



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

MINUTES OF COMMISSION MEETING  
March 18, 1992  
5401 Westbard Avenue  
Bethesda, Maryland

The March 18, 1992, meeting of the U.S. Consumer Product Safety Commission was convened in open session by Chairman Jacqueline Jones-Smith. Commissioners Carol G. Dawson and Mary Sheila Gall were present.

Agenda Matter.

Choking Hazards.

The Commission considered options for action with regard to four rulemaking proceedings initiated by the Commission under the Federal Hazardous Substances Act to address choking hazards associated with 1) balloons, 2) marbles, 3) small balls, and 4) toys with small parts intended for children three years of age and older. These proceedings began by publication of advance notices of proposed rulemaking (ANPRs) in the Federal Register of June 26, 1990. At Commission meetings on January 15, January 22, January 29, and February 7, 1992, the Commission was briefed by the staff on the four proceedings, including analysis of the comments received on the ANPRs, and on options for Commission action, including the staff's recommendation that the proceedings continue with publication of notices of proposed rulemaking. (Ref: Staff briefing package dated December 30, 1991.) In response to questions raised by the Commission at the briefings, the staff provided additional information in memoranda dated February 5, February 26, and March 10, 1992.

At today's meeting, following introductory comments by Chairman Jones-Smith concerning the issues before the Commission and the legal criteria for Commission decision-making in these proceedings, (copy attached), Chairman Jones-Smith offered the motion with respect to the rulemaking proceeding for balloons that the staff be directed to prepare a notice of proposed rulemaking containing the labeling requirements recommended in their briefing materials for packages of balloons. By a vote of 1-2, with Chairman Jones-Smith voting in favor and Commissioners Dawson and Gall voting against, this motion was defeated.

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Commissioner Dawson then moved that the Commission terminate the rulemaking proceeding for balloons, withdraw the corresponding ANPR published on June 26, 1990, and direct the staff to prepare a Federal Register notice announcing the Commission's decision. The motion was adopted by a vote of 2-0-1, with Commissioners Dawson and Gall voting in favor and Chairman Jones-Smith abstaining.

Further with respect to balloons, Commissioner Gall moved that the staff be directed to continue efforts with ASTM on improving the voluntary standard for balloons. The motion was adopted by a vote of 2-0-1, with Commissioner Gall and Chairman Jones-Smith voting in favor and Commissioner Dawson abstaining.

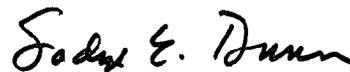
On separate motions offered by Chairman Jones-Smith with respect to the rulemaking proceedings for marbles, small balls, and toys with small parts, the Commission decided by unanimous vote (3-0) in each case to terminate the rulemaking proceeding, withdraw the corresponding ANPR published on June 26, 1990, and direct the staff to prepare a Federal Register notice announcing the Commission's decision.

The staff was directed to submit to the Commission by March 27, 1992, a schedule for completion of the Federal Register notices required by the Commission's decisions.

Separate statements concerning the choking hazards matter have been filed by Chairman Jones-Smith and Commissioners Dawson and Gall, copies of which are attached.

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

For the Commission:



Sadye E. Dunn, Secretary

Attachments

OPENING STATEMENT BY THE CHAIRMAN ON CHOKING HAZARDS

MARCH 18, 1992

Today, the Commission will vote on whether the staff should proceed with rulemaking -- and prepare formal Notices of Proposed Rulemaking -- for certain alleged choking hazards. The staff has conducted four separate briefings on four distinct regulatory proposals involving: balloons, marbles, small balls and toys with small parts intended for children between the ages of three to five. In so doing, the staff has recommended that the Commission go forward with rulemaking in each of these areas; but, has also presented the Commission with several additional options.

Let me say at the outset, that this decision-making process has been an extremely difficult one. The cautious and deliberate nature of our proceedings, to date, clearly illustrates the seriousness with which the Commission regards its responsibilities in this matter -- just as they underscore the delicacy of the questions before us. After all, we are dealing with small children.

But, can this Commission, or any government body, simply eliminate such a problem through regulation? Unfortunately, the answer is no! We must recognize that children and infants choke on food -- like hot dogs and pop corn -- on small pieces of hardware -- like screws and bolts -- on coins and paper clips and on just about any small object -- including toys and balloons -- lying around the house, or the streets, or the playgrounds. It's a tragic reality and nothing we do or say can console those whose children have -- and will -- die.

Nonetheless, there is some consolation in the fact that this Commission, as a direct consequence of the small parts' regulations it promulgated in 1979, has achieved some measure of success in addressing choking incidents. We all agree on this point and it is a source of tremendous pride at the Commission.

Still, choking incidents continue to occur. According to information collected by the Commission, between January 1980 and July 1991, there were a total of 284 choking deaths of children under the age of 10. Of these, 186 incidents -- about 16 annually -- involved children's products and toys, most of which are subject to the proposals before us today. This Commission must be particularly sensitive to toy safety. Toys are unique products, since they are marketed directly for the ultimate use of infants and children.

Thus, numbers like these simply cannot be ignored. And they most certainly have not been ignored by this Commission, which has

been diligently re-examining this issue since 1988. Initially, as a result of a Petition, the Commission reviewed and rejected the propriety of a general revision of its small parts' regulations. It concluded that the small parts' test cylinder has functioned successfully and should not be modified.

Since 1990, the Commission has focused its attention on those specific children's products that have been involved in the preponderance of identified choking incidents. On June 26, 1990, four separate ANPR's were published in the Federal Register addressing these specific hazards. Today, the Commission will vote on whether it should proceed further on these proposals.

The fundamental issues before the Commission today are:

- 1) How can the number of choking incidents most effectively be reduced?, and
- 2) Whether there is substantial evidence before the Commission, on the record, that satisfies the statutory requirements governing its ability to proceed with a rulemaking?

The first question is complicated by the difficulty in evaluating the impact of labeling in changing human behavior and actually leading to a predictable reduction in the number of injuries and deaths. Addressing this matter is one critical element of the multifaceted inquiry mandated under the law.

Naturally, on any given issue, individual Commissioners may reach differing conclusions. There is no dispute, however, as to what criteria the Commission must weigh and analyze pursuant to its statutory obligations. In this context, the Commission believes that it would be instructive to clarify the specific factors it must evaluate in fulfilling these requirements.

In brief, the statutes, as interpreted by the courts, require that the Commission first resolve two fundamental issues:

1. Does the hazard in question present an "unreasonable risk of personal injury or illness"?
2. And, if so, is the proposed remedy "reasonably necessary" to justify the promulgation of the specific regulations under consideration?

As interpreted by the courts, each of these basic questions, while somewhat overlapping, contains a number of criteria which the Commission must weigh in order to reach a final decision. Thus, for it to find that there is an "unreasonable risk of injury", the Commission first must balance three factors:

1. The **"severity"** of the injury that may result from the product's use;
2. The **"likelihood"** that such injuries will occur; that is, its relative frequency of occurrence, and
3. The impact, or the **"harm"** such a regulation will exact upon manufacturers and consumers; that is, a risk/utility analysis.

The answers to these questions are rarely self-evident. Thus, the courts distinguish between what may be a reasonable, as opposed to an unreasonable risk. A critical factor here is the public's