

UNITED STATES GOVERNMENT

Memorandum

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

del KB 6.10

TO : Commission

DATE: June 9, 1977

AGENDA

FROM : Richard A. Danca *RR for*
Office of the Secretary

THRU: *RR for*
Richard E. Rapps
Secretary

SUBJECT: Baby Rattles

The attached staff briefing package presents several options for Commission action on hazards associated with baby rattles. In its memo, also attached, the Office of the General Counsel comments on the matter.

Please indicate below your vote on this matter. The options below are based on pages 6-8 of the staff briefing paper.

TAKE ACTION UNDER THE FHSA:

A PRODUCT-BY-PRODUCT BAN

DIRECT STAFF TO DEVELOP
TECHNICAL CRITERIA FOR
RATTLES

TAKE ACTION UNDER CPSA:

INITIATE SECTION 7 ACTION

INITIATE SECTION 15 ACTION

INITIATE AN INFORMATION AND
EDUCATION PROGRAM

SUPPORT VOLUNTARY ACTION

PROCEED WITH MORE THAN ONE
OF THE OPTIONS ABOVE
(please specify)

(Other vote options listed on page 2)

TAKE NO ACTION: _____

ABSTAIN _____

Comments/Additional Instructions:

Attachments

UNITED STATES GOVERNMENT

Memorandum

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A PRODUCT-BY-PRODUCT BAN

DIRECT STAFF TO DEVELOP
TECHNICAL CRITERIA FOR
RATTLES

Richard A. Danca

6/1/77
6/23/77

TAKE ACTION UNDER CPSA:

INITIATE SECTION 7 ACTION

INITIATE SECTION 15 ACTION

INITIATE AN INFORMATION AND
EDUCATION PROGRAM

SUPPORT VOLUNTARY ACTION

PROCEED WITH MORE THAN ONE
OF THE OPTIONS ABOVE
(please specify)

(Other vote options listed on page 2)

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TAKE ACTION UNDER THE FHSA:

A PRODUCT-BY-PRODUCT BAN

DIRECT STAFF TO DEVELOP
TECHNICAL CRITERIA FOR
RATTLES

*based on Canadian
regulation, if feasible*

TAKE ACTION UNDER CPSA:

INITIATE SECTION 7 ACTION

INITIATE SECTION 15 ACTION

INITIATE AN INFORMATION AND
EDUCATION PROGRAM

SUPPORT VOLUNTARY ACTION

PROCEED WITH MORE THAN ONE
OF THE OPTIONS ABOVE
(please specify)

(Other vote options listed on page 2)

TAKE NO ACTION _____

ABSTAIN _____

Comments/Additional Instructions:

Provide options as soon as possible
on what is best course of action to
deal with those rattles identified
with serious injury which are
still on the market.

Attachments

SNK

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

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A PRODUCT-BY-PRODUCT BAN

DIRECT STAFF TO DEVELOP
TECHNICAL CRITERIA FOR
RATTLES

Thurman

6/23/77

TAKE ACTION UNDER CPSA:

INITIATE SECTION 7 ACTION

INITIATE SECTION 15 ACTION

INITIATE AN INFORMATION AND
EDUCATION PROGRAM

SUPPORT VOLUNTARY ACTION

PROCEED WITH MORE THAN ONE
OF THE OPTIONS ABOVE
(please specify)

(Other vote options listed on page 2)

JUN 10 1977
56

TAKE NO ACTION

ABSTAIN

Comments/Additional Instructions:

Develop recommendations on dealing with worst offenders
on an imminent hazard basis

Forster
6/23/77

Attachments

JUN 10 1977

UNITED STATES GOVERNMENT

Memorandum

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

TO : Commission

DATE: June 9, 1977

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THRU: *RR for*
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Secretary

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TAKE ACTION UNDER THE FHSA:

A PRODUCT-BY-PRODUCT BAN

DIRECT STAFF TO DEVELOP
TECHNICAL CRITERIA FOR
RATTLES

R. David Pittle

6/23/77

TAKE ACTION UNDER CPSA:

INITIATE SECTION 7 ACTION

INITIATE SECTION 15 ACTION

INITIATE AN INFORMATION AND
EDUCATION PROGRAM

SUPPORT VOLUNTARY ACTION

PROCEED WITH MORE THAN ONE
OF THE OPTIONS ABOVE
(please specify)

R. David Pittle

6/23/77

*Rapid removal of existing rattles with
similar characteristics as those causing
(Other vote options listed on page 2) serious injuries*

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SAFETY COMMISSION
WASHINGTON, D.C. 20207

TO : Commission

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DIRECT STAFF TO DEVELOP
TECHNICAL CRITERIA FOR
RATTLES

RR

TAKE ACTION UNDER CPSA:

INITIATE SECTION 7 ACTION

INITIATE SECTION 15 ACTION

INITIATE AN INFORMATION AND
EDUCATION PROGRAM

SUPPORT VOLUNTARY ACTION

Presently the
~~PROCEED WITH MORE THAN ONE~~
~~OF THE OPTIONS ABOVE~~
(please specify)

RR

Commission with various short term (immediate) + long
(Other vote options listed on page 2)

term option

RECEIVED
OFFICE OF THE SECRETARY

UNITED STATES GOVERNMENT

Memorandum

JUN 6 11 58 AM '77
060610
U.S. CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207
CONSUMER PRODUCT
SAFETY COMMISSION

TO : The Commission
THROUGH: Richard A. Rapps, Secretary
THROUGH: Theodore J. Garrish, General Counsel
FROM : THROUGH: Margaret A. Freeston, Deputy General Counsel
Carole Roth, OGC CR

DATE: JUN 6 1977
TG
MAR

SUBJECT: Briefing Package on Baby Rattles

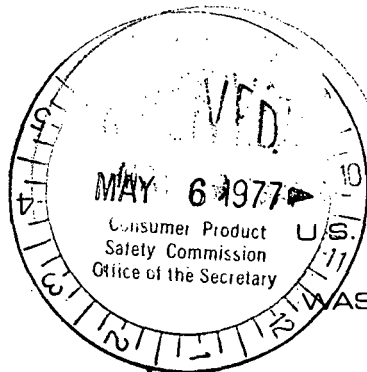
Our office has reviewed the subject briefing package, and we only have brief comments at this time.

We have no legal problems with a product-by-product ban of baby rattles under the FHSA. We point out, however, that in any banning regulation each banned rattle must be clearly identified and linked with the aspiration hazard the regulation is designed to eliminate. It is not necessary, though, that each banned rattle be connected with a particular choking incident; it is sufficient if staff analysis has shown that the rattle is capable of causing such injury. In addition, the Commission need not wait until it has investigated all rattles before initiating action under a product-by-product approach. If the Commission begins banning the hazardous rattles it knows about now, it can continue to investigate and then ban additional hazardous rattles in subsequent product-by-product or generic banning actions.

One of the major considerations in the Commission's deciding whether to use a generic ban for hazardous rattles or a product-by-product ban seems to be the amount of time it would take to develop a generic banning regulation. If the development of such a regulation could be accomplished within a relatively short time-frame, then the Commission may not wish to pursue the idea of a product-by-product ban. If, however, the development of a generic ban would require a generous amount of time, then the Commission may choose to ban certain hazardous rattles immediately to be followed at a later date by a regulation covering all rattles.

UNITED STATES GOVERNMENT

Memorandum



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

DATE: 5 MAY 1977

TO : The Commission
Through: Office of the Secretary
Through: Office of the Executive Director
Through: Charles R. Casper, Director, TAD/OSCA
FROM : William P. Menza, TAD/OSCA

Charles R. Casper
William P. Menza

SUBJECT: Briefing Package on Baby Rattles

Attached is a briefing package to inform the Commission about injuries and deaths associated with baby rattles.

Hazards associated with rattles were recently brought to the attention of Commission staff by the Canadian government's work on a proposed regulation to ban hazardous rattles.

The briefing package has been approved by the Bureaus of Engineering Science, Compliance, Epidemiology, Economic Analysis, and the Offices of the Medical Director and Product Defect Identification.

Attachment

cc:
OMD
BES
BEP
BCM
BEA
OPDI

April 19, 1977

BRIEFING PAPER

on

BABY RATTLES

**William P. Menza
Technical Analysis Division
Office of Standards Coordination and Appraisal
492-6470**

ISSUE:

Whether or not to regulate certain baby rattles and under what regulatory authority.

BACKGROUND:

The Canadian Consumer Standards Directorate informed the Commission's Bureau of Engineering Sciences (BES) in September 1976 about 2 deaths caused by heart-shaped rattles, 3 nonfatal incidents involving other types of baby rattles, and a proposed Canadian rattles standard (Tab A).

At the same time the Seattle Area Office reported that a bell-shaped rattle had choked a child, and shortly after the Office of the Medical Director (OMD) reviewed information on a death in Florida caused by a telephone handset-shaped rattle.

The rattles involved in the Canadian incidents are Cases 5, 6, 17 18, and 19; the one in the Seattle incident is Case 13; and the one in the Florida incident is Case 4 in the BES chart in Tab B. The Seattle incident is the 4th case and the Florida incident is the 8th case listed in the Bureau of Epidemiology's (BEP) memorandum in Tab C. BEP does not mention the Canadian incidents since they were already listed by the BES.

HAZARD INFORMATION:

BEP (Tab C) reports that its files of in-depth investigations, death certificates, and injury surveillance desk reports show 4 deaths and 6 near deaths associated with rattles. BEP believes the baby rattles involved in these incidents should be regulated.

BES (Tab B) reports on the death and injury incidents listed by BEP, 5 Canadian incidents, and 9 other consumer complaints about rattles.

BEP and the Bureau of Information and Education (BIE) have consumer complaint letters about rattles that have choked or suffocated children; have lacerated children's mouths and faces; have broken, exposing sharp or small parts; and have released dye or paint.

DISCUSSION:

The hazard of rattles with toxic dye or paint is presently regulated by the Federal Hazardous Substances Act (FHSA). The small parts hazard of rattles will be addressed in the small parts regulation. However, there is no regulation that addresses the hazard of the total rattle choking or asphyxiating a child.

There is a ban under FHSA [Section 1500.18(a)(1)] on:

"Any toy rattle containing, either internally or externally, rigid wires, sharp protrusions, or loose small objects that have the potential for causing lacerations, puncture wound injury, aspiration, ingestion, or other injury."

The Office of Product Defect Identification (OPDI, Tab D) thinks the most appropriate and effective remedy for eliminating hazardous rattles is by a specific FHSA ban. Such a remedy does not exclude a concurrent use of the CPSA Section 15 authority to efficiently correct products containing a defect which could create a substantial product hazard.

OMD (Tab E) suggests that the telephone-shaped rattle like the one involved in the death in Florida, be considered for regulatory action. Three deaths are known to have been caused by a telephone-shaped rattle. (See Cases 2, 3, and 4 in Tab B and Cases 7 and 8 in Tab C)

BES (Tab B) recommends that the rattles involved in reported death and injury incidents, and those rattles identical to them, be banned from the marketplace. It also recommends that a mandatory safety standard be developed for all rattles, teethingers, and other crib toys.

It should be noted that any rattle regulation would be in addition to the proposed requirements for pacifiers and small parts in toys. The rattles in question have ends which are of a size that can lodge in the throat of an infant but do not fit into the small parts cylinder. These rattles do not fit the definition of a pacifier as defined in that proposed regulation and, therefore, are not within its scope.

From the information on death and injury incidents involving rattles, a ban of specific rattles by model name and number or description and manufacturer's name could be proposed. The advantage of a product-by-product ban is speed, because it could be done quickly. But, it has the disadvantage of not banning rattles that are similar or identical which would have to be identified and banned by separate proceedings.

A limited survey of stores that sell baby rattles market in Washington, D. C. (24 stores), in Dallas (26 stores) in New York City (20 stores) and in San Francisco (5 stores), and a review of children product catalogs found 26 rattles that are identical to the rattles identified in report choking incidents. The BES also believes that 8 additional assorted shaped rattles appear to present choking hazards. These 34 rattles are produced and distributed by 13 manufacturers and distributors. See Tab F.

The Toy Manufacturers of America (TMA) was asked at a March 2, 1977, public meeting for a list of manufacturers of rattles identical to those reported in death and near-death incidents, but no list has been received at this time.

A general product regulation could ban all rattles determined to be hazardous. It would eliminate the disadvantage of banning specific products model by model. It would ban all hazardous rattles so it would not penalize some manufacturers while others selling identical ones would not be affected. It is not known how long and what amount of resources would be required to develop this general regulation.

ECONOMIC CONSIDERATIONS:

The Bureau of Economic Analysis (BEA, Tab G) has presently identified 21 manufacturers, importers, and distributors of rattles. These firms account for over 80 percent of the firms marketing rattles. Most of the rattles that are available in this country are imported from the Orient.

Rattles are usually manufactured by injection molding. There are many plants in the Orient with this type of equipment. Production can be switched from one article to a different one without much difficulty. As a result, manufacturers easily enter and leave the rattle business.

Inventories vary depending on the type of business and can range from a 3-to-6-month supply of rattles.

COMPLIANCE STRATEGY:

The Bureau of Compliance (BCM) has supplied a brief discussion of the enforcement and enforcement resources needs associated with the various options (Tab H). Projections have been made for the investigatory sample analysis and compliance litigation resources that would be necessary to implement each option.

INDUSTRY COMMENTS:

Draft copies of an initial briefing package on hazardous baby rattles were requested by TMA. It included a list of 5 rattles involved in death or near-death incidents that could be considered for a ban. Two members of the association commented (Tab I) on this package. In summary their comments were as follows:

1. The rattles identified for a ban conform to voluntary standard PS 72-76 developed by the TMA with the assistance of the National Bureau of Standards, and to the proposed small parts regulations. (NOTE: Like existing CPSC toy regulations, the voluntary toy safety standard does not address the hazard of choking through impaction of rattles.)
2. No information is given as to what are acceptable rattles.
3. A product-by-product ban arbitrarily gives competitive advantage to companies who make the same rattle but are not named in the ban.

4. A product-by-product ban tarnishes the image of those manufacturers identified but not the others selling identical rattles.
5. A generic ban would be more equitable than a product-by-product ban.
6. Lead time to meet any changes in production molds caused by any new regulatory requirements should be reasonable.
7. Since November 1976, one rattle manufacturer has not shipped any telephone rattles identical to one involved in an incident in which a child choked to death.

