

This may be because they believe the minor problem will not take long to resolve.

"Go across to the table to get a towel."

"Didn't leave the bathroom, but just turning to get a towel or something and finding the bath ring floating up or the bath ring up around her chest."

"Somehow (my older child) got the ring loose and was trying to shake her (the baby) in it... And that was just a split second out the door for pajamas and back."

"I have left my son before to run and get something like a towel that I forgot or something."

"Once I just turned my back to get something from under the cabinet. I was right there still physically next to the bathtub and turned around. And this is my two year old who plays for forty minutes a day and somehow he twisted and he was scared. I could see him squirm to get himself up. I could just turn around and pick him right up, but I just literally turned my back to get the towel from the cabinet. It's amazing." (Bath ring was not being used)

- Some parents report that several things would make them feel more comfortable leaving a child unattended for a moment in the bath. These things include: using a bath ring/seat, having an older sibling in the bath with the younger child, and still being able to see and hear the child even though they have physically left the bathroom.

"[In the ring/seat] He cannot slide. He cannot jump out."

"I would think it would be safer, but on the other hand I haven't used it."

"It would make a difference to me. It depends on the time that you are talking about. If you are talking under two minutes, I would feel more comfortable with my baby in a seat. Because it does give him support. Because he can hold on. Because he can't put his face under."

"I would feel much safer leaving him in the seat than I would without. I've never had him in the bathtub without the seat. But with my oldest child I didn't even know about these bath rings. So it's a new invention for me and I think it's great. And again, he is upright and he is there to stay. At least at this point."

"I said watch him for a second. I no sooner got to the door and he went schoomp under the water and it was like I almost had to jump over her to get to him and it was... no, you can't do that."

"As long as you have your eye on them that's okay."

"I will admit to leaving mine to run down... but my bathroom is at the end of the hall so I can open the door and run down. And I can see where he is and hear what's going on."

- There is no single age at which parents feel comfortable leaving a child unattended in the bath. In addition, there is no single age at which parents will trust an older sibling to supervise a child in the bath. Parents report that trust and confidence is dependent on the maturity and nature of the individual child. In other words, some children are safe to leave for a certain amount of time at 2 ½ or 3 while others can't be trusted until they're 4 or 5 years of age. Likewise some children can be trusted to supervise younger siblings at around 6 years of age while others need to be older.

"You sort of think first grade." (Is the time that the sibling is ready to supervise a younger child in the bath.)

"It was only when he was maybe 2 and a half that I would feel comfortable enough to grab the phone and bring it in. But I wouldn't hold a conversation in another room."

- Those parents who admit that, on occasion, they have turned away from their young child in the bath or who have even left the bathroom say their time away accounted only for a few seconds or up to 2 minutes; enough time to retrieve a

diaper, a towel or retrieve a portable telephone. However, some leave their 2 to 5 year olds for longer periods of time.

"Ten seconds."

- Some parents report that a successful experience leaving a child unattended in the bath does build their confidence and contribute to their likelihood of repeating the high risk behavior. On the other hand, those who had experienced a problem after having left a child unattended in the bath were more cautious if not reluctant to attempt the behavior again.

"That instance I felt, gee this worked, but I wouldn't usually do it."

"Yes, it would instill confidence in me if I came back and he was just sitting there. Then I would feel more comfortable to do it another time."

"Not so much my attitude, but her attitude, that she didn't perceive it as a problem that I left... Still playing comfortably and happily and didn't take notice of my leaving, I think I would feel good about her comfort if I left her by herself... Or that she didn't take the opportunity to do something negative."

"It's almost like that was a warning..." (Respondent is referring to an incident where her older child was unable to successfully handle her younger child in the bath.)

2.4 Obtain Reactions to Labeling and Packaging of Baby Bath Rings/Seats

To meet this objective respondents were asked if they recall seeing any product information about baby bath rings/seats. They also were asked to identify precisely where they had seen the product information. Finally, respondents were asked to discuss what could be done to improve product information and warnings in order to alert parents to the risks related to use of bath rings/seats.

- Most respondents are aware that manufacturers of baby bath rings say the appropriate age for product use is 6 months to about 18 months. Respondents also are aware that the product warning states "never leave your child

unattended while using this product." They believe the warning means a parent should be present at all times when the product is in use. Respondents say the warning is on the box and some recall it is also on the ring/seat itself. However, respondents say this warning or others similar to it have become common place on baby products. Parents believe the warnings are put there only as a reminder and as protection for the manufacturer against potential liability. However, they are not certain the warnings mean the product represents a significant threat to the well-being of their child. Interestingly, some parents almost resent the warning and imply that it is an insult to their intelligence, since they already know they are never supposed to leave their child unattended in the bath.

"The one on the bath seat seems warranted. Although I've seen some of them that are just bogus. Although it is kind of like a slap in the face like you are going to leave your kid in the bathtub full of water. Of course you are not going to do that. But still, just that mental reminder. Hey, this is serious and this is a safety seat so your child will be safer in this hostile environment."

"It is on there, the warning, never leave child unattended."

"It's sort of expected. It's like cigarettes, if you smoke you might get cancer so you expect to see that on the box."

"It's on everything."

"I'm sure it's on the box."

"In big letters at the back of the box... Where they have the description of what it is, down at the bottom underneath all of that."

"And on the ring too."

"I think it's also for their benefit for liability too. The jumpers and the walkers and all of that too."

2.5 Obtain Reactions to Bath Rings/Seats

To meet this objective, sample rings/seats were displayed in the focus groups. The following rings/seats were shown in all three groups:

- [REDACTED] - A blue ring/seat with a flat base. An activity center is attached to the front and the seat swivels.

- [REDACTED] - A white chair with a blue pad on the seat. This model has a strap to restrain the child.

- [REDACTED] - A yellow ring with a yellow sponge pad for the baby to sit on.

A fourth ring was displayed only in the third and final group because a respondent in an earlier group session said it was her ring/seat of choice and other respondents seemed to find her description of the product particularly appealing. This fourth ring is manufactured by [REDACTED]. It is white, can be collapsed for storage, has a mechanism that unhooks the front bar to get the child in and out of the seat, and has an activity center on the front for the child to play with.

Once the rings/seats were revealed, respondents first were asked to select the seat/ring they would be most likely to purchase or want as a gift and to state why. Then they were asked which ring or seat they would be least likely to purchase or want as a gift. Finally, respondents were asked to select the ring or seat they felt was safest. This exercise was done individually to avoid the risk of peer pressure that can easily occur in a focus group setting. Once respondents made their selections, the moderator asked respondents for their top-of-mind reactions to each ring/seat.

- In the first two groups where only the [REDACTED] rings/seats were displayed, [REDACTED] was typically selected as respondents' preferred model. It is considered the safest model because of the "3-point bar system" (the description provided by respondents which in their minds conveys stability) and sturdy backrest. Those who selected [REDACTED] as their preferred model did so because it is visually more appealing, allows the child some freedom to play, and it seems sturdier, more durable and much safer than the

others. It also appears less likely to tip over. In addition, respondents feel the suction cups would work well. Since the ability of the suction cups to adhere properly to the tub surface was identified by a number of parents as a major problem with their current ring/seat model, parents particularly like [REDACTED] model because of its suction cups attribute. Parents also like the [REDACTED] model because of its swivel base. They think this feature might make it easier for them to wash the baby. Finally, they liked [REDACTED] because the model has an activity center which is likely to increase the baby's fun in the bath.

"If someone were to give it to me I would like the blue one because I'd think that they're thinking of safety. But thinking of the baby and how she would like to climb. That's a challenge to her, she would love to learn how to climb out of it."

"If I were to leave a child, I would probably be with the blue one."

"It has all the support and it has the bar in front so you can put one leg on the other side if you want."

"It does look more secure than either of these other models for the age of a baby that is very small."

"The blue one to me is the safest. I like that wrap around. That one is closest to what I have at home that I'm very happy with."

"I think it has the best suction."

- Those who reacted less favorably to the [REDACTED] did so because they believe it would be difficult to get their child's legs in and out of this model because of the size of the leg openings. They also expressed concern about the finishing of the plastic saying it is likely to scratch children when putting them in or taking them out of the ring/seat. In addition, some respondents think the ring is too high and that this would inhibit the child from splashing in the water or reaching for a toy. They feel this would increase the likelihood that the child would want to climb out or reach over the ring and thereby topple the ring/seat. Finally, respondents believe the center bar could be uncomfortable for the child, if they slip down while they are inside the ring.

"I'm trying to imagine a heavier child in the blue one. Maybe the weight would make him tip over."

- The few parents who preferred the [REDACTED] model did so primarily because the lack of bars would enable the child to play with the water and be washed more easily. These parents also feel this ring/seat would be much easier to use for an older child, since the child's legs do not have to be poked through. This feature increases the life span of the ring/seat and eliminates the problem of the child getting scratched. Finally, respondents like the strap saying that this feature is truly a restraining device that will keep the child upright and prevent the child from slipping. Other respondents said they like the suction cups.

"I like [REDACTED] because none of them do I use for safety. Convenience wise that looks like what I used and what I wanted. It would be easy to put them in and it would be easy to wash him and he would be secure in it. I think [REDACTED] looks good."

"The child has more reachable freedom."

"This was more attractive to me for the older child if you had a concern about using the baby seat at all. Because you could get bigger babies in it. And as she said have an arm free to work with them."

"In a Safeway cart she can push herself up out of the seat. At least in the chair she is strapped, so she wouldn't really be concerned with climbing out of the seat."

"That one has the actual restraint."

[REDACTED] is the only one that has a strap."

"First of all the suction cups are larger. And also this is a little more convenient."

"The only think I do like about [redacted]s the rubber of the suction cups. It seems this is definitely more of a rubber. The only advantage of is the feel of the suction cups."

- Those who did not like the [redacted] model feel the strap would be too confining and uncomfortable. They expressed greatest concern over the fact a child could so easily reach out for a toy and topple the ring over because the base doesn't seem secure or steady enough. They also feel the strap might prevent children from rescuing themselves if the seat does topple.

"I can see why people would think it's good to be strapped in, but then if it would come down then they are stuck in one spot. Here at least they can get out and get themselves up, possibly."

"I don't think it would be comfortable either. You have this strap right there. At least with a ring they can move around and lean over and pull at the toys"

"I'm just thinking of my daughter being in that one. It seems to me that she would kind of lunge forward and just take it with her. ... I don't know why I think she wouldn't do that in that one, except that she is sitting on and weighing it down a little more and maybe wouldn't be able to throw her weight around the tub as much as the white one. ... This may give her the idea that she's got to sit in there more. That it looks like she's free. And I think she would be pitching forward to go places in that one."

"But look at the base. It's not wide enough to really stay."

- There were very few parents who liked the [redacted] model. Those who did feel this model gives the baby maximum freedom to move around. Some also liked the suction cups and the idea that a sponge is included to protect the child from slipping on the tub surface.

"Actually I like that one. I thought because of the foam on the bottom. I thought the suction cups weren't very good. If the suction cups were better I thought it was pretty good because you can get to the kid as compared to the other ones. The child can still play and they're actually sitting in the water. With the foam she'd be less likely to skid."

- The [redacted] ring/seat was typically selected as the least preferred model and the least safe. These parents feel the ring/seat is too flimsy and small and that it is the least sturdy model. They feel a child could easily tip over or slide under the ring. Respondents generally did not like the sponge feature that comes with this model because the sponge is likely to slip out from under the child and leave the baby on the slippery tub surface and because the sponge is likely to mildew and tear apart with continued use.

"This one I'd never in a million years use. Where would his legs go? Way too small. It would never fit."

"It's so small that a small baby shouldn't even be in the bathtub left alone like that."

"You know how long that would last? One minute. The child could pull this up and there's no support, he'd lean over it anyway, it's not high enough, it's not wide enough. It's nothing. It's not going to work."

- In the final focus group, the [redacted] model ring was displayed along with the [redacted] models. The [redacted] ring/seat was selected over [redacted] model as the most preferred and safest. Those who preferred this model like it because it seems sturdy and convenient to use. It is perceived as convenient because the front comes down to make it easy to put the child in and take the child out. They also like the model because it collapses for easy storage and because it has an activity center to amuse the child. The only complaint voiced about the model is that it is white and therefore likely to be hard to clean.

"It's probably the nicest one of the lot."

"It's the heaviest. It's not something that maybe after you get a little water underneath the suction cups would lift up a little."

"That would be great to put in the wading pool in the summertime when they're at that age when you can sit there and let them play in the water. Something like that would work better for me outside. It looks perfect."

"You have to clean it too much."

- Most parents believe information about the hazards of using baby bath rings/seats or seats needs to be publicized more through articles in appropriate consumer magazines, on television news shows, or in public service announcements. Warning information on the packaging or product alone is not considered sufficient since safety warnings are now so prevalent parents are becoming somewhat immune to them and their meaning. One parent even believes the only solution is to ban most of the bath ring/seat models.

"They should be banned by the CPSC. That is awful. Just look at that. It will fall apart."

"I don't think they're durable. I don't think they're stable. These really should be outlawe [REDACTED]"

- One respondent described her [REDACTED] bath ring/seat saying it was far better than the models shown in the focus group. She feels her model is sturdier and roomier. It allows her child to play in the bath both with the water and with toys. She has no problem with the suction cups not sticking to the tub surface. This model ring/seat gives the mother a sense of security that she can leave her child alone in the bath for a short time if necessary.

