harness straps could present a strangulation hazard if the design is faulty. These are just a few examples of restraint features that need to be considered in a restraint system.

The design aspect becomes more complex when the restraints are viewed as part of a system that must take into account the users, both adult and child, the environment in which the product is used, as well as the characteristics of the product. One change in any aspect of the system can affect the way other parts of the system function, both positively and negatively. Changing the anchor points' geometry may remedy problems caused by lack of sufficient depth in the seat. Widening waist and crotch straps may make the child uncomfortable and discourage use of restraints. Footrests may give a restless child a foothold to enable the child to ease out of the seat. Restraint bars might give adults a false sense of security that their child is adequately restrained.

¹ Kotwal, Bari, M. and Lerner, Netl, D. (1995). Product Labeling Guide - Literature Review. Contract CPSC-C-93-1132. Bethesda, MD: Consumer Product Safety Commission

At present, we cannot predict the consequences of these or other restraint designs. This is why it is critical that the testing of designs consider the entire restraint system. When a design change is made, it can impact all the aspects of the system. For instance, a design may meet the criteria to effectively restrain a child from leaning over in a stroller, but it may present an entrapment or strangulation hazard. In addition, consumer feedback should be sought on changes to restraints because these are the people who put the system to the test in realistic situations.

The CPSC initiated a Child Restraint Project to look at these different aspects of child restraints for juvenile products. The objective is to establish performance requirements that address not only mechanical but also human-use issues. The outcome is to have child restraints that effectively secure children in juvenile products with comfort, ease, simplicity, and with little effort on the part of the adults.