At the March 2, 1977, public meeting on baby rattles, the association repeated the comments made about the draft briefing package. It also indicated concern about the listing of specific manufacturers and their rattles in that package when the rattle involved in reported death and near-death incidents may not have been accurately verified. Not only is such a banning list unfair; but also, if it erroneously lists a manufacturer, the consequences would be most unfortunate.

It should be noted that the identification of the manufacturer or distributor for each rattle placed on any ban list would be certified as correct. Verification of the rattles in question is addressed in the attached BEP memorandum in Tab C and BES memorandum in Tab B.

At this meeting, when asked if any notification to the OPDI had been made of a possible substantial product hazard associated with rattles, one manufacturer reported he had done so with one of his safety pin-type rattles.

After the March 2 meeting, 3 additional TMA letters (Tab I) were received by the Commission. These letters reiterated some of the previous comments made by the association's members and reported that an estimated 12 to 15 million baby rattles are sold each year.

On March 11, 1977, TMA issued a press release (Tab I) about a proposed development of a modified safety standard for certain baby rattles. The toy industry would work closely with the Commission to draft a modified voluntary baby rattle safety code. The Chairman of TMA said that manufacturers voluntarily stopped shipment of layette-type rattles late last year after receiving Commission information about them.

CONCLUSION:

At least 4 children are known to have choked to death on baby rattles. There are at least 14 incidents where a child had a rattle lodged in the throat but did not die.

In 3 of the deaths and in 5 of the nonfatal incidents, a telephone-shaped rattle was involved (Tab B, C, and E).

OMD, BEP, BES, and OPDI believe that some baby rattles present a hazard to children and should be regulated.

The Commission could ban specific rattles involved in reported death or near-death incidents. This product-by-product ban could be followed by a ban of all identical and similar rattles, or the ban could wait until they are identified and include them. This initial ban could be followed by a general product regulation that would ban all rattles not meeting certain requirements.

ALTERNATIVES:

1. FHSA Product-By-Product Bans

Under the FHSA, the Commission could by regulation determine that specified rattles are "hazardous substances" [Section 2(f)(1)(D)]. Section 3(e)(1) of the FHSA requires that this finding be made according to the Notice and Comment Rulemaking Proceedings of 5 U.S.C. 533 (unless the Federal Food, Drug, and Cosmetic Act Section 701 Rulemaking Proceedings are selected instead). The Commission would apply the following relevant portion of the definition of "mechanical hazard":

"(Any toy or other article intended for use by children) 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 ... because the article (or any part or accessory thereof) may be aspirated or ingested ..." [Section 2(s)]

Any rattles so determined to be "hazardous substances" would also be classified as "banned hazardous substances" [Section 2(q)(1)(A)], and thus would be prohibited from interstate commerce (Section 4) and subject to the automatic repurchase provisions of the FHSA (Section 15).

If the Commission, before or during the rulemaking proceedings described above, finds that the mechanical hazard of any rattle present "an imminent hazard to the public health," it can deem them to be "banned hazardous substances" and order them banned until the proceedings have been completed.

For purposes of product-by-product bans, the Commission would identify the rattles by manufacturers, model name and number, and any other identifying characteristics that exist. The Commission, if it utilizes the 5 U.S.C. 553 procedures, would publish a proposed ban in the Federal Register, and, after providing an opportunity for comment on the proposal (in most cases for a period of not less than 30 days), issue a final ban; if an imminent hazard is determined affected manufacturers would be given personal notice of the proposed ban.

BCM (Tab H) also points out that although a Federal Register Notice to inform the public of any decision to ban specific rattles is appropriate, the CFR codification of banned baby rattles could create another "Banned Product List" with all the attendant problems of the original list.

2. FHSA Product Regulation

The Commission could, in accordance with the FHSA provisions discussed under Number 1. above, pursue a product approach for regulating aspiration, ingestion, or impaction hazards associated with rattles. The Commission could also direct the staff to develop technical criteria to identify all rattles that present a mechanical hazard from aspiration, ingestion, or impaction. Any rattles not meeting a final banning regulation based on such criteria would be automatically classified as a hazardous substances and therefore banned.

3. CPSC Regulatory Action

If the Commission determined by rule under Section 30(d) of the CPSA that it would be in the public interest to regulate a risk of injury associated with infant rattles under the CPSA rather than under the FHSA (assuming the risk could be eliminated or reduced to a sufficient extent by action under the FHSA), it could do so.

Under the CPSA, the Commission could initiate proceedings under Section 7 leading to a consumer product safety standard for all rattles and/or under Section 15 leading to an order or orders applicable to particular rattles that are found to be substantial product hazards.

4. Combinations

As long as such actions are consistent, the Commission could proceed under more than one of the above alternatives.

5. Information and Education

An information and education campaign alone or as a part of one of the other alternatives could be initiated by the Commission.

6. Voluntary Action

The Commission could support a voluntary safety standard with TMA through the National Bureau of Standards voluntary standards setting process.

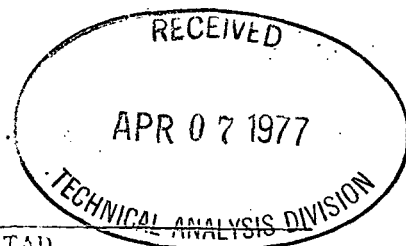
7. No Action

The Commission could decide to take no action against the rattles which are discussed in the briefing paper.

LIST OF ATTACHMENTS

- Tab A Gellman's October 5, 1976, letter
- Tab B BES's April 5, 1977, November 19, 1976, and March 18, 1977, memoranda
- Tab C BEP's December 2, 1976, and March 15, 1977, memoranda
- Tab D OPDI's December 1, 1976, and March 30, 1977, memorandum
- Tab E OMD's November 30, 1976, and March 14, 1977, memoranda
- Tab F BES's April 11, 1977 memorandum
- Tab G BEA's March 17, 1977, memorandum
- Tab H BCM's January 19 and March 17, 1977, memorandum
- Tab I Hoover's February 7 and 9, 1977, and March 8, 1977, letters
Freeman's February 11, 1977, letter
Simon's March 7, 1977, letter
Sherwin's March 8, 1977, letter
TMA's March 11, 1977, press release

DATE :
 TO : Those Checked Below
 FROM : William Menza
 Office of Standards Coordination and Appraisal, TAD
 SUBJECT : Sign-off for the briefing paper
 (Standard, petition, etc.)



on Baby Rattles Dated March 23, 1977
 (subject)

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by _____. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

<u>ORGANIZATION</u>	<u>SIGNATURE</u>	<u>APPROVE/DISAPPROVE</u>
Office of the General Counsel		
Office of the Executive Director		
Office of Program Planning and Evaluation		
Office of Resource Utilization		
Office of Field Coordination		
Office of Medical Director		
Bureau of Epidemiology		
Bureau of Economic Analysis		
Bureau of Engineering Sciences		
Bureau of Biomedical Sciences		
Bureau of Information and Education		
✓ Bureau of Compliance	<i>Richard E. Hayes</i>	✓
Office of Product Defect Identification		
Office of Standards Coordination and Appraisal		

DATE : March 28, 1977

TO : Those Checked Below

FROM : William P. Menza

Office of Standards Coordination and Appraisal, TAD

SUBJECT : Sign-off for the briefing paper
(Standard, petition, etc.)

on "Baby Rattles"
(subject)

Dated March 23, 1977

Your signature below signifies that you have reviewed the attached material. Please denote your approval or disapproval of the material and forward this sign-off sheet to us by c.o.b. Thursday, March 31, 1977. If you do not approve the material, reason(s) for your not approving must be attached to the sign-off sheet.

ORGANIZATION

SIGNATURE

APPROVE/DISAPPROVE

Office of the General Counsel

Office of the Executive Director

Office of Program Planning and Evaluation

Office of Resource Utilization

Office of Field Coordination

Office of Medical Director

Bureau of Epidemiology

Bureau of Economic Analysis

✓ Bureau of Engineering Sciences - 926

Bureau of Biomedical Sciences

Bureau of Information and Education

Bureau of Compliance

Office of Product Defect Identification

Office of Standards Coordination
and Appraisal

NOTE: All comments have
been considered and where
appropriate changes to the
briefing material have been
made. W. Menza 4/5/77

William Menza

We approve this
proposed subject
to the conditions
covered in John's
memo attached

WPM
4/11/77

FROM : William P. Menza
Office of Standards Coordination and Appraisal, TAD

on "Baby Rattles"
(subject)

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APPROVE/DISAPPROVE

Office of Standards Coordination
and Appraisal

* See ATTACHED MEMO OF CLARIFICATION IN TAB D

DATE : March 28, 1977.

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on BABY RATTLES
(subject)

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Office of the Executive Director		
Office of Program Planning and Evaluation		
Office of Resource Utilization		
Office of Field Coordination		
Office of Medical Director	<i>Albert F. Esch</i>	✓
Bureau of Epidemiology		
Bureau of Economic Analysis		
Bureau of Engineering Sciences		
Bureau of Biomedical Sciences		
Bureau of Information and Education		
Bureau of Compliance		
Office of Product Defect Identification		
Office of Standards Coordination and Appraisal		

[illegible]

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(Standard, petition, etc.)

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(subject)

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ORGANIZATION

SIGNATURE

APPROVE/DISAPPROVE

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Office of the Executive Director
Office of Program Planning and Evaluation
Office of Resource Utilization
Office of Field Coordination
Office of Medical Director
Bureau of Epidemiology
✓ Bureau of Economic Analysis - 533
Bureau of Engineering Sciences
Bureau of Biomedical Sciences
Bureau of Information and Education
Bureau of Compliance
Office of Product Defect Identification
Office of Standards Coordination
and Appraisal

3/28/77

WPM

April 13, 1977

BRIEFING PAPER

on

BABY RATTLES

William P. Menza
Technical Analysis Division
Office of Standards Coordination and Appraisal
492-6470

ISSUE:

Whether or not to regulate certain baby rattles and under what regulatory authority.

BACKGROUND:

The Canadian Consumer Standards Directorate informed the Commission's Bureau of Engineering Sciences (BES) in September 1976 about 2 deaths caused by heart-shaped rattles, 3 nonfatal incidents involving other types of baby rattles, and a proposed Canadian rattles standard (Tab A).

At the same time the Seattle Area Office reported that a bell-shaped rattle had choked a child, and shortly after the Office of the Medical Director (OMD) reviewed information on a death in Florida caused by a telephone handset-shaped rattle.

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HAZARD INFORMATION:

BEP (Tab C) reports that its files of in-depth investigations, death certificates, and injury surveillance desk reports show 4 deaths and 6 near deaths associated with rattles. BEP believes the baby rattles involved in these incidents should be regulated.

BES (Tab B) reports on the death and injury incidents listed by BEP, 5 Canadian incidents, and 9 other consumer complaints about rattles.

BEP and the Bureau of Information and Education (BIE) have consumer complaint letters about rattles that have choked or suffocated children; have lacerated children's mouths and faces; have broken, exposing sharp or small parts; and have released dye or paint.

DISCUSSION:

The hazard of rattles with toxic dye or paint is presently regulated by the Federal Hazardous Substances Act (FHSA). The small parts hazard of rattles will be addressed in the small parts regulation. However, there is no regulation that addresses the hazard of the total rattle choking or asphyxiating a child.

There is a ban under FHSA [Section 1500.18(a)(1)] on:

"Any toy rattle containing, either internally or externally, rigid wires, sharp protrusions, or loose small objects that have the potential for causing lacerations, puncture wound injury, aspiration, ingestion, or other injury."

The Office of Product Defect Identification (OPDI, Tab D) thinks the most appropriate and effective remedy for eliminating hazardous rattles is by a specific FHSA ban. Such a remedy does not exclude a concurrent use of the CPSA Section 15 authority to efficiently correct products containing a defect which could create a substantial product hazard.

OMD (Tab E) suggests that the telephone-shaped rattle like the one involved in the death in Florida, be considered for regulatory action. Three deaths are known to have been caused by a telephone-shaped rattle. (See Cases 2, 3, and 4 in Tab B and Cases 7 and 8 in Tab C)

An expedient method for identifying rattles similar to those in the reported incidents, OMD suggests, is to make negative impressions (molds) of the identified rattles and to use these molds as inspection tools. Rattles which fit into the molds would be considered similar.

BES (Tab B) recommends that the rattles involved in reported death and injury incidents, and those rattles identical to them, be banned from the marketplace. It also recommends that a mandatory safety standard be developed for all rattles, teethingers, and other crib toys.

It should be noted that any rattle regulation would be in addition to the proposed requirements for pacifiers and small parts in toys. The rattles in question have ends which are of a size that can lodge in the throat of an infant but do not fit into the small parts cylinder. These rattles do not fit the definition of a pacifier as defined in that proposed regulation and, therefore, are not within its scope.

From the information on death and injury incidents involving rattles, a ban of specific rattles by model name and number or description and manufacturer's name could be proposed. The advantage of a product-by-product ban is speed, because it could be done quickly. But, it has the disadvantage of not banning rattles that are similar or identical which would have to be identified and banned by separate proceedings.

A limited survey of stores that sell baby market in Washington, D. C. (24 stores), in Dallas (26 stores), in New York City (20 stores) and in San Francisco (5 stores), and a review of children product catalogs found 26 rattles that are identical to the rattles identified in report choking incidents. The BES also believes that 8 additional assorted shaped rattles appear to present choking hazards. These 34 rattles are produced and distributed by 13 manufacturers and distributors. See Tab F.

The Toy Manufacturers of America (TMA) was asked at a March 2, 1977, public meeting for a list of manufacturers of rattles identical to those reported in death and near-death incidents, but no list has been received at this time.

A general product regulation could ban all rattles determined to be hazardous. It would eliminate the disadvantage of banning specific products model by model. It would ban all hazardous rattles so it would not penalize some manufacturers while others selling identical ones would not be affected. But, it would take time. It is not known how long and what amount of resources would be required to develop this general regulation.

ECONOMIC CONSIDERATIONS:

The Bureau of Economic Analysis (BEA, Tab G) has presently identified 21 manufacturers, importers, and distributors of rattles. These firms account for over 80 percent of the firms marketing rattles. Most of the rattles that are available in this country are imported from the Orient.

Rattles are usually manufactured by injection molding. There are many plants in the Orient with this type of equipment. Production can be switched from one article to a different one without much difficulty. As a result, manufacturers easily enter and leave the rattle business.

Inventories vary depending on the type of business and can range from a 3-to-6-month supply of rattles.

