



United States
CONSUMER PRODUCT SAFETY COMMISSION
Washington, D.C. 20207

MEMORANDUM

DATE: August 28, 2003

TO : Patricia Hackett, ES
Through: Todd A. Stevenson, Secretary, OS
FROM : Martha A. Kosh, OS
SUBJECT: Baby Bath Seats

ATTACHED ARE COMMENTS ON THE CH 03-3

<u>COMMENT</u>	<u>DATE</u>	<u>SIGNED BY</u>	<u>AFFILIATION</u>
CH 03-3-1	8/05/03	Ken Romney	kmr@chesapeake.net
CH 03-3-2	8/11/03	Paul Ware Chair, ASTM F15.20 Sub- Committee	PW Resources, Inc. 34 McNamara Street Stoughton, MA 02072
CH 03-3-3	8/22/03	Heather Paul Executive Director	National Safe Kids Campaign 1301 Pennsylvania Ave, NW Washington, DC 20004
CH 03-3-4	8/25/03	Kelly Grimmond Senior Product Safety Officer	Department of Tourism Racing and Fair Trading
CH 03-3-5	8/28/03	R. Rauchschalbe	CPSC
CH 03-3-6	9/04/03	Clay Mann Associate Professor	University of Utah School of Medicine Intermountain Injury Control Research Center 615 Arapeen Dr, Ste 202 Salt Lake City, UT 84108



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Through: Todd A. Stevenson, Secretary, OS
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CH 03-3-5	8/28/03	R. Rauchschalbe	CPSC

Baby Bath Seats 1

Stevenson, Todd A.

From: Information Center
Sent: Tuesday, August 05, 2003 10:08 AM
To: 'kmr@chesapeake.net'
Subject: Please forward this message to Commissioner Gall

Hello,

Thank you for contact the U.S. Consumer Product Safety Commission. We have forwarded your request for information to the appropriate agency personnel. If additional information is needed, a representative will contact you directly.

Please be advised that you may obtain CPSC publications, recalls and general safety related information via our web site at www.cpsc.gov. Click on the "Search" icon and type in your topic. You may also file an incident report via the web site mentioned above. If you have additional inquiries, you may call our toll-free hotline at 1-800-638-2772, Monday - Friday, 8:30am to 5:00pm, Eastern Standard Time. Press 1 to begin and then press 300 to speak with a representative.

man/tm

-----Original Message-----

From: Ken Romney [mailto:kmr@chesapeake.net]
Sent: Monday, August 04, 2003 8:06 PM
To: Information Center
Subject: Please forward this message to Commissioner Gall

Have just read an article in the Washington Post regarding your comments about "baby bath seats".

I only have a few words: RIGHT ON! KEEP IT UP! I LOVE YOU! I VOTE FOR YOU FOR PRESIDENT OF THE UNIVERSE!!!!

PW Resources

PW Resources, Inc. ■ 34 McNamara Street, Stoughton, MA 02072 USA
781-341-2488 ■ Fax 781-341-5012 ■ pware@worldnet.att.net ■ www.pwresources.com

Paul Ware
President

August 11, 2003

Secretary
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814-4408

Re: Comments to the Commission Regarding the CPSC Meeting on Baby Bath Seats
July 28, 2003

The attached comments are submitted with regard to the subject Commission meeting.

Please enter them into the written record and distribute them to the Commission Chair, Commission members and members of the staff as appropriate.

Sincerely,



Paul Ware
Chair, ASTM F15.20 Subcommittee on Bath Seats

PWResources

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781-341-2488 ■ Fax 781-341-5012 ■ pware@worldnet.att.net ■ www.pwresources.com

Paul Ware
Chair, ASTM F15.20 Subcommittee on Bath Seats

August 11, 2003

The Honorable Harold Stratton, Chair
The Honorable Thomas Moore, Commissioner
The Honorable Mary Gall, Commissioner
Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814-4408

Dear Commissioners:

Re: Comments to the Commission Regarding the CPSC Meeting on Baby Bath Seats
July 28, 2003

As Chair of the ASTM Subcommittee F15.20 on Bath Seats, I am providing the following comments regarding the briefing package prepared by the CPSC staff for the Commission meeting on July 28, 2003. Please enter these comments into the record and consider them when deliberating your decision.

Executive Summary

The second revision of the ASTM standard for Bath Seats, F1967-03, was published in April of this year. It includes five separate revisions, four of which specifically address performance and labeling requirements that are intended to strengthen the standard, as well as to provide additional safeguards for the user and additional usage and safety information for the caregiver.

The subcommittee is continuing to address the outstanding issues that have been identified as potential hazardous conditions, including stability and climbing out. Currently a proposal is under discussion for revising the stability performance requirement in the standard. An active task group is working on revisions to the warnings to be required on bath seat products and packaging, and discussion on these is scheduled at the next meeting of the subcommittee. At the conclusion of the next meeting on October 1, 2003, these two issues will most likely be scheduled for balloting through the ASTM process.

Implementation of the above actions by the ASTM subcommittee either already has addressed, or will soon address, ALL of the issues discussed in the staff briefing package, as well as their recommended remedies.

With the implementation of the original standard in 1999, the subsequent revisions published in 2001 and 2003, and the current discussions that have occurred in the subcommittee to further revise the standard, the pertinent issues have been, and will continue to be, thoroughly addressed through the combined efforts of industry, consumers and their advocacy groups, and the CPSC.