"It's stronger. It's thicker. It has like fifty million suction cups on the bottom. It stays right down there. You can't believe how many suction cups. They're big. Each of them are wider than this. There's three and they're really wide and it has a really fat thing and it comes up to the chest. He can reach around and play with all the toys. He can like stick his little head down in there and like drink the water. He's splashing and playing and kicking. I can get in there and bathe all the parts except for the bottom. That's what I do last just when I take him out. We bathe his bottom and wrap a towel around him. It's been out three or four years. [Do you feel comfortable leaving child alone?] Yes."

3.0 CONCLUSIONS AND RECOMMENDATIONS

Recommendations are based on study findings and the interpretation of those findings by the moderator/project analyst. These recommendations may or may not represent the views of CPSC.

1. Mothers tend to be the parent primarily responsible for bathing their young children, especially those under 2 years of age. Therefore, the primary target audience for CPSC information/messages about baby bath rings/seats is mothers. Product safety information should be placed in media that reaches women in their child bearing/rearing years. Secondary target audiences include fathers, grandparents, babysitters and older siblings. Appropriate selection of communications channels to reach these audiences with safety information on baby bath rings/seats also is needed.
2. Young children are frequently bathed with their older siblings. Therefore, the bathtub is typically filled to meet the needs of the oldest child in the tub. In addition, the presence of older siblings, especially those considered mature, increases parents' confidence that their young child will be safe if they must leave the bathroom for a moment. Information on the dangers of leaving siblings to supervise young children in bath rings/seats during bath time needs to be communicated.
3. Many respondents use bath mats, or adhesive appliquéés on porcelain tubs to minimize the slipperiness of their tub surfaces. Others have non-skid fiberglass tub surfaces. Respondents frequently report their ring/seat's suction cups do not adequately adhere to their tub surface. Therefore, consumers may not be aware which surface-type is safest and/or how to improve the grip of the bath ring/seat to the tub. Information in product literature should strongly advise consumers specifically about the optimal tub surface for proper and safe use of baby rings/seats.
4. Parents are more inclined to think of the bath ring/seat as a convenience product rather than a safety product. However, consumers believe to some extent that their young children are safer in the bath when they are in a ring/seat. Therefore, the bath ring/seat gives parents a false sense of security that their child won't slip or topple over into the water. The emphasis some manufacturers put on their bath

rings/seats being a safety bath aid should be monitored carefully and use of the word "safety" should be minimized.

5. Parents are more likely to purchase a baby bath ring/seat than receive the product any other way (e.g., as a gift). Therefore, they are often the key decision maker in the purchasing process. An information consumer guide on whether to purchase a baby bath ring/seat and, if purchased, how to choose the most appropriate ring/seat might be considered for development to assist consumers in making informed buying decisions.
6. Parents were able to recall the information on age appropriateness for the bath ring/seat as well as the product warning information from the box. (Although the information recalled may not necessarily be accurate.) However, the age and safety guidelines are not always followed. Therefore, safety and age information need to be enhanced and, perhaps, augmented through use of more obtrusive mass communications tools (e.g., getting articles placed in papers, placing speakers on talk shows, etc.).
7. Consumers have significant complaints about the baby bath ring/seat including unreliable suction cups, use of rough materials that can scratch the child, and the inability of models to adequately restrain slightly older or larger young children. Therefore, product improvements are needed to reduce the potential hazards associated with existing bath ring/seat models.
8. Parents do leave their young children alone in the bath, albeit infrequently and only for a few moments. Presence of older siblings, use of baby rings/seats and the ability to keep the child in view tend to encourage trial of this high risk behavior. This finding suggests that although parents acknowledge intellectually the hazards involved, they do not truly believe something bad will happen to their child. Lack of a direct personal experience with a drowning seems to increase the chance that a parent might engage in high risk behavior. Conversely, having personal knowledge of someone who has drowned seems to decrease the possibility that a parent will engage in high risk behavior. Therefore, parents need to be informed that siblings, bath rings/seats or the ability to keep the child in view provide them with a false sense of security and that bath drownings can happen to any family.

9. Parents seem more likely to turn away from their child in the bathtub or leave the bathroom for non-emergency reasons than for emergency reasons. The assumption is that minor tasks (e.g., getting a diaper, towel, etc.) take only a few seconds to accomplish. However, people typically do not accurately judge how long they are away from their child. What seems like seconds or one or two minutes might actually be longer. Safety information has to communicate that it only takes a few seconds for something to happen and that there is no major reason or minor one important enough to leave a child unattended in the bathtub given what could potentially happen when the parent is gone.
10. Respondents were unable to come to any consensus regarding what age a child can be trusted in the bath alone or at what age a sibling is old enough to supervise a younger child in the bath. CPSC should examine its case studies to track trends on this issue to determine if more stringent product safety guidelines on age are required.
11. Successful experiences with leaving a child unattended in the bath tend to encourage parents to repeat the high risk behavior. Public education is needed to help parents understand that they should not become over confident and that such high risk behavior should not be repeated.
12. The sturdier, more luxury looking baby bath ring/seat models (e.g. [REDACTED]) are preferred by parents and perceived to be safer than the more basic models. Parents indicate that if they were ever to leave their child unattended in the bathtub they would feel more confident in leaving if the child was in one of the luxury models. Therefore certain models, more so than some others, potentially make parents feel over-confident that their children will be safe in the bath while using these particular baby bath rings/seats. Statistics should be carefully monitored to see if use of the luxury models is resulting in a higher incidence of bath accidents.

APPENDIX A
RECRUITMENT SCREENER

SHUGOLL RESEARCH
 7475 Wisconsin Avenue
 Suite 200
 Bethesda, Maryland 20814
 (301) 656-0310

JOB CPS301
 11/17 CIRCLE
 6PM 1
 8PM 2
 11/18 CIRCLE
 6PM 1

FINAL 10/28/93
 SCREENER

RESPONDENT NAME: _____
 ADDRESS: _____
 CITY: _____ STATE: _____ ZIP: _____
 TELEPHONE: _____
 DATE RECRUITED: _____ RECRUITED BY: _____
 CONFIRMED BY: _____ DATE CONFIRMED: _____

Hello, this is _____ calling from Shugoll Research, an independent market research company. We are conducting a 3-minute survey to learn more about the types of equipment used on a day-to-day basis to care for young children and would greatly value your opinions. This is strictly market research and no sales effort is involved.

A. First, do you or does anyone in your family work: (READ LIST)

		<u>CIRCLE</u>	
		<u>Yes</u>	<u>No</u>
	For an advertising agency, a public relations firm or a market research firm	1	2
	For a federal government agency	1	2
	For a manufacturer of or retail store that sells baby equipment	1	2
OR	In the medical field, in a doctor's office, in a hospital, in a clinic or as a health care volunteer	1	2



IF YES TO ANY, TERMINATE

1. Do you have any children living at home?

		<u>CIRCLE</u>	
Yes	1		→(CONTINUE)
No	2		→(THANK & TERMINATE)

2. How old are your children? (DO NOT READ LIST)

CIRCLE ALL MENTIONS

- | | | |
|--------------------------|---|---|
| Less than 6 months | 1 | |
| 6 months to 16 months | 2 | (ALL RESPONDENTS MUST HAVE CHILDREN 6 MONTHS TO 16 MONTHS. TRY TO RECRUIT HALF WHO ALSO HAVE ANOTHER CHILD UNDER 5 YEARS) |
| 17 months to 23 months | 3 | |
| 2 to 4 1/2 years old | 4 | |
| 5 years or older | 5 | |
| Other _____
(SPECIFY) | 6 | |

3a. Which of the following types of equipment are you currently using? (READ LIST)
(CIRCLE UNDER Q.3a BELOW)

3b. (FOR THOSE NOT CIRCLED IN Q.3a ASK:) Which of the following types of equipment have you ever used?
(CIRCLE UNDER Q.3b BELOW)

CIRCLE

- | | <u>Q.3a</u> | <u>Q.3b</u> | |
|--|-------------|-------------|---|
| High chair (a seat your child sits in at mealtime) | 1 | 1 | |
| Bath seat (a seat your child sits in at bath time) | 2 | 2 | →(AT LEAST 8 MUST USE OR HAVE USED A BATH SEAT) |
| Car seat (a seat your child sits in when in the car) | 3 | 3 | |

3c. Are you the parent who has primary responsibility for bathing your child who is between 6 months and 16 months old, Is your spouse/partner primarily responsible, or do you both share the responsibility equally?

CIRCLE

- | | | |
|--|---|--|
| I'm primarily responsible | 1 | →(QUALIFIES) |
| We share equally in responsibility | 2 | |
| My spouse/partner is primarily responsible | 3 | →(ASK TO SPEAK TO PARTNER PRIMARILY RESPONSIBLE IN ORDER TO QUALIFY) |

4. And, now just a few final questions to make sure we have a balanced sample. Which of the following categories includes your age? (READ LIST)

CIRCLE

- | | | |
|-----------------------|---|------------------------|
| Under 25 | 1 | |
| 25 to 34 | 2 | |
| 35 to 44 | 3 | →(RECRUIT A MDQ) |
| 45 or more | 4 | |
| (DO NOT READ) Refused | 5 | →(THANK AND TERMINATE) |

5. And, are you? (READ LIST)

	<u>CIRCLE</u>	
White	1	
Black	2	
Hispanic	3	→(RECRUIT A MIX)
Asian	4	
Other (Specify) _____	5	
Refused	6	→(THANK AND TERMINATE)

6. Which of the following categories best reflects your total family income before taxes? (READ LIST)

	<u>CIRCLE</u>	
Less than \$30,000	1	
\$30,000 to \$49,999	2	
\$50,000 to \$69,999	3	→(RECRUIT A MIX)
\$70,000 to \$79,999	4	
\$80,000 to \$99,999	5	
\$100,000 or more	6	
(DO NOT READ) Refused	7	→(TERMINATE)

7a. Finally, have you ever attended a panel discussion for market research purposes?

	<u>CIRCLE</u>	
Yes	1	→(CONTINUE)
No	2	→(SKIP TO INVITATION)

7b. When did the last group discussion take place?

	<u>CIRCLE</u>	
Within the past 6 months	1	→(THANK & TERMINATE)
More than 6 months ago	2	→(CONTINUE)

RECORD GENDER:

	<u>CIRCLE</u>
Female	1
Male	2

INVITATION

We are conducting a panel discussion with 10 people like yourself to discuss the child care equipment needs of young children and factors that influence parent selection of equipment. The discussion will take place on November 17/18 at 6/8PM. The discussion will take about 2 hours. A cash gift of \$40 will be given to each participant and a light dinner/refreshments will be served. Are you available to attend the meeting?

CIRCLE

Yes

1 →(GIVE DIRECTIONS)

No

2 →(THANK & TERMINATE)

APPENDIX B
MODERATOR'S GUIDE

MODERATOR'S TOPIC GUIDE
FINAL 12/02/93

PROJECT: CPS301
DATE: November 17 (6/8pm) & November 18 (6pm)
LOCATION: Bethesda, Maryland
TOPIC: Baby bath rings

Introduction

- Who I am
- What I do

Ground Rules

- Audio taping and why
- Talk one at a time
- Articulate loudly enough to be heard
- Avoid side conversations
- Mirror and observers
- Videotaping and why
- Avoid peer pressure
- Be candid
- No right or wrong answers
- Need to hear from everyone
- Gratuity for your time and opinions

Respondent Introductions

Tell us:

- Your name
- Area of residence
- Family status - number of children, genders, ages
- Types of baby equipment owned and used (e g , car seat, high chair, walker, bath seat etc)

Examine General Bathing Practices for Children

- Determine bath frequency in a typical week for children under 2 years old and children 2 to 5
- Identify typical bather (e.g., mom, dad, older sibling, babysitter, grandparent, etc.) for children under 2 and children 2 to 5
- Identify other bathers (e.g., mom, dad, older sibling, babysitter, grandparent, etc.) for children under 2 and children 2 to 5
- Determine typical length of bath for children under 2 and children 2 to 5
- Determine amount of water typically used in bath for children under 2 and children 2 to 5 (e.g., inches or proxy measurement such as up to what body part)
- Determine if children of different ages are ever bathed together—under what circumstances and why (e.g., more efficient, older child can supervise younger child, for fun or play, etc.)
- Describe the type of bath tub typically used (e.g., size, whirlpool, type of surface—shiny/mat, skid or non-skid, (Probe: what does skid/non-skid mean, how they know) surface material such as porcelain, cast iron, etc., surface pads used, if any—decals, mats, etc.)