COMPLIANCE STRATEGY:

The Bureau of Compliance (BCM) has supplied a brief discussion of the enforcement and enforcement resources needs associated with the various options (Tab H). Projections have been made for the investigatory sample analysis and compliance litigation resources that would be necessary to implement each option.

INDUSTRY COMMENTS:

Draft copies of an initial briefing package on hazardous baby rattles were requested by TMA. It included a list of 5 rattles involved in death or near-death incidents that could be considered for a ban. Two members of the association commented (Tab I) on this package. In summary their comments were as follows:

1. The rattles identified for a ban conform to voluntary standard PS 72-76 developed by the TMA with the assistance of the National Bureau of Standards, and to the proposed small parts regulations. (NOTE: Like existing CPSC toy regulations, the voluntary toy safety standard does not address the hazard of choking through impaction of rattles.)

2. No information is given as to what are acceptable rattles.
3. A product-by-product ban arbitrarily gives competitive advantage to companies who make the same rattle but are not named in the ban.
4. A product-by-product ban tarnishes the image of those manufacturers identified but not the others selling identical rattles.
5. A generic ban would be more equitable than a product-by-product ban.
6. Lead time to meet any changes in production molds caused by any new regulatory requirements should be reasonable.
7. Since November 1976, one rattle manufacturer has not shipped any telephone rattles identical to one involved in an incident in which a child choked to death.

At the March 2, 1977, public meeting on baby rattles, the association repeated the comments made about the draft briefing package. It also indicated concern about the listing of specific manufacturers and their rattles in that package when the rattle involved in reported death and near-death incidents may not have been accurately verified. Not only is such a banning list unfair; but also, if it erroneously lists a manufacturer, the consequences would be most unfortunate.

It should be noted that the identification of the manufacturer or distributor for each rattle placed on any ban list would be certified as correct. Verification of the rattles in question is addressed in the attached BEP memorandum in Tab C and BES memorandum in Tab B.

At this meeting, when asked if any notification to the OPDI had been made of a possible substantial product hazard associated with rattles, one manufacturer reported he had done so with one of his safety pin-type rattles.

After the March 2 meeting, 3 additional TMA letters (Tab I) were received by the Commission. These letters reiterated some of the previous comments made by the association's members and reported that an estimated 12 to 15 million baby rattles are sold each year.

On March 11, 1977, TMA issued a press release (Tab I) about a proposed development of a modified safety standard for certain baby rattles. The toy industry would work closely with the Commission to draft a modified voluntary baby rattle safety code. The Chairman of TMA said that manufacturers voluntarily stopped shipment of layette-type rattles late last year after receiving Commission information about them.

CONCLUSION:

At least 4 children are known to have choked to death on baby rattles. There are at least 14 incidents where a child had a rattle lodged in the throat but did not die.

In 3 of the deaths and in 5 of the nonfatal incidents, a telephone-shaped rattle was involved (Tab B, C, and E).

OMD, BEP, BES, and OPDI believe that some baby rattles present a hazard to children and should be regulated.

The Commission could ban specific rattles involved in reported death or near-death incidents. This product-by-product ban could be followed by a ban of all identical and similar rattles, or the ban could wait until they are identified and include them. This initial ban could be followed by a general product regulation that would ban all rattles not meeting certain requirements.

ALTERNATIVES:

1. FHSA Product-By-Product Bans

Under the FHSA, the Commission could by regulation determine that specified rattles are "hazardous substances" [Section 2(f)(1)(D)] . Section 3(e)(1) of the FHSA requires that this finding be made according to the Notice and Comment Rulemaking Proceedings of 5 U.S.C. 533 (unless the Federal Food, Drug, and Cosmetic Act Section 701 Rulemaking Proceedings are selected instead). The Commission would apply the following relevant portion of the definition of "mechanical hazard":

"(Any toy or other article intended for use by children) 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 ... because the article (or any part or accessory thereof) may be aspirated or ingested ..." [Section 2(s)]

Any rattles so determined to be "hazardous substances" would also be classified as "banned hazardous substances" [Section 2(q)(1)(A)], and thus would be prohibited from interstate commerce (Section 4) and subject to the automatic repurchase provisions of the FHSA (Section 15).

If the Commission, before or during the rulemaking proceedings described above, finds that the mechanical hazard of any rattle present "an imminent hazard to the public health," it can deem them to be "banned hazardous substances" and order them banned until the proceedings have been completed.

For purposes of product-by-product bans, the Commission would identify the rattles by manufacturers, model name and number, and any other identifying characteristics that exist. The Commission, if it utilizes the 5 U.S.C. 553 procedures, would either publish a proposed ban in the Federal Register or provide the affected manufacturer with personal notice of the proposed ban. After then providing an opportunity for comment on the proposal (in most cases for a period of not less than 30 days), the Commission could issue a final ban.

BCM (Tab H) also points out that although a Federal Register Notice to inform the public of any decision to ban specific rattles is appropriate, the CFR codification of ban baby rattles could create another "Banned Product List" with all the attendant problems of the original list.

2. FHSA Product Regulation

The Commission could, in accordance with the FHSA substantive and procedural statutory criteria discussed under Number 1. above, pursue a product approach for regulating aspiration, ingestion, or impaction hazards associated with rattles. The Commission could direct the staff to develop technical criteria to identify all rattles that present a mechanical hazard from aspiration, ingestion, or impaction. Any rattles not meeting a final banning regulation based on such criteria would be "banned hazardous substances."

3. CPSC Regulatory Action

If the Commission determined by rule under Section 30(d) of the CPSA that it would be "in the public interest" to regulate a risk of injury associated with infant rattles under the CPSA rather than under the FHSA (assuming the risk could be eliminated or reduced to a sufficient extent by action under the FHSA), it could do so.

Under the CPSA, the Commission could initiate proceedings under Section 7 leading to a consumer product safety standard for all rattles and/or under Section 15 leading to an order or orders applicable to particular rattles that are found to be "substantial product hazards."

4. Combinations

As long as such actions are consistent, the Commission could proceed under more than one of the above alternatives.

5. Information and Education

An information and education campaign alone or as a part of one of the other alternatives could be initiated by the Commission.

6. Voluntary Action

The Commission could support a voluntary safety standard with TMA through the National Bureau of Standards voluntary standards setting process.

7. No Action

The Commission could decide to take no action against the rattles which are discussed in the briefing paper.

LIST OF ATTACHMENTS

- Tab A Gellman's October ~~4~~, 1976, letter
- Tab B BES's April 5, 1977, November 19, 1976, and March 18, 1977, memoranda
- Tab C BEP's December 2, 1976, and March 15, 1977, memoranda
- Tab D OPDI's December 1, 1976, and March 30, 1977, memorandum
- Tab E OMD's November 30, 1976, and March 14, 1977, memoranda
- Tab F BES's April 7, 1977 memorandum
- Tab G BEA's March 17, 1977, memorandum
- Tab H BCM's January 19 and March 17, 1977, memorandum
- Tab I Hoover's February 7 and 9, 1977, and March 8, 1977, letters
Freeman's February 11, 1977, letter
Simon's March 7, 1977, letter
Sherwin's March 8, 1977, letter
TMA's March 11, 1977, press release

TAB A



Consumer and
Corporate Affairs

Consommation et
corporations

Consumer
Standards
Directorate

Direction
générale
des normes

Your file Votre référence

Our file Notre référence

7560-R10
7305-3-1

Product Safety Branch
18th Floor, Zone 3
Place du Portage
Ottawa/Hull
K1A 0C9

October 5, 1976

Mr. John Preston
Bureau of Engineering Sciences
Consumer Product Safety Commission
5401 Westbard Avenue
Bethesda, M.D.
U.S.A. 20207

Dear Mr. Preston:

As promised in the course of the meeting of the Toy Manufacturers of America, I am enclosing for your interest copies of the technical information which we have amassed in the course of our studies relative to the proposed Rattles Regulations to the Hazardous Products Act. In addition, I enclose copies of a letter from the Toy Manufacturers of America to the Branch and our reply.

I trust you will find the information useful and look forward to further exchanges of information and expertise in the future.

Yours sincerely,

Vera Gellman, M.D.
Chief
Development Division

Encls.



Consumer and
Corporate Affairs

Consommation et
corporations

Consumer
Standards
Directorate

Direction
générale
des normes

Your file Votre référence

Our file Notre référence

7560-R10

Product Safety Branch
18th Floor, Zone 3
Place du Portage
Ottawa/Hull
K1A 0C9

October 4, 1976

Mr. Aaron Locker
Law Offices
One Penn Plaza
New York, N.Y.
U.S.A. 10001

Dear Mr. Locker:

Mr. Black has asked me to reply to your letter of September 17, 1976 in which you advise him of the concerns of the Toy Manufacturers of America, Safety Standards Committee, relative to the proposed Rattles Regulations to the Hazardous Products Act. I will deal with these concerns in the order in which you expressed them.

1. In developing the proposed regulations, the Product Safety Branch has examined many rattles. We are satisfied that rattles with proportions outside the range which we consider to be hazardous do indeed exist. One Canadian distributor alone sent sixteen samples for our assessment. Eight of them were acceptable when subjected to the testing procedure. We do not consider that a major redesign of rattles in general is necessary in order to prevent impaction, but even if it were necessary, we believe the accident data which we possess would be sufficient to justify such a change. The data are as follows:

- (a) Two well-documented cases of death in young Canadian infants due to suffocation following the impaction of a rattle in the hypopharynx. In both cases the same model of rattle was involved (see attached photo # 2).

...../2

- (b) One well-documented fatality in U.S.A. and a further fatality mentioned in a letter to the Consumer Product Safety Commission from a Registered Nurse, but not documented.
- (c) Three non-fatal cases (U.S.A.) in which mother found rattle lodged in child's throat.

In all five of the U.S.A. cases, a small telephone-shaped rattle was implicated. (See attached photo # 4).

- (d) Three non-fatal cases in which rattles have been lodged in Canadian infant's throats. Two were reported by parents, one by police. In the latter case hospital treatment was required. We possess the actual rattles in two of the cases but not in the third.

2. The proposal is not contrary to, but in addition to the requirements of existing regulations and proposals thereof for small parts in toys in Canada and in the United States.

The purpose of the so-called "small parts" regulations is to reduce the hazard of ingestion and inhalation of small objects. The problem which we are attempting to eliminate is neither ingestion nor inhalation but impaction.

Impaction in the hypopharynx (lower portion of the pharynx) may occur with objects which are large enough to preclude ingestion and inhalation, yet small enough to pass through the buccal orifice (entrance to the mouth). It is an entirely different problem and in our view must be attacked from a different angle. Our answer to the problem is the proposed template. The theory behind its design is that if an object can pass through the buccal orifice, it should not be long enough to project into the hypopharynx.

3. The dimensions of the template are based on the best information which is available to us at the present time. It is not known exactly how large an object must be to prevent its entry into an infant's mouth. There is a great deal of individual variation and tissues are distensible.

Paediatricians have a dictum that an infant should never be given any plaything smaller than a golf ball. In carrying out tests in the development of our Pacifier

Regulations, our orthopaedodontic consultant personally observed an infant of 4 months totally engulf in his mouth a disc 50 mm. in diameter and 2 mm. thick. One of the rattles which was involved in a non-fatal accident has a handle 45 mm. across and 3 mm. thick. It was this handle which was impacted in the back of the child's throat. In the opinion of Prof. Latham, the Faculty of Dentistry, University of Western Ontario, objects smaller than 5 cm. in diameter could be responsible for the problem with which we are concerned.

On this information, together with documented information on mandibular and maxillary widths, we based the measurement of 50 mm. in the template orifice.

The 30 mm. measurement in the orifice was based on the largest object reported to us that became lodged in an infant's throat. Actually, we now find that this measurement will have to be increased to somewhere between 32 and 35 mm. The depth of the template, 30 mm., was based on measurements, taken from cadavers and live infants, of the antero-posterior dimension of the mouth cavity (see attached tables).

4. Since rattles are also subject to the so-called "small components test" the ingestion problem is already taken care of. The problem, as I explained above, is impaction.
5. The proposed regulation addresses itself solely to the problem of impaction of rattles. It does not concern "other common household objects". It would be ludicrous to attempt to regulate a feeding spoon in this way. A feeding spoon has to go into a child's mouth. A rattle does not have to go into a mouth.

At this time round we are concerned with rattles only. It would be reasonable to expect that, when once the ground work has been established, teethers might be subjected to similar regulations. You may argue that teethers have to go into the mouth. My reply is that they do not have to be completely engulfed.

6. Our Minister has personally expressed interest in the progress of our proposed regulations and, in view of the fact that two deaths have occurred in this country within a year, I doubt very much if he will agree to any further delay in their implementation. However,

the proposed U.S. study will certainly be brought to his attention.

A propos the study the review committee may be interested in a collection housed at the Hospital for Sick Children, Toronto, of more than a thousand ingested and inhaled objects. Our own collection may also be of value.

7. The Montreal Children's Hospital has promised to obtain measurements for us taken from skull X-rays. We still await this data.
8. Information on the U.S. accidents is available from the Consumer Product Safety Commission, NEISS reports. Information on Canadian accidents is as follows:

(a) February 14, 1975

7 months infant rushed to York County Hospital where a "pink plastic baby's article" (in a police report described as a rattle) was removed from her throat. Documentation on this incident incomplete at present time.

Rattle identification: Not available.

(b) June 19, 1975

Consumer complaint to the Product Safety Branch. Handle of rattle lodged in baby's mouth. Infant 6 months.

Rattle identification: Photo N° 1.

Medical information: Medical help not obtained. Non- fatal.

(c) April 24, 1975

8 months old infant. Found dead in crib with rattle protruding from mouth.

Rattle identification: Photo N° 2.

Coroner's report states: "Presumably the baby collapsed face down while on her hands and knees with the rattle in her mouth, thereby jamming it into her throat."

Cause of death: Asphyxiation.

(d) September 30, 1975

Consumer complaint referred from TV open-line type program. "The end of the rattle I have enclosed got caught in our son's throat when he was smaller and my husband had a hard time to pry it out".

Rattle identification: Photo N° 3.

Medical information: Medical assistance not obtained. Non-fatal.

(e) February 14, 1976

7 months old infant. Found dead in crib with rattle lodged in the throat.

Rattle identification: Photo N° 2.

Pathological report: "Pulmonary oedema which could have been caused by a foreign body such as described in the history or by unexplained and unexpected death in infancy. In such cases, the clinical history surrounding the death is more important than the autopsy."

I trust that this information will serve to answer the eight points raised in your letter. We would be very pleased to meet with you for further discussion at any time which is convenient to you.

