

MINUTES OF COMMISSION MEETING August 16, 1990 5401 Westbard Avenue Bethesda, Maryland

The August 16, 1990, meeting of the U.S. Consumer Product Safety Commission was convened in open session by Chairman Jacqueline Jones-Smith. Commissioners Carol G. Dawson and Anne Graham were present.

<u>Ballot Vote Decisions</u>. The following decisions made by ballot vote of the Commissioners were placed in the record:

1. <u>Proposed Civil Penalty Settlement: Ecodyne Corporation,</u>
Water <u>Refining Company, Inc., and Guthrie North America, Inc.,</u>
CPSC <u>Docket No. 90-C0012</u> (Water softener, OS# 3764, Ballot due 7/20/90)

The Commission voted unanimously (3-0) to provisionally accept a Settlement Agreement and Order containing a civil penalty In the Matter of Water Refining Company, Inc., a corporation; Ecodyne Corporation, a corporation; and Guthrie North America, Inc., a corporation. If the Commission does not receive any written request not to accept the Settlement Agreement and Order within 15 days after publication in the Federal Register, the Agreement and Order will be deemed finally accepted on the 16th day. Voting to provisionally accept the Agreement were Chairman Jones-Smith, Commissioner Dawson, and Commissioner Graham.

2. <u>In the Matter of Philip A. Dye and Marilyn J. Dye: Order Scheduling Oral Argument for August 24, 1990</u> (OS# 3409, Ballot due 7/27/90)

The Commission voted unanimously (3-0) to approve an Order In the Matter of Philip A. Dye and Marilyn J. Dye, d/b/a P & M Enterprises, which scheduled an oral argument for August 24, 1990, on Respondents' appeal to the Commission from the decision of the Administrative Law Judge. Voting to approve the Order were Chairman Jones-Smith, Commissioner Dawson, and Commissioner Graham.

Commission Minutes August 16, 1990

3. <u>Sauna Petition</u>, <u>CP 89-1 - Draft Letter of Denial</u> (OS# 3761, Ballot due 7/30/90)

The Commission voted unanimously (3-0) to approve the draft letter of denial for petition CP 89-1. The Commission had previously voted on June 28, 1990, to deny the petition from Edward Press, M.D. requesting the development of a safety standard for saunas. Voting to approve the draft letter were Chairman Jones-Smith, Commissioner Dawson, and Commissioner Graham.

4. <u>General Order for Submission of Information on Methylene</u> Chloride-Containing Products (Ballot due 7/31/90)

The Commission voted unanimously (3-0) to approve for publication in the <u>Federal Register</u> a General Order to obtain information on consumer products containing 1% or more of methylene chloride, also known as dichloromethane (DCM). Voting to approve the General Order were Chairman Jones-Smith, Commissioner Dawson, and Commissioner Graham.

Agenda Matters.

1. <u>Poison Prevention Packaging Act Protocol Revisions</u>

The Commission considered proposed amendments to the current Poison Prevention Packaging Act (PPPA) protocols for testing child-resistant packaging with children and adults. The proposed amendments are designed to result in packages that are easier to use by adults, especially older adults, so as to increase the number of adults who will purchase and properly use child-resistant packaging, thereby reducing the number of poisonings of children; to reduce testing time and costs; and to produce more consistent test results. The staff had briefed the Commission on July 26, 1990, on the proposed protocol revisions as set forth in a draft Federal Register notice transmitted on July 20, 1990 (revising an earler draft transmitted April 10, 1990).

On motion of Chairman Jones-Smith, the Commission voted unanimously (3-0) to issue a notice of proposed rulemaking and to approve the draft Federal Register notice transmitted to the Commission on July 20, 1990, with the changes specified in the memorandum to the Commission dated July 25, 1990, based on comments from the staff of the Environmental Protection Agency. Chairman Jones-Smith has filed a statement concerning her vote in this matter, a copy of which is attached.

2. Crib Toy Petition, HP 89-1

The Commission considered Petition HP 89-1 from the Consumer Federation of America and the Attorney General of the State of New York requesting the Commission to issue a rule banning certain crib gyms, crib mobiles, and crib toys because of entanglement and strangulation hazards to infants and young children. The staff had provided the Commission with a briefing package on the petition, dated May 30, 1990, and supplemental information dated June 26 and August 7, 1990, and had briefed the Commission on the matter at the Commission meetings of June 13 and July 26, 1990.

