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

MINUTES OF COMMISSION MEETING
June 15, 1994
4330 East West Highway
Bethesda, Maryland

The June 15, 1994, meeting of the Consumer Product Safety Commission was convened in open session by Chairman Ann Brown. Commissioner Mary Sheila Gall and Commissioner Jacqueline Jones-Smith were present.

Agenda Items

1. Baby Bath Rings and Seats

The Commission considered options for Commission action to address risks of injury and death associated with baby bath rings and seats. The Commission had been briefed by the staff on the options at the Commission Meeting of June 2, 1994 (Ref: staff briefing package dated May 17, 1994). In response to questions raised at the briefing, the staff also provided the Commission supplemental information by memoranda dated June 6, June 7, and June 14, 1994.

Following introductory remarks by the Chairman and Commissioners, Chairman Brown moved that the Commission issue an advance notice of proposed rulemaking (ANPR) to address the risk of infant drowning from baby bath rings and seats. The motion failed by vote of 1-2, with Chairman Brown voting to approve and Commissioners Gall and Jones-Smith voting in opposition.

The Commission then voted 2-1 on motion of Commissioner Gall to direct the staff to work with industry to initiate a public information campaign focusing on the risks taken by parents and other caregivers when they leave children unattended in bathtubs. Commissioner Gall and Commissioner Jones-Smith voted to approve; Chairman Brown voted against the motion.

Separate statements regarding the baby bath rings/seats matter have been filed by Chairman Brown, Commissioner Gall, and Commissioner Jones-Smith, copies of which are attached.

Minutes of Commission Meeting
June 15, 1994

2. Fireworks

The staff briefed the Commission on options for Commission action to address the risk of injury and death from a tip-over-while-functioning hazard associated with multiple tube mine and shell fireworks devices. (Ref: staff briefing package dated May 31, 1994.) The Commissioners asked questions of the staff and discussed the issues raised in the briefing material. No decisions were made at today's meeting.

There being no further business on the agenda, Chairman Brown adjourned the meeting.

For the Commission:

Sadye E. Dunn

Sadye E. Dunn
Secretary

Attachments

U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

STATEMENT OF COMMISSIONER MARY SHEILA GALL
BABY BATH RINGS AND SEATS

JUNE 15, 1994

I have voted today to direct the staff to initiate a public information campaign focusing on the risks taken by parents and other caregivers when they leave children unattended in bathtubs. I have also voted against the staff's recommendation that the Commission initiate formal rulemaking proceedings to develop a standard relating to baby bath rings and seats. Put simply, these products do not present a mechanical hazard under the Federal Hazardous Substances Act (FHSA). The hazard is the caregiver, not the product.

The design or manufacture of these products does not present an unreasonable risk of personal injury or illness to the children who use them. The in-depth investigation (IDI) reports pertaining to the fatalities associated with these products clearly show that, almost without exception, it was the irresponsible actions of those entrusted with caring for these children which caused their deaths. I strongly believe that it is the responsibility of the CPSC to address this issue directly. If we fail to do so, the Commission will have fallen short in its quest to be a positive force to protect and improve the health and safety of the American people.

Section 2(s) of the FHSA states: "An article may be determined to present a mechanical hazard if, in normal use or when subjected to reasonably foreseeable damage or abuse, its design or manufacture presents an unreasonable risk of personal injury or illness...(9) because of any other aspect of the article's design or manufacture." The record before us does not provide a basis for concluding that these products present a mechanical hazard.

In virtually all of the cases investigated, the adult responsible for the care of the child left the victim unsupervised for an extended period of time. This is a far cry from a momentary turning away that was assumed at the start of the Commission briefing two weeks ago and is not normal use as envisioned by the statute. Further, the reports do not indicate that these products were subjected to reasonably foreseeable damage or abuse. In fact, in most of the investigating, the seats were found either affixed to the tub or perfectly functional when tested.

Absent a factual basis for action, the Commission has been asked to adopt a theory of "foreseeable misuse" as a rationale for regulating. This approach suggests that the design or manufacture of these products is hazardous because they are too well made, leading consumers to

believe that it is safe to leave children alone in water-filled bathtubs. By relying on this erroneous impression, consumers misuse this product in a foreseeable manner. The Commission's lawyers suggest that such foreseeable misuse falls within the scope of the statutory standard "normal use" or failing that, "foreseeable abuse."