Examine Consumer Knowledge and Use of Baby Bath Seats/Rings

- Determine if respondents use bath aids to assist them in bathing their children, identify types of bath aids typically used (specifically bath rings/seats) and frequency of use (e.g., always, sometimes—such as when you expect an interruption like an important phone call, rarely)
- Describe specifics about bath aid used in terms of size, shape, features, brand name, consumer information provided (e.g., how to assemble, how to use)
- Identify reasons why parents use bath rings/seats
- Determine how respondents got their bath ring/seat (e.g., purchased—where, hand-me-down, as a gift, etc.)
- Identify for what age child parents use bath rings/seats - identify youngest age parents believe can use bath ring/seat and the oldest age that the product is still appropriate for
- Identify what parents particularly like and dislike about the bath rings/seats
- Determine if parents or other bathers have ever experienced any problems or difficulties (e.g., suction cups not holding, child trying to get out, seat tipping

over, etc.) using the bath ring/seat; identify the problems and the circumstances surrounding the problems

- Determine if parents have continued to use the bath ring/seat after experiencing their problem/difficulty
- Determine if parents believe the bath ring/seat stabilizes their children enough to allow them to turn away from and/or leave the bathroom for a few moments in case of an interruption or emergency

Examine High Risk Behavior Patterns During Bath Time

- Determine how often parents have had to leave their children in the bath
- Identify specific situations where bather has had to leave the child alone in the bath, or if no such situations have ever occurred, make respondents imagine situations/occasions where such action might have to occur (e.g., phone call, doorbell, attend other children or household emergency, etc.)
- Identify the youngest age child parents have ever left/or might leave in the bath and determine if older siblings (how old were siblings?) were or were not present/would be present at the time
- Determine how comfortable parents are leaving their children in the bathtub. Why/why not comfortable?
- Determine what factors impact parent's decision as to whether or not they can leave a child in the tub --(age, presence of sibling, previous successful experience leaving child alone in tub, use of a restraining device, etc.)
- Estimate how long parents have been away from a child/or would consider being away from a child who is in the bath
- Determine where the bather went/might go in relation to the location of the bath the child is in (e.g., determine if parent could or could not/would be able to hear or see the child in the bath)
- Determine what, if anything, parents did/might do to restrain the child (e.g., used a bath ring/seat, used a harness of some kind, asked an older sibling to support the younger child or other)
- Determine how parent found/might expect to find their child upon their return in terms of position in the tub, position in restraint, mood, etc. and whether or not they were surprised by what they found

Obtain Reactions to Labeling and Packaging of Baby Bath Rings/Seats

- Determine awareness and recall of product safety information on your box and ring/seat itself
- Identify where parents remember seeing the information (e.g., on the box, on the ring/seat, in the instructions for assembly/use, other)
- Determine what should be done to alert parents about use of and potential hazards related to baby bath rings/seats (e.g., improve/change wording of warning, use a warning symbol/graphic, product redesign, take product off the market, other--client to specify)

Obtain Reactions to Bath Rings/Seats

(Show respondents bath rings/seats without packaging)

- Most likely to purchase and why
- Least likely to purchase and why
- Which one do you think would be safest?
- Determine if respondents have ever seen any of the models displayed and which one, if any, they have used/currently use
- Identify how, if at all, their bath ring/seat differs in terms of size, shape, seat, features, etc.
- Obtain top-of-mind reactions to each ring/seat first by asking what they like and dislike about each one and by identifying which one respondents would be likely to purchase and why (e.g., seems sturdier, prefer the shape of the seat, color, special features--specify, etc.)
- Evaluate each ring/seat on: visual appeal, stability, restraint capability, safety--including a child's ability to climb out, tipping, surface injury, durability, and versatility in terms of range of ages the product could serve
- Determine which ring/seat gives parents more confidence that their child could be supported if they were to turn away or leave the bathroom for a moment to attend to an interruption or emergency

False Close

- Determine what advice respondents would give other parents about use of the rings/seats
- Willingness to participate in follow-up telephone study, pass sign-up sheet (strictly voluntary)

Final Comments



U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D C 20207

August 25, 2000

Ms Rachel Weintraub
Staff Attorney
U. S. Public Interest Research Group
218 D. Street, SE
Washington, DC 20003

Dear Ms. Weintraub:

This is to officially inform you that U S. Public Interest Research Group, at your request, has been joined with the Consumer Federation of America et. al. as petitioner requesting a ban of infant bath seats and bath rings used for bathing infants in bathtubs. This matter has been docketed as a petition under the Federal Hazardous Substances Act with the designation HP 00-4.

You may be aware that in the Federal Register of August 22, 2000, the Commission has solicited comments concerning Petition HP 00-4, with comments due by October 23, 2000.

Following the close of the comment period, staff will be preparing a briefing package on the petition for consideration by the Commission. I will send you a copy of that package when the matter is scheduled for Commission action.

If you have any questions about the petition process, please do not hesitate to call or write to me. My telephone number is (301) 504-0800, X1230, fax number is (301) 504-0127.

Sincerely,

A handwritten signature in black ink that reads "Sadye E. Dunn". The signature is written in a cursive style.

Sadye E. Dunn
Secretary to the Commission

cc: Mary Ellen Fise, General Counsel
Consumer Federation of America

TAB B



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

Date March 30, 2001

TO : Jacqueline Elder, Deputy Assistant Executive Director, EXHR
THROUGH: Warren J Prunella, AED, EC *WJP*
FROM : Mary F. Donaldson, EC *MD*
SUBJECT : Baby Bath Seat Petition, HP-00-4

The Consumer Product Safety Commission is considering a petition from the Consumer Federation of America, The Drowning Prevention Foundation, and others for a ban of baby bath seats and baby bath rings due to the potential for drowning. Baby bath rings are no longer sold in the U.S. retail market. This memo presents an overview of available information about the market for baby bath seats.

The Products

Baby bath seats are marketed as an aid for bathing infants from the time they can sit up, at around 6 months. They are used in full size bath tubs and allow the child to be held in a seated position, thus freeing the caregiver from holding onto the child during bathing. The bath seats contain a seating area and a restraint and are held in place by suction cups located at the bottom of the seat.

Although no longer found on the U.S. market, baby bath rings also are held in place by suction cups, but use the floor of the tub or a mat as the seating surface. Additionally, some infant bath tubs are convertible to infant bath seats. Examples of different designs of baby bath seats are included in the appendix.

Suction cups used on baby bath seats and rings are designed to work with smooth surface bathtubs. Using these products with textured bathtubs is not recommended by the manufacturers. Since 1979, however, there has been a voluntary standard requiring new bathtubs to be slip resistant, which has resulted in textured surfaces on tub bottoms.

Producers and Market Share

Baby bath seats are produced and/or marketed by juvenile product manufacturers and distributors. Currently, two manufacturers of baby bath seats are known to be active in the U.S.

market. They are Safety 1st and The First Years. Safety 1st is the only manufacturer currently producing traditional bath seats. The First Years produces a model that converts from a baby bathtub to a baby bath seat. At the time of the 1994 Commission briefing on baby bath rings, there were about 10 manufacturers of baby bath rings/seats¹. Manufacturers that no longer produce baby bath seats include Fisher Price, Gerry, Century, Pansy Ellen, C Meyer Associates, Ilco, Sanitoy Inc., Sassy, A-Plus, and Shelcore. Some of their products are still in use and may be found for sale on the secondhand market.

Baby bath seats and rings are available in many other countries, including Canada. Although only two firms are currently selling bath seats in the U.S., any foreign manufacturer is a potential supplier to the U S market.

Based on a survey of new and expectant mothers conducted in 1999 for American Baby Group², the leading brand of baby bath seat in use is Safety 1st. In that survey, 46 percent of respondents who specified the brand of bath seat owned indicated Safety 1st. Fisher Price and The First Years followed with 14 percent each. However, it should be noted that 63 percent of bath seat owners did not specify their bath seat brands.

Products in Use

The Juvenile Products Manufacturers Association (JPMA) estimates that there may be up to 2 million baby bath seats in use³. This is not inconsistent with an estimate derived from the *Baby Products Tracking Study, 2000*. With about 4 million annual births in the United States and the tracking study information which indicated that 33 percent of new mothers own baby bath seats or rings, about 1.3 million bath seats are available for use for infants under the age of one. Including bath seats used by infants greater than one, the total number of bath seats in use may be about 2 million, as estimated by JPMA.

Retail sales of new baby bath seats may range from 700,000 to 1,000,000 annually. The American Baby Group survey indicated that 46 percent of baby bath seats or rings owned by new or expectant mothers were obtained from an older child or borrowed. This suggests that about 54 percent of the bath seats were acquired new, resulting in annual sales of about 700,000 (.54 x 1.3 million). The JPMA estimate of sales is somewhat higher, about 1 million annually.

Baby bath seats have increased in popularity over the past 12 years. Table 1 shows ownership rates for new mothers for survey years from 1987 to 1999. In 1987, only 22 percent

¹ CPSC EC memo from Anthony C. Homan to Celestine Trainor, subject *Baby Bath Rings – Market Information and Preliminary Regulatory Discussion*, April 25, 1994

² *Baby Products Tracking Study 2000 Nursery Décor and Accessories*, conducted for American Baby Group, Bruno and Ridgeway Research Associates, Inc, #5861

³ "Initial Comments in Opposition by the Juvenile Products Manufacturers Association" in response to Petition HP00-4, October 20, 2000

of new mothers owned them. By 1999, 33 percent of new mothers owned them, which is an increase in the ownership rate of 50 percent.

Table 1: Trends in Baby Bath Ring/Seat Ownership Rates, 1987-1999

Year	Ownership Rate (% of New Mothers)
1987	22
1990	24
1993	31
1996	32
1999	33

Sources: *Baby Products Tracking Study, 1987, 1990, 1993, 1996, 1999*, American Baby Group, *Statistical Abstract of the U.S., 1999*

Prices

Baby bath seats are sold in stores that sell infant products, such as mass merchandisers, discounters, department stores, infant and child specialty retailers, and through catalogs and the Internet. Prices for infant bath seats range from about \$10 to \$16. Seats which convert from an infant bath tub to an infant bath seat sell for about \$20 to \$25.

Trade Associations and Standards

The Juvenile Products Manufacturers Association (JPMA) is the major trade association that represents juvenile product manufacturers and importers. The major manufacturers of infant bath seats are members of this association.

A voluntary standard for infant bath seats and bath rings is provided by *ASTM F1967-99 Standard Consumer Specifications for Infant Bath Seats*, which was published in June 1999⁴. This standard addresses issues such as safe use instructions and stability. According to the JPMA, all infant bath seats currently on the market are in compliance with this standard⁵. The population of infant bath seats still available for use that were made prior to this standard (and not in compliance) is not known.

⁴CPSC ESME memo from M. Kumagai to Celestine Kiss, February 2001, subject: Review of BATH SEAT ASTM STANDARD F1967

⁵“Initial Comments in Opposition by the Juvenile Products Manufacturers Association” in response to Petition HP00-4, October 20, 2000

While the ASTM infant bath seat standard recommends *against* using bath seats in tubs with textured slip resistance, the standard for slip resistant bathtubs has been in place since 1979. About 58 million bathtubs have been installed in homes built since the inception of the bathtub standard, based on data from *the 1999 American Housing Survey*.⁶ It is likely that many of these tubs have textured or slip resistant surfaces.

Costs of Infant Deaths

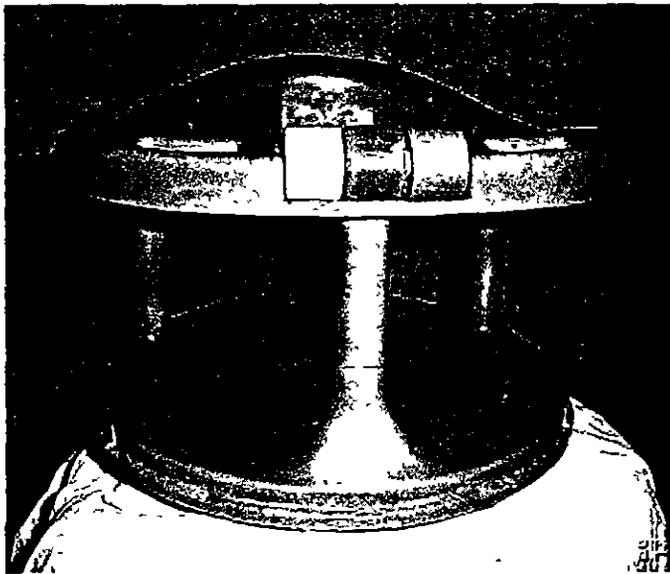
CPSC is aware of 69 deaths to infants associated with baby bath seats between January 1983 and November 2000. However, from 1993 to 1997, the last year that CPSC has complete data on deaths, about 41 deaths or about 8 deaths per year occurred⁷. Using a statistical value of life of 5 million dollars⁸, the societal “cost” of the deaths associated with baby bath seats is around \$40 million annually. This is about \$20 per baby bath seat in use per year, assuming an average of about 2 million baby bath seats in use per year over the 1993 to 1997 time period.

⁶ 1999 American Housing Survey, U S Bureau of the Census

⁷ CPSC HA memo from Debra Sweet to Celestine Kiss, subject Hazard Analysis Memorandum for Bath Seat Petition, February 2001.

⁸ A statistical “value of life” of five million dollars is consistent with current economic literature

Examples of Infant Bath Seats



Example of a Convertible Bath Seat



TAB C



UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Memorandum

December 7, 2000

TO: Celestine Kiss, M.S., Project Manager, Baby Bath Seat Petition, (HP 00-4),
Directorate for Engineering Sciences, Division of Human Factors

Through: Mary Ann Danello, Ph.D., Associate Executive Director for Health Sciences (HS) *med*
Lori E Saltzman, M.S., Division Director, HS *MSA for DE*

FROM: Suad W. Nakamura, Ph.D., Physiologist and Sandra E. Inkster, Ph.D., *SEI*
Pharmacologist, HS

SUBJECT: The Pathophysiology of Drowning.