As a result of the implementation of the original and revised publications of ASTM standard F1967 for Bath Seats, including the most recently published revision in April, 2003, as well as the continued review and updating of that standard, there are no compelling reasons to continue the rulemaking process for this product as recommended by CPSC staff.

I recommend that the Commission take this opportunity to implement Option #2 of the listed options, and terminate the rulemaking process.

Detailed Comments

Status of the Current Standard

The current version of the ASTM standard F1967-03 for Bath Seats was approved at the subcommittee meeting on March 4, 2003, and published in April, 2003. It includes four substantive revisions to the requirements for bath seats, including:

- A new performance requirement and test method to address the incidents of sliding down and out through leg openings
- Additional warnings on the product and package to alert the caregiver not to use suction cups on slip-resistant surfaces and an explanation in the instructions of how to determine the presence of slip-resistant surfaces
- Additional labeling on the package to define the age/developmental guidelines for the caregiver in determining the appropriateness of the product for their infant
- Additional warnings in the instructions regarding appropriate water level to use during bathing and the avoidance of having siblings present to substitute for an adult caregiver

Hazard Scenarios and Their Resolution

All three hazard scenarios identified in the briefing package, as well as the staff recommended means to address them, have either already been addressed by the current standard, or are under consideration by the subcommittee to address them in the next ballot for this standard.

The "entrapment/submersion" scenario has already been implemented in the recently published ASTM F1967-03 standard. In this current revision, a requirement for leg openings is included to address the potential for infants to slide down and out between the openings in the sides of a bath seat product, and to minimize these openings with respect to the anthropometric dimensions of the infant users of the product. CPSC staff participated in the standard revision to include these leg opening requirements and concurred with the approved wording that is now in the standard.

Frankly, it is difficult to understand why staff would continue to propose these leg opening requirements for inclusion in a proposed rule when identical requirements are already in the published standard. It is redundant and unnecessary that such requirements be proposed for, or included with, any type of rulemaking recommendations.

A resolution to the "tip over" scenario was presented and discussed at the most recent subcommittee meeting in March, 2003. At that meeting, a vote was taken to approve the inclusion of the proposed revision to the stability requirement in the next ballot that is issued for bath seats. Contrary to the statement in Item B, section 3, on page 9 of the staff briefing package that indicates the "subcommittee deferred any decision on balloting of the requirements until after the next subcommittee meeting," the proposed stability requirements were approved at the March meeting to be included on the next ballot. These requirements reflect the CPSC staff proposal as described in the briefing package, and therefore should adequately address the "tip over" scenario on smooth surfaces.

The only remaining scenario of "coming out" of the bath seat is one which seems to be the most difficult to address and resolve. However, with the implementation of the new requirements for leg openings, the available space for the infant's legs to protrude through the product's sides will be reduced, thus further preventing infants in the usage age range from physically being able to attempt to climb out of the bath seat. This will undoubtedly reduce the incidents of infants attempting to climb out of the product.

The staff recommendation for revised warnings on the product seems to be offered primarily in response to the potential for the appearance of "safer designs" to be generated by newer generation bath seats in order to comply with the proposed stability requirement. It is indeterminate as to whether future designs will actually create more of a so-called "false sense of security" and if a revised warning label will counteract this perception to instill in the caregiver a heightened awareness that they should not leave the infant in the product unattended at any time. We continue to believe that these products do not create a false sense of security and that this concept is really a straw man argument intended to divert attention from the broader issues associated with neglectful care of infants in bathtubs. The CPSC staff is well aware of these broader problems involving risky behavior related to household drowning hazards.

It should be pointed out that in previous meetings and discussions, much attention was given to the phraseology of the warnings on the bath seat that are required in the current standard. Many points of view were considered and debated, including those of the CPSC staff. At the time of the development of the original warning and the additional warnings included in the 2003 revision, the conclusion was that these words were the strongest, most direct, and most concise directive to the caregiver to explain the danger of leaving the infant unattended. In fact, the wording for the warning originally published in the 1999 standard, and which has remained unchanged, was recommended and endorsed by the CPSC staff

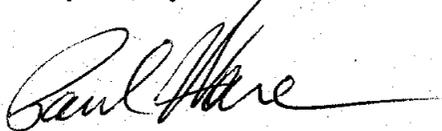
The reasoning included in the briefing package to explain why a different warning should be applied to the product at this time, and how this would actually affect caregiver behavior or perceptions, is neither logical nor definitive. How the words for

this warning were arrived at and the rationale as to why these words would be stronger to induce changed behavior on the part of the caregiver are not explained in any more reasoned logic than the use of the words "may" and "believes" and "some". We do not believe that sufficient evidence has been provided by the staff to legally support the proposed wording. Additionally, there is concern that such wording may actually encourage risky behavior by creating a false impression that it is acceptable to leave infants alone in bathtubs without bathing aids.

With this said, it should also be pointed out that this staff recommendation for such a change to the product warnings was discussed at the ASTM subcommittee meeting in March, 2003. The original wording proposed by CPSC staff was revised at that meeting, with the last sentence of the warning changed to read as it does now in the briefing package. A task group was established to further discuss and refine the proposed warning(s) and then to present a recommendation to the subcommittee at the October, 2003 meeting to be finalized for balloting. The deliberations of this task group are ongoing and discussion of the task group findings and recommendation will be accomplished at the October meeting of the subcommittee.