In support of this theory, the staff has noted that more substantial seats were introduced in the early 1990's and that there have been eight deaths from 1991 through 1993 while there were 5 from 1983 to 1990. Further, the package cites focus group feedback indicating that caregivers who are aware that they should never leave a child unattended in the bathseat or ring do so anyway because they believe that it is safe to do so for a moment. Thus, when a child drowns while alone in the tub, it is the product's design or manufacture which is to blame.

I reject this rationale. First, these products, the directions which come with them, and their packaging are all clearly labelled, warning the consumer that a child may drown if left unattended in the seat or ring. The focus group data demonstrates that consumers are aware of these labels and understand the message that children are never to be left alone in the seat or ring. This indicates that some consumers take this risk knowing that the risk of drowning is real even if small.

Second, the staff has reported that there were approximately 1.4 million of these products in use in 1992. In each of the thirteen deaths reported by the staff, the child who died was unsupervised for an extended period of time or the circumstances surrounding the caregiver's behavior was unclear. Even if one accepts at face value the facts included in the two cases where one adult "froze" and a second left the bathroom "for a moment," the exposure rate to the alleged mechanical hazard is extremely low, particularly when one considers the frequent use of these products by the individual consumer.

Third, when asked to compare the drowning hazard associated with these products with that posed by bathtubs alone for same-aged children, the staff was at a loss to provide information. While I accept that we may not have the data needed to make a comparative judgment, the fact that fifty children under the age of one drown in bathtubs without rings or seats suggests that these products may be saving lives rather than placing them in jeopardy. And if caregivers used these products as intended --and as they know they should-- these deaths might be avoided entirely.

The factual record, including the circumstances reported in the IDI's, does not support the initiation of rulemaking proceedings. I cannot agree with the contention of the staff that informed risktaking by consumers was envisioned by the Congress as a mechanical hazard when this law was enacted. Thus, there is no sufficient legal basis on which the Commission may initiate rulemaking.

If the Federal government is to be accepted as a part of the solution to our national problems, it must first act in a judicious and responsible manner. Initiating rulemaking based on this legal theory and on these facts would send the signal that in order to justify government intervention, we are willing to reinterpret the law to accommodate otherwise inadequate factual records. If a majority of the Commissioners had chosen this approach to governing, our shared commitment to strong and effective government regulation would have been undermined, and the Commission would have added to our Nation's problems rather than addressed them properly.

STATEMENT OF COMMISSIONER JACQUELINE JONES-SMITH
ON A STAFF PROPOSAL TO ISSUE AN ANPR
ON BABY BATH RINGS AND SEATS

June 15, 1994

Today, I voted to reject a staff recommendation to issue an Advance Notice of Proposed Rulemaking (ANPR) for baby bath seats and rings. I also voted to direct the staff to work with industry to initiate an information and education campaign related to bathtub drownings.

It is my determination, based upon the evidence before the Commission, that the alleged drowning hazard associated with these articles neither presents a "mechanical hazard," as defined under the Federal Hazardous Substances Act (FHSA), nor constitutes an "unreasonable risk" of injury due to any "aspect of the article's manufacture or design."

This Commission is constantly alerted to product related hazards that have the potential of causing injuries, illnesses and death. During the course of my tenure on the Commission, I have read hundreds of coroners' reports and in-depth investigatory reports; each of which involved a tragic and senseless death. These can be quite emotional, particularly when they involve the death or permanent injury of a child.

As a Member of this Commission it is my duty, as well as my personal commitment, to be responsive to such incidents and, where appropriate, to adopt corrective -- or even punitive -- measures to try to eliminate or reduce the risks posed by defective products. Yet, precisely because of the power vested in government regulatory agencies, such as the CPSC, our capacity to take such action is controlled and limited by the terms of our authorizing laws. Thus, the particulars of every case before this Commission must be closely scrutinized in accordance with these legal mandates.

In the matter before us today, the FHSA requires that the Commission first determine that the particular product under review presents a "mechanical hazard" that poses an "unreasonable risk" of injury as a consequence of its "normal use or when subjected to reasonably foreseeable damage or abuse," in order to ban or regulate it.