Yours sincerely,



Vera Gellman, M.D.
Chief
Development Division

Enclosures

J. W. B.
7-5-75-3
(ap)

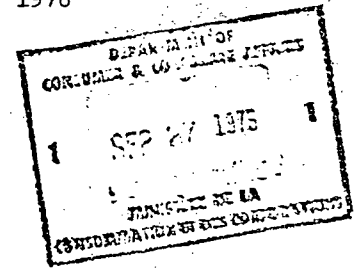
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(212) 594-7000
TWX 710-581-2884

September 17, 1976

Mr. J. W. Black
Director, Product Safety Branch
Consumer and Corporate Affairs
18th Floor, Zone 3
Place Du Portage
Ottawa, Canada
KIA OC 9



Dear Mr. Black:

I represent Toy Manufacturers of America, Inc. (TMA) a trade association consisting of manufacturers and importers who account for approximately 85% by volume of all toys sold in the United States today, estimated at \$4 billion annually at the retail level.

Your Trade Communique Issue No. 3 July 1976 relating to toys (rattles) has been brought to my attention and has been reviewed by the TMA Safety Standards Committee. The Committee has requested that I advise you of the industry's concern regarding the effects of the proposals outlined in the Trade Communique.

1. The proposal, as we understand it, would ban most existing rattles sold in the United States, and, indeed, throughout the world. The dimensions it suggests would require a major redesign of rattles in an effort to prevent ingestion and we believe they are contrary to human experience.

2. The proposal is contrary to the requirements of existing regulations or proposals therefor for small parts in toys in the United States, in Canada and throughout the rest of the world.

3. There appears to exist no scientific basis for the dimensional requirements of the rattle proposal. Our investigation of medical literature in the possession of the United States Government relating to small parts discloses no dimensional requirements which approximate those contained in the

LAW OFFICES
AARON LOCKER

Page-2-

September 17, 1976

Mr. J. W. Black

directive. If you are aware of any basis for the proposed dimensional requirement, we would appreciate receiving any evidence in your possession. ✓

4. In the view of the Safety Standards Committee the proposal would not prevent (ingestion) of the rattle or components thereof. *ingestion not the problem*

*feeding spoon
has to go into mouth
Rattle does not*

5. The proposal is contrary in its dimensional requirements to other common household objects which are easily accessible or available to infants. For example, a child's feeding spoon would violate the dimensional requirements.

*understanding
it would take
report when
available*

6. The United States Government has recently authorized a detailed study of small toy parts which present aspiration, ingestion or asphyxiation hazard potential. The Consumer Product Safety Commission on September 7, 1976, issued a request for proposal for completion of the study to determine the dimensions of a toy or toy parts which presents such hazards. The contractor when selected by the Consumer Product Safety Commission will have one year to search and abstract all available cases of suffocation in children, ages 0-6, reported in medical literature relating to such injuries. The contractor in this connection will establish a review committee composed of practitioners in the following medical disciplines: 1 MD Anatomy, 1 MD Pathology, and 1 medical opinion regarding reasonable measurable perimeters of small parts which have caused suffocation. The contractor will be required to submit four quarterly reports and a final report.

*18 - collection
of Toy Sick Ch
Hosp.*

We urgently recommend that you defer any precipitate action in this regard pertaining to this product until the results of this scientific study are made available.

*available
data*

7. We understand that Dr. Leitch of the Consumer and Corporate Affairs Product Safety Branch has been in the process of accumulating Xray studies of children and the dimensions of their vital passages at several hospitals. We would appreciate any information that you have in this regard.

8. If you are in the possession of any information relating to infant injury or death as a result of play with rattles,

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Page-3-

September 17, 1976

Mr. J. W. Black

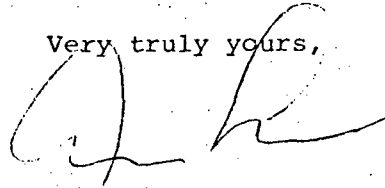
we would appreciate receiving the following:

- (a) the date of each occurrence;
- (b) an identification of the rattle, by name, model number and manufacturer; and
- (c) the medical evaluation of injury or death.

I look forward to hearing from you at your earliest convenience.

As I indicated in our telephone conversation, I would like to arrange to meet you with a delegation of American toy manufacturers involved in the manufacture of these products as quickly as possible.

Very truly yours,



AL:dd

W. Menza, SCAT
TAB-B

APR 5 1977

Carl Blachschmidt, Director, OPDI

THROUGH : William S. West, Acting Director, BES
James I. Price, Director, BESE
John D. Preston, BESE

Misidentification of Hazardous Baby Rattle

This memo provides a correction to an error in identification made in my November 19, 1976, memo to you on the subject of Hazardous Baby Rattles (attached). I would appreciate it if you could append this memo to the original copy in your files.

On page 2 of the November 19 memo we named as the manufacturer of a baby rattle, shaped like a telephone receiver, the company known as Tiny Tots, Sanitoy, Inc. This identification was obtained from IDI #760113BEP7001 and has been proved to be incorrect. Presumably, the investigator obtained the information from the consumer with whom he made contact to investigate a near death to a child.

We are sending a copy of this memo to BEP so that they may also correct their records. A recent survey of the retail marketplace has produced a rattle which, in the judgment of BESE, is identical to the one involved in the IDI #760113BEP7001. We will attempt to have this identification confirmed with the distributor.

cc: R. Verhalen, BEP
✓ W. Menza, SCAT



521134, Rattles, 1517
CPSC:BESE:JDPreston/elc/4/4/77

UNITED STATES GOVERNMENT

Memorandum

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

TO : Carl Blechschmidt, Director, OPDI
THRU: William S. West, Acting Director, BESB
James I. Price, Director, BESB
FROM : John D. Preston, BESB

DATE: NOV 19 1976

SUBJECT: Hazardous Baby Rattles

This memo follows up previous contacts by BES with OPDI staff members concerning reports of hazardous children's rattles and transmits additional information.

At the TMA toy safety conference in Chicago on September 23, 1976, I spoke with Dr. Vera Gellman of the Canadian Consumer Standards Directorate. Dr. Gellman informed me of several incidents involving the impaction of baby rattles into the hypopharynx of infants. In two of these cases, the infants died as a result of suffocation. BESB believes that rattles similar to the products reported in the Canadian incidents are also marketed in the United States.

Shortly after my return from Chicago, I received from the Seattle Area Office, an in-depth investigation report together with samples of a rattle involved in an incident. The rattle is similar in shape and size to one involved in a similar incident reported in Canada. The child involved did not sustain a lasting injury only because of intervention of the mother who was able, with some difficulty, to remove the rattle which was protruding from the child's mouth. Samples of this rattle have been delivered by BESS to OPDI (J. Keenan to R. Haltermann). Alvin Pong and I have since had discussions on the subject of hazardous children's rattles with representatives of several other CPSC operating units (BEP, OSCA, OGC, BCM).

BESB has photographs of several types of rattles which we believe present very serious hazards, even loss of life, to infants. The hazard present is that the end of the rattle is small enough for the baby to insert into

its mouth, a perfectly normal action. The rattle may then be driven deep into the baby's mouth and throat by the child rolling or falling, thus causing blockage of the air passage. Some examples of hazardous rattles we are aware of are as follows:

<u>Description</u>	<u>Name</u>	<u>Source</u>
Telephone Handset	"Little Angel"	Childhood Interest Alan Jay Rosselle Park, NJ 07201
Telephone Handset	-	Tiny Tots Sanitoy Inc. 200 5th Ave. N.Y., N.Y.
Bells w/connecting bar	"Protecto No. 420"	Reliance Products Corp. Woonsocket, RI

BESB believes that action should be taken to remove these and similar products from the market place. This might be done by authority under the FHSA, by action under sections 8, 12, or 15 of the CPSA or by other means. In addition, it may be appropriate to consider some communications or other media action concerning this product.

Attached is a tabulation of some data from a number of incidents of which we are aware.

In addition to immediate action under existing authority, BESB believes that in the long term CPSC should develop a regulation to address the hazard of suffocation by the entrance of rattles into the hypopharynx of small children. Such a regulation should also apply to teethingers and possibly other crib toys. The products identified

Page 3 - Memo to Blechschmidt

above would pass the small parts regulation as currently proposed and would not be covered by the proposed pacifier regulation.

Attachment

cc: M. Brown, Acting ExDirector
A. Dimcoff, Assoc ExDirector
J. Langston, Assoc ExDirector
J. Donovan, Assoc ExDirector
A. Esch, CMD
J. Bigio, BESS

INCIDENTS INVOLVING RATTLES LODGING IN CHILDREN'S THROATS

AGE/SEX In MONTHS	DATE	PRODUCT	PLACE OF OCCURRENCE	SOURCE
----------------------	------	---------	------------------------	--------

DEATHS BY ASPHYXIATION IN USA

1.	May 63	Bar Bell Rattle	Miami, Fla.	Examiners Report
2. 6 F	June 73	Telephone Rattle	Charleston, SC	Examiners Report
3. 8 M	Jan 75	Telephone Rattle		Death Certificate
4. 7 F	Aug 75	Telephone Rattle	Sattelite Beach, Florida	In-depth 750912BEP7001

DEATHS BY ASPHYXIATION IN CANADA

5. 8	April 75	Heart Shaped Rattle	Canada	**
6. 7	Feb 76	Heart Shaped Rattle	Canada	**

** Canadian incidents cited in letter from Dr. Vera Gellman of the Canadian Consumer Standards Directorate

NON-FATAL INCIDENTS (Lodged in Throat) IN USA

7. 11	Oct 74	Telephone Rattle	Kinnelman, NJ	Complaint H 015495
8. 11	May 75	Safety Pin	Worthing, Ohio	In-depth 760309BEP7001
9. 4½		Telephone Rattle	Saratoga, CA ?	Complaint H 085822Z
10. 13 M	Nov 75	Telephone Rattle	Harrison, ME	In-depth 760113BEP7001
11. 6	Mar 76	Tulip (flower) Rattle		In-depth 760323ATL5004

Page 2 - INCIDENTS INVOLVING RATTLES LODGING IN CHILDREN'S THROATS

AGE/SEX In MONTHS	DATE	PRODUCT	PLACE OF OCCURRENCE	SOURCE
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NON-FATAL INCIDENTS (Lodged in Throat) IN USA (continued)

6	May 76	Clothespin Rattle	Hagaman, N.Y.	In-depth 760614BEP7002
13. 4½	June 76	Bell Shaped Rattle	Seattle, WA	In-depth 760610BEP7002
14. 5		Ball End Rattle	Otisville, N.Y.	Consumer Letter
15. 3		Telephone Rattle	Sturgis, Mich.	Consumer Letter
16. 8	Winter 75	Telephone Rattle	Brighton, Mich.	Consumer Letter

NON-FATAL INCIDENTS (Lodged in Throat) IN CANADA

17. 7	Feb 75	Pink Plastic Rattle	Canada	**
18. 6	June 75	Handle of Rattle	Canada	**
19. ?	Sept 75	Bell Shaped Rattle	Canada	**

** Canadian Incidents cited in letter from Dr. Vera Gelman of the Canadian Consumer Standards Directorate

UNITED STATES GOVERNMENT

Memorandum

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

TO : W. P. Menza, OSCA/TAD
THROUGH : James I. Price, Director, BESB
FROM : A. Pong, BESB

DATE: MAR 18 1977

SUBJECT: Hazardous Rattles

REF : Memo from A. Pong to W. Menza dated February 10, 1977,
"Hazardous Rattles"

BESB recommends that a package of all currently available facts and considerations be forwarded to the Commissioners as soon as possible in order that the staff can concentrate and expedite their efforts along the lines of action which the Commissioners wish to undertake.

Industry in a March 2, 1977, meeting with Commission staff, emphatically stated that the Commission surveys (BCM sample survey and BEA telephone canvass) would confirm the manufacturers' prior comments that a large number of manufacturers and distributors are selling a large number of rattles essentially identical to the five identified rattles. Further, the naming of only four companies as proposed in the January 17 draft briefing package would be grossly unfair to those companies named.

Additional investigation into the identity of the products involved in incidents leaves the identification of the clothes pin rattle as a Plakie product questionable and indicates that the safety pin rattle was not a Plakie product. In reading the consumer's letter that started the investigation, it appears that the consumer had sent the Plakie rattle in as an example of the type of rattle which was involved in her son's accident and which she wished to have removed from the market. The complainant believed that the rattle involved in her son's incident was larger than the Plakie rattle which she had forwarded to the Commission. BESB recommends not listing either of the Plakie products as being associated with any particular incident, but as a similar hazardous rattle.

RECEIVED

MAR 18 1977

TECHNICAL ANALYSIS DIVISION

Aside from the question of equity to the manufacturers and distributors, if there is a large number of distributors and each has several models of rattles which present identical hazards to infants, the Commission would not be fully protecting the public from the hazard with the previously suggested product by product ban which only identifies and bans five models of rattles. In addition to the rattles identified in choking incidents, the Commission staff has become aware of rattles which are not similar in shape to the identified rattles, but in the staff's opinion, pose an identical threat to children. These rattles should also be included in the list of rattles which should be banned.

Considering the rate of fatalities and the potentially fatal incidents, BESB strongly recommends immediate banning action of all rattles identified as hazardous. BESB has a partial listing of 25 hazardous rattles from 11 companies. Although such an action may not initially identify all hazardous rattles, the time and effort that it would take for incremental improvements in identifying hazardous rattles weighs against withholding action against the known hazardous rattles until all hazardous rattles are identified. Such a delay in offering the public protection from a hazard, even if incomplete, would in fact be a denial of protection against a known hazard.

To augment the product by product ban and to counter the possibility that the public will be lulled into thinking that any rattle not mentioned is safe, an information and education program might be considered. Such a public information effort outlining the hazards of certain rattles and presenting facts which will afford the public an opportunity to make a judgment in the purchase and use of a rattle could be undertaken.

In addition to an immediate ban on known hazardous rattles, BESB strongly recommends development of generic crib toy requirements. This regulation would be built around knowledge gleaned from in-depth investigations and anthropometric and product use studies. Such a requirement is needed to protect a particularly vulnerable segment of the population against hazards from products similar in shape, size, and use of rattles but not identified as such.