Background

On July 25, 2000, the Consumer Federation of America (CFA) submitted a petition to ban baby bath seats (also known as infant bath seats or baby bath rings) to the U.S. Consumer Product Safety Commission (CPSC). The petition was subsequently docketed, and a notice soliciting public comments was published in the Federal Register (65 FR, 50968, August 22, 2000). As part of the petition process, Health Sciences (HS) staff has been asked to provide information on the pathophysiology of drowning, particularly regarding factors relevant to the bathtub drowning scenario.

Introduction

The early medical literature contains several inconsistent definitions for drowning injuries that differ in both the terminology and the various time frames used to classify the injuries. More recent attempts to standardize drowning classification have resulted in the following widely accepted definitions. Drowning is defined as submersion in a fluid medium (usually water) that results in the victim's death within 24 hours of the submersion incident. Near-drowning is defined as a submersion incident in which the victim survives for at least 24 hours, irrespective of whether they subsequently survive or die from complications related to the submersion incident (Orlowski, 1987; Fields, 1992; Modell, 1993). Although some experts discourage use of the term "secondary drowning", it is sometimes used to describe near-drowning cases that ultimately result in death from delayed complications related to the submersion incident (Beyda, 1998).

While drowning usually involves complete body submersion, it is not necessary and drowning can occur when just the nose and mouth are covered by water (Byard and Lipsett, 1999). Infants and young children have relatively large heads so their center of gravity is higher than older children and adults. They are also less coordinated and more prone to falling and tipping over. A baby or young child, lacking the muscular strength and developmental skills to right themselves after having fallen, can drown in as little as 2 inches of water (Pearn and Nixon, 1977; Griest and Zumwalt, 1989; Kasian, O'Farrell, Linwood, 1987). Some reports indicate that

less than 1 inch of water can be sufficient to drown a young child (Chisholm, Chapman, and Spares, 1998)

Drowning deaths occur across all age groups, but the underlying causes differ with age, and a clear relationship between victim age and the site of drowning is evident. Drowning is one of the leading causes of preventable death in children under five years of age, and unlike adult deaths, the majority of these deaths occur in freshwater environments. While many drowning and near-drowning incidents involving young children occur in residential swimming pools, the bathtub is the primary drowning site for victims less than one year old. The majority of drownings involving victims under five years of age reportedly occur during brief lapses in adult supervision. In many cases, these lapses are estimated to be less than 5 minutes, however, the reliability of such estimates is uncertain. The medical literature reports that children with a history of seizure disorders (e.g. epilepsy) have a 4 to 10-fold increased risk of drowning, with the risk being greatest in bathtub settings and in children over 5 years of age. This probably reflects the fact that older children are more likely to be unsupervised while bathing than while swimming, thus, immediate help is not available should they collapse into the bathwater during a seizure (Diekema, Quan, Hoyt, et al., 1993). It should be noted that child abuse is implicated in up to 19 percent of pediatric bathtub drownings, particularly if the victim is older than 14 months of age (Fields, 1992, Pearn, 1992, Fiser, 1993). Indeed, Griest and Zumwalt (1989) have opined that deliberate drowning of young children is “no doubt underreported and underdiagnosed because of the lack of physical evidence or criteria on which to base a diagnosis of abuse.”

Pathophysiology of Drowning

The single most important physiological consequence of drowning is cerebral hypoxia, (oxygen deprivation of the brain). While no single sequence of events can describe the development of hypoxia during all drowning and near-drowning incidents, it is convenient to view the human response to unexpected submersion in water as progressive stages (Orlowski, 1987, Fields, 1992, Pearn, 1992, Chisholm et al., 1995)

Immediate Events

The initial stage starts immediately at the time of submersion when the surprised victim aspirates a small volume of water. This mechanical stimulus can trigger a protective reflex response of the airways to close the larynx, i.e., laryngospasm, which prevents both water and air from entering the airways. The panicked victim may also engage in breath-holding to prevent entry of water into the airways. Either or both the laryngospasm and breath-holding behavior serve to initiate the development of hypoxemia (reduced oxygenation of the blood). This stage can vary from about 0 to about 2 minutes.

In the second stage, the temporary cessation of breathing increases the level of hypoxemia and causes acidosis due to carbon dioxide retention. The victim further panics and may then struggle and try to swim, possibly swallowing large amounts of water into the stomach. This increases the risk of regurgitation and aspiration of acidic stomach contents, which can further compromise lung function, and negatively impact the victim's chance of recovery. This stage can last from 1 to 2 minutes.

In the next stage, the level of hypoxemia reaches a critical point where brain function starts to be affected and the victim gasps involuntarily. The drowning event can then proceed along two alternative pathways depending on whether “wet” or “dry” drowning occurs (see below). The duration of this stage is variable, lasting from one to several minutes.

So called “wet-drowning” occurs in 80 to 90% of drowning and near-drowning victims. In wet drowning, hypoxia results in unconsciousness and loss of airway reflexes. Consequently, the laryngospasm relaxes, allowing large amounts of fluid to enter the lungs. There is immediate and drastic mechanical impairment of gaseous exchange and lung function, and respiration ceases shortly thereafter. Initially, although the oxygen concentration of arterial blood starts to drop, the heart is still able to circulate blood to the brain, albeit with a progressively decreasing oxygen content. The increasingly severe tissue hypoxia eventually will cause the heart to fibrillate, then ultimately stop, resulting in a rapidly worsening hypoxic-ischemic assault. Death occurs shortly thereafter in the absence of intervention.

The remaining 10-20% of drowning and near-drowning victims experience “dry drowning”. In dry-drowning, the initial laryngospasm finally relaxes, but the further aspiration of small amounts of water into the lungs stimulates another severe and persistent laryngospasm¹ episode. This maladaptive, exaggerated response of a normal airways protective mechanism is life-threatening and can be likened to anaphylaxis, an exaggerated hypersensitivity immune reaction to a foreign protein seen in sensitized individuals (Kidder, 1995). The mechanical obstruction of the airways by the laryngospasm continues to prevent entry of water or air into the lungs. Without intervention, this scenario can rapidly progress to profound hypoxic-ischemia, associated cardiac arrhythmia, convulsions, and death. This process explains the paradoxical autopsy findings of dry lungs in some drowning victims (Orlowski, 1987, Fields, 1992, Pearn, 1992, Chisholm et al, 1995).

Near Drowning

Delayed Events

The response of victims who are initially rescued from the drowning environment is highly variable and depends on multiple factors. Some victims who are submerged for less than a minute or so might not stop breathing, or may spontaneously restart to breathe, and will recover uneventfully. As the duration of submersion increases, the need for use of resuscitative techniques increases. It is not uncommon for victims to be resuscitated at the scene, only to succumb to late-onset complications of the submersion injury several hours to days later. Therefore, any individuals who need to be resuscitated (breathing and possibly heart rhythm reestablished) after being submerged for more than a minute or so are at risk of developing delayed pathological effects. The level and duration of hypoxia is the most important factor influencing outcome of near-drowning victims, and the brain is the tissue most sensitive to oxygen deprivation. Pathological changes can occur in brain cells within minutes of severe hypoxia/anoxia, and while continued oxygen deprivation will rapidly cause lethal brain death, more subtle effects might not be evident immediately if oxygenation of blood is reestablished after a short interval. In the most frustrating cases, after apparent recovery, the effects of

¹ Laryngospasm, the reflex closure of the glottis, can be triggered by mechanical or chemical stimulation of the laryngeal mucosa (Nishino, 2000). Clinically, it is most frequently encountered as a complication of general anesthesia. For unclear reasons, it occurs 2–3 times more frequently in young children than in adults, children with upper respiratory infections or bronchial asthma have the greatest risk of experiencing laryngospasm during general anesthesia (Landsman, 1997).

delayed, neuronal cell death from hypoxia are manifested 2-3 days later. A vicious cycle is activated in which cell death causes cerebral edema (fluid retention), leading to increased intracranial pressure, with subsequent reduction of cerebral blood flow and worsening of the cerebral hypoxia. Further neuronal cell death continues until death, attributed to cerebral edema, ultimately ensues (Swick, 1997, Gabriella and Layon, 1997). After the brain, heart tissue is most vulnerable to oxygen deprivation, and fatal arrhythmias can develop in near-drowning victims. Delayed, multiple end-organ failure (heart, kidneys, circulatory system, etc.) is also a possible consequence of hypoxic-ischemic effects of submersion injuries.

Near-drowning victims who aspirate water also have to contend with additional, delayed respiratory problems that can occur days after submersion and are caused by direct effects of water on lung tissues. Small amounts of fluid in the lungs (1 to 3 ml/kg body weight) can severely alter gaseous exchange in lung tissues. Freshwater is believed to destabilize lung surfactant by altering surface tension properties, leading to alveolar collapse (atelectasis), it also readily enters pulmonary capillaries causing lung congestion. Although saltwater does not directly affect lung surfactant, it draws fluid from the capillaries into the lung space, effectively diluting surfactant and leading to alveolar collapse. Thus, both fresh and saltwater can ultimately cause delayed hypoxemia acting by different mechanisms to disrupt surfactant, collapse lung areas, and cause pulmonary edema with consequent ventilation-perfusion mismatch. Lung damage and leakage of proteinaceous materials from alveoli can worsen progressively, resulting in life-threatening acute respiratory distress syndrome (ARDS) and pneumonia (Fields, 1992, Swick, 1997, Sachdeva, 1999). It should be noted that results of animal studies, describing significantly different effects of fresh and salt water on blood volume and electrolyte balance, are not usually reflected in human drowning victims, and clinical intervention to treat these conditions is rarely required. This is most likely due to the fact that humans rarely aspirate as much as 22 ml/kg body weight of fluid (fresh or salt water). Animal studies indicate that aspiration of this amount is necessary for development of any respective increase/decrease in blood volume or decrease/increase in electrolyte concentration (Sachdeva, 1999, Fields, 1992, Orłowski, 1987).

Treatment of Submerged Individuals and Victim Prognosis

Given that the hypoxic insult is the primary pathophysiological effect of drowning, it is imperative that rescuers rapidly focus on opening of the airways and establishing oxygenation of the victim. Rapid reversal of the hypoxic state is essential to prevent/limit the development of pulmonary and cerebral edema that will ultimately govern the degree of brain damage and the victim's survival. Mouth to mouth resuscitation started immediately upon reaching the victim is the preferred method. Chest cardiac massage should also be initiated if the victim has no pulse. Most experts consider that use of the Heimlich maneuver (application of an external, upward abdominal thrust) to clear water from the upper airways is contraindicated because of the propensity for inducing vomiting and subsequent aspiration of acidic gastric contents, which can seriously compromise the victim's survival (Orłowski, 1987, Fields, 1992).

Generally speaking, the neurological outcomes of children who suffer any kind of brief hypoxic event are good, in fact, brief episodes of brain hypoxia without ischemia rarely result in injury because cerebroprotective mechanisms are triggered. If however, there is prolonged hypoxia that results in cardiac hypoxemia, cardiac output is diminished, and the event becomes a

more serious hypoxic-ischemic challenge with a much less favorable prognosis (Biagas, 1999) Large studies of adult victims of non-traumatic cardiac arrest (ventricular fibrillation) have shown that there is a window of less than 10 minutes for successful intervention after circulation of blood has stopped Furthermore, there is little evidence to suggest that young pediatric victims, in cardiac arrest from submersion, are able to tolerate longer periods of hypoxia than older victims (Quan and Kinder, 1992)

Despite the attempts of numerous researchers, it is still not possible to accurately assess the prognosis of all drowning and near-drowning victims However, the most important prognostic indicator is generally accepted to be the victim's level and duration of oxygen deprivation The critical factors affecting this are (i) the duration of submersion, (ii) how quickly and efficiently resuscitation attempts are initiated, and (iii) the time to the victim's first spontaneous gasp (Pearl, 1992). It is easiest to predict the outcome of those who suffer extremely short or extremely long submersions As would be expected, victims who were submerged for short durations (<5 minutes), and who rapidly begin to breathe spontaneously or respond to resuscitation attempts, have the most favorable prognosis for a full recovery Victims who have aspirated minimal amounts of water due to laryngospasm are least likely to develop delayed respiratory complications from submersion In contrast, victims who were submerged for longer than 10 minutes and/or who fail to respond to resuscitation attempts within 25 minutes rarely have a favorable outcome, with severe neurological impairment or death being most likely (Quan and Kinder, 1992, Fiser, 1993) The reliability of the estimated submersion times in the fatal bathing drownings reported to CPSC is uncertain Nonetheless, HS staff's review of fatal bathing drowning incidents indicates that, in the majority of cases where appropriate intervention might have been successful, the parent or caregiver (like the majority of the general public) did not know how to perform cardiopulmonary resuscitation (CPR) Some caregivers initially panicked, a few made initial untrained attempts at CPR, but most tried to contact emergency services before initiating any CPR attempts Thus, the window of opportunity for successful resuscitation shrank progressively as the level of hypoxemia worsened While in a few cases, trained emergency responders were able to re-establish cardiac rhythm and breathing, the victims died later from cerebral edema associated with delayed neuronal death, and secondary respiratory complications (i.e. lung congestion) were a common autopsy finding.

