



HARVARD SCHOOL OF PUBLIC HEALTH

Department of Health Policy and Management

ban bath seat commission

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Chairman Ann Brown
U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

Re: Comments on Briefing Package Petition No. HP 00-4, Request to Ban Baby Bath Seats

Dear Chairman Brown,

I appreciate the opportunity to offer comments on this petition to the Consumer Product Safety Commission (CPSC) requesting that baby bath seats be banned based on the petitioners' statements that "baby bath seats pose an unreasonable risk of injury and death to children." As noted in the Executive Summary of the briefing document, the petitioners also assert that bath seats induce a "false sense of security," which "leads to increased risk-taking behavior among those using the product even when the irresponsible nature of the caregivers is taken into account."

After reviewing the briefing document and performing my own independent assessment of the risks associated with baby bath seats compared to the risks of drowning without the seats, I find that the analysis in the briefing package does not support the CPSC staff recommendations to grant the petition to ban baby bath seats and as a result I do not support granting the petition. While I could comment on many parts of the Briefing Package, my comments focus on the issues that lead to disagreement between my risk assessment and the one provided in the Briefing Package, particularly the information provided on pages 8 through 10 and the associated Tabs (D and E).

Unfortunately, since I am still waiting for additional information to arrive from a pending Freedom of Information Act request, I have not been able to independently assess the staff's evaluations of the 78 deaths that occurred in 1996 and 1997, or to compile adequate information about risk factors. As a result, I will rely on the information provided in the Briefing Document indicating that the "CPSC is aware of 16 children between ages 5 months and 10 months who died in bath seat-related deaths and 28 children between ages 5 months and 10 months who died in bathtub drownings in 1996 and 1997" when the 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." Thus, based on these numbers, 16 out of 44 of the included bathtub deaths (36%) involved a bath seat and 28 of the 44 (64%) did not involve a bath seat. Backing

the distributions of the deaths for different ages of children for each month from Table 11, I believe that the staff has used the numbers of deaths provided in the following Table:

Deaths Inferred from the Briefing Document Risk Assessment Results

Child's age (months)	Bath Seat	No Bath Seat
5	2	0
6	3	3
7	3	3
8	3	7
9	3	7
10	2	8
Total	16	28

To estimate the risks of drowning, the staff made several assumptions (from p. D17) including that:

- “approximately 32% and 32.3% of new mothers owned bath seats in 1996 and 1997, respectively”
- “that the number of children and [bath seat] users are uniformly distributed from age 1 day to 1 year”
- “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”
- “owners of bath seats used them during baths and non-owners bathed their children in the bathtub without any bath aids”

Based on these assumptions, the staff estimated the risks of drowning for bath seat users and non-users by month of age shown in Table 2 on page 9 (and also in Table 11 on page D17) and concluded 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. At 8 to 10 months old, the risk of death is greater in a bathtub as opposed to a bath seat. Although the staff does not know why the risk of bath seat drowning is less than bathtub drowning at 8 months of age, one possible explanation may be related to the diminished utility of the product as children reach this age.... The staff's risk analysis assumes that the number of bath seats being used is constant for 5 through 10 months of age. If, in fact, fewer bath seats are being used by older children, then the risk of bath seat drowning would be greater than shown.”

While I applaud the staff for conducting this analysis, several important limitations leave me concerned about the inference being made by the staff.

First, the small numbers of deaths that occur during any single year make further disaggregation to the age of months both problematic and misleading. In particular, I believe that it is irresponsible to suggest that the relative risk of a 5-month old infant dying in a bathtub is 0. This is not consistent with other drowning death data from other years where 5-month olds did die in bathtub drowning deaths without bath seats. This disaggregation by month is also inconsistent with the assumption of users consistently using the bath seats over the entire period as noted by

the staff. I believe that the staff's risk analysis should define the relevant age range and compare the overall numbers without speculating about why the risks appear to be higher or lower for younger age children. Thus, I think the staff should be using the numbers of 16 deaths associated with seats and 28 deaths not associated with seats in its analysis of drowning death risks for infants between 5 and 10 months of age.