In summary, the ASTM subcommittee has acted, and will continue to act, in the interests of the infants at risk in bath seats. The current ASTM standard for bath seats is adequate now, and may be further strengthened in the very near future, to address incidents and hazards associated with (but not caused by) this product category. Mandatory rulemaking is not necessary for, and is redundant to, the implementation of adequate requirements for bath seat safety.

Respectfully submitted,



Paul Ware
Chair, ASTM F15.20 Subcommittee on Bath Seats



August 22, 2003

Todd Stevenson
Secretary
Consumer Product Safety Commission
Washington, D.C. 20207-0001

Baby Bath Seats

7/21/03 2:25 P 1:30

RE: Bath Seat NPR

Dear Mr. Stevenson:

On behalf of the National SAFE KIDS Campaign, I am writing in regard to the Consumer Product Safety Commission's (CPSC) proposed rulemaking for baby bath seats/rings, as summarized in the June 12, 2003 issue of the *Federal Register*. The National SAFE KIDS Campaign recognizes that baby bath seats, when used according to manufacturer's instructions and under an adult's constant supervision, can be a valuable convenience device to bathe an infant. However, as lack of supervision and/or failure of some mechanical features, such as suction cups and leg openings, have resulted in some deaths and injuries, SAFE KIDS is in full support of a mandatory standard for baby bath seats/rings that would help to eliminate the risk of injury and death associated with the current form of the product. SAFE KIDS offers the following comments to assist the CPSC in its decision-making process and to improve the safety and use of baby bath seats.

I. SAFE KIDS Background/Position

The National SAFE KIDS Campaign is the first and only national nonprofit organization dedicated solely to the prevention of the number one killer of children ages 14 and under – unintentional childhood injury. Launched in 1987, the Campaign's current nationwide grassroots network of over 300 SAFE KIDS coalitions have provided hands-on assistance to families to help prevent these needless tragedies from occurring in the first place. The on-going work of SAFE KIDS coalitions has helped lead to the decline of the unintentional injury death rate over the past decade – a nearly 40 percent decline for children ages 14 and under.

In 2000, SAFE KIDS supported the petition filed by the Consumer Federation of America and other consumer groups to ban baby bath seats. However, in 2001, given the CPSC's research into the hazard scenarios surrounding the use of baby bath seats, we amended our previous position calling for a ban of the product in favor of supporting a mandatory standard to improve the design of the product itself. SAFE KIDS still believes today that a ban is unnecessary and that baby bath seats must be modified in order to create a safer bathing environment for a child. With an increase in CPSC reports of drowning deaths and "near misses" (96 drowning deaths and 153 non-fatal incidents were reported from January 1983

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President
Martin R. Eichelberger, M.D.

Executive Director
Heather Paul, Ph.D.

A Member Of



SAFE KIDS
Worldwide

www.safekidsworldwide.org

Founded By



to December 2002), the CPSC should act without delay on a notice of proposed rulemaking (NPR). In fact, the Campaign believes that these incidents are probably underreported. Overall, SAFE KIDS feels that the current design of baby bath seats can be changed to better improve its overall safety.

SAFE KIDS hopes that the CPSC will vote to issue a NPR – without waiting for ASTM International to revise their current voluntary standard. While ASTM has adopted performance standards on entrapment and submersion, the voluntary labeling provisions can be improved and changes can be made to adequately address hazards associated with tip-overs or children coming out of bath seats. From our previous experiences serving on ASTM subcommittees for various consumer products, the Campaign knows firsthand that the time between deliberation of changes to a standard to actual adoption can be years. Therefore, we encourage the CPSC to issue a mandatory standard to ensure compliance and uniformity of safety features in the baby bath seat market.

II. SAFE KIDS General Support for CPSC Staff Recommendations and Suggested Improvements

SAFE KIDS strongly supports much of the draft baby bath seat standard as proposed by the CPSC staff. The components of the suggested requirements address the primary hazard scenarios associated with bath seats: 1) tip-over hazard/stability performance requirement; 2) entrapment and submersion hazard/leg opening performance requirement; and 3) coming out hazard/labeling requirement.¹ We commend the CPSC staff on the thoroughness of their recommendations and supporting rationale. SAFE KIDS does, however, have a few suggested modifications that we believe will further increase the safety of the product itself and encourage safe product use by the consumer.

A. Staff Proposed Marking and Labeling Requirements and Suggested Improvements

In order to address incidents of children coming out of bath seats, the CPSC staff has proposed a forceful warning label to advise about the need for constant caregiver attendance and attention to a bathing child. As baby bath seats may encourage dangerous consumer behavior by making caregivers believe that a baby is in a relatively safe environment, and as a result, the baby may be left unattended in the water, SAFE KIDS supports the staff-recommended labeling change to the current ASTM warning. The strong wording of the suggested label, with references to the drownings associated with the product and the fact that the bath seat is not a safety device, should be an effective tool to combat, in part, a caregiver's potentially dangerous false sense of security. However, SAFE KIDS has some suggested improvements.

¹ The ASTM standard for baby bath seats contains requirements addressing product stability, occupant retention, resistance to folding, release mechanisms, static loading, and labeling. Proposed CPSC staff recommendations consist of labeling, stability, and leg/side opening provisions only. If a mandatory standard is passed, SAFE KIDS knows that manufacturers will be required to conform with the new requirements and we expect that they will comply with any provisions of the voluntary standard not in conflict with the CPSC standard. We encourage the CPSC to monitor the effectiveness of both standards when and if appropriate.