While almost all drowning victims suffer lethal hypoxia if submerged for longer than 25 minutes, the medical literature contains several reports of young children who have been submerged for longer durations, but yet recover without any apparent deficit. The common factor in these cases is the extremely cold or icy temperature of the water (<5-10°C, 40-50°F) and it should be recognized that these cases are the exception to the rule Although incompletely understood, survival in some victims after such cold water submersions is likely due to a combination of the diving reflex and the rapid induction of hypothermia The diving response, typically seen in marine mammals, serves to conserve oxygen for vital tissues by markedly slowing the heartbeat and by greatly reducing or even stopping blood flow to non-vital organs by means of peripheral vasoconstriction Rapid induction of hypothermia reduces the metabolic need for oxygen The normothermic human brain typically suffers some irreversible brain damage if subjected to acute hypoxia for longer than 10 minutes, but is significantly more resistant to hypoxia if rapidly reduced to about 30°C (86°F) (Gooden, 1992) Although smaller children develop hypothermia most rapidly due to their large surface area and small body mass,

any survival advantages of a cold water setting are not likely to apply to pediatric drowning in bathtubs since bathwater is usually warm or at least tepid (32-38°C, 90-100°F). Indeed, victims of warm water submersion who are not resuscitated at the scene, and who are still undergoing resuscitation attempts in an emergency room setting, have a uniformly poor outcome, i.e., death or severe neurological impairment (Fields, 1992).

Conclusions

The bathtub is the primary setting for drowning deaths in infants under 1 year-old. Brief lapses in adult supervision are involved in the majority of such fatalities. The primary pathophysiological effect of submersion is brain hypoxia (oxygen deprivation), due to mechanical impairment of respiration. This is frequently compounded by ischemia due to cardiac arrest as the hypoxemia worsens. The actions taken by the parents or caregivers during the first few minutes of discovering the submerged infant have a critical impact on the victim's chance of recovery. While an immediate opportunity exists to rescue victims of short duration submersion (~5 minutes) without long term effects being incurred, caregivers rarely use appropriate CPR techniques in a timely manner, apparently due to initial panic and a lack of training. Thus, in the absence of rapid resuscitation, severe brain damage or death is a likely outcome for victims who stop breathing, and fail to spontaneously rebreathe, after brief submersions in warm bathwater, that can be as short as a minute or so. Unlike cold water submersions, where rapid hypothermia can sometimes result in full recovery of young children after prolonged submersions, prolonged warm water submersions have a uniformly poor outcome. Any victim of a warm water submersion who cannot be resuscitated at the scene (i.e., spontaneous breathing and heart rhythm cannot be re-established) will most likely suffer death or severe neurological impairment that will leave them in a vegetative state.

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TAB D



UNITED STATES
 CONSUMER PRODUCT SAFETY COMMISSION
 WASHINGTON, DC 20207

Memorandum

Date: March 27, 2001

TO Celestine Kiss, Project Manager
 Division of Human Factors

THROUGH Sue Ahmed, Associate Executive Director *SA*
 Directorate for Epidemiology
 Russ Roegner, Division Director *RR*
 Division of Hazard Analysis

FROM Debra Sweet, *DS*
 Division of Hazard Analysis

SUBJECT Hazard Analysis Memorandum for Bath Seat Petition

This memorandum provides incident data on baby bath seats and rings. Information was obtained from the following U.S. Consumer Product Safety Commission (CPSC) databases: Injury and Potential Injury Incident file (IPII), In-Depth Investigation file (INDP), Death Certificate file (DTHS) and the National Electronic Injury Surveillance System (NEISS). This data is anecdotal data and should not be used to project national estimates. DTHS is not complete for 1998 through 2000.

I. BATH SEAT DEATHS

CPSC is aware of 69 deaths in the U.S. from January 1983 through November 2000 resulting from infants drowning while seated in a baby bath seat or ring. The previous briefing package cited 13 drownings involving bath seats in the U.S. from January 1983 through October 1993¹.

A. Supervision by Caregiver

Three of the 69 drowning deaths to children from 1983 through November 2000 took place when the victim was under supervision (by the caregiver) in the bathtub. Two caregivers turned away momentarily and looked back to find the victim's face down in the water. In the other incident, the caregiver saw the incident occur but panicked briefly. Attempts by the caregivers to save the children were unsuccessful.

The remaining 66 of 69 drowning deaths occurred while the caregiver left the child unattended in the bathroom. The reported times that the caregiver was out of the room varied from a reported 2 minutes to over one hour. Some reasons for leaving the child unattended were unexpected phone calls or company and retrieving towels or clothing. Some caregivers left the

¹ "Options to Address Risks with Baby Bath Rings" Celestine Tramor, U.S. Consumer Product Safety Commission, Division of Human Factors, May 1994

bathroom to tend to another child in the home. Some caregivers left the victims unattended for more deliberate reasons such as performing household chores, playing video games or watching television. Two of the caregivers were intoxicated when they left the victims unattended.

B. Caregiver

The children who died in bath seat-related drownings were being cared for predominately by parents but also by baby sitters. Fifty-eight of the victims were being cared for by a parent or a parent and another family member simultaneously. The remaining 11 children died while under the supervision of a baby sitter. The caregivers were as young as 11 years old and often caring for multiple children.

C. Water Depth

In many of the bath seat-related deaths, the reports of water depth varied according to the individual and were often given in ranges. Some of the reports of water depth are those of officials who measured the water and other reports are those the caregiver provided as estimates of the water depth. The minimum reported water depth was less than two inches and the maximum reported water depth was 18 inches. The median reported water depth was seven and a half inches. Other reports of water depth were given as fractions of the tub height, but these are not included in the median since bath tub heights vary.

D. Victim Age

The victims involved in the 69 fatal drowning incidents with bath seats ranged in age from 5 months-old to 20 months-old. However, the 20 month old child had numerous health problems and was small for her age, weighing only 18 pounds at the time of the incident. *The age of the victims most frequently involved in these incidents was 7 months (18 children)*

According to the Juvenile Product Manufacturers Association (JPMA), a trade association of manufacturers, importers and distributors of juvenile products, "Bath seats and rings are generally not recommended for use until 6 months of age or when the child can sit upright unassisted. They [bath seats] are usually discontinued in use when a child seeks to escape the confines of the product or can stand up while holding onto other objects."² CPSC's Division of Human Factors has indicated that an infant begins to pull himself up to a standing position around 9 months of age.

Allowing for developmental differences in children, the recommended age of children using bath seats could be 5 months to 10 months-old. Of the 69 reported deaths involving bath seats, 61 of the victims were between 5 months and 10 months-old.

E. Other Children in Bathtub

Of the 69 deaths of children in bath seats, 26 were put into the bathtub with another young child (or children). Eight of the children who were being bathed with the victims were either taken out of the bath by the caregiver or got out of the tub by themselves before the victim was found. *This leaves 18 incidents where another young child was in the bath when the victims*

² Public comment to bath seat petition from Frederick Locker, Counsel to JPMA

drowned. Two deaths are believed to be directly related to the presence of the other children in the bathtub. One caregiver returned to the bathroom to see the 2 year-old sibling holding the victim's head underwater. Another caregiver returned to the bathroom to find a 3 year-old sibling holding the victim. This sibling told officials that she picked the victim up to hold her and put the victim's head underwater to stop the victim's crying. These two incidents involved children who were at an age at which they apparently did not understand their actions.

F. Manufacturer Information

Six different manufacturers' products were involved in 59 of the 69 incidents. The manufacturer information was unknown in the remaining 10 incidents. A-Plus Products, Inc manufactured four of the bath seats involved in the first five fatal incidents that CPSC is aware of. Safety 1st, Inc produced 32 of the 59 manufacturer-known bath seats. Table 1 breaks down bath seat manufacturer and the years of the deaths associated with those products.

**Table 1.
Bath Seat Deaths: Product Manufacturer by Year of Incident**

Manufacturer	1983-1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	Total
A-Plus Products, Inc	4											4
Pansy Ellen	1	1										2
Safety 1 st , Inc		2	4	1	5	5	4	3	2	1	5	32
Fisher-Price			1		2	2	1	1			2	9
Gerry Baby Products				2	1	1	1	3	1			9
The First Years, Inc.							1	1		1		3
Unknown						4	2	1	2		1	10
Total	5	3	5	3	8	12	9	9	5	2	8	69

Source: CPSC incident reports and in-depth investigations

II. BATH SEAT DEATHS, INJURIES AND COMPLAINTS BY SCENARIO

The hazard scenarios associated with bath seat deaths and injuries can be grouped into three areas. 1) those that involved problems with the bath seat design and materials; 2) those in which the bath seat stayed upright and held the child in the seat; and 3) those in which the circumstances of the incident are unknown or uncertain.

The deaths reported in the following sections are the same 69 mentioned previously. In addition to the deaths, there have been 95 reports of non-fatal incidents involving bath seats. The incidents and complaints are those reported to the Commission from 1983 through November

2000³ Not all reports of non-fatal incidents or complaints resulted in injury. The complaints are usually associated with unknown ages and unknown caregiver supervision.

Table 2 is a breakdown of the hazard scenarios seen in the data and the number of deaths and non-fatal incidents associated with the scenarios

Table 2.
Bath Seat Deaths and Non-Fatal Incidents by Hazard Scenario
(1/1983 through 11/2000)

Hazard Scenario	Age Range Of All Victims	Fatalities	Non-Fatal Incidents and Complaints
Tip-Over	5-15 months	22	50
Children Coming Out of the Bath Seat	6-14 months	11	6
Entrapment and Submersion	3-16 months	3	15
Bath Seat Breaking	Unknown	0	7
Children Slumped Over	5-20 months	8	2
Overflowing Bathtub	5-8 months	2	0
Children Found in Water; Bath Seat Position Unknown	5-11 months	16	5
Bath Seat Upright; Child Position Unknown	8 months	2	0
Unknown or Uncertain Circumstances	5-12 months	5	10
Total Incidents	3-20 months	69	95

A. Problems with the Bath Seat Design and Materials

Hazard scenarios associated with the design and materials problems of the bath seat include cases in which 1) the bath seat or bath ring tipped over submerging the occupant in the water or allowing the child to escape the confines of the seat, 2) the occupant was found outside of the bath seat, presumably by coming over the top of the bath seat and the bath seat remained upright; 3) the bath seat remained upright and the occupant slid through the leg opening, becoming trapped and submerged in the water; and 4) the bath seat broke and could have led to

³ In the previous briefing package, six near misses were cited and about 30 reports of incidents without injury. Since it is difficult to differentiate between a near miss and a case with no injury, all non-fatal incidents and complaints are combined in this memorandum

subsequent tip-over, child coming out of the seat or entrapment if the incident was not caught in time

1. Tip-overs

**Table 3.
Tip-over Incidents
(1/1983 - 11/2000)**

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		22	50	72
Supervision	Supervised	2	21	23
	Unsupervised	20	11	31
	Unknown	0	18	18
Median Water Depth		7 inches	Unknown	Unknown
Age Range of Victims		5-12 months	5-15 months	5-15 months
Sibling in Bathtub at Time of Incident		3	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations

a. Fatalities

From 1983 through November 2000, CPSC is aware of 22 drowning deaths that resulted from a bath seat or bath ring that tipped over while the occupant was seated in the product. Of these incidents, two are reported to have occurred while the caregiver was present in the bathroom. One caregiver momentarily turned away from the bath tub, turned back and the bath seat had detached from the bathtub and tipped over. In the other attended incident, the caregiver saw the child reach for a toy and the bath seat tipped. The caregiver panicked and then had difficulty removing the child from the water.

The water depth was numerically reported in 17 of the 22 cases. The median reported water depth was seven inches. The water depth in the remaining five fatal incidents was either unknown or given as a fraction of the bathtub height.

The victims of the tip-over drownings ranged from 5 months-old to 12 months-old. Eight of these children were 7 months old at the time of the fatal incident.

The distribution of the manufacturers for tip-over deaths is similar to the distribution of the manufacturers of the products involved in all of the deaths. It does not appear that one manufacturer's products were involved in significantly more tip-over incidents than any other manufacturer's products.

A sibling was in the bathtub with the victim at the start of the bath in four of the 22 tip-over drowning deaths. In one case, the sibling in the bathtub got out of the tub and the caregiver

followed the sibling leaving the victim unattended in the bath. Thus in three of the 22 fatal tip-over incidents, a sibling was in the bathtub at the time the tip-over occurred. This suggests that tip-over incidents are generally not the result of other children in the bathtub.

b. Non-Fatal Incidents and Complaints

Since 1983, the Commission has reports of 50 incidents of non-fatal bath seat tip-overs and complaints of potential tip-overs. Twenty-one of the incidents occurred when the caregiver was present and bathing the child. Eleven incidents occurred while the child was unattended. The attendance of the caregiver at the time of the 18 remaining incidents is unknown; however, the description of the tip-over contains enough detail to suggest the parent was present in many of these incidents.

The age of the children most frequently involved in the non-fatal bath seat tip-over incidents was 7 months.

Most of the complaints about potential tip-overs were based on incidents in which the suction cups released from the bathtub surface.

c. Fatal and Non-Fatal Incidents and Complaints

Combining non-fatal and fatal bath seat tip-overs from 1983 through November 2000, there have been 72 bath seat tip-overs reported to the Commission. Thirty-one incidents occurred without the presence of a caregiver, resulting in 20 deaths. Twenty-three children were supervised during the incident. Caregiver supervision is unknown in the remaining 18 incidents. This data shows that bath seat tip-overs occur regardless of the caregiver supervision at the time of the incident.