Following introductory comments, Commissioner Dawson moved that the Commission deny petition HP 89-1, and direct the staff to (1) prepare a letter to be signed by the Commission requesting that the ASTM toy safety voluntary standard committee amend the current voluntary standard for crib toys to reduce the cord length, eliminate hazardous protrusions, and add cautionary labeling to crib mobiles and other crib toys where appropriate, (2) proceed with the staff's planned project on crib toys in the 1991 budget to further identify specific criteria for additional safety measures for crib toys, and (3) prepare for the Commission's consideration a comprehensive educational campaign directed at first-time parents to warn of the hazards inherent in placing crib toys in infant cribs and of the urgent necessity of removing such toys when the infant is about to achieve the ability to push up or is able to reach out for anything hanging from the top of the crib. This motion was defeated by a vote of 1-2, with Commissioner Dawson voting in favor and Chairman Jones-Smith and Commissioner Graham voting against.

On motion of Chairman Jones-Smith, the Commission then voted 2-1 to grant petition HP 89-1 to initiate a rulemaking proceeding, and to direct the staff to prepare an advance notice of proposed rulemaking for approval by the Commission to address the risks of strangulation death and injury presented by the crib toys named in the petition. Chairman Jones-Smith and Commissioner Graham voted in favor, and each has filed a statement concerning her vote, copies of which are attached. Commissioner Dawson voted in dissent and filed a statement concerning her vote, which is attached.

3. Sleepwear Enforcement Status

The Commission was briefed by the staff on the compliance enforcement program for children's sleepwear, highlighting the continuing problem of distinguishing between children's sleepwear and other garments such as daywear, beachwear, and underwear. (Ref. Briefing package dated July 2, 1990.)

Commission Minutes August 16, 1990

Following the discussion in open session concerning the children's sleepwear compliance program, the Commission went into closed session for further briefing by the staff regarding enforcement strategies and possible enforcement actions relating to children's sleepwear. No decisions were made.

There being no further business on the agenda, Chairman Jones-Smith adjourned the meeting.

For the Commission:

Saly E. Drum

Sadye E. Dunn Secretary

Attachments



Statement of
Chairman Jacqueline Jones-Smith
on PPPA Protocol Revisions
August 16, 1990

Today the Commission voted to issue a notice of proposed rulemaking to revise the regulations on test protocols under the Poison Prevention Packaging Act of 1970.

In voting to issue a notice of proposed rulemaking, I considered preliminarily the relevant statutory findings that the Commission will be required to make in issuing final rules. At this time, there appears to be sufficient information to issue final rules with respect to most of the proposed changes. Additional information may be needed on the proposed changes to reduce the test time for the older adult panel, or the younger adult panel, if retained, for blister, pouch, pump, nozzle, or aerosol packaging within a one-year effective date. However, rather than terminate proceedings regarding these proposed changes at this time, I favor seeking comments from the public on the feasibility of these changes.

Child-resistant closures for prescription medications have been proven to save lives. However, poisoning incidents are still occurring. The data indicates that ingestions by children of their grandparents' medications is significant. One of the reasons some older persons are reluctant to use child-resistant packaging is because the packaging is difficult for them to open.

The development of child-resistant closures that are older adult "friendly" will further reduce injuries and deaths associated with child ingestions of prescription medications. By publishing a notice of proposed rulemaking, the Commission moves closer to achieving that goal.



Statement of
Chairman Jacqueline Jones-Smith
on Crib Toy Petition
August 16, 1990

Today the Commission voted to grant petition HP 89-1 to address the risks of strangulation death and injury presented by certain crib toys. For the reasons stated below, I voted in favor of that decision.

The crib toys identified in the petition and the incidents involving them warrant further study by the Commission. Based on the information contained in the Commission staff's Human Factors study prepared in 1987, these toys appear to present a risk of strangulation death and injury to children. The study identified specific mechanical problems with these toys that may contribute to the strangulation incidents. Moreover, the incidents occur in cribs, an environment in which there is an expectation of safety, and in which young children spend a lot of time, often unattended, almost every day. The hazards posed by crib toys are not obvious to parents or caretakers. Infants, one of the most vulnerable populations, do not possess the skills or physical abilities necessary to protect themselves.