BABY RATTLES

Type : Telephone Receive

Staff I.D. #	Sample Number	Source	Product / Distributor Name	Remarks
1	NLA 8063		Believed to be Young Years Stahlwood Mfg. Co.	Subject of IDI 760113 BEP 7001
2	C-855-4021	Dallas A.O.	Young Years, Stahlwood Toy Mfg. Co.	Identical to #1
3	D-820-2104	San Francisco A.O.	Little Angel Childhood Interests/Alan Jay	Believed to be Identical to rattle involved in IDI #750912 BEP 7001
4	None	Store in Washington DC Arma	Happy Rattles Happy Mates Div/ Electro Plastics Inc.	Similar to #1 & #3
5	D-805-4601		Baby King Regent Baby Products Corp	Similar to #1 & #3
6	D-805-4601		Baby King Regent Baby Products Corp	Not identical to #5 but similar. Also similar to 1 & 3
7	-	Kresge BE Congressional Plaza, Md.	Tiny Tot's Sanitoy Inc.	Bigger than 1 and 3 Not known to have been involved in incident
8	-	Hecht Co (1-18-77) Montgomery Mall	Nursery Needs	Identical to #7
9	-		Toys for Tots Baby World Co Inc.	Different design from all others.

Type : Clothes pins

Staff I.D.#	Sample Number	Source	Product/Distributor Name	Remarks
#9	-	Hecht Co. 1-14-77 Washington DC.	Plakie Toys Inc.	Appears from the description to be similar or identical to rattle in 760614 BEP 7002. Also sold under J.C. Penney label.
20	-	Manufacturer	Plakie Toys Inc.	Larger version of #19 not yet on market Does not meet Canadian rattle requirements
21	D-820-2103		Little Angel, Childhood Interests / Alan Toy	{ Appear to be identical products }
22	D-805-3255		Baby King Regent Baby Products Corp.	
23	D-805-2357		Protect-O #420 Reliance Products Corp.	
24			Happy Rattles #H 600 Happy Makes/Div Electro Plastics	{ Appear to be identical products }
25	C-855-4020	Dallas A.O.	Young Years No. 313 Stahlwood Toy Mfg. Co..	
26	D-805-3253		Tiny Tots Santoy Inc.	{ Appear to be identical products }
27	D-820-2108		Nursery Needs	

Type : Diaper Pin

Type : Diaper Pin

[illegible]

Type : Barbells

[illegible]

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2. The second part of the paper is devoted to a discussion of the general principles of the theory of the structure of the atom.

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TAB-C

UNITED STATES GOVERNMENT

Memorandum

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

TO : William Menza, SCAT *WMM*
Through: Albert Dimcor, AED, OPM; Joann Langston, AED, HIA, *DLR*
Dr. Robert Verhalen, Director, BEP *DR*
FROM : George Rutherford, BEP *GR*
DATE: December 2, 1976
SUBJECT: Suggested Banning Action for Certain Rattles

In accordance with your request we have reviewed our files and have located the following in-depth investigations, death certificates, and injury surveillance desk reports pertaining to victims choking on rattles:

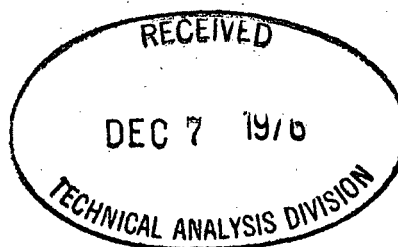
<u>Source</u>	<u>Accident Scenario</u>	<u>Description of Rattles</u>
<u>Maine</u> 760113 BEP7001	Thirteen-month-old child broke rattle and choked on one of the halves. Dead on arrival at hospital but revived without permanent damage.	Telephone shaped rattle approximately 1-1/4" wide, 7/8" high at the end
<u>Ohio</u> 760309 BEP7001	Ten-month-old child fell while trying to walk. Rattle was in mouth and broke. Large end lodged in throat. Victim was hospitalized for 1-1/2 days.	Rattle shaped like diaper pin
<u>California</u> <u>Hotline</u> 40858222	Rattle became lodged in throat of 1-year old.	Telephone shaped rattle
<u>Washington</u> 760610 BEP7002	Four-month old choked on rattle. Mother was able to pull it loose.	Dumbbell shaped rattle 4 inches long. Each end was 1-1/4" wide, 1" long. Handle 2" long, 1/2" diameter.

<u>Source</u>	<u>Accident Scenario</u>	<u>Description of Rattles</u>
California Consumer 760813 SFO6001	Child, 5-1/2-months old, pushed rattle into mouth and began to choke on it. Father pulled it out before any damage occurred.	Clothes pin rattle
Florida Medical Examiner's Report	Rattle occluded airway resulting in death of 8-month-old child.	Bar bell rattle 3-1/2" long. Each end 1-1/8 inch diameter. Center bar 5/16" in diameter
South Carolina Medical Examiner's Report	Six-month-old child fell with rattle in mouth lodging it in posterior larynx. Death resulted after mother and police were unable to dislodge rattle.	Telephone shaped rattle
Florida 750912 BEP7001	Baby was found with rattle in mouth, subsequently died.	Telephone shaped rattle 4-1/2" long. Ends were 1-1/4" wide and 1/2" deep. Handle was 2" long and 1/4" thick
New York 760614 BEP7002	Six-month-old child choked on rattle. Approximately 1-1/2" of rattle were down victim's throat. Mother only able to remove by force resulting in lacerations to victim's throat. Removal difficult.	Clothes pin shaped rattle 5" long, 1" diameter ball shaped head. Trunk smaller diameter One and one-half inch wide at other end, fork shaped with balls on ends

<u>Source</u>	<u>Accident Scenario</u>	<u>Description of Rattles</u>
<u>New Jersey</u> Hotline H015495P	Eleven-month-old child got rattle caught in throat.	Telephone shaped rattle

One case involving choking on a slightly different type of rattle is excluded. That incident involved a part of the rattle which detached. Although this is a hazardous condition the problem is somewhat different than that associated with the rattles listed above.

The products involved in these incidents were of similar size and configuration. Further, the sucking reflex of infants increases the likelihood of lodgement once objects are in the mouth. For these reasons, BEP concurs with the suggestion that the Commission consider action on this type of product.



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MAR 21 1977

UNITED STATES GOVERNMENT

Memorandum

TECHNICAL ANALYSIS DIVISION

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

TO : See Distribution List
Through: Joann Langston, AED, HIA;
Dr. Robert Verhale, Director, BEP
FROM : George Rutherford, BEPH

DATE: March 15, 1977

SUBJECT: Summary and Status of Epidemiological Support for Proposed Commission Banning
Action on Rattles

Herein are listed accident scenarios, product identification, and status of support for product brand name-specific approach, for each rattle identified for banning.

1. CHILDHOOD INTEREST "Little Angel"
750912BEP7001 7-month Female Suffocation DOA

A 7-month-old female was discovered by her mother and father in her crib with the rattle in her mouth. The grandfather removed the rattle and attempted to revive the baby through artificial respiration. The victim died of suffocation. The baby rattle was identified as a "Little Angel," a telephone handset-shaped rattle. It was made in Hong Kong and distributed by Childhood Interest, Rosselle Park, New Jersey. The rattle measured 4-1/2" in length. It was 1-1/2" wide, 1/2" in depth, and its handle was 2" long and 1/4" thick, according to the investigator. BES measurements of an identical rattle were 4-3/8" length, 1-5/16" receiver diameter, 7/8" thickness receiver. STATUS: Parents' attorney has original rattle in safe deposit box.

2. RELIANCE PRODUCTS CORPORATION "Bar and Bell-Shaped Rattle"
760610BEP7002 4-1/2 month Male No Injury

A 4-1/2-month-old male was sitting in a high chair playing with a rattle when he suddenly jabbed the rattle into his mouth. The rattle became lodged in his throat and the victim began breathing abnormally and turned red. His mother was able to dislodge the rattle. The victim's father, who is a doctor, examined him and found that there was no apparent injury. The rattle was identified as Protecto No. 420 bar-shaped rattle with connected bells, Reliance Products Corporation, Woonsocket, Rhode Island. The rattle was 4" long. Each end was 1-1/4" wide and 1" long. Its diameter was 1/2". STATUS: BEP has actual rattle and five identical rattles. In-depth investigation contains photograph of actual rattle.

3. PLAKIE "Safety Pin-Shaped Rattle"
760603BEP7001 10-month Male Choking T & A (2 D)

A 10-month-old male was walking and had the rattle in his mouth. He fell and this caused the rattle to break and part of it to lodge in the victim's throat. The victim was taken to the hospital by ambulance. After arriving at the hospital, the doctors were able to remove the rattle by using an instrument used to remove tonsils. The rattle was a safety pin-shaped rattle, Plakie Toy, Ohio. The large end of the rattle was the part that lodged in the victim's throat. STATUS: Photographs of actual rattle not available. Consumer mailed similar rattle to CPSC headquarters. Parent went to local stores to identify the brand name. Definite product identification is not possible.

4. PLAKIE "Clothespin-Shaped Rattle"
760614BEP7002 6-month Female Laceration T & R

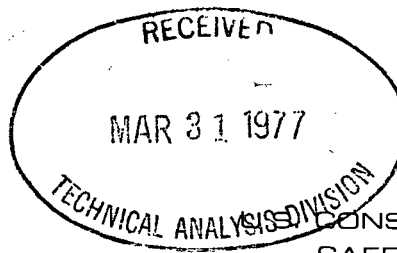
A 6-month-old female had been placed in her crib to take a nap. The mother had given the baby a clothespin-shaped rattle to play with. As the mother was leaving the baby's room, she heard a strange noise and upon examining the baby, she saw that the rattle was lodged in the baby's mouth (throat). The mother hesitantly pulled the rattle from the baby's throat. The rattle was a Model No. 430 clothespin-shaped rattle, Plakie Toy, Ohio. The baby rattle measured 5" in length. Its ball type head was 1" in diameter, its trunk was 1" in diameter. The side width of the fork was 1/2" and the fork width at bottom was 1-3/8". STATUS: Victim's father checked department stores to find the identical rattle for product information. Photographs of actual rattle are included in in-depth investigation. A statement by the investigator states that the photographs are of the actual rattle involved. Sample of actual rattle destroyed 9/20/76, under BES procedures.

5. SANIToy "Tiny Tots" Clothespin-Shaped Rattle"
760813SF06001 6-month Male

A 6-month-old male was given a rattle as a teething toy. Mother noticed that victim was able to stick the straight end of the rattle far back into his mouth. The victim began to choke and his mother removed the rattle. The mother noticed that as a reflex action of the victim's throat, the rattle was being drawn farther into his throat. The rattle was a clothespin-shaped rattle, Tiny Tots, Sanitoy, Inc. STATUS: Consumer sent actual rattle to manufacturer. She received acknowledgement from them. She is sending a letter to BEP stating that at the time of her complaint, she still had the actual packaging. If upon checking her files she still has the original label, she will send it to BEP.

Distribution List:

E. Besson, OEX
W. Menza, SCAT
J. Preston, BESB
A. Pong, BESB
E. Kandell, BEA
E. Jones, BCMI
C. Beline, OPDI
T. Van Houten, OMDH
M. Everhart, SCAD



UNITED STATES GOVERNMENT

Memorandum

CONSUMER PRODUCT
SAFETY COMMISSION
WASHINGTON, D.C. 20207

TO : William P. Menza
Technical Analysis Division, OSCA

FROM : Carl W. Blechschmidt, Director *cwb*
Office of Product Defect Identification

SUBJECT: Clarification Re OPDI Position On Baby Rattles

DATE: March 30, 1977

In determining the most effective method to remedy unnecessary risks of injury associated with baby rattles, it is the opinion of this office that a generic regulation, focused upon the readily-observable defects in baby rattles, would be most efficient in correcting the problem. While other remedies described below may at first blush appear to provide a more instantaneous response, much time and resources would need be spent in careful identification of each of the hundreds of models available to consumers. Such identification would require the establishment of criteria to determine whether a specific product presents a "substantial product hazard." These criteria would need to be similar to those for an FHSA ban, indicating a more effective approach to compliance through FHSA.

However, other remedies are foreseeable. In approaching remedial action to correct identified hazards associated with baby rattles, it is important to understand that remedies under CPSA and FHSA are not mutually exclusive. Using our regulatory tools to the fullest extent may require the concurrent use of both Section 15 and FHSA, in an effort to correct the problem as efficiently as possible.

In the clarification to 16 CFR 1115, published at 40 F.R. (Dec. 17, 1975), the Commission clearly stated that the reporting requirement (Section 15(b)) applies directly to products regulated under the transferred acts. Reports of defects which "could create" a substantial product hazard must be made for products within the purview of FHSA, FFA, PPPA regardless of a violation of a standard. Therefore, notification is obligatory for a manufacturer, distributor, retailer or importer whose product contains a defect which could create a substantial product hazard.

Once this information is received, a voluntary corrective action plan can be negotiated. If no plan is forthcoming, an FHSA product specific ban would be appropriate.

Either approach would provide product correction. The FHSA generic ban route would not abrogate responsibilities under Section 15(b). It appears to this office however, that efficient regulatory action under FHSA is the proper curative approach.

UNITED STATES GOVERNMENT

Memorandum

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

TO : William Menza, TAD/OSCA
Through: Carl Blechschmidt, Director, OPDI *curb*
Through: Frank Pipkin, OPDI *fbp*
FROM : Dennis Trietsch, OPDI *DT*

DATE: December 1, 1976

SUBJECT: Hazardous Baby Rattles

On November 19, 1976 OPDI received a memorandum from John D. Preston, BESB on hazardous baby rattles. We are attaching a copy of that memo to this statement.

OPDI has carefully reviewed the BESB memo, as well as relevant injury data, and has concluded that the most appropriate and effective remedy for eliminating this kind of potentially hazardous product from the marketplace is through the use of a specific ban under the Federal Hazardous Substances Act.

The reasons behind this conclusion are: (1) in order for OPDI to use section 15 to remove this product from consumers' hands, it would be necessary to make a preliminary determination that this specific company's product presents a substantial product hazard. No criteria now exists by which to measure what constitutes a defect which could create a substantial product hazard insofar as these rattles are concerned. Further, not enough data now exists to make such a preliminary determination that a substantial product hazard is presented; (2) a company-by-company approach would be required to deal with this issue via section 15; (3) a section 30(d) determination through a lengthy process would have to be made by the Commission in order to use Section 15, since this product is an article intended for use by children and therefore within the purview of FHSA; (4) FHSA provides a more immediate and expeditious method for addressing this specific toy rattle problem through the available procedures for banning.

We request that you review our position and reasoning, as well as the BESB memo in conjunction with your previous efforts in this area directed toward the formulation of a positive approach for addressing this problem.