2. Children Coming Out of the Bath Seat

Table 4.
Incidents with Children Coming Out of the Bath Seat
(1/1983 - 11/2000)

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		11	6	17
Supervision	Supervised	0	1	1
	Unsupervised	11	4	15
	Unknown	0	1	1
Median Water Depth		8 inches	Unknown	Unknown
Age Range of Victims		6-14 months	8-10 months	6-14 months
Sibling in Bathtub at Time of Incident		1	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations

a. Fatalities

The 11 deaths that resulted from children coming out of the bath seat from 1983 through November 2000 were unattended by the caregiver. The children were found out of the bath seat floating in the bath water and the bath seat was still in its upright position. Staff believes these incidents occurred when the child flipped or floated over the top of the bath seat and into the open bath water. The scenario suggests the inability of the bath seat to restrain the child in the seat.

The water depth in these 11 drowning deaths was a reported median of eight inches. The children who died after coming out of the bath seat ranged in age from 6 months to 14 months.

The manufacturer distribution of the products involved in these 11 deaths does not reflect the manufacturer distribution for all bath seat-related deaths. Safety 1st's products were involved in 32 of the 69 total deaths (46%) and only one of the 11 deaths (9%) where a child came out of the bath seat. Fisher-Price's products were involved in nine of the 69 total deaths (13%) and four of these 11 deaths (36%). The remaining six deaths in which children came out of the bath seat were somewhat uniformly distributed over three other manufacturers (A-Plus, Gerry Baby Products and the First Years) or an unknown manufacturer.

In three of these 11 deaths, a sibling was in the bathtub at the start of the bath. One of the siblings got out of the bath voluntarily before the incident occurred and in another incident, the caregiver removed another sibling from the bath before the incident occurred. Therefore, only one of the drownings occurred while another child was present at the time of the incident.

b. Non-Fatal Incidents and Complaints

Since 1983, CPSC has received reports of six other children who came out of the bath seat but suffered minor or no injuries. In two of these cases the restraining belt in the bath seat released and the occupants came out of the seat. Of the six children, four were left unattended in the bathtub, one was being tended to by the caregiver, and the supervision is unknown in the last incident. The children were 8 to 10 months-old, approaching, or at the age, where a child can pull himself to a standing position with assistance.

c. Fatal and Non-Fatal Incidents and Complaints

From 1983 to November 2000, a total of 17 children came out of the bath seat. Fifteen of the children were left unattended in the bathtub when the incident occurred, one was being supervised, and the caregiver-attendance of the last is unknown. Eleven of the 15 unsupervised incidents resulted in death.

3. Entrapment and Submersion

**Table 5.
Entrapment and Submersion Incidents
(1/1983 - 11/2000)**

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		3	15	18
Supervision	Supervised	1	8	9
	Unsupervised	2	2	4
	Unknown	0	5	5
Median Water Depth		6 inches	Unknown	Unknown
Age Range of Victims		7-16 months	3-11 months	3-16 months
Sibling in Bathtub at Time of Incident		1	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations

a. Fatalities

Three drowning deaths were caused by simultaneous entrapment and submersion in bath seats from 1983 through November 2000. The leg openings on the bath seats involved in these deaths were large enough for an infant to fit two legs through, but not large enough for passage of the shoulders and head. The three children who died when they became entrapped in the seat

got both legs through an opening and their faces were partially or completely submerged in the bath water. One of the incidents occurred while the caregiver was in the room

The median water depth in these fatal incidents was six inches. This is slightly lower than the average water depth for all of the bath seat-related deaths. The children were 7 months-old, 9 months-old and 16 months-old. The 16 month-old had stood up in the bathtub while in the bath ring, turned around and then slipped, getting stuck in the leg openings of the bath seat. This incident is the only one of the three that occurred under the supervision of a caregiver.

A-Plus Products, Safety 1st and Fisher-Price made the bath seats involved in these entrapment deaths. Another child was in the bathtub in one of the entrapment deaths, but the child was only 9 months-old and not believed to have contributed to the death

b. Non-Fatal Incidents and Complaints

CPSC has reports of 15 additional incidents of entrapment in bath seats since 1983. There was caregiver supervision in eight of these entrapment incidents, no caregiver supervision in two incident and supervision details are unknown in the last five incidents. To free the child from the seat, three of the incidents ended with the caregiver having to cut or break the bath seat and one caregiver called the paramedics because she could not free the child. One of the unattended incidents involved a bath seat that was missing the crotch post, creating a larger space in which the child was stuck. The injured children ranged from 3 months-old to 11 months-old

c. Fatal and Non-Fatal Incidents and Complaints

In total, from 1983 through November 2000, 18 children were involved in entrapment and submersion incidents. Nine incidents occurred under the supervision of an adult, four occurred while there was no supervision and five cases are unknown. Three children died from drowning when entrapped in the leg opening of the bath seat. As illustrated in the data, this type of incident is happening regardless of the presence of a caregiver in the bathroom

4. Bath Seat Breaking During Use

From 1983 through November 2000, seven complaints were reported to CPSC in which the bath seat broke, but did not result in a tip-over, submersion or child coming out of the product. These complaints included legs breaking or detaching, the rings around the child breaking, mats ripping away from the legs/suction cups and the bath seat cracking

It is unknown whether the caregiver was present in all but one of the incidents, which the caregiver was present. Staff *assumes* the caregiver was present during these incidents since nothing further happened to the child or the bath seat (i.e. seat did not tip-over after it broke, child did not fall under water after the ring broke, etc.)

B. Bath Seat Remained Upright and Retained Child

Some children died or nearly died when the bath seat stayed upright and retained the child in the seat, but other circumstances affected the outcome of the incident.

1. "Slumped Over" Children

Table 6.
Incidents with "Slumped Over" Children
(1/1983 - 11/2000)

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		8	2	10
Supervision	Supervised	0	1	1
	Unsupervised	8	0	8
	Unknown	0	1	1
Median Water Depth		Unknown	Unknown	Unknown
Age Range of Victims		5-20 months	6-7 months	5-20 months
Sibling in Bathtub at Time of Incident		3	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations

a. Fatalities

In the period from 1983 to November 2000, eight children were found "slumped over" in the bath seat, unresponsive. All of these children were left unattended in the bathtub when the incident occurred. The children were found still sitting in the bath seat, with the bath seat upright in the bathtub. In five of the incidents, the caregiver returned to the bathroom to find the occupant slumped over in the bath seat with his/her face in the water. In one incident, the child's head was tilted back, and in one incident the head position was not stated; however, the official cause of death in both of these cases was drowning. The final death appeared to be a direct result of a sibling in the bathtub. The mother returned to the bathroom to find the sibling, who was bathing with the victim, holding the victim's head underwater.

The water depth in some of these cases is an important factor; however, the median water depth is not a good descriptor in these incidents due to the lack of reported water depth. If the depth of the water in the bathtub were extremely low (one or two inches), then the child's head may not be able to fall into the water if he slumps over in the chair. A deeper level of water in the bathtub brings the water closer to the child's face and if he then slumps over, he can easily put his head (mouth and nose) in the water. Of these 8 fatalities, the water depth in three cases was not stated. The water was described as filling the bathtub 3/4 full in a fourth case and 5/6 full in a fifth case. If a bathtub is a minimum of 14 inches deep (minimum observed in internet search), these two bathtubs would be filled to above the top of the bath seat (measuring approximately 9 inches in height). A child could easily drop his head into the water with a water level this high. The sixth incident had a reported water depth of seven inches, slightly below the top of the bath ring. This water depth also allows for a child's head to fall in the water. The last

two incidents involved reported water depths of two inches and four and a half inches. These are the same two incidents in which the children were found with their heads either leaning back or in an unknown position. The scenarios leading to these two deaths are unknown, but as previously mentioned, the autopsies on both children pronounced drowning as the cause of death. The data suggests that the deeper water levels allowed for the children to fall face into the water and thus drown.

The children who were found slumped over in the bath seats were between 5 and 11 months-old, except for one child who was 20 months-old, but weighed only 18 pounds.

The manufacturers of the products involved in these incidents were distributed similarly in these eight incidents as the distribution of the manufacturers of the products involved in all the deaths.

A sibling was in the bathtub at the beginning of the bath in five of the death incidents. One sibling, as previously stated, appeared to have caused the death. Two other siblings got out of the bathtub before the incident occurred. In the two remaining incidents with siblings, the sibling was still in the bathtub when the caregiver found the child slumped over in the bath seat.

b. Non-Fatal Incidents and Complaints

Two children who slumped over in the bath seat nearly drowned. One incident was attended by the caregiver while the caregiver-supervision in the other incident is unknown, but detail about the incident suggests that the caregiver was present. The 6 and 7 month-old children both slumped over and their faces landed in cavities in the bath seat. These cavities are shallow indentations on the top of the front support bar of the bath seat. At the time of the incidents, these cavities held water.

c. Fatal and Non-Fatal Incidents and Complaints

From 1983 through November 2000, 10 children were involved in incidents where they slumped over in the bath seat while the seat remained upright in the bathtub. The eight unattended incidents resulted in death. The remaining two incidents were near drownings in which the child suffered no permanent injuries.

2. Overflowing Bathtubs

Table 7.
Incidents in Overflowing Bathtubs
(1/1983 - 11/2000)

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		2	0	2
Supervision	Supervised	0	N/A	0
	Unsupervised	2	N/A	2
	Unknown	0	N/A	0
Median Water Depth		N/A	N/A	N/A
Age Range of Victims		5-8 months	N/A	5-8 months
Sibling in Bathtub at Time of Incident		0	N/A	0

Source: CPSC incident reports and in-depth investigations

a. Fatalities

Two children died after being placed in a bath seat and the water overflowed the bathtub or laundry tub. Both children were left unattended.

In one incident the caregiver left the 5 month-old child alone in a bath seat in a laundry tub. The caregiver stated that she turned the water off and suggested that the victim turned the water on. The child drowned in the laundry tub that overflowed with scalding hot water.

The other incident occurred when an intoxicated caregiver left the 8 month-old victim in the bathtub and passed out.

The products involved in these incidents were made by Safety 1st and Gerry Baby Products. There were no other children involved in these incidents.

b. Non-Fatal Incidents

There have been no reports to the Commission of children seated in bath seats in bathtubs that overflowed with water.

c. Deaths and Injuries with Some Unknown Circumstances

A total of 23 children died in situations where certain details of the situation are unknown. Therefore, the incidents cannot be categorized into a specific scenario.

1. Children Were Found in the Water and the Bath Seat Position was Unknown

Table 8.
Incidents in which Children were Found in the Water and
the Bath Seat Position was Unknown
(1/1983 - 11/2000)

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		16	5	21
Supervision	Supervised	0	0	0
	Unsupervised	16	5	21
	Unknown	0	0	0
Median Water Depth		7 inches	Unknown	Unknown
Age Range of Victims		5-11 months	6-11 months	5-11 months
Sibling in Bathtub at Time of Incident		6	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations

a. Fatalities

In 16 deaths from 1983 to November 2000, the child was reported to have been in the water but the position of the bath seat and the relationship of the bath seat and the child were unknown. It cannot be determined how the incidents occurred and specifically how much of the child or what part of the child was in the water. All of the children were left unattended in the bathtub at the time of the incident.

The median water depth in these deaths was seven inches. The children ranged in age from 5 months to 11 months-old.

In eight of the 16 incidents, a sibling was in the bath tub at the start of the bath. The sibling got out of the tub in two of these, leaving siblings present in the bathtubs when the deaths occurred in six incidents.

b. Non-Fatal Incidents and Complaints

From 1983 through November 2000, five children were found in the bath water after being left unattended in a bath seat in the bath tub. The position of the bath seat was not mentioned in the report and thus the scenario of the incident is unknown.

One of the children involved in the non-fatal incidents was 6 months old, three children were 10 months-old and one child was 11 months-old.

c. Fatal and Non-Fatal Incidents and Complaints

Combining the fatal and non-fatal incidents since 1983 where children were stated as found in the water and the seat position was not stated produces 21 incidents. All of the children were left unattended in these incidents and 16 resulted in deaths.

2. The Bath Seat was Upright and the Position of the Child was Unknown

Table 9.
Incident in which the Bath Seat was Upright and
the Position of the Child was Unknown
(1/1983 - 11/2000)

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		2	0	2
Supervision	Supervised	0	N/A	0
	Unsupervised	2	N/A	2
	Unknown	0	N/A	0
Median Water Depth		7 inches	N/A	7 inches
Age Range of Victims		8 months	N/A	8 months
Sibling in Bathtub at Time of Incident		1	N/A	1

Source: CPSC incident reports and in-depth investigations

a. Fatalities

Since 1983, two children were found in the bathtub after being left unattended. The position of the child was not stated in the investigations, but the seat was said to have been upright. The relation of the bath seat and the child is unknown and a scenario cannot be presumed for these incidents.

The reports of water depth varied in one incident from four inches to 10 inches and was reported as seven inches in the second incident. The children were both 8 months-old at the time of the incident. Pansy Ellen and Safety 1st produced the two bath seats involved in these deaths.

b. Non-Fatal Incidents and Complaints

CPSC has not received reports of non-fatal incidents in which the bath seat was found upright in the bathtub and the position of the child was unknown.