1. Suggested Warning Label Language Additions

1a. Emphasis on Parental Supervision

SAFE KIDS suggests that an additional warning may be useful to emphasize the important concept of constant adult supervision. The CPSC should consider adding the following language to the label, after the instruction about keeping a baby within arm's reach:

"NEVER leave a child unattended in a bath."

SAFE KIDS recognizes that this warning language is deliberately redundant in that it communicates the same directive as keeping a baby within arm's reach. We believe, however, that this suggested addition emphasizes the most important concept for safe use of a baby bath seat. The inclusion of this statement will provide another opportunity to convey the critical importance of constant adult supervision.

1b. Alternative to Water Mark Requirement

Additionally, SAFE KIDS realizes that there are differences of opinion as to whether bath seats should contain markings indicating water levels. The Campaign agrees with staff that the inclusion of a water mark on a product suggests that there is a safe amount of water to use while bathing a child – when, in fact, there is none. We believe that the concept can still be communicated without a mark, instead using label or instruction language. SAFE KIDS asks the CPSC to consider that language be added to the label or to the instructions regarding the use of the "least amount of water" needed to bathe a child. For instance, the instructions or labels could include the following language:

"ALWAYS use the least amount of water necessary when bathing a child." (*Or equivalent concept*)

Such a phrase might prevent caregivers from putting too much water in the bathtub, which may be a contributing factor to the deaths and injuries associated with bath seats.

1c. Required Reference to CPSC Standard

The Campaign notes that when the CPSC moved from voluntary bicycle helmet standards (ASTM, ANSI, and Snell) to a mandatory federal standard, it required helmet manufacturers to include a label stating the product's compliance with the new federal requirements. The same notification should be included on this product. Baby bath seats that comply with the new federal standard should contain a label that states, "**Complies with U.S. CPSC standard for baby bath seats**". This requirement allows the consumer to differentiate between older, non-complying bath seats and the newer, safer government-compliant products. It also forces the manufacturer to publicly state that its product does comply with government safety standards.

2. Enhanced Conspicuousness Requirement

The CPSC is recommending that the warning label be printed in a contrasting color from the background. SAFE KIDS believes that this requirement can be improved to better communicate important safety messages. Based on our history monitoring the marketplace for toys' small parts warning labels, we have seen how warning labels can, in some instances, be communicated ineffectively – but still be in compliance with the applicable regulation. For instance, federal regulations require that the small parts warning for toys be in a contrasting color to the background. As a result, SAFE KIDS has seen toy labeling packaging in one shade of pink with the warning label in a lighter shade of pink – contrasting, but not necessarily conspicuous. The ASTM baby bath seat regulation, in its present form, would also allow this same marketplace result. The Campaign believes that the bath seat safety labels should be contrasting and conspicuous by requiring the warning to be in a completely different color from the packaging or the product itself.

3. Label Permanence Requirement

SAFE KIDS suggests that a more effective permanence requirement, unlike the present ASTM standard, be incorporated in the mandatory standard. The ASTM standard calls a label permanent if it can withstand a one-time, 20-minute submersion test in water only. This test does not adequately reflect real life use of a baby bath seat. Given the high use and environmental exposures for bath seats, the Campaign believes that the label and its accompanying safety information must be permanent to continue its communicative value throughout the useful life of the product. Bath seats are used frequently and in an environment of warm water and soaps, so the label should be able to withstand the high use and bath time elements. Permanence will ensure that no matter the age of the product or its usage history, a parent will always have access to critical safety information.

4. Requirement of Safety Warning on Accompanying Descriptive Material

The Campaign suggests that the warning label not only be conveyed on the product and packaging, but reprinted in all accompanying descriptive materials, such as product instructions. This would give the manufacturer another opportunity to convey important safety instructions required for proper use. SAFE KIDS notes the toy labeling regulations require safety information in all descriptive materials. The requirement should apply to baby bath seats. The Campaign believes that the ASTM standard regarding “instructional literature” provides excellent guidance for this requirement.

5. Warning Labels Present on Front and Back of Product's Packaging Requirement

SAFE KIDS recommends that the warning label be present on the front and back of the product's packaging (as opposed to just the principal display panel as required by the current ASTM baby bath seat standard). As currently written in the draft requirements, there is no location specified

for the warning label on the bath seat's packaging. SAFE KIDS believes that this safety information is vital to convey to consumers at the point of purchase, and therefore should be printed on both the front and back of the baby bath seat box.

6. Inconsistent Wording

Although SAFE KIDS is not necessarily recommending a particular change, we do note that the label in its present form uses inconsistent wording when referring to the child bather. In some cases, the bather is referred to as a baby, and in other cases as a child. This may be a distinction without a difference, but the CPSC should ensure that this is an intended inconsistency.

B. Staff Proposed Stability Requirements

In order to address incidents of children tipping over in baby bath seats, the CPSC staff has proposed to amend the existing ASTM voluntary standard to require stability testing on slip-resistant surfaces. In many incidents, the seat's suction cups did not adequately adhere to the bathtub's surface, causing the seat to tip over and for the baby to be immersed underwater. As seats are designed to stick to smooth surfaces and many bathtubs sold today have textured, non-skid surfaces, SAFE KIDS supports this requirement since it should help create a safer environment for a child bather.

C. Staff Proposed Leg/Side Opening Requirements

In order to address incidents of children becoming entrapped or submerged, the CPSC staff has proposed to incorporate ASTM's voluntary leg/side opening requirements into the draft mandatory rule. SAFE KIDS supports this recommendation in order to prevent entrapment of a child's legs in the bath seat and resulting submersion of his/her face in the bath water. This new federal requirement should be acceptable to product manufacturers since it has been adopted into the voluntary standard.