Staff has presented the Commission with evidence that, between 1983 and 1993, baby baths seats and rings have been associated with at least 13 drownings and 7 near drownings. I have read the reports for each of these incidents. Whatever might be my personal reaction to these disturbing events; my responsibility remains to determine whether these incidents were directly caused by some "mechanical hazard" posed by these bath seats and rings, or by some other combination of factors. It is my firm conclusion that these

articles do not present a "mechanical hazard" as defined by the FHSA.

Virtually all of these incidents involved the absence of a parent or caregiver for a period of time. Staff suggests that the very sturdiness of these products may have lulled the caregivers into a false sense of security and that it is, thus, reasonably foreseeable that they might, briefly, leave an infant unattended in the bath tub.

This reliance theory presents a novel and ambitious legal theory as a basis for regulatory action by this Commission under extraordinary circumstances; however, I find it to be neither compelling nor appropriate. Detrimental reliance may well apply in certain instances, such as the one cited in the legislative history, where caregivers were affirmatively mislead into believing that a product had certain characteristics. In that case, the manufacturer of a baby pool seat explicitly advertized that this product was "tip-resistant." Such claims were included on the packaging itself. In this instance, the purchaser's justifiable reliance on the false and deceptive claims of the manufacturer lead to tragedy.

This is totally different from the circumstances surrounding the drownings in the instant case. Here the manufacturers explicitly warn purchasers of the danger -- with labeling clearly impressed on the product itself. It states:

"WARNING: Prevent Drowning. NEVER leave child unattended."

Such labels leave no room for misunderstanding. These drownings were precipitated by the questionable behavior of caretakers who deliberately acted in a manner contrary to these warnings. There can be no justifiable reliance here. To infer legally cognizable reliance based exclusively upon the perceived sturdiness of a product, by a consumer, would be grossly irresponsible and would invite manufacturers to produce articles of an inferior nature. I reject this theory.

Furthermore, the statutory definition of a mechanical hazard simply precludes any regulatory proceedings in this instance. Staff suggests that the fact that caregivers will leave children unattended in these seats and rings is a "reasonably foreseeable" use of the product and, thus, subsumed under this definition. I reject this interpretation.

First, even assuming, for the sake of argument, while such conduct may be foreseeable -- it certainly can not be regarded as reasonable. Secondly, the statutory definition of a mechanical hazard requires that the <u>product itself</u> present an unreasonable risk either "in normal use or when subjected to reasonably foreseeable damage or abuse."

In most of the cited incidents, the articles themselves performed properly and as intended -- they remained upright and in place. It was not the normal use -- or any reasonably foreseeable damage or abuse of the product itself that occasioned these incidents; but, rather the inattentive behavior of the caregiver. Of note is the fact that, annually, approximately 100 children -- about 50 under the age of one -- drown in bathtubs of unknown causation. Thus, on a very practical level, it is difficult for me to envision a regulatory solution that could reasonably and adequately address this problem.

Of critical importance in evaluating this case, is that a broad and encompassing interpretation of the concept of a mechanical hazard was consciously and explicitly rejected by the drafters of this legislation, as detailed in its legislative history. This legislation, as originally introduced in the House of Representatives, covered incidents that might occur "during or as the proximate result of the customary or reasonably foreseeable use of the article." Such a definition would in fact have covered these events, since they occurred "during" its "customary use" and was the "proximate result" of the inattention of the caregiver. However, this definition was consciously rejected in favor of a more limited interpretation, in the adopted version, which requires that the injury be a direct "result of" the "normal use" of the article, or a direct "result of" the "reasonably foreseeable damage or abuse" of the product itself.

It is evident that the drafters purposely removed and, thus, rejected the more open-ended concepts of "reasonably foreseeable use" and "proximate result" from the definition of mechanical hazard. In short, simply by following the plain meaning of the statute, it is indisputable, to me, that these bath seats and rings present no mechanical hazard. I am, therefore, compelled to vote against publishing an ANPR with respect to these products.

An example of a product that presents a mechanical hazard is infant cushions -- which the Commission banned in 1991. These articles were distinguishable from bath seats in that, in normal use, their very design posed an unreasonable risk. The design of these cushions tended to conform to a baby's face, restricting its breathing, and trapping carbon dioxide which the infant would then breath and suffocate. Here it was the inherent design of the product itself that posed an unreasonable risk -- and not the careless actions of parents and caregivers.

This is not to say, however, that this Commission may not conclude that specific models, containing specific defects pose a substantial product hazard under Section 15 of the CPSA. Should such a determination be made, appropriate corrective action certainly will be pursued. This, in fact, was recently undertaken in a case involving the replacement of defective suction cups on a bath seat.