By granting the petition and initiating rulemaking, I hope the Commission will be able to gather incident, economic and other information to enable us to find solutions to the strangulation incidents involving crib toys.



Statement on Crib Toys

I am pleased that the Commission voted to grant the petition filed by the Consumer Federation of America and the New York State Attorney General's Office, requesting the Commission to begin rule making procedures regarding crib toys, because of possible entanglement and strangulation hazards to children. The Commission now has received reports of 27 deaths, 19 "near-miss" incidents, and one incident involving brain damage, related to strangulation hazards associated with manufactured crib toys. These data include the recent death of a one year old infant, on July 20, 1990, involving a crib mobile. In addition, since the republication of the ASTM Toy Safety Voluntary Standard in 1986, the Commission has been involved in 15 voluntary corrective action cases with crib toys. These cases represented more than 1 million individual crib toys.

In my view, the evidence indicates clearly that the Commission has enough data to conclude that certain crib toys present a risk of strangulation and entanglement. Given this information, the Commission has a responsibility to initiate procedures for rule making. I believe that a broad Advance Notice of Proposed Rulemaking (ANPR) should be developed that seeks information on all crib toys that may present a strangulation and entanglement hazard, rather than focusing solely on those specific toys for which incident data currently exist. Obviously, the purpose of an ANPR is to solicit information on risk of injury so that the Commission can decide whether final regulatory action is To gather information does not necessarily dictate new regulations. Clearly the Commission's obligation is to explore whether final rule making is in order. It is not yet the time to limit ourselves to certain crib toy products, rather it is time to explore the possible hazards this class of products may represent to one of the most vulnerable of populations.

> Anne Graham, Commissioner August 16, 1990



DISSENTING OPINION

OF

COMMISSIONER CAROL G. DAWSON

ON

PETITION TO BAN CERTAIN CRIB TOYS

August 16, 1990

The Commission's decision to grant or deny the subject petition by the Consumer Federation of America and the State Attorney General of New York was a very close call. However, my study of the data led me to advocate an alternative to rulemaking; therefore, I voted to deny the petition.

Several considerations led me to this conclusion. First, the data strongly suggest, since most of the victims were from six to twelve months of age, that the risk presented by many crib toys exists primarily because they are frequently left on the crib too long--that is, after the infant reached the stage of development at which it could push up or otherwise reach the toy. Measures can and should be taken to better warn parents of this hazard.

Secondly, the staff's view that there may be widespread noncompliance with the 1986 voluntary standard is unproven. Further, I am not at all sure a mandatory rule would be any more effective in attaining a greater rate of compliance. Case-by-case Section 15 efforts already appear to address products in which noncompliance with the standard presents hazards. It is significant that thus far we have not seen incidents involving crib toys which comply with the 1986 voluntary standard.

Third, my evaluation of the data persuaded me that the initiation of rulemaking would be unlikely to result in a mandatory rule supported by the evidence. Additional comments received in a rulemaking proceeding would not, in my view, be likely to produce enough data to support the issuance of a rule.

While I opposed issuing an ANPR, I did propose that the Commission send a letter to the ASTM Toy Safety Voluntary Standard Committee (F963-86), requesting that it seriously consider several amendments or additions to the current standard: i.e., a reduction in cord length, the elimination of hazardous protrusions, and the addition of more cautionary labeling to crib

mobiles and other crib toys where appropriate. The provisions applicable to crib toys in this voluntary standard are due for revision in 1991.

I have also indicated my support of the staff's planned project on crib toys in the 1991 budget. The purpose of such a project would have been to identify and test specific criteria for additional safety measures. In addition, I advocated that the Commission consider a comprehensive educational campaign aimed at first-time parents to warn of the hazards inherent in crib toys, and of the urgent necessity of removing such toys when the infant reaches five months or it can push up.