III. SAFE KIDS Support for Educational Campaign

In addition, SAFE KIDS encourages the CPSC to undertake an aggressive education program to reinforce the vital message that babies should never be left alone in water. Furthermore, if a mandatory standard is issued, we hope that ample resources are allocated to persuade consumers to discard their old baby bath seats in favor of products that meet the new safety requirements. Along with our over 300 state and local coalitions, we stand ready to assist the CPSC in whatever way possible to further your educational efforts.

I am available to answer any questions that the CPSC might have relating to our position. As always, SAFE KIDS looks forward to working with the Consumer Product Safety Commission on this and other issues in the future.

Sincerely,

A handwritten signature in black ink, appearing to read "Heather Paul", followed by a long horizontal line extending to the right.

Heather Paul, Ph.D.
Executive Director

Stevenson, Todd A.

Bath Seat comment 4

From: Kelly Grimmond [Kelly.Grimmond@dtrft.qld.gov.au]
Sent: Monday, August 25, 2003 8:26 PM
To: Stevenson, Todd A.
Subject: RE: Comments on baby bath seats



Infant bath cradle.jpg

Mr Stevenson

I would like to submit the following comments for consideration in regard to baby bath seats.

In researching the feasibility of banning these types of products, my initial belief was to have the entire range of bathing aids banned. My logic being "without the product - the opportunity of leaving a child unattended in a bath would be eradicated".

I am passionate about passive protection of children and consequently, during a lunch, I discussed this issue with my mother who has cerebral palsy and her response was "oh, they would have been a great help to me with my one gammy hand and arm". She stated often my brother and I had accidentally slid into the water as infants because the soap suds made us too slippery for her to manage with the use of only one hand. She also asserted she would never have considered it safe for us to be left in such a device and posed the question that "wouldn't most people know never to leave a child alone around water". (which working in this field we know this behaviour occurs all too often, unfortunately !). However, her comments provided food for thought as I didn't want to proceed with recommending the introduction of a ban which would inadvertently increase the net risks. Also, I wanted to ensure under scrutiny the evidence and reasoning could readily justify the impacts of reduced consumer choice and the removal of a very profitable product range from business.

In Australia the number of product types and styles are ever increasing (in both their form and function) and therefore the standard proposed regarding product specifications could not be applied to all the devices presently available in the Australian market. In 1994 the Product Safety Branch developed a draft "Consumer Safety Specification for Infant Bath Seats" with similar recommendations as presented by you, however, the final decision at that time was to continue educating parents/carers of the inherent risks associated with leaving children unsupervised around water.

The most recent death in Australia was of an 8 week old infant in February 2000 who was left lying on a cloth bath cradle (see attached photo). Therefore, it would appear the application of a standard which is product specific is defeated by the continuing diversity of the product styles being made available in the marketplace.

Figures collected by the National Centre for Health Statistics in the US has shown the overall numbers and the risk of infant tub drownings remained constant during the 1980's and slightly declined in the 1990's whereas the ownership of bath seats increased significantly during the 1980's and slightly during 1990's. This data and an analysis performed by K M Thompson (March 2003) on the relative risks of infant drowning based on estimates of bath seats in use with a cohort design and exploring the potential confounding by a range of factors revealed that: (I downloaded from the Medscape website):

"The unintentional bathtub drowning deaths of American infants aged

6-10 months for the years 1994 through to 1998 revealed 40 infants drowning deaths associated with bath seats and 78 deaths not associated with bath seats. Based on the available data on sales and use that exists suggests approximately 45% of infants in the age group use bath seats, therefore the existing data does not support a hypothesis that bath seats increase the risk of bathtub drowning for infants."

Thompson further asserts:

"Based on the present data that exists, albeit limited, suggests that bath seats either have no effect or they may provide some slight unexplained protection against unintentional bathtub drowning risk (with an odds ratio for the risk of drowning with a bath seat vs without a bath seat of approximately 0.6% [95% confidence interval (CI) 0.4-0.9])."

The suggestion being the printed warning on the product reminds carers not to leave a child unattended in a bathtub.

A conclusion from the study by Rauchschalbe/Mann/Olson/Cvijanovich, of which I believe the most compelling evidence for banning these products was in relation to data obtained on "Willful versus Impulsive Decision to Leave an Infant Alone" with the difference being 75% for willful decision with a bath seat compared to 45% for willful decision without a bath seat. Your research evidenced there was an increase in the propensity for carers to engage in more risk taking behaviour with the use of bath seats.

Also, it has been suggested the inherent design of bath seat products induces a "false sense of security" which may overshadow the message printed on the warning labels which leads to an increase in this risk taking behaviour (along with "successful" experiences of leaving the child unattended without incident).

Given this, and other findings in relation to carers perceptions associated with bathing aids (ie. the sturdier, more luxury looking baby bath ring/seat models which are preferred by parents and are perceived to be safer than the more basic models - Shugoll Research for CPSC) it could possibly be argued that if a "more robust looking product" was developed it may only serve to increase the risk-taking behaviour along with the misperception a child will be safe to be left alone in dangerous situations.

Enquiries to the 2 main injury data collection agencies, Queensland Injury Surveillance Unit (QISU) and Melbourne University Accident Research Centre (MUARC) showed that in Australia we do not have the detailed data in relation to bathtub drownings (ie. no records are made of whether a bathing aid was in use at the time of injury or death).