3. Unknown or Uncertain Situations

Table 10.
Incidents with Unknown or Uncertain Situations
(1/1983 - 11/2000)

		Fatalities	Non-Fatal Incidents and Complaints	Fatal and Non-Fatal Incidents and Complaints
Total Incidents		5	10	15
Supervision	Supervised	0	0	0
	Unsupervised	5	5	10
	Unknown	0	5	5
Median Water Depth		6 inches	Unknown	Unknown
Age Range of Victims		5-10 months	6-12 months	5-12 months
Sibling in Bathtub at Time of Incident		3	Unknown	Unknown

Source: CPSC incident reports and in-depth investigations

a. Fatalities

From 1983 through November 2000, five children died in bath seat related drownings, but information about the incidents is unknown or uncertain. All the deaths occurred when the children were left in the bathtub unattended. One of the incidents was reported to CPSC by police in October and an investigation is pending, therefore, the product information, water depth and hazard scenario are unknown. Once this information is obtained, the incident may be added to a different hazard category. Another of these five deaths where the specific scenario is unknown is believed to have been directly caused by a sibling in the bathtub. The two young children in the bathtub with the victim stated that they picked the victim up and put the victim's head underwater to stop her crying.

The median water depth of the five unknown deaths was six inches. The children ranged in age from 5 months to 10 months-old. Three of the products involved in these deaths were made by Safety 1st. The product information is unknown on the two remaining incidents.

In four of the deaths with unknown or uncertain circumstances, another sibling was in the bathtub with the victim at the start of the bath. The siblings were in the tub at the time of the deaths in three of the four incidents. As previously mentioned, in one incident with siblings, the sibling is believed to be the direct cause of the death.

b. Non-Fatal Incidents and Complaints

From 1983 through November 2000, the Commission is aware of an additional 10 incidents where children had near drowning experiences but the information about the incidents remains unknown. Five of the incidents were unattended and in the remaining five incidents, supervision is not known. The ages ranged from 6 months to 12 months-old. Any other information about the incident is unknown.

c. Fatal and Non-Fatal Incidents and Complaints

Both non-fatal and fatal incidents since 1983 with bath seats in unknown or uncertain circumstances total 15. Ten of the cases were known to have been while the victim was left unattended in the bathroom. Five children died in these situations.

III. BATHTUB DEATHS IN 1996 AND 1997

To address comments about the relative risk of children drowning in bathtubs with a bath seat and without a bath seat, staff compared bath seat-related deaths to bathtub-related deaths. The most recent years in which CPSC has complete data on deaths are 1996 and 1997.⁴ The National Center for Health Statistics (NCHS) collects information on all deaths in the U.S. each year. NCHS categorizes all accidental deaths by external cause of death codes, e-code 910.4 is for deaths in bathtubs. CPSC collects death certificates for those deaths associated with consumer products. Since the target population of bath seat users is under one year of age, staff compared NCHS data to CPSC data for bathtub deaths versus bath seat-related deaths for 1996 and 1997, for children under one year of age. This was done to see how complete CPSC's data is for 1996 and 1997. If the number of deaths in CPSC data was equal, or similar, to NCHS data then the CPSC database is complete.

NCHS data revealed 38 deaths in 1996 and 38 deaths in 1997 of children under one year of age in bathtubs, with or without additional products in the bathtub. CPSC has reports of 40 deaths to children under one year-old in bathtubs in 1996 (one of these 40 deaths has a different e-code but was reported as a drowning in a bathtub). The Commission has reports of 38 deaths to children under one year-old in bathtubs in 1997 (2 deaths had different e-codes but were reported as drownings in bathtubs). Staff believes that CPSC data contains most of the U.S. deaths in bathtubs in 1996 and 1997 to children under 1 year-old, approximately the same number of deaths counted in NCHS data. Of the 78 reports to CPSC in 1996 and 1997, 73 were investigated by the Commission to determine if a bath seat was present. Therefore, staff is confident in saying how many of the bathtub deaths in 1996 and 1997 involved the use of a bath seat.

For comparison of bathtub deaths to bath seat-related deaths, staff narrowed the focus only to bathtub deaths by drowning in which the victim was placed in the bathtub by the caregiver for the purpose of taking a bath. This eliminated incidents where the victim climbed or fell into a bathtub, another sibling placed the child in the bathtub and scalding incidents. Bathtub drownings in which the child was in a bath seat, bathinette or infant carrier were also excluded from the bathtub drowning deaths to isolate incidents in which the child drowned in the bathtub.

⁴ CPSC collects death certificates for consumer product-related deaths. The Commission also gets reports of deaths through medical examiners' and coroners' reports, media reports and direct reports to CPSC staff about deaths.

with no product association. This reduced the total of 78 incidents of deaths in bathtubs reported to CPSC to children under one year old in 1996 and 1997 to 36

As previously stated, bath seats are intended for users that can sit up unassisted but cannot yet pull themselves up with assistance, or 5 to 10 month-old children allowing for differences in the development of children. In 1996 and 1997, CPSC is aware of 16 children between ages 5 months and 10 months who died in bath seat-related deaths and 28 children ages 5 months to 10 months who died in bathtub drownings in 1996 and 1997. There is limited data available on the number of bath seats in use in the U.S. One study, however, estimates the percentage of new mothers that own bath seats. This study, the Baby Products Tracking Study⁵ is conducted every three years. Based on information from the study, approximately 32% and 32.3% of new mothers owned baby bath seats in 1996 and 1997, respectively. Therefore, correlating the bath seat ownership rates with NCHS data of live births, approximately 2,500,000 bath seats were available for use for children under one year of age in 1996 and 1997 combined.⁶

Staff is assuming that owners of bath seats used them during baths and non-owners bathed their children in the bathtub without any bath aids. Because the number of bath seat users is not available by age of child, the staff is also assuming that the number of children and users are uniformly distributed from age 1 day to 1 year. These assumptions are used to calculate a relative risk of death for bath seat use versus bathtub use for 5 to 10 month-old children in 1996 and 1997 (Table 11). The data suggest that children 5 to 7 months-old are more at risk of death when bathed in a bath seat as opposed to being bathed in the bathtub without other bathing aids. The risks of death in bath seats and bathtubs are more similar for children 8 to 10 months-old. Staff believes that there are fewer older children in bath seats (i.e. there is less reliance on bath seats as the child ages and grows), however, without knowing the true age distribution of users, the analysis of death rates was based on a uniform allocation. If in fact there are fewer older children in bath seats (ages 8 to 10 months), then the difference in risk of death in bath seats and bathtubs would decrease (the number of bath seat deaths/user would increase and the number of bathtub deaths/user would remain the same).

**Table 11:
Relative Risk of Death for Bath Seats Versus Bath Tubs -
5-10 month-old children 1996 and 1997**

Age of Child	# Deaths/Bath Seat Users	#Deaths/Bathtub Users
5 months-old	4.8/500,000	0.0/500,000
6 months-old	7.2/500,000	3.4/500,000
7 months-old	7.2/500,000	3.4/500,000
8 months-old	7.2/500,000	8.0/500,000
9 months-old	7.2/500,000	8.0/500,000
10 months-old	4.8/500,000	9.1/500,000

Source: CPSC databases (DTHS, IPIL, INDP), Baby Products Tracking Study and NCHS data

⁵ The Baby Products Tracking Study was conducted by the American Baby Group by Bruno & Ridgeway

⁶ This estimated number of bath seats available is based on the 1996 (study year) data on bath seat ownership rates and an estimate of the 1997 (non-study year) ownership rates in relation to the actual number of U.S. live births in these two years. The Directorate for Economic Analysis cites 1,300,000 bath seats available in 1999 for children under 1 year-old. This economic estimate is based on 1999 data on bath seat ownership and an approximation of the number of U.S. live births in 1999.

IV. RESPONSE TO PETITION TO BAN BABY BATH SEATS

A. Injury Data

The petition states, "Each year at least eight babies die as a result of a drowning associated with bath seat use... Drownings typically occur when the infant tips over, climbs out of, or slides through the product... Two deaths were reported where the caregiver witnessed the [tip-over] but was unable to free the child from the seat." CPSC is aware of 69 deaths from January 1983 through November 2000. Due to incomplete reporting of drownings involving bath seats, an average of the 69 deaths over almost 18 years (approximately 4 deaths per year) is an inadequate statistic. The petitioners have correctly cited the three hazard scenarios that comprise the majority of incidents in which the details of the incidents are known. Of the 69 drowning deaths, two incidents of bath seat tip-over occurred under the supervision of the caregiver. The caregiver was unable to remove the child.

The petition further cites 66 deaths, 52 of which were reported since the previous briefing package, and 37 reports of near drowning identified by the Commission. The petitioners also state that five bath seat-related deaths were reported in the first six months of 2000. As previously stated, staff is aware of 69 deaths involving bath seats from 1983 to November 2000 and 95 incidents of potential drowning involving bath seats. This memorandum summarizes 56 drowning deaths that were not noted in the original briefing package. From January to November 2000, CPSC is aware of eight deaths involving bath seats.⁷ The large number of incidents reported to CPSC from 1995 through 2000 are not necessarily due to an increase in frequency of the events. After the Commission's actions in 1994, staff increased data collection efforts by investigating all bathtub drowning deaths. Media attention increased public awareness of the hazard and number of deaths, thus increasing the reporting of the incidents. The reports of deaths and injuries involving bath seats are anecdotal data and should not be used to suggest trends in deaths and injuries.

B. Research Reported at the National Congress on Childhood Emergencies Meeting

On March 27, 2000, Dr. N. Clay Mann reported findings of a research project, "Infant Seat Bathtub Drowning: Who's to Blame?" Dr. Mann compared infant drowning deaths in bathtubs with infant drowning deaths in bath seats in bathtubs. The petition refers to two main conclusions from the paper: 1) water depth - the water at the time of the fatal incident is significantly deeper in incidents involving baby bath seats, and 2) decision to leave an infant alone in the bathroom - caregivers are more likely to leave a child unattended in the bathtub for conscious, willful decisions if there is a bath seat present in the bathtub.

Dr. Mann received data from select NCHS and CPSC databases. Based on the focus of the analysis, cases were eliminated from the original data set in which 1) the victim was over 12 months of age, 2) the victim was in the bathtub with another sibling at the time of the incident, 3) complicating factors were involved, and 4) limited data was available. The final data set included 64 incidents: 32 drowning deaths in bathtubs and 32 drowning deaths in bathtubs with bath seats. For the analysis cited in the petition, Dr. Mann included incidents that involved other bathing aids, such as bathinettes and flotation devices. Mann did a separate analysis on bath seats only, excluding bathinettes and flotation devices, however, this *separated* bath seat analysis was not

⁷ Reporting is not complete for January through November 2000.

cited in the petition. Some of the "bathtub death" incidents included in Dr. Mann's study were not conclusive enough to be included in the analysis

The following CPSC analysis is based on the 24 cases in which bath seats were involved (not bathinettes or flotation devices) and the 30 bathtub deaths with conclusive information. Despite the difference in the number of cases included in the analyses, Dr. Mann's conclusions and staff conclusions regarding water depth and reasons for leaving the child unattended are not dramatically different.

Staff analysis shows the median water depth in bathtub drowning deaths was 6 inches based on 18 incidents, including four overflowing bathtubs (12 incidents had unknown water depths). The median water depth for incidents involving bath seats was 7 inches based on 19 incidents including one overflowing bathtub (five incidents had water depths unknown). The reported water depth is slightly higher for those deaths where children were in bath seats. This is the same conclusion reached by Dr. Mann, who reported median water depths of 4.5 inches in bathtub incidents and 7 inches in bath seat incidents.

Mann's research classifies reasons for leaving the child unattended in the bathtub as willful decisions and impulsive decisions. Willful decisions were defined as watching television, performing household chores, and getting clothing for the victim. Impulsive decisions were defined as answering the telephone, responding to the doorbell, responding to another distressed child and tending to cooking food. Staff agrees with the classification of these reasons except that tending to cooking food appears to be a willful decision as opposed to an impulsive decision as defined by the research paper. Tables 12 and 13 show Mann's results as to reasons for leaving the child unattended and staff's conclusions, respectively.

**Table 12:
"Infant Seat Bathtub Drowning: Who's to Blame?"
Reported Reason for Leaving Child Unattended**

Variable	Bath Seat Used	No Bath Seat Used
Willful Decision	75%	45%
Impulsive Decision	25%	55%

Source: N. Clay Mann Ph.D., M.S., "Infant Seat Bathtub Drowning: Who's to Blame?" Data obtained from CPSC databases and NCHS databases.

**Table 13:
CPSC Staff Analysis
Reported Reason for Leaving Child Unattended**

Variable	Bath Seat Used	No Bath Seat Used
Willful Decision	67%	40%
Impulsive Decision	17%	20%
Impulsive Decision followed by Willful Action*	8%	7%
Unknown Reason	8%	33%

Source: Data used in "Infant Seat Bathtub Drowning: Who's to Blame?" Inappropriate incidents removed before analysis

* Impulsive decision followed by willful decision would be where the caregiver leaves the bathroom initially by an impulsive decision, then continues with tasks that are willful decisions to do. An example would be, the phone rings and after the caregiver gets off the phone, she then decides to sit down and watch television.

The two sets of percentages are not extremely different from one another. The main difference is that Dr. Mann's research does not seem to account for the unknown reasons, which constitute a large number of the bathtub drownings.