Nevertheless, my position did not prevail, and I can only hope that it will become apparent that the rulemaking path is not likely to solve the problem. Working with the ASTM, developing better information campaigns, and urging voluntary industry action would have, in my view, achieved our safety objective in a more direct, less costly and more timely manner.

NEWS from CPSC

U. S. CONSUMER PRODUCT SAFETY COMMISSION

FOR RELEASE: MONDAY, AUGUST 20, 1990
RELEASE #90-145

CPSC Decisions:

CRIB TOY PETITION GRANTED;

RULE TO IMPROVE POISON PREVENTION

PACKAGING APPROVED

WASHINGTON, DC — The U.S. Consumer Product Safety Commission (CPSC) announced that it has granted a petition which could lead to mandatory safety regulations for crib toys and approved a proposed rule intended to increase the use of childresistant packaging that is easier for adults to use.

Crib Toy Petition

By a vote of two to one, CPSC granted a petition (HP 89-1) submitted by the Consumer Federation of America and the Attorney General of New York to issue mandatory regulations addressing the risks of strangulation presented by certain crib toys. Commissioner Carol Dawson cast the dissenting vote.

CPSC Chairman Jacqueline Jones-Smith said, "The crib toys identified in the petition and the incidents involving them warrant further study by the Commission."

In making this decision, the Commission relied on data and information contained in two 1987 CPSC studies, an Epidemiological Analysis and a Human Factors Staff Study.

These two studies cited 49 strangulation-related incidents involving crib toys (including four home-made toys) which had been reported to the Commission between 1973 and April 1987.

Since these studies were completed, additional cases have been reported, bringing the total to 51 cases including 31 deaths, 19 "near misses" and one case of severe brain damage.

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The crib toys involved were designed to be strung across a crib or playpen, attached to a corner post or siderail or suspended above an infant.

Chairman Jones-Smith said, "The incidents occur in cribs, an environment in which there is an expectation of safety, and in which young children spend a lot of time, often unattended, every day. By granting the petition and initiating rulemaking, I hope the Commission will be able to gather incident, economic and other information to enable us to find solutions to the strangulation incidents involving crib toys."

In the near future, the Commission will publish an advance notice of proposed rulemaking (ANPR) for crib toys under provisions of the Federal Hazardous Substances Act. Publication of the ANPR begins the rulemaking proceeding which could result in labeling or other requirements for crib toys. The ANPR will solicit comments from the public about crib toys and risks of injury associated with those products, and about existing standards which may address those risks of injury. After consideration of comments received in response to the ANPR and information developed by the Commission staff, the Commission will decide whether to continue the rulemaking proceeding or pursue other options to address risks of injury associated with crib toys.

PPPA Test Protocol Revisions

The Commission voted unanimously to propose amending its regulations under the Poison Prevention Packaging Act that requires child-resistant packaging for certain hazardous household substances. The Commission action is intended to make packaging easier to open by adults, but still retain child resistance.





The Commission estimates that the widespread use of child-resistant closures on oral prescription medicines saved the lives of 340 children under age five since 1974. However, deaths and injuries continue. In 1987, the most recent year for which complete data are available, there were 31 deaths to children under age five who accidentally swallowed medicines and household chemicals. Approximately 100,000 children were treated in hospital emergency rooms, and poison control centers received more than half a million calls about children exposed to medicines and household chemicals.

Current regulations specify that a package design must be capable of resisting opening by 85 percent of a panel of 200 children after a five-minute test and by 80 percent of the panel after an additional five-minute test. These regulations also require that 90 percent of a panel of 100 persons from 18 to 45 years of age also must be able to open the package and, if appropriate, close it within five minutes.

The Commission decided to change the regulation by requiring that the 100 adults on the panel be 60 to 75 years of age and that these adults be able to open the package within one minute. This is expected to increase the use of child-resistant closures by all adults.

Other revisions will provide a more efficient test protocol.

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NOTE: To report an unsafe consumer product or a product-related injury, consumers may call the U.S. Consumer Product Safety Commission toll-free hotline at 1-800-638-2772. A teletypewriter for the hearing impaired is available at 1-800-638-8270; the Maryland TTY number is 1-800-492-8104.

(Statements from the Commissioners relating to these decisions are attached)





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> Anne Graham, Commissioner August 16, 1990

> > (A) (v)