With the ever increasing product diversity and demand (with over a 1 million sales per annum in the US and according to a submission by C. Stuart Pty Ltd to the New South Wales Product Safety Committee over 6.5 million uses over 5 years without a reported incident in Australia for their products alone), it may be argued, demonstrates an industry response to the consumer demand for the products and possibly the "merits" associated with these product types such as:

- 1) being able to secure a child in the bathtub without having to constantly hold them
- 2) assist less able carers to remain independent in caring for their infants
- 3) allow for both hands to be used for bathing
- 4) avoid injuries associated with children from accidentally dropping them during bathing
- 5) reduce the amount of time needed to spend leaning over the bathtub and
- 6) reduce the anxiety some new parents may experience whilst bathing a new born infant.

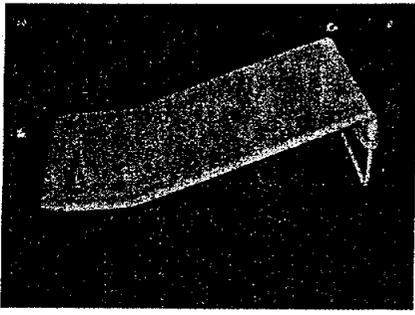
There seems to be a consensus amongst injury prevention "activists"

(for want of a better term) there may be a commonly held belief by people (albeit inaccurate!) that a "child will be alright to be left unsupervised for a moment or two" around water regardless of whether they are an infant, toddler or small child and regardless of whether they are in a bath, wading pool or typical pool and the injury data in the US and Australia supports this assertion.

In conclusion, I have turned my attention to proposing a ban on products that would provide "an opportunity for a carer to leave an infant where none would have otherwise existed". I believe in respect to the Brandon Muddles death, if a bathing cradle was not available no opportunity would have existed for his father to leave him unattended.

Respectfully submitted for consideration

Kelly Grimmond
Senior Product Safety Officer
Product Safety Branch
Department of Tourism, Racing and Fair Trading
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kelly.grimmond@dtrft.qld.gov.au
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Bath Seat 5

Rena Rauchschalbe
Silver Spring, Maryland 20904

August 28, 2003

Todd Stevenson
Office of the Secretary
Consumer Product Safety Commission
Washington, D.C. 20207

Re: Bath Seat NPR

Dear Mr. Stevenson:

I am submitting this comment in my individual capacity and not as a CPSC employee. The views I express are mine alone and do not represent those of the Commission staff. During the public meeting concerning bath seat rulemaking on July 28, 2003, the Chairman, Commissioners and presenters raised several questions. As I have studied the issue of bath seats for many years, I feel compelled to respond with the following information in response to several questions.

Multiple times Chairman Stratton asked questions about bathtub drownings. Specifically, he wanted to know: "Are more kids dying in tubs or are less kids dying in bath seats? Why don't we have that data?" The following several paragraphs contain what I describe as a "mini-study" on parental behavior taken from data available in the US Consumer Product Safety Commission's (CPSC) four data banks: (1) CPSC Death Certificate file; (2) CPSC Injury or Potential Injury Incident (IPII) file; (3) CPSC In-Depth (INDP) Investigation file; and (4) the National Electronic Injury Surveillance System (NEISS).

For the years 1994 through 1999, the CPSC data banks contain 181 tub drownings (i.e., 30 per year) of children aged 5 to 10 months. In observing parental behavior in response to the bathing environment, 36 deaths are not included as part of this mini-study as the parent or caregiver did not place the child in the tub or, in four cases, suffered a seizure or "blackout" after placing a child in the tub (i.e., scenarios not included are those in which a child awoke from a nap and fell into a partially drained tub.) Also excluded are 11 tub drownings with incomplete information. The chart below categorizes 134 drownings by bathing environment.

1994 - 1999 Environment of Bathtub Drownings for Children Aged 5 to 10 Months

No.	Perct.	Bathing Environment
35	26%	does not include a sibling or bath aid - victim is alone in the tub
29	22%	includes a bath seat with the victim
38	28%	includes a sibling with the victim
6	5%	includes a baby tub with the victim
14	10%	includes a bath seat and a sibling with the victim
5	4%	includes a flotation device with victim
1	<1%	includes an infant carrier seat with the victim
1	<1%	includes a baby tub and a sibling with the victim
5	4%	<u>includes caregiver negligence*</u>
134	100%	

* Caregiver may have been under the influence of drugs or alcohol.

Even without details of the incident scenarios, the death data above suggests that parents/caregivers behave differently depending on the bathing environment. For example, 38 of the 134 victims drowned when a sibling was present in the tub. Based on the death data for this age group, it appears that caregivers are taking riskier behavior when a sibling is placed in the tub with the victim.