In addition, the fact that some consumers apparently are ignoring the warning labels attached to these products suggests to me that responsible manufacturers ought to be affirmatively engaged in undertaking a rigorous and comprehensive education initiative instructing consumers as to the proper use of these products and the potential drowning hazard associated with leaving a child unattended in a bath tub. I believe that industry has a responsibility to the users of its products to provide such instruction. Thus, I voted to direct staff to work with industry in pursuing a comprehensive information and education campaign.

Bath tubs and unattended babies are a deadly combination. No product, no device, no convenience of any kind can substitute for the physical presence of a parent or caregiver. The incidents associated with bath tub seats that have occurred were all tragic and preventable events. But these were all human tragedies and not product failures. These bath seats and rings contained no manufacturing or design defects that constituted a mechanical hazard. My sense of compassion and sadness can not alter these facts. The law is clear and our responsibility to enforce it must govern our conclusions. That being the case, I rejected this proposal to publish an ANPR.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, D.C. 20207

The Chairman

ADDENDUM TO
STATEMENT OF CHAIRMAN ANN BROWN
BABY BATH SEATS AND RINGS
JUNE 15, 1994

Today I voted against a motion to engage in an information campaign to focus on the risks taken by parents and caregivers when they leave children unattended in bathtubs. While parents should never leave children unattended, I voted against this action because as Chairman, I refuse to go about "business as usual" at this agency. The Commission vote not to start a rulemaking proceeding for baby bath seats means to me that the Commission has failed to do what it should be doing--protecting the public from unreasonable risks of injury associated with consumer products. If we are to be an agency that effectively, actively and aggressively fulfills its responsibility, we must do more than warn parents and caregivers about what they are doing wrong. The days of caveat emptor are over. Instead, when a product presents a hazard we must address the hazard through the most appropriate voluntary or regulatory actions available. Although warnings may be an appropriate part of an overall solution, they are not generally, nor are they in this case, a substitute for appropriate design fixes or bans.

UNITED STATES
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The Chairman

STATEMENT OF CHAIRMAN ANN BROWN
BABY BATH SEATS AND RINGS
JUNE 15, 1994

I am extremely disappointed in today's Commission vote not to proceed with an Advance Notice of Proposed Rulemaking (ANPR) for Baby Bath Seats and Rings. I believe the vote is inconsistent with the Commission's responsibility to protect the public from unreasonable risks of injury associated with consumer products.

As I have stated before, I view an ANPR as an information gathering tool. While information, of course, can be obtained outside the context of an ANPR, publishing an ANPR is appropriate when the Commission has focused on a particular product such as bath rings and seats. It assures proper attention will be given to the issue, both by the staff and the Commission.

My assessment of data related to baby bath rings and seats demonstrates the need to publish an ANPR. I would note several factors which are vital to my conclusion. First, these products are designed for use by very young children - those less than a year old. The Commission's files are replete with evidence that this population is not only susceptible to but defenseless from the risk of drowning, often in water as shallow as three inches. Second, these products are used in water, which can pose a grave risk of drowning to children. Given these facts, products such as these should be the subject of heightened scrutiny by this agency to assure that they provide the highest level of safety for infants placed in such a dangerous scenario.

What then are the results of that scrutiny? Between 1990 and 1993, ten infants between the ages of 6 and 12 months drowned while in a bath seat. Another eight incidents involved near drownings in which parents or caregivers were fortunate to have saved their infants. Many of the products involved in the incidents contained labels warning of the risks of leaving children unattended. However, focus panel research and in-depth investigations conducted by the Commission staff support the conclusion that the construction of these products seduces parents and caregivers into thinking it is safe to leave a child unattended at a younger age than would normally be the case and into disregarding labels, should they even be present. Paradoxically, as the sturdiness of these products has increased over the years, that very sturdiness appears to have contributed to this false sense of security.

The question then is what action, if any, is appropriate to address children's products used in such an inherently dangerous setting. Under the Federal Hazardous Substances Act, the Commission may determine that bath seats/rings present a mechanical hazard and thus are banned articles intended for use by children if, in normal use or when subjected to reasonably foreseeable damage or abuse, their design or manufacture presents an unreasonable risk of personal injury or illness. 15 U.S.C.