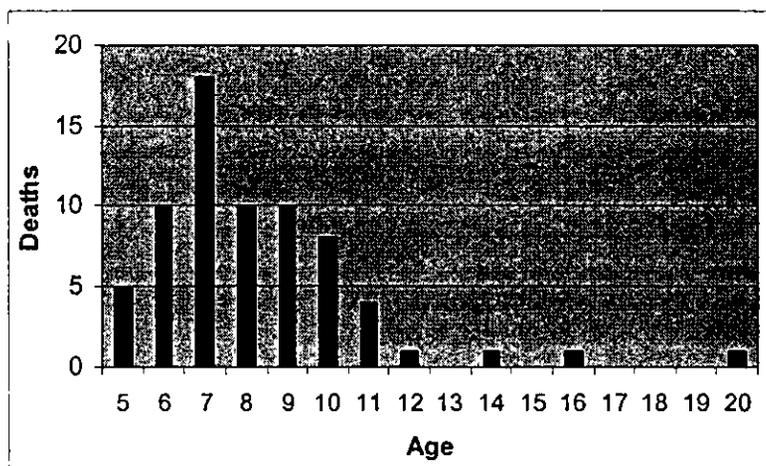
V. RESPONSE TO PUBLIC COMMENTS

During the comment period for the petition, 6 individuals stated knowledge of a child who died on June 9, 2000 after an incident with a bath seat and near drowning. CPSC is aware of this incident and it is included in the count of 69 incidents since 1983.

A. Comment #40: Letter from Margie Cowan

The Commenter states that most children who die in bath seat-related incidents are under 7 months of age. CPSC data show that the most frequent age of children who die in bath seat-related incidents is 7 months-old. Sixty-one of the 69 reported deaths since 1983 were to children between 5 and 10 months old. Figure 1 shows the distribution of the 69 reported deaths according to the age of the victim.

**Figure 1:
Bath Seat Deaths by Age of Victim**



The commenter also states that the number of children who died in bath seat-related incidents is 74 as of October 2000. This count is from the ASTM Bath Seat Subcommittee chairman and not CPSC. The ASTM subcommittee's list includes incidents which occurred in Canada, duplicate incidents, incidents that involved bathing aids instead of bath seats. There were also incidents that CPSC has listed and the ASTM subcommittee did not list. CPSC's official count from 1983 to November 2000 remains at 69.

B. Comment #59: Letter from Florida University Students

The commenter quotes 9 total drownings from tip-overs and 8 drownings per year from the bath seat slipping. CPSC staff believes that 22 drownings are a result of bath seat tip-overs, not 9. Staff did not cite "slipping" as a scenario of the deaths. However, there have not been 8 reported drownings in any but 3 years since 1983. Therefore staff does not agree that 8 drownings per year are a result of the bath seat slipping.

In the submitted comment, drowning is cited as the third leading cause of accidental death in the United States. According to the National Safety Council, for children under age 1 (the target population of bath seat users) unintentional (accidental) injuries were the fourth leading cause of death in 1996. More specifically, drowning is listed as the fourth leading cause of unintentional death.

The commenter also suggests that in tip-over incidents the seat itself has contributed to the drownings by weighting the child down. It is true that in some tip-over incidents the victim is still in the seat when found, both product and child lying in the water. However, other victims were found outside of the seat floating in the water and the seat was tipped over.

C. Comment #61: Letter from Frances Smith

According to the commenter, 50 incidents a year involve small children drowning in bathtubs, nine of which involve bath seats. NCHS data for bathtub deaths to children under 1 year-old has an average of approximately 43 deaths per year from 1991 through 1998. For 1996

year-old has an average of approximately 43 deaths per year from 1991 through 1998. For 1996 and 1997, two years in which most bathtub deaths were investigated by CPSC, nine deaths each year were associated with bath seats.

D. Comment #63: Letter from Frederick B. Locker

The commenter states that an average of four deaths occur per year with bath seats versus 50 deaths per year in bathtubs for children under 1 year-old. Averaging the 69 deaths over a 17 year time period produces an average of approximately four deaths per year from bath seats. However, due to incomplete reporting, especially in the first years of data collection on the subject, this average is not an adequate statistic. The commenter fails to incorporate the number of users into his comparison of bath seat and bathtub deaths. Since more children are bathed in a bathtub than in a bath seat, one would naturally expect the number of children who die in bathtubs to be greater than the number of children who die in bath seats. In addition, the quoted 50 deaths per year include those deaths in bathtubs with other products, including bath seats.

For these reasons, the data for 1996 and 1997 are important because of the completeness of the data. In these two years, 16 children 5-10 months-old drowned in bath seat-related incidents compared to 28 drownings in bathtubs for children 5-10 months-old. Based on the bath seat ownership rates and the number of live births in 1996 and 1997, it appears that younger children are more at risk of death when bathed in a bath seat than in a bathtub (refer to Table 11). For older children, the difference in the risk of death in bath seat versus bathtub is less.

TAB E

**U.S. Consumer Product Safety Commission
LOG OF MEETING**

SUBJECT: Baby bathing aids

DATE OF MEETING: January 18, 2001

LOG ENTRY SOURCE: Dennis Wilson, Special Assistant (Legal) to Commissioner Gall

DATE OF LOG ENTRY: March 1, 2001

LOCATION: CPSC Headquarters, Bethesda, MD

CPSC ATTENDEE(S): Dennis Wilson, Pam Weller, Celestine Kiss, Renae Rauchschalbe

NON-CPSC ATTENDEE(S): Dr. Clay Mann, University of Utah

SUMMARY OF MEETING: In a conference telephone call, the participants discussed some statistical and technical aspects of Dr. Mann's study of the use of baby bath seats and their association with infant tub drownings. The conversation is reflected in the attached e-mails sent before and after the telephone conference call.

Wilson, Dennis B.

From: Wilson, Dennis B
Sent: Thursday, January 18, 2001 10:48 AM
To: Rauchschalbe, Renae, Weller, Pamela L, Kiss, Celestine T., 'Clay Mann@hsc Utah.edu'
Subject: RE: Questions to be discussed at 1:30 conference call

Ladies and Gentlemen

Renae's e-mail accurately states most of the questions. I have some clarifications and an additional question.

1. Are the differences between "median elapsed time unattended" either statistically significant or reliable? I don't think that you consider them either significant or reliable, but I'd like confirmation.
2. Are the differences between "median bath water depth" both statistically significant and reliable? I think that you consider them both significant and reliable, but I'd like confirmation?
3. What was the variance in the case of median bath water depth?
4. What about the materiality of the differences in median bath water depth? In other words, if an infant can drown in 4-5 inches of water, does it matter that a caregiver filled the tub to a level of 7 inches (on average) in the presence of a bath seat?
5. Renae's question number 2 goes to the issue of sensitivity analysis. If you did the same analysis in cases where a sibling was present, do you get results similar to, or dramatically different from, the results that you got in your analysis?
6. Following up on question 5, did you do the analysis and exclude the 5 bath nets and one flotation device that were included in the original study? If so, what were the results?
7. What is the meaning of the "1.13-11.05" under the line of "95% CI" in the reported reason left alone? That seems to be a large spread.
8. Finally, what is your opinion of the reliability of the reported reason left alone, given that it, like the estimate of time, is based on recollection?

I appreciate Dr. Mann's willingness to answer questions and hope that this e-mail helps.

Dennis Wilson

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

From: Rauchschalbe, Renae
Sent: Thursday, January 18, 2001 9:40 AM
To: Wilson, Dennis B, Weller, Pamela L, Kiss, Celestine T., 'Clay Mann@hsc Utah.edu'
Subject: Questions to be discussed at 1:30 conference call

For review and to update Celestine Kiss, here are the questions Dennis Wilson asked after Clay Mann's taped presentation of "Infant Seat Bathtub Drowning: Who's to Blame."

- 1) At some time it sounds as though Dr. Mann dropped the log transformed elapsed time methodology. When and why did he drop it?
- 2) What would happen to the outcome if you added the cases in which a child was in the tub with the victim?
- 3) The figure .05 means it is significant, correct? The lower the number, the more significant, right?
- 4) Isn't this about the smallest sample you can have and still be able to report meaningful statistics? (I said we could pick up another year to increase the sample size.)
- 5) Is the study going to be published?

I think that's it.

Pamela - Do you mind if we use your conference room again? As you know, the time has been changed to 1:30.

SUMMARY OF CONVERSATION WITH DR. CLAY MANN

January 18, 2001

1. Median Elapsed Time Unattended

The differences between those instances in which a seat was present and those instances in which no seat was present were not statistically significant. As far as reliability is concerned, the wide ranges shown are acceptable as long as they are not demonstrating a bias. The distribution of elapsed times are not normally distributed for either sample for the instances in which a seat was present is not a bell-shaped curve; the times instances tend to cluster toward the shorter estimates of time elapsed. Thus, median values and interquartile ranges are reported. In addition, the difference in elapsed time between the two samples was tested with a nonparametric test (the lack of a bell-shaped curve was the reason why the first analysis was done with a log transformed elapsed time)

There was a great deal of "slop" in the data, in the sense that there were often multiple estimates of how long the child was left unattended in the tub in each incident report. In order to control for recall bias in the case of elapsed time, the study used the time report that was closest to the incident. Where multiple times were recorded, the study did an ancillary analysis using the mean time drawn from ~~all~~ all of the reported times. For the study report, ~~the first time report was used as a~~ because it was standard. You do not recall what effect the different analyses using mean or all of the times had on the differences in median elapsed time unattended when a bath seat was present and when it was not, or of the statistical significance of any such differences. However, these additional tests can be made available upon request

2. Median Bath Water Depth

The differences between those instances in which a seat was present and those instances in which no seat was present were statistically significant. The interquartile ~~total~~ ranges are very wide. There were reliability problems with the estimates of water depths since there were lots of empty tubs by the time anyone got around to reconstructing events, and

some reports showed two or more estimates of tub water depth. In order to control for recall bias, a system similar to that used for median elapsed time unattended was used; the first recorded depth of bath water was used.

3. Variance in the Case of Median Bath Water Depth

Since the measure here was median rather than mean, a formal measure of variance was not reported~~ed~~. The pertinent measure is the interquartile ~~range~~. You noted previously that the interquartile range was very wide. You noted further that these measures are very sensitive to sample size.

4. Materiality of Differences in Median Bath Water Depth

Your study did not attempt to assess whether the difference in median bath water depth (7 inches in the cases where a seat was present versus 4.5 inches in the cases where a seat was not present) represented a greater danger to the infant involved. (Drownings occurred in cases of as little as 2.5 inches of water.) You know of no data indicating that a child is more likely ~~to drown in a~~ depth of seven inches of water compared to ~~4.5 inches of water~~. Alternatively, your study assumed that people regarded deeper ~~water~~ bath water as more dangerous and, therefore, that median bath water depth was ~~the~~ a measure of risk-taking behavior.

5. Presence of a Sibling

You did not do any sensitivity analysis to see whether cases involving both bath seats and siblings left alone in a tub yielded results similar to, or different from, the results that you found. This approach was taken since published work (and earlier analyses of these data) indicate that the presence of a slightly older sibling in the tub with the victim is an independent risk factor promoting unsupervised time in the bathtub. In an effort to isolate the effect of bathing aids in parental risk-taking behavior, cases with a sibling present in the tub at the time of death were removed. You emphasized that data involving siblings in tubs is even "dirtier" than data involving infants left alone in tubs because there are more complicating factors. For example, cases document that siblings may inadvertently be implicated in the death of the child by removing the infant from the bath seat while left unattended.

6. Cases Involving Bath Nets and a Flotation Device

An analysis has been performed of the data excluding the five cases involving bath nets and one case involving a flotation device (which had been lumped with conventional bath seats in the first analysis). The results of that analysis have been provided to Renae Rauchschalbe, who will pass them along to the Special Assistants.

7. Confidence Interval for Odds Ratio

The 95% confidence interval for the odds ratio means that can be 95% confident ~~we have confidence~~ that the actual odds ratio for “reported reason left alone” lies somewhere between 1.13 and 11.05. An odds ratio ~~of 1.00~~ of 1.00 would mean ~~be~~ essentially “no effect” ~~as a result~~; people would be just as likely to leave a child unattended for a willful reason in a bath seat as they would in the absence of a bath seat. If the figure was approximately 11, it means that people would be eleven times more likely to leave a child unattended for a willful reason in the presence of a bath seat than in the absence of a bath seat. The “best estimate” odds ratio of 3.54 lies ~~between~~ between these two intervals.

8. Reliability of Reported Reason Left Alone

You emphasized that this data was difficult to work with. You had two research assistants independently read the reports and categorize the reason as either “impulsive” or “willful.” The classification was by category and there was no attempt to numerically rank decisions as “more willful” or “more impulsive.” The research assistants did not know in which a case a bath seat was involved and in which case a bath seat was not involved, but they did know that: (1) a drowning had occurred; and (2) that something had been “blacked out” in cases involving a bath seat (although they did not know that the “blacked out” portion involved a bath seat).

The research assistants agreed on most ~~the~~ categorizations of willful versus impulsive except in the cases, for example, of burning food, which one researcher characterized as willful because the food had been cooking prior to the start of the bath, and which the other characterized as impulsive because the burning occurred after the bath had started. In situations where the research assistants disagreed on a categorization, a third vote was cast (by Dr. Mann) after a consensus discussion with the two assistants ~~for~~

There was no attempt to control for recall bias in this case. The reason stated in the report was accepted as the reason why the person involved left the infant unattended.