Second, part of my concern from the previous point arises because I believe that the staff incorrectly interpreted the bath seat ownership data reported in the Baby Products Tracking Study that it used to estimate the relative numbers of bath seat users and non-users. In particular, the analysis in the Briefing Document failed to look at trends in ownership as a function of the age of the infants. The Baby Products Tracking Study asks mothers of new babies (which it refers to as "New Mothers" because they have an infant at home independent of whether the new baby is a first child or not) about their current ownership of baby accessories. While 32% of all "New Mothers" in the 1996 study self-reported owning a bath seat, this population includes a significant number of mothers whose children are too young to use a bath seat at the time of the survey (specifically mothers of children under 5 months old). This means that it includes people who may later own bath seats in the total as non-bath seat owners. Since the staff's analysis focuses on 5 to 10 month old children as the group of bath seat users, in my opinion, the staff should have used the specific ownership data for this cohort. In fact, 41% of New Mother's of children between the ages of 5 and 10 months at the time of the study self-reported current bath seat ownership, and 45% of New Mother's of children between the ages of 6 and 10 months at the time of the study self-reported current bath seat ownership (based on data I obtained from the authors of the Baby Products Tracking Study). Looking at the data reported by month for both the 1996 and 1999 studies, a significant increase in self-reported bath seat ownership from approximately 25% to approximately 40% appears for New Mothers of children aged 5 and 6 months, respectively. This increase may reflect the developmental transition to sitting up many infants make around the age of 5 to 6 months. Looking at the pooled estimates from the 1996 and 1999 studies, which I assume is essentially just increasing the sample size based on the assumption that bath seat usage probably did not change dramatically during that period, the percentages of New Mothers of 5, 6, 7, 8, 9, and 10 month-olds were approximately 26%, 41%, 44%, 44%, 52%, and 44% suggesting that ownership is fairly constant over this age range, or at least that it does not appear to decline significantly if one assumes that owners use the seats. Thus, based on these data, I believe that the staff should be using an estimate of 41% for the percentage of bath seat users for the age range of 5 to 10 month-old children.

Finally, based on these beliefs, in my opinion the null hypothesis to be tested is that bath seats do not increase the risk of bathtub drowning for infants between 5 and 10 months of age, and it appears to me that this hypothesis cannot be rejected with the existing data. Remarkably, the data appear to be more consistent with bath seats providing a protective effect than a hazardous one. Specifically, if we use what I consider to be the best estimates of the numbers discussed above, then the relative risk of drowning deaths for bath seat users is approximately $16/3,177,500 = 5 \times 10^{-6}$ and for non-bath seat users it is approximately $28/4,572,500 = 6 \times 10^{-6}$ with an odds ratio of 0.8 (95% C.I. of 0.4 to 1.5). Thus, based on this analysis, the results suggest that bath seats might have a small protective effect, although a much larger study would be needed. Based on the data presented, I do not believe that this analysis supports the petition's claim that bath seats pose an unreasonable risk and I am concerned that if they actually provide a protective

effect that banning them will lead to an overall increase in drowning death rates. The staff appears to have overlooked the very important trend that during the 1990s overall bathtub drowning risks for children ages 5 to 10 months-old declined significantly at the same time that sales of bath seats increased substantially.

I have been unable to adequately review the data that would be required to assess the hypothesis suggested by the Mann et al. study or to review the study itself since it remains unpublished and only available in the form of a presentation. In my opinion the Mann et al. study is not currently of sufficiently high quality to support the petitioner's claim that bath seats induce a "false sense of security," which "leads to increased risk-taking behavior among those using the product even when the irresponsible nature of the caregivers is taken into account." I believe that further study of these data is needed and that the study should be subjected both to independent peer review and more rigorous analytical methodology. I find the distinctions between "willful decisions" and ones that are presumably "not willful" to be difficult to make, and note that it is not possible to evaluate these because the criteria used in categorization are not provided. I have been unable to reconstruct this database or do an independent assessment to date, but I expect to do so once I receive the information that I have requested under the Freedom of Information Act.

on such preliminary results as the basis for its decision, and I would like to see the staff apply this analysis to the set of data that is has assembled for the 1996 and 1997 drowning deaths since it has investigated nearly all of these. Are these the data that the staff and Dr. Mann are using in their analysis of risk factors in drowning deaths that occurred with and without bath seats? If not, then what are the selection criteria for the data that are being used? Also, since this study mainly compares cases to cases (and for this reason it differs in important structural ways from a case-control epidemiological study or from the type of risk analysis discussed above), the results are subject to interpretation. For example, the observation that deaths that involved bath seats occurred in baths with higher water levels on average is consistent with both the hypothesis that parents use more water in bathtubs when using a bath seat, and with the hypothesis that higher water levels in bathtubs are required for infants to drown when seated in a bath seat because the seat tends to keep them upright. Thus, while the reported results raise the interesting hypotheses, these remain untested.