1261(s). In my view, this statutory language gives the Commission authority to find that bath seats present a mechanical hazard.[1]

I believe that the hazard patterns demonstrated by the focus panels and in-depth investigations can be construed to be the result of the normal use or foreseeable abuse of baby bath rings, notwithstanding the presence or absence of warnings. Indeed, warning labels on products are designed to warn people of the consequences of "normal use" of those products. Even if one accepts the proposition, and I do not, that the phrase "normal use" excludes reasonably foreseeable misuse, the reference in the legislation to the design of a product, when subjected to reasonably foreseeable abuse, presenting an unreasonable risk of injury is more than legally sufficient to cover the facts of this issue.

This legal issue is not one of first impression. Prior decisions of the Commission and its predecessor, the Food and Drug Administration, confirm that foreseeable patterns of use of a product which otherwise functions safely when used as intended afford a sufficient basis to declare that the product presents a mechanical hazard. Almost twenty-five years ago, the FDA applied such a theory to ban lawn darts intended for use by children. Only two years ago, the Commission dealt with an issue almost identical to the bath ring problem when it banned infant cushions. In that proceeding, the Commission expressly determined that no form of labeling alerting parents to the dangers associated with the cushions would have a significant effect in preventing suffocation deaths associated with these cushions. In other words, the Commission recognized that, when parents or caregivers used the cushions normally (or, under the alternative view, "misused" the cushions in a reasonably foreseeable manner), the cushions constituted a mechanical hazard. I see little difference between that issue and the issue of baby bath rings.

But more importantly, I believe that the prior actions of the Commission constitute longstanding agency interpretations of the legislation it is charged with administering. Such interpretations should not be jettisoned lightly, especially when the risk to very young children is so extreme.

The evidence before the Commission is more than adequate to support issuance of an ANPR. It is simply shortsighted not to proceed.

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[1]The legislative history of the FHSA supports the view that the risk of drowning associated with bath seats and rings constitutes a mechanical hazard. The legislative history identifies a variety of children's products Congress considered to present a mechanical hazard. Congress included on this list a "baby pool seat" that could tip over. See H.R. Rep. No. 389, 91st Cong., 1st Sess. 6 (1969). The pool seat which Congress considered to be a mechanical hazard is no different than a bath seat or ring that can tip over or from which a child can slide out or crawl out.

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The Chairman

Statement by Chairman Ann Brown on Baby Bath Rings and Seats June 2, 1994

We are here today to receive a briefing by the staff on its recommendation that the Commission begin a rulemaking proceeding for baby bath rings and seats. I asked the staff to prepare an options package for the Commission because I am extremely concerned about the drownings that are occurring with baby bath seats. I also am not convinced that the Compliance activity under Section 15 of the Federal Hazardous Substances Act to obtain better warning labels and an information and education program is necessarily the most appropriate approach to the drownings associated with bath seats.

According to the briefing package, since 1983, there have been 13 drownings in the United States involving infants left in these seats. Just this morning, I was given a copy of a newspaper article in the May 10, 1994 edition of "The Herald" in Miami, Florida, reporting on a fourteenth drowning that occurred a few weeks ago. Ten of these deaths occurred between 1990 and 1993. In all but two cases, the infants were left unattended for various periods of time. There are an additional 50 drownings in bathtubs involving children under one year of age. We don't know at this time how many of those drownings involve bath seats.

I am concerned that the new generation of bath seats, seats that are sturdier and more substantial than their flimsier predecessors, seduce parents and caregivers into believing it is safe to leave children unattended at a younger age than would normally be the case. As bath seats have become sturdier and more stable, they may very well be contributing to a false sense of security. This is the paradox. As the bath seats have become sturdier, the drowning deaths appear to be increasing.

Parents and caregivers should never leave young children alone in a bath seat even for a moment. Focus panel research conducted by the Commission shows that parents understand this. Nonetheless, parents do leave children alone, even if only for a few minutes. I wish we could eliminate parental neglect, or could assure that all parents watch their children all of the time. We can't. But what we can do is address unreasonable risks of injury presented by a product. We have a responsibility to assure that consumer products do not present an unreasonable risk of injury during normal use or reasonably foreseeable misuse. This is particularly true when vulnerable populations such as infants are at risk. If a product design can be modified to eliminate a hazard, than we have a responsibility to act by starting a rulemaking proceeding through publication of an ANPR.