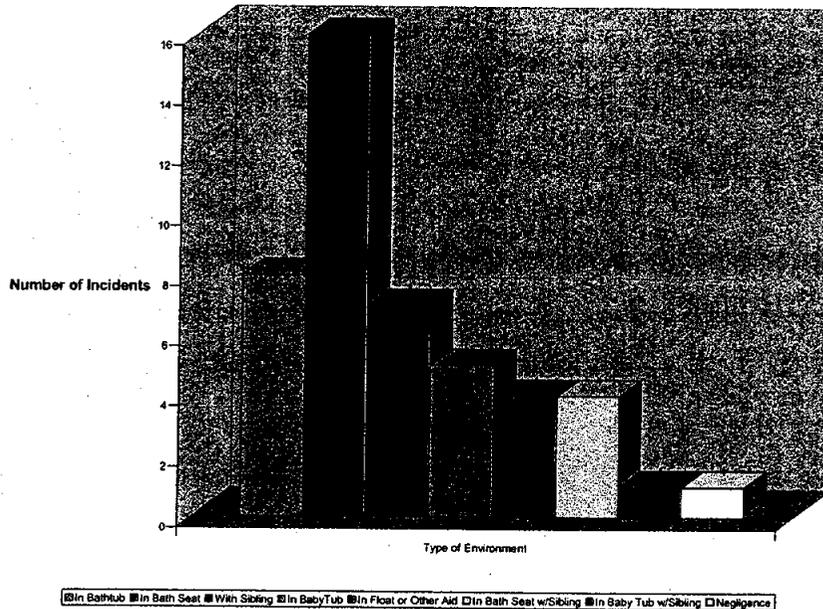
According to CPSC staff, younger children – aged five to seven months are at a higher risk of drowning when in a bath seat than not in a bath seat. The chart below categorizes 46 drownings by bathing environment. Of the 53 total bathtub drownings for this age group, six are not included because the caregiver did not place the child in the tub or, in one case, suffered a seizure after placement of the child in the tub; one death is not included due to incomplete information.

1994-1999 Environment of Bathtub Drownings for Children Aged 5 to 7 Months

No.	Perct.	Bathing Environment
8	18%	does not include a sibling or bath aid – victim is alone in the tub
16	35%	includes a bath seat with the victim
7	15%	includes a sibling with the victim
5	11%	includes a baby tub with the victim
4	9%	includes a bath seat and a sibling with the victim
3	6%	includes a flotation device with the victim
1	2%	includes an infant carrier seat with the victim
1	2%	includes a baby tub and a sibling with the victim
1	2%	includes caregiver negligence*
46	100%	

*Caregiver may have been under the influence of drugs or alcohol.

1994-1999 Environment of Bathtub Drowning Victims Aged 5 to 7 months



Again, even without details of the incident scenarios, the data above suggests that parents/caregivers behave differently depending on the bathing environment. Additionally, the data suggests that parents/caregivers behave differently according to the age of the child. For the age group 5 to 7 months, parents/caregivers are more likely to take riskier behavior when the child is in a bath seat. This supports the risk analysis completed by the CPSC staff and also supports Dr. Clay Mann's comparative analysis that

concludes that there is "increased risk taking behavior in the presence of a bath seat."¹ In addition, the data for this age group supports the statement that the "use of such products may increase the risk of drowning among infants by increasing the likelihood that an infant will be left alone in the tub."²

After the CPSC staff presented its risk analysis, Chairman Stratton asked: "Why are younger children at a higher risk?" The reason is that parents/caregivers are depending on the bath seat to keep their child safe in the tub. For the age group 5 to 7 months, they are more likely to take riskier behavior when the child is in the bath seat.

A question asked by Commissioner Moore follows: "In terms of the manufacturer taking a look at their product [did they] ... see whether there may be a product solution or [did they] ... walk ... away and say ... this is a caregiver problem?" In response to Commissioner Moore's question, I have quoted a section from a deposition of Paul Ware, Vice President, Quality Assurance at Safety 1st, Incorporated. This is in reference to the bath seat drowning of a one-year-old child who died in May of 1996. The child died two days after his mother left him in a bath seat in a tub for just a few minutes while she attended other children in the house (CPSC in-depth investigation 960924CCC5643). Along with discussions about warnings, use of the word "safety," non-skid surfaces, and Paul Ware stating that there is a "valid concept there that perhaps the parent does have a sense of security,"³ the deposition contains the following excerpt between the Plaintiff's attorney and Mr. Ware:

Q. - 16 deaths prior to the time of the occurrence complained of, Safety 1st had knowledge that children were being left, however momentarily - sometimes longer, sometimes shorter - alone in these bath seats; is that not correct?

A. Yes.

Q. And that put these infants at great risk, did it not?

Mr. Campo [Attorney for the defendant]: Objection.

A. It put them at risk; yes.

Q. 16 babies died because of that risk, did they not?

A. Yes.

Q. And 21 to date, correct?

A. Yes.

Q. Given that body count, are you telling us that Safety 1st did not change their warnings, did not change their instructions, did not change the design, did not change their marketing practices with these seats?

Mr. Campo: Objection.

A. (No response.)

Q. I want to be accurate to save time. Is that what you're telling us?

Mr. Campo: Objection.

A. In not so many words, yes.⁴

Also in the same deposition, there is reference to Mr. Ware recalling the first meeting Safety 1st attended with the CPSC staff pertaining to this type of product during the summer of 1993. According to Mr. Ware, also present at the meeting were representatives from Fisher-Price, Gerry and Sassy. Note that - with the exception of Safety 1st - all of these manufacturers no longer produce bath seats.

¹ N. Clay Mann, PhD, MS; R. Rauchschalbe, MS; L. Olson, MA; N.Z. Cvijanovich, MD, *Infant Seat Bathub Drownings: Who's to Blame?* Presented at the National Congress on Childhood Emergencies conference in Baltimore, Maryland on March 27, 2000.