NOTE: The November 19, 1976 BES memorandum referred to in the OPDI
December 1, 1976 memorandum is in Tab B.

E

TAB-E

UNITED STATES GOVERNMENT

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

Memorandum

TO : William P. Menza, TAD/OSCA
thru : Albert F. Esch, M.D., Director, OMD
FROM : Leo T. Duffy, M.D., Deputy Director, OMD
SUBJECT: Hazardous Baby Rattles

DATE: November 30, 1976

Albert F. Esch
L. T. Duffy

In response to your request for comments concerning the subject memorandum, this Office has attached a copy of a memo sent November 11, 1976, to the Commission Chairman. It indicates that a specific rattle appears to be an unreasonably hazardous product.

This office considers that any toy rattle of similar size and shape should be considered for appropriate Commission action as an unreasonable hazard.

Attachment



UNITED STATES GOVERNMENT

Memorandum

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

TO : S. John Byington, Chairman
THRU : Albert F. Esch, M.D., Director, OMD *Albert F. Esch*
FROM : Charles T. Desmond, M.D., Director, *C. T. Desmond*
Division of Medical Review, OMD
SUBJECT: Suffocation Death Caused by a Toy Rattle

DATE: November 11, 1976

The Bendix Corporation, Launch Support Division, was awarded a contract entitled "Study to Determine the Size of Small Parts Which Could Cause Suffocation" on September 30, 1976. The Bendix Project Director for this contract contacted the Project Officer on October 12, 1976, requesting information relative to a case of suffocation death caused by a toy rattle, published in the Brevard "Today" newspaper dated October 11, 1976 (copy attached).

In seeking an adequate response to the request for information, it appears that a letter initiated by the victim's grandfather, Robert F. Spielman, addressed to Mr. Ralph Nader and dated September 5, 1975, was forwarded to the CPSC.

The date of the unfortunate incident was August 29, 1975. An in-depth investigation was started in a timely manner on September 16, 1975. A copy of the in-depth investigation and report along with the letter addressed to Ralph Nader is also attached.

As recently as October 29, 1976, another letter from Mrs. Thornton was received in the Commission and transmitted to the Office of the Medical Director (copy attached). This specific case had never been previously submitted to OMD for an opinion.

In an attempt to put together the pieces of information available in the Bethesda Office, it appears that Mrs. Thornton has contacted CPSC on many occasions and is critical of the Commission's responses.

Since the appearance of the news items in the October 11, 1976 "Today" paper, a number of responses have been received from consumers from various geographical locations who read the account of the accident in their local newspapers. (Sample letters are attached.)

A call to the Product Safety Branch of the Consumer Standards Directorate, Ottawa, Canada, indicated that they had two recent deaths by suffocation associated with a toy rattle manufactured in Hong Kong; apparently a very similar rattle as identified in our case. It has resulted in a proposed toy rattle regulation for Canada. A voluntary recall of the rattle which caused the infants deaths has been accomplished. The Canadian Ministry has developed a test instrument, and when given the measurements of the rattle from the Thornton case, it would fail their test method.

It is the opinion of the Office of the Medical Director that some appropriate action be considered by the Commission to preclude this type of injury from occurring again with this specific rattle. It appears to be an unreasonably hazardous product.

We bring this directly to your attention because of the gravity of the situation.

Attachments (4)

cc: C. Candella

Memorandum

TO : William P. Menza, TAD/OSCA
THRU : Albert F. Esch, M.D., Director, OMD *Albert F. Esch*
FROM : Charles T. Desmond, M.D., Director, OMDR *William P. Menza*
Donald T. Van Houten, OMDH *D. T. Van Houten*
SUBJECT: Baby Rattle Safety Regulation

DATE: March 14, 1977

In your February 25, 1977 memo you solicited comments on how certain rattles "identical" to those under consideration could be identified. The following are our suggestions as well as our philosophical considerations on the matter.

The hazard associated with the five rattles specified in our deliberations is the obstruction of the air passage; a mechanical hazard termed 'aspiration' under section 2(s) (7) of the Federal Hazardous Substances Act. This hazard manifests itself through some dimensional attribute(s) with the rattles under consideration. We emphasize that it is only the dimensional attributes which cause the problem; it has nothing to do with color, material (within certain limits) packaging or origin. Therefore, in order to effectively eliminate the hazard, all such size and shape rattles should be addressed by regulatory action. To this end we suggest the following course of action.

We suggest negative impressions (molds) of each of the five rattles subject to the ban be fabricated from some stable material. These impressions would be used for evaluating the relative similarity of other baby rattles which may also present the hazard. When guidance is received from the Commission (presuming approval to pursue the matter is granted) staff should be prepared to submit drawings of the impressions with appropriate text to the Federal Register. These drawings should be cross sectional (preferably at the mold line-since these products are symmetrical about the plane formed by that line).



The objective of the above actions would be to:

- 1) Obtain timely guidance from the Commission to either to ban all identified similar items or disband the entire effort.
- 2) Provide a public means of identifying these rattles.

There has been substantial discussion pertaining to developing a so-called generic crib-toy standard directed towards minimizing choking hazards to infants. We believe such an effort would be quite appropriate and would define part of section 2(s) of the FHSA. However we wish to point out that to sustain a standard of this nature, a considerable amount of work would be required resulting in a protracted delay in removing identified hazards from the market.

We believe the items involved in the choking do have some common attribute which either by itself or in combination with a use pattern, lead up to the creation of an incident. However, it is too early to even speculate what this common attribute may be. We therefore, recommend that guidance from the Commission on suffocation hazards be sought with the utmost urgency.

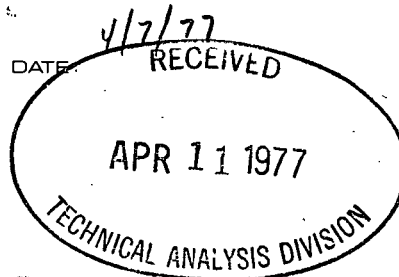
TAB F

UNITED STATES GOVERNMENT

Memorandum

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

TO : William P. Menza, OSCA/TAD
THROUGH: James I. Price, Director, BESB *JIP*
FROM : A. Pong, BESB *A. Pong*
SUBJECT: Results of a Limited Survey of the
Baby Rattle Market



As a result of a partial survey of stores in Washington, DC, (24 stores); Dallas, TX, (26 stores); New York, NY, (20 stores); and San Francisco, CA, (5 stores); and a review of four product catalogs, the Commission staff has identified distributors or manufacturers of 25 rattles (plus one unidentified clothespin rattle) which are identical or essentially identical to the rattles associated with choking incidents. In addition to these 26 rattles, BESB is aware of eight other rattles of different shapes which appear to present the same hazard. These 34 rattles are produced and distributed by 13 manufacturers and distributors. According to BEA, there are an estimated 65 companies in the U.S. involved in the production and distribution of rattles. This limited survey appears to confirm statements that product identification is complicated by manufacturers distributing their products through a number of distributors and private labels and distributors obtaining supplies from a number of manufacturers.

Several companies use the same model number to designate an assortment of rattles. To identify the hazardous rattles, a detailed description of the size and shape would be needed. Another impediment to identifying rattles is that in two instances, unlabeled assortments of rattles were displayed in a basket or bin. The following table relates the number of rattles found in the survey to the shapes of the rattles which have been responsible for choking incidents.

Rattles Identical or Essentially Identical to
Rattles Involved in Choking Incidents from
13 Manufacturers and Distributors

<u>Description of Rattles</u>	<u>Number of Distributors/Manufacturers</u>
Telephone	7
Bells w/Connecting Bar	2
Safety Pin	6
Clothespin	10 (plus one unidentified)
Assorted Shapes, which appear to present the same hazard	8 —
TOTAL products found in stores in 4 areas and 4 catalogs	34

UNITED STATES GOVERNMENT

Memorandum

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

TO : William Menza, TAD/OSCA
THRU : Joann Langston, Acting AED/HIA *RL*
Walter R. Hobby, Director, BEA
FROM : Ellen F. Kandell, BEA *EFK*

DATE: March 17, 1977

SUBJECT: Firms Marketing Rattles

The available hazard information has identified four rattles of the following shapes which have been associated with fatal or near fatal incidents: clothes pin, safety pin, telephone and barbell. Four manufacturers were involved in these cases and have been named in the proposed product-by-product ban. These firms also private label for retailers and distributors so identification by manufacturer in the market is not always possible. Similar rattles are manufactured by companies other than these four.

These rattles are quite popular and are usually distributed as an assortment with perhaps one or two additional rattles of other shapes. At retail they are sold separately for \$.26 - \$.64 each. It is likely that each of the firms in the proposed ban make all of the rattles in question.

The molds from which they are made are very similar from company to company and may have only slight variations in dimensions. Though manufacturers say they can identify their own rattles, there are usually no distinguishing marks. Without the packaging it would be quite difficult for consumers or others to identify the manufacturer of a given rattle.

To date, BEA has identified 21 firms which have in the past made or at present, manufacture, import or distribute the telephone, barbell, safety pin and clothes pin rattles. These account for over 80% of the firms marketing rattles. The remaining firms are probably small importers and distributors which we are currently attempting to identify. The firms which are involved with each type of rattle are listed below:

Clothes Pin

Baby Needs, Inc.
Baby World Co.
Childhood Interests
Susan Crane Packaging Co.
Formulette, Inc.
Kiddie Products
Pilgrim Infants Wear Co.
Plakie Toy, Inc.
Regent Baby Products
Sanitoy
Stahlwood Toy Mfg.
TLC Products, Inc.
Tidy Ties Corp.

Telephone

Baby Needs, Inc.
Baby World Co.
Binky Baby Products
Childhood Interests
Susan Crane Packaging Co.
Earl & Arlington
Kiddie Products
Pilgrim Infants Wear Co.
Regent Baby Products
Reliance Products Corp.
Sanitoy
Stahlwood Toy Mfg.
Tidy Ties Corp.

Dumbbell or Barbell

Baby Needs, Inc.
Baby World Co.
Earl & Arlington
Electro Plastics, Inc.
Formulette, Inc.
Pilgrim Infants Wear
Plakie Toy, Inc.
Regent Baby Products
Reliance Products Corp.
Sanitoy
Stahlwood Toy Mfg.
TLC Products, Inc.
Tidy Ties Corp.

Safety Pin

Baby Needs, Inc.
Baby World Co.
Binky Baby Products
Childhood Interests
Earl & Arlington
Kiddie Products
Pilgrim Infants Wear Co.
Plakie Toy, Inc.
Regent Baby Products
Reliance Products Corp.
Sanitoy
Stahlwood Toy Mfg.
TLC Products, Inc.
Tidy Ties Corp.

It is apparent that rattles similar to the four which were involved in the fatalities or near fatalities are being marketed by firms other than the four which have been identified.

These rattles are widely distributed through various types of retail establishments from small specialty baby stores to large department stores. Four of the five national retailers contacted sell one or more of these rattles. Some of the retailers sell under private labels. These companies buy their rattles from importers or distributors listed above. They do not import them directly.

The four firms which have been named in the product-by-product ban stopped shipping the four specified rattles as of January 10, 1977, but have not recalled them. Another firm has recalled their telephone, safety pin, and clothes pin rattles.

In the event of a product-by-product ban, a competitive advantage might be given to firms other than those named in the ban. They might continue to distribute similar rattles and retailers might probably sell them. Thus, they would be able to deplete their existing stocks of rattles which usually range from a 3 to 6 month supply.

UNITED STATES GOVERNMENT

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

Memorandum

TO : Bill Menza, TAD/OSCA
Through: Act. Assoc. Exec. Director for Compliance & Enforcement *RJR*
FROM : Through: Director, Division of Inspection & Enforcement
Liz Jones, BCMI *WJ* *RC*
DATE: 17 MAR 1977
SUBJECT: Compliance and Enforcement Resources Associated
with the Regulatory Options Set Forth in the
Baby Rattle Briefing Package

The following is a brief discussion of the compliance and enforcement resource needs associated with each of the options presented in the briefing package. We have projected the investigatory, sample analysis and compliance litigation resources that would be necessary to implement each option. However, no projection of the regulatory development resource expenditures required to implement the options has been attempted.

1. Product-by-Product Ban Under FHSA.

There are two alternatives under this option. The first alternative is to immediately ban the rattles that have been involved in a fatal or potentially fatal incident and follow-up that action with the subsequent ban of other identical rattles as identified. The second alternative is to delay the ban of any rattles until as many of the identical rattles as possible have been identified.

The compliance and enforcement resources required for these two alternatives is essentially the same and we anticipate no significant enforcement problems in that the name of the responsible firm is usually displayed on the rattle package and the rattles in question can be identified relatively easy by size and shape.

If the first alternative is selected, each manufacturer and/or importer of the banned rattles will be immediately inspected to determine their plans for repurchase and to obtain a list of their consignees so that we may effectively monitor the repurchase. This initial effort including the monitoring of repurchase will require a projected 850 manhours.^{1/} (120 MH for initial inspection and sample collection and 730 MH to monitor repurchase). No laboratory resources will be expended as sample analysis will not be necessary.

^{1/} The projected manhours cited throughout the memorandum are Field and/or headquarters professional non-supervisory time.

As a follow-up to this effort, all other firms known to be involved in the manufacture and/or import of rattles identical or similar to the previously banned rattles will be inspected. BEA has identified 85 manufacturers and/or importers of rattles; however, based upon recent telephone inquiries and a limited retail surveillance effort, we believe that only 20 to 30 of these firms are involved in the manufacture and/or import of the rattles in question and that these 20 to 30 firms represent over 80% of the market. The initial investigatory efforts covering these 20 to 30 firms, including inspection, sample collection and sample analyses, will require a projected 700 manhours. The exact number of rattles that are identical or similar to the rattles involved in a fatal or potentially fatal incident and therefore likely to be banned is currently unknown. However, we believe they number between 50 and 200 different types or models of rattles produced by these 20 to 30 firms. The subsequent effort to monitor the repurchase of each of these rattles if banned will require 100 to 500 manhours per banned rattle, depending upon the number of consignees reported by each firm.

We would anticipate that many firms will voluntarily discontinue selling questionable rattles following the ban of similar or identical rattles. However, the repurchase of rattles previously sold would be mandatory unless the individual product ban is prospective.

Case development and litigation resources would not be necessary unless a manufacturer, importer, distributor and/or retailer continues to sell a rattle after it has been banned or refuses to repurchase the banned rattle.