Finally, in my opinion, focusing on the concept of "willful" decisions obscures the fact that essentially all children between 5 and 10 month-old who accidentally drown in bathtubs are left unattended by parents and caregivers. The reports of parents who have had to take action to avoid drowning when an incident occurred with a bath seat tipping over or a child climbing out shows that children can get into dangerous situations in bathtubs in bath seats, whether they are attended or not, and that the key to a good outcome is the presence of a caregiver who can save them. The same is true if we look at children in bathtubs not in bath seats. I believe that more information is needed to better understand how bath seats change the probabilities of children drowning, but that the overall statistics reported above for the 1996 and 1997 drowning deaths and the fact that overall bathtub drowning death rates for this group of infants has decreased significantly as bath seat use has increased must lead the Commission to recognize that bath seats might actually have a protective effect. In particular, the phenomenon of parents and caregivers having a "false sense of security" about the ability of a young child to get out of a dangerous situation in a bathtub precedes the invention and development of bath seats. I question whether banning bath seats simply leads parents to trade a "false sense of security"

about the protective effect of the bath seat, which might actually turn out to be a real effect once we do a better job analyzing the data, for a "false sense of security" that the infant is strong enough to keep his head out of water.

All of this leads me to raise the question, what does the staff expect to result from banning bath seats? Is there any evidence to suggest that banning bath seats will lead to a positive change in caregiver behavior with respect to infant bathtub drowning risks? We can simply look at the mortality data to see that parents and caregivers do leave children unattended in bathtubs, whether they are in a bath seat or not. While banning bath seats may change the distribution of which children are left unattended and the duration of caregiver absences, we have limited evidence on which to base a determination of the impact of banning bath seats. I find this particularly a problem because the evidence is more suggestive to me of a protective effect of bath seats than a harmful one, and one result of banning bath seats might be a net increase in the number of overall bathtub drowning deaths, a situation that directly conflicts with the mandate of the CPSC. This leads me to wonder why the Commission is not looking at bathtubs as the product that might require action, and why we do not pursue aggressive and on-going educational campaigns about drowning risks.

I appreciate your consideration of these comments, which reflect my personal opinion only and which should not be construed to represent the opinion of Harvard University or any other individuals or organizations. I will be in Washington on Friday May 11 to speak at an unrelated meeting in the afternoon, but I would be happy to speak with you or members of your about my comments that morning if you are interested in meeting. I remain eager to receive the results from my Freedom of Information Act request so that I can independently validate the staff's analysis. I was disappointed to see that the only data set reported in the Briefing Document is that attached to the comments submitted by the Juvenile Products Manufacturers Association, Inc. (see pages J125-J136) and I noted that these data appear to be inconsistent with the data set used by the staff. I believe that the staff must make its data available to the public and that these data should have been published in an Appendix to the Briefing Document, and I will continue to request that it do so under the Freedom of Information Act. Thank you for your consideration.

Sincerely,



Kimberly M. Thompson, Sc.D.
Assistant Professor of Risk Analysis and Decision Science

cc:\ Commissioner Mary Sheila Gall,
Commissioner Thomas Moore,
Sadye Dunn, Office of the Secretary, for placement in the official record related to this petition



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Department of Health Policy and Management

May 7, 2001

Sadye Dunn
Office of the Secretary
U.S. Consumer Product Safety Commission
4330 East-West Highway
Bethesda, MD 20814

Dear Ms. Dunn,

I am sending you copies of my comments on Briefing Package Petition No. HP 00-4, Request to Ban Baby Bath Seats, in an envelope addressed to you that I request that you please include in the official record associated with this petition. I have also included individual copies of the letter that I've written to Chairman Brown for each of the three Commissioners and I am hoping that by sending these to you it will facilitate the Commissioners receiving a copy of these comments. I appreciate you including these in the record and ensuring that Chairman Brown and Commissioners Gall and Moore receive them. Thank you very much.

Sincerely,

Kimberly M. Thompson, Sc.D.
Assistant Professor of Risk Analysis and Decision Science