² R. Rauchschalbe, MS; R.A. Brenner, MD, MPH; G. Smith, MB, ChB, MPH, *The Role of Bathub Seats and Rings in Infant Drowning Deaths*; *Pediatrics* Vol/ 100 No. 4 October 1997

³ Commonwealth of Massachusetts, Middlesex Superior Court No. 97-5748; Tammy White, Administratrix of the Estate of Matthew Wetherbee, Plaintiff, v. Safety 1st, Inc., Defendant on Tuesday, June 1, 1999; p.31.

⁴ *Ibid.*, pp.50-51.

Fisher-Price, the primary competitor to Safety 1st in 1994 with nearly equal market share of bath seats at that time, responded differently when learning of the deaths in its bath seats. On November 1, 2000, Walter Sanders, Counsel to former Chairman Ann Brown, by email asked Jim Walter of Fisher-Price the following question:

"Jim,

Fisher-Price once produced baby bath seats. Why did they get out of the business?

Walt"

Jim Walter's response follows:

"Walt:

After a thorough review of incident data and use patterns, Fisher-Price decided that the risks, both to the company and the consumers, associated with this business were not warranted. We elected to exit the business rather than work to ensure that the product could be manufactured in a way that would be considered safe. While this may be possible, Fisher-Price elected not to pursue this.

For example, it did not seem possible to properly warn consumers of the risks since the product itself, during normal use, seemed to imply that supervision was not necessary, despite any warnings to the contrary.

Regards,

Jim Walter"⁵

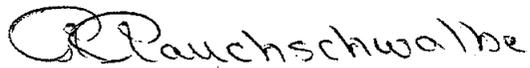
There was some discussion during the July 28, 2003 bath seat briefing between Commission Gall and Sally Greenberg of Consumer Reports regarding peer review and publication of Dr. Clay Mann's study and Dr. Kimberly Thompson's study. As noted in a footnote above, Dr. Mann's study "Infant Seat Bathtub Drowning: Who's to Blame?" was presented at the National Congress on Childhood Emergencies conference in Baltimore, Maryland on March 27, 2000. With the exception of the three co-authors and representatives from the Centers for Disease Control (CDC) who provided a research grant for the study, it was not peer reviewed. Peer review was not required for Dr. Thompson's on-line publication of an article in Medscape. The article "The Role of Bathtub Seats and Rings in Infant Drowning Deaths" published in Pediatrics on October 4, 1997, remains the only peer-reviewed article on this topic.

As I began writing these comments on the Baby Bath Seat Briefing of July 28, 2003, I considered the CPSC staff's recommendation proposing three requirements addressing the three main hazard scenarios an acceptable solution. But, as I again review all the pieces of information and actions (or lack thereof) that have taken place over the past ten or more years, I now support a ban of bath seats. If bath seats were not present in the 1994 -1999 bathtub drownings for children aged 5 to 7 months and half of the caregivers walked away anyway, eight children would be alive today. However, from the data provided above, it is probable that all 16 caregivers were influenced by the presence of the bath seat in the bathing environment - and that all 16 children would be alive today. If Safety 1st - by far the largest manufacturer of bath seats - had shown respect for the loss of child's lives through the years by taking the initiative to carefully evaluate

⁵ Original email message from Sanders, Walter A. of CPSC on Wednesday, November 01, 2000 12:09 PM with response from Walter, Jim on Wednesday, November 01, 2000 6:56 PM.

the role their product played in these deaths and injuries – as Fisher-Price and other companies apparently have done - I could support the staff's decision. However, I agree with Sally Greenberg of Consumers Union that children can no longer be treated as "guinea pigs." Instead, bath seats should be banned.

Respectfully submitted,

A handwritten signature in cursive script that reads "Rauchschalbe". The first letter 'R' is large and loops around the start of the name.

Renae Rauchschalbe

Stevenson, Todd A.

*Bath
seats* 6

From: Clay Mann [Clay.Mann@hsc.utah.edu]
Sent: Thursday, September 04, 2003 10:49 AM
To: Stevenson, Todd A.
Cc: rweintraub@consumerfed.org; Rauchschalbe, Renae
Subject: Comments regarding bath seats

Mr. Stevenson:

Thank you for the opportunity to comment on current discussions regarding bath seats via e-mail. Several individuals have contacted me regarding comments made about a bath seat study I conducted some years back by a representative of manufacturers. I believe his name is Mr. Rick "Locker" and he was commenting during a formal hearing.

The study he referred to was conducted to determine if parents were more likely to participate in "risky" child bathing behaviors if a bath set was used compared to when one was not used. The study demonstrated that parents filled the tub with more water and were more likely to make a "willful" decision to leave a child alone in the tub when a bath seat was in use compared to when one was not in use. During recent testimony, the representative of manufacturers recalled a conversation I had with him on the phone several years ago. He indicated that I considered my findings somewhat suspect for various reasons.

Although I have reconsidered my approach in several studies after peer-review and some reflection. I, to this date, see no reason to "step-back" from the findings of this study. We utilized a matched case-control approach which eliminated many of the biases often associated with parental recall studies. The study, although somewhat small in sample size (64 children), demonstrated statistically significant differences ($p < 0.05$) between the use and non-use of a bath seat, as stated above.

In this type of research, robust study designs cannot be used. That is, a randomized controlled trial assessing the risk of bath seats will never be done (for ethical reasons). Yet, the study berated by the representative of manufacturers probably utilizes one of the strongest scientific approaches that can be applied to retrospective product evaluation studies.

Please feel free to contact me if you have any questions.

Thank you for this opportunity.

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