The total projected compliance and enforcement manhours for this alternative is 6500.

If the second alternative is selected, the resource expenditures will be essentially the same, unless the ultimate decision is not to ban any of the rattles in question. In that event the resource expenditures would be limited to the projected 700 manhours for the initial investigatory efforts covering the 20 to 30 known firms, plus the 120 manhours for the same coverage of the manufacturers and/or importers of the rattles involved in a fatal or potentially fatal incident.

2. FHSA Product Specific Rattle Regulation.

Again, we would anticipate no significant enforcement problems and the compliance and enforcement efforts would be similar to the effort described above. The regulation would however probably set forth size and shape specifications which would be applicable to all rattles, including but not limited to the rattles covered by the first option. Therefore, we would anticipate inspecting all 85 manufacturers and/or importers of rattles. Rattle samples would be collected for compliance testing and the repurchase of banned rattles would be monitored. Due to the time required to develop and promulgate a product specific regulation and the usual delayed effective date, we would anticipate a relatively high level of industry compliance. Therefore, the resource expenditures associated with sample analysis and monitoring the repurchase of banned products would be reduced. However, case development and litigation resources may be necessary.

The total projected compliance and enforcement manhours for this option is 5900.

3. Action Under the CPSA.

There are two alternatives under this option. One alternative is to initiate proceedings under Section 7 of the Act leading to a consumer product safety standard for all rattles. The second alternative is to initiate action under Section 15 of the Act leading to an order or orders applicable to particular rattles that are found to be "substantial product hazards".

If the first alternative is selected, the compliance and enforcement effort would be similar to the efforts previously discussed under the FHSA Product Specific Rattle Regulation. However, the product certification and labeling requirements mandated under Section 14 of the Act should reduce the need for extensive sample collection and analysis by the Commission. In addition, failure to comply with the standard would not lead to a mandatory repurchase, as appropriate corrective action would be determined on a case by case basis depending upon the extent of the violation. While this requires less resources to enforce, it may not separate hazardous goods from the consumer as effectively as mandatory repurchase.

The total projected compliance and enforcement manhours for this alternative is approximately 3700.

If the second alternative is selected, the compliance and enforcement effort would be similar to those previously discussed under the FHSA Product-by-Product Ban. Although, repurchase would not be mandatory, we would anticipate requesting a voluntary recall as part of the corrective action program; therefore, extensive field time would be necessary to monitor the recall. In addition, case development and litigation resources may be necessary if the requested recall is not initiated voluntarily and an Order as provided under Section 15(c) or (d) of the Act is pursued.

The total projected compliance and enforcement manhours for this alternative is 7000.

4. Voluntary Industry Standard

Compliance and enforcement resources utilized to monitor the marketplace would be minimal. However, the level of industry compliance is likely to be less than with a mandatory safety rule.

UNITED STATES GOVERNMENT

Memorandum

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

TO : William Menza, TAD, OSCA

DATE: 19 JAN 1977

FROM : Liz Jones, BCMI
Harry Garber, BCM

SUBJECT: Proposed Ban of Specific Baby Rattles

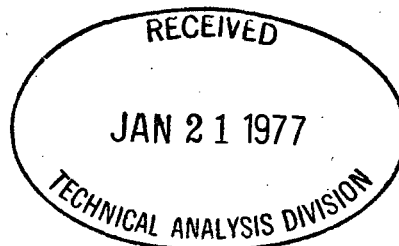
We have reviewed the draft of the proposed ban of six specific baby rattles.

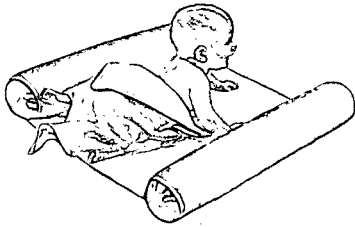
We are concerned that the ban is proposed as an amendment to 16 CFR 1500.18 which is a regulation of general application. We suggest that an opinion be obtained from the Office of the General Counsel as to whether a ban of specific products should be codified as part of regulations of general application.

Listing of these specific products could in effect create another "Banned Product List" with all the attendant problems of the original list. For example, if the products should be redesigned and lawfully marketed they would nevertheless be listed in the Code of Federal Regulations as banned. A Federal Register Publication to inform the public of the ban would be appropriate but unless OGC advises that codification in CFR is legally required we believe that consideration should be given to the elimination of the CFR codification in the proposed banning notice.

We also suggest that some further specific description of the rattles proposed to be banned would be desirable for the purpose of more adequately identifying the product for enforcement purposes and also to relate the products to the injury data described in the notice. OGC comments on the adequacy of the descriptions would be desirable.

cc: Marvin Everhart, LDD, OSCA





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PLAKIE TOYS INC.

P. O. BOX 3386 • YOUNGSTOWN, OHIO 44512 • 216/788-4121

February 7, 1977

Dec/CB
TAB-I

CONSUMER PRODUCT
SAFETY COMMISSION

FEB 11 10 25 AM '77

RECEIVED
OFFICE OF THE SECRETARY

Ms. Sadye Dunn, Secretary
Consumer Product Safety Commission
1111 18th St.
Washington, DC 20207

Dear Ms. Dunn:

Through our industry association, Toy Manufacturers of America, Inc. we have learned that a rattle banning proposal is soon to be submitted to the commissioners by the CPSC staff. Because we are apparently one of the companies to be identified in the banning proposal, we strongly believe that the commissioners should consider our thoughts and position in the process of reaching their decision.

At this moment, we understand the staff briefing package will include a recommendation for a product-by-product banning, by company name, product description and number. Such action is unquestionably discriminatory against the four companies to be named! The fact is that there are many other manufacturers and importers of identical or similarly designed products to those identified in the banning proposal. Most, if not all, of these companies have already been identified by the CPSC staff and if a banning order is determined to be in the public interest, all manufacturers and importers should be treated equally.

We have been told that the product-by-product banning proposal has been selected as the quickest means to remove a hazardous product from the market. We would like it to be known that all of the proposed banned products in question meet or exceed current safety testing guidelines and voluntary industry standards. The important criteria for judging small parts, at least prior to this proposal, has been the truncated right hand cylinder. All of the items in question easily pass this test.

As a manufacturer, a member of TMA, and a concerned parent, I can assure you that the toy manufacturers and importers who survived the bannings of the early 1970's are socially and morally responsible concerns. Most of us have experienced a banning and know the dangers and disasters associated with it. The products we are producing and have produced are safe by all previous known standards, guidelines and testing procedures. We do appreciate the need for regulatory action when a new hazard is

Ms. Sadye Dunn, Secretary

February 7, 1977

Page 2

discovered in order to properly protect the public. But it most certainly should include all products of a similar or identical design on a generic basis or as an alternative, a product-by-product ban identifying all companies producing like items as recently compiled by the CPSC staff.

Finally, we understand that the items and companies named in the proposed banning were products associated with injuries. Most products in the rattle field are only identified by company name on the packaging which is quickly discarded after purchase. This raises a serious question as to the correct identity of the products associated with the injuries, particularly since so many companies produce identical items. What a gross injustice it would be to identify the wrong company when it is possible to identify generically all products and/or companies.

We sincerely appreciate your consideration of our thoughts and position regarding this matter.

Sincerely,

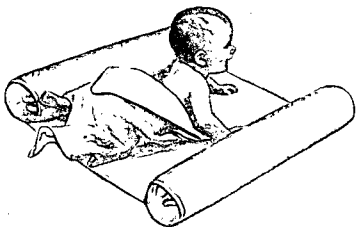
PLAKIE, INC.



Dean R. Hoover
President

cjt

CC Mr. William Menza, Office of Standards, Coordination and Appraisal,
Consumer Product Safety Commission
Aaron Locker, Esq., Toy Manufacturers of America



Plakie®

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PLAKIE TOYS INC.

P. O. BOX 3386 • YOUNGSTOWN, OHIO 44512 • 216/788-4021

February 9, 1977

Mr. William Menza
Office of Standards, Coordination and Appraisal
Consumer Product Safety Commission
818 B
Washington, DC 20207

Dear Mr. Menza:

Attached is a copy of my letter to the Consumer Product Safety Commission regarding our position on the forthcoming rattle banning proposal.

We are totally opposed to a product-by-product banning order limiting such ban to a few named companies. Not only does this discriminatory action allow our competitors to continue selling identically designed products but they do so without the tarnished image that a banning order causes.

All of the proposed banned items meet voluntary industry standards as well as known government guidelines and testing procedures, including the truncated right hand cylinder. Furthermore, we question the correct identity of the injury-associated items with the actual manufacturer due to the similarity of the items on the market.

We are anxious to have our position known by the commissioners and request that you include a copy of both this letter and the attached CPSC letter in your briefing package.

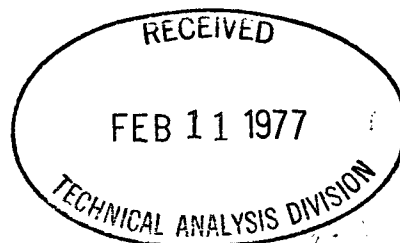
Most sincerely,

PLAKIE, INC.

Dean R. Hoover
President

cjt

CC Aaron Locker, Esq., TMA Counsel



February 7, 1977

Ms. Sadye Dunn, Secretary
Consumer Product Safety Commission
1111 18th St.
Washington, DC 20207

Dear Ms. Dunn:

Through our industry association, Toy Manufacturers of America, Inc. we have learned that a rattle banning proposal is soon to be submitted to the commissioners by the CPSC staff. Because we are apparently one of the companies to be identified in the banning proposal, we strongly believe that the commissioners should consider our thoughts and position in the process of reaching their decision.

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Ms. Sadye Dunn, Secretary
February 7, 1977
Page 2

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Finally, we understand that the items and companies named in the proposed banning were products associated with injuries. Most products in the rattle field are only identified by company name on the packaging which is quickly discarded after purchase. This raises a serious question as to the correct identity of the products associated with the injuries, particularly since so many companies produce identical items. What a gross injustice it would be to identify the wrong company when it is possible to identify generically all products and/or companies.

We sincerely appreciate your consideration of our thoughts and position regarding this matter.

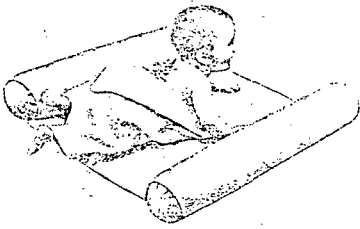
Sincerely,

PLAKIE, INC.

Dean R. Hoover
President

cjt

CC Mr. William Menza, Office of Standards, Coordination and Appraisal,
Consumer Product Safety Commission
Aaron Locker, Esq., Toy Manufacturers of America



B. Menze
Plakie.

SINCE 1938

PLAKIE TOYS INC.

P.O. BOX 3386 • YOUNGSTOWN, OHIO 44512 • 216/788-4021

March 8, 1977

Mrs. Elaine Besson
Assistant to Executive Director
Consumer Product Safety Commission/OEX
5401 Westbard Avenue
Bethesda, MD 20207

Dear Mrs. Besson:

The opportunity to meet with you and other CPSC staff members in Washington last Wednesday was most appreciated. Our telephone discussion on Friday also served to clarify each of our positions with regard to the staff's current work in the area of toy safety.

There is no doubt that our joint common goal is to insure that only safe toys are available for infants. The positions expressed by both the Toy Manufacturers of America member companies and your staff clearly indicated complete agreement and full cooperation on this matter.

Our disagreement comes, however, in the position the staff has taken regarding the recently identified "impaction" hazard. The fact that the CPSC recognizes this alleged problem obligates it to take the appropriate action commensurate with the degree of risk involved in order to protect the safety and welfare of the general public. Knowing the number of actual injuries and fatalities as a result of impaction incidents and weighing this against the estimated play hours of use as provided by TMA, it should not be considered an "imminent" or "substantial" hazard.

If the CPSC believes the hazard is serious enough to require a banning action, then a generic ban of all products, both known and medically suspected to cause impactions, should be included in the ban. To ban only five items produced by four manufacturers when the staff is aware of scores of other manufacturers and importers distributing the identical and similar styles, would be an arbitrary and discriminatory action.

If the staff could present one common element linking the five items proposed for banning, such as each being involved in a known death, it would be a more objective determination. At our meeting I learned that two of the five items caused fatalities; however, the two products allegedly manufactured by Plakie were each involved in one injury incidence, no fatalities. Considering the millions of such products placed on the market each year, the staff should have on file numerous injury reports on

Mrs. Elaine Besson

March 8, 1977

Page 2

identical or similarly shaped products by other manufacturers and importers in order to consider it a serious hazard. I don't by any means belittle one accident but if one accident is sufficient to propose a ban and retroactive recall, isn't the same risk present for all other items of the same shape and size not presently being considered for banning?

In matters involving the safety and health of infants and where it is known that so many companies produce the same items, it would be totally unfair to offer a competitive advantage to many at the expense of a few. But should the staff continue to feel that a banning action of a limited number of products is desirable, then it becomes an essential responsibility to correctly identify the manufacturer and/or importer of such products. As of this date, I have been told that the actual samples involved in the incidents are unable to be located or not available. As an alleged manufacturer of such items, I should have the opportunity to examine the actual injury related item since our company's reputation and employees' welfare is at stake as well as the financial implications inherent with a banning action.

The specific cases allegedly involving Plakie products have left me with a number of unanswered questions. First, in the case of the clothes pin rattle (CPSC No. 760 614 BEP 7002), inspector Bernard Duer in his narrative states in paragraph 1 of page 3 "The product was pulled out intact and was subsequently sampled under C/R #C-805-9844". Further in his narrative, he states that three Plakie baby rattles were purchased in the local market and that the "Three units were collected under sample #C-805-9845". It appears that the sample procedure was normal and the samples should, therefore, be available for inspection in the CPSC offices. In our telephone conversation last Friday, you stated that a TWX from inspector Duer had just been placed on your desk stating that he certified that the photos attached to his report are of the actual sample involved in the incident. I do not agree that his statement conclusively identifies it as a Plakie product since other companies, both domestic and foreign, produce the same product with the same decoration. Copying successful products is unfortunately a common practice by many companies in the infant toy business and Asian manufacturers are particularly skillful at duplications. Incidentally, I would appreciate receiving a photocopy of inspector Duer's TWX to complete my records of your file report.

Further to inspector Duer's narrative on page 3, it was stated that "The product was received from a friend as a decoration on a baby sweater gift set, given at a baby shower a week or so after the baby was born. The rattle was given without its original packaging and it could not be

Mrs. Elaine Lesson

March 8, 1977

Page 3

remembered which friend gave the gift. Thus at the time of the accident, the manufacturer of the product and where it was purchased was unknown." Since the name of the friend who gave the gift could not be remembered, how can it be assumed that it came from The Boston Store and not another retail outlet that might have carried an inferior copy?

The over-riding question remains. By banning only Plakie's clothes pin while other similar and identical products are permitted to remain on the market, how can this meet the intended purpose of protecting the public from the newly identified "impaction" hazard?

The diaper pin incident (CPSC No. 760 309 BEP 7001) is somewhat different in that the injury report states that the alleged Plakie product broke on impact. As in the clothes pin incident, the actual product associated with the injury has not been currently available for inspection. On page 2 of the report, it was stated under the Product Identification section "A positive product identification of the actual product could not be made. The actual product that contributed to the accident on May 16, 1975 was sent to the Washington office." Once again, Plakie stands accused of producing a product alleged to have caused an injury.

As stated in our meeting, this product, like all Plakie products, is tested in-house to exceed the minimum testing standards set forth in PS 72-76. Our products liability insurance carriers can verify that we have a spotless record for as long as I have been associated with the business which goes back to 1961. These facts and others cause us to seriously question if the injury-associated product was a Plakie and if so, was it produced in straight high impact styrene as we have been doing since 1971?

The banning of only five products produced by four companies does not serve the interest of the general public but regulated on a generic basis, the general public would be better served.

Although we disagree on the method of controlling the impaction hazard, I commend you and your staff for your efforts to protect infants from unreasonable risks of injury and will fully support and cooperate with you to that end. If the alleged impaction risk is as great or greater than the CPSC has identified, then let's remove all products of a common size that could produce such an injury.

Mrs. Elaine .sson

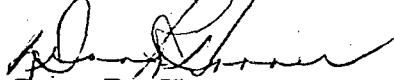
March 8, 1977

Page 4

Thank you for taking time to consider my comments and I would appreciate it if you would include this letter with your briefing package to the commissioners.

Respectfully,

PLAKIE, INC.



Dean R. Hoover

President

cjt

CC Mr. Aaron Locker, TMA Counsel



180 W. WESTFIELD AVENUE, ROSELLE PARK, N.J. 07204
TELEPHONE: 201-245-8700



SALES OFFICE: 200 5th AVENUE, NEW YORK, N.Y. 10010
TELEPHONE: 212-675-4633

February 11, 1977

Mr. Bill Menza
Office of Standards Coordination
c/o Consumer Product Safety Commission
818 B Street
Washington, D. C. 20207

Dear Mr. Menza:

I have written quite a lengthy letter outlining my thoughts with reference to possible action on the part of your agency in connection with layette-type rattles.

It is requested that this letter, in its entirety, be made a part, or included, in your Briefing Package to the Commissioners.

Respectfully yours,

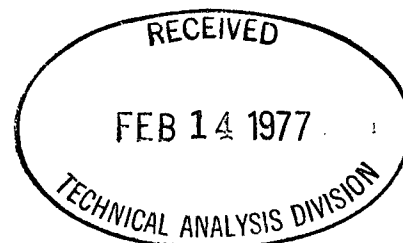
CHILDHOOD INTERESTS, INC.

Gilbert R. Freeman
President

GRF:MB

Encl.

cc: Ms. Sadye Dunn
Secy. Consumer Product Safety Commission
1111 18th Street
Washington, D. C. 20207
Room 202





180 W. WESTFIELD AVENUE, ROSELLE PARK, N.J. 07204
TELEPHONE: 201-245-8700

SALES OFFICE: 200 5th AVENUE, NEW YORK, N.Y. 10010
TELEPHONE: 212-675-4633

February 11, 1977

Mr. Bill Menza
Office of Standards Coordination
c/o Consumer Product Safety Commission
818 B Street
Washington, D. C. 20207

Dear Mr. Menza:

It has come to my attention that your office is preparing a Briefing Package for the Commissioners in which you possibly will recommend the banning of a telephone rattle, which currently is being sold by this company, as well as the possible demand for a recall of those which we had shipped.

I should like to point out that these rattles have been sold to the public for many years and that these rattles fully conform to the voluntary standards as issued by the U. S. Department of Commerce, Bureau of Standards. In other words, what I am saying is that we have been producing these rattles, and all others, in accordance with every existing standard regulation as provided by the toy industry or by an agency of the Federal Government.

It is also noted that no information is available, including yours, as to what would be acceptable for us to manufacture.

I respectfully take issue with the contention that these layette-type rattles constitute an imminent hazard. When one looks at the number of units sold, it is quite obvious that the odds are over six million to one against an accident of any sort, and when this is multiplied by the number of playhours involved it is even more obvious that there are many, many other products which deserve your more immediate attention.

I also respectfully take exception to a banning procedure, if it is still insisted upon, whereby it would be done on an item by item and company by company basis. By following that procedure you are arbitrarily granting a competitive advantage to dozens of other companies who either



180 W. WESTFIELD AVENUE, ROSELLE PARK, N.J. 07204
TELEPHONE: 201-245-8700

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TELEPHONE: 212-675-4633

Mr. Bill Menza

-2-

February 11, 1977

manufacture or distribute exactly the same item and whom you have failed to name for one reason or another. If such a bann is insisted upon, it absolutely must be a generic bann whereby you say any and all manufacturers or distributors of this product or that product are automatically banned. That is the only way the matter can be handled with legitimate justice and equity.

If your commission sees fit to proceeds with a bann rather than instructing the industry as to what it should start making, then there is absolutely no justice or equity in insisting upon a recall. These rattles obviously are not an imminent hazard when one looks at the basic statistics. These rattles also have been produced in accordance with the guidelines furnished by a supposedly reputable agency of our government, namely, the Bureau of Standards, Department of Commerce. It is inconceivable to me when a manufacturer has lived up to its full obligation and conforms with every piece of existing standard, that you now would consider punishing him and make him suffer considerable loss because of a possible change of mind as to what the standards should be.

As a responsible citizen and as the manufacturer of the famous "Cradle Gym" which is so well known, I have absolutely no objection or argument with the concept of your saying to the industry that you have suddenly developed new information which would require a change in what we are currently doing. If this information is valid and holds up, then the entire industry will have to change in accordance with your new definitive specifications. This will involve tremendous costs and will involve the scrapping of current molds and the making of new molds. If given a reasonable length of time to accomplish this, then it is one of the things we will do, even though it will hurt, but at least; tell us what we should do and give us a reasonable time in which to do so.

On the basis of the information which had been given to me, we had to withdraw the telephone rattle in our line and have not shipped one piece since November 1976. It is not the one item--the telephone rattle--



180 W. WESTFIELD AVENUE, ROSELLE PARK, N.J. 07204
TELEPHONE: 201-245-8700

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TELEPHONE: 212-675-4633

Mr. Bill Menza

-3-

February 11, 1977

which has been so disturbing, rather it is the overall concept of a small manufacturer who is trying his level best to go "By the book" and then finds himself being punished severely because of a sudden change on the part of the government.

I will be happy to place myself at your disposal to discuss this matter further if you feel it will be of any use.

Respectfully yours,

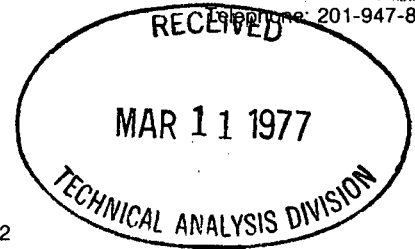
CHILDHOOD INTERESTS, INC.

Gilbert R. Freeman
President

GRF:MB



SANITOIY, INC. • EXECUTIVE OFFICES: 140 SYLVAN AVENUE, P.O. BOX 1563
ENGLEWOOD CLIFFS, NEW JERSEY 07632
New York Showroom: 200 Fifth Avenue - Room 552



March 7, 1977

Mr. William Menza
U. S. Consumer Product Safety Commission
Washington, D. C. 20207

Dear Mr. Menza:

It was good meeting you and the other members of your staff during our "rattle" conference March 2. I came away from the session with a feeling of both concern and confidence.

First my concern. My concern is based upon a feeling that the staff's efforts to quickly assemble data for the briefing package may not be balanced by an equal effort to thoroughly verify the accuracy, quality or significance of the data gathered.

For example, you are now aware that a telephone rattle, involved in an accident, was improperly attributed to Sanitoy in your files and in the draft Federal Register notice.

Over a period of weeks I pointed out this inaccuracy to the CPSC field men in my office. I discussed it by telephone with George Rutherford. I set forth our position in a letter to Aaron Locker - who passed it on. Ultimately these efforts prevailed. Your staff did re-examine its data. The records were corrected and our name was dropped in connection with that matter. It is to the credit of you and your staff that this review was made, but it is of grave concern to us that an inaccurate identification was made in the first place, was placed on record and would have "gone public" if we had not taken a vigorous initiative.

As another example, we have an incident involving a Sanitoy clothespin rattle. At our meeting on March 2, I asked George Rutherford for the complete file and sample. At the end of the meeting George provided me with his data. I have now had an opportunity to review it. Frankly, I am appalled! The total file consists of a photo copy of a single letter from one consumer which she wrote to us last summer. The incident described was non-fatal and non-injury producing.

(continued)

3/7/77

The letter was accompanied by a CPSC Form 175 which provides no additional information. Thats it. Nothing more.

Should a single unsubstantiated letter of that kind form a sound and sufficient basis for publishing a banning notice by manufacturers name and product description? Clearly it should not! Yet that is exactly what your draft briefing package proposes.

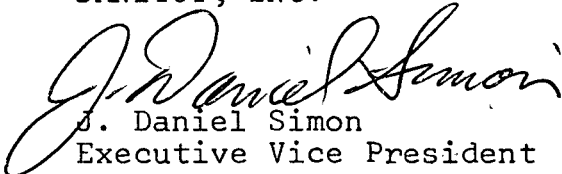
We believe such a letter, together with all other available complaint information, should properly become part of a pool of background data. As such it can properly be used as a basis for framing a generic regulation or possible industry-wide banning action - if such is deemed necessary.

In view of the above considerations in this case, I respectfully ask that you delete from your recommendations the publishing of a Sanitoy/Clothespin Rattle ban as such.

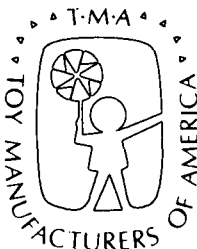
In my opening paragraph I referred to both "concern" and "confidence". I have expressed our concern. - Our confidence derives from the open and candid manner in which you and your colleagues discussed the situation with us. We recognize your obligation to discharge your duties. We sense that you intend to do so in a fair and responsible way.

Very truly yours,

SANITOIY, INC.


J. Daniel Simon
Executive Vice President

JDS:ek



March 8, 1977

Mr. William Menza
Consumer Product Safety Commission
5401 Westband Avenue
Bethesda, MD, 20016

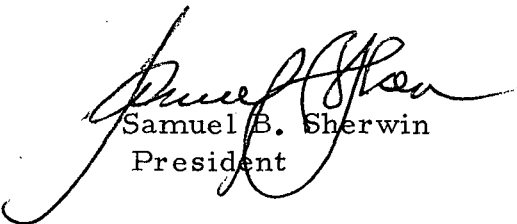
Dear Bill:

As you inquired during our meeting of March 2nd, we estimate that 12 to 15 million baby rattles are sold per annum. This is the best market estimate that we can make.

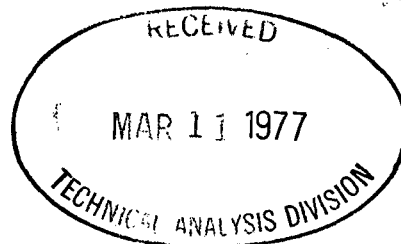
It is of course, impossible to determine the amount of time that infants play with rattles, which would be needed in order to make a judgement on exposure hours.

Sincerely,

SBS/mmm


Samuel B. Sherwin
President

cc: Elaine Besson, CPSC



FROM: JESSE L. ROTMAN (New York Office)

3-11-77

FOR: TOY MANUFACTURERS OF AMERICA
200 Fifth Avenue
New York, NY 10010

FOR RELEASE ON RECEIPT

TOY MANUFACTURERS' ASSOCIATION PROPOSES
MODIFIED BABY RATTLE SAFETY STANDARD

NEW YORK, March 10 -- Development of a modified safety standard for certain baby rattles was proposed today by Toy Manufacturers of America (TMA), the industry association.

The trade group acted after evaluating data from the U.S. Consumer Product Safety Commission's (CPSC) national injury-surveillance system which contained reports of a new type of potential hazard to infants involving baby rattles. The data showed that three fatalities and six other nonfatal incidents may have involved small layette-type baby rattles typically shaped like telephone handsets, barbells or clothespins.

The last reported fatality associated with these rattles occurred in 1975, according to the recently released CPSC data. It is believed the rattles became lodged in children's throats after they fell or rolled over while holding the rattles in their mouths.

David Miller, chairman of the toy association, said manufacturers voluntarily stopped shipments of these rattles late last year immediately after receiving the CPSC information. At the same time, an industry task force was convened to consider

modifying the toy industry's existing voluntary safety standard to eliminate the chance of a recurrence of these reported incidents.

"We have today decided that a modification of our baby rattle safety standard is needed," Miller stated. "When the standard was first drafted six years ago, no one could have anticipated the unusual nature of these incidents."

Miller said that all of the rattles in question were produced in compliance with the industry standard which contains comprehensive design and testing specifications for playthings, including specific criteria for baby rattles.

The standard, titled PS72-76, was published in September, 1976 by the U.S. Department of Commerce after certification by the National Bureau of Standards. Developed with CPSC assistance, the standard was approved by such organizations as Consumers Union and the National Safety Council.

Miller said the toy industry would again work closely with the CPSC and the National Bureau of Standards to draft the modified baby rattle safety code.

The TWA chairman pointed out that these reported incidents involving a particular baby rattle design constituted a very small percentage of the millions of baby rattles that are purchased and used with complete safety every year.

"When selecting playthings for children, especially for infants under 18 months, consumers should remember to choose toys appropriate for a child's age and abilities," Miller advised. "Follow manufacturers' age-grading labels on toy packaging and supervise children's play with toys to teach rules of safe play."

Miller heads the national industry association whose 240 manufacturer-members account for nearly 85 percent of the industry's \$3.1 billion annual sales of toys, games, dolls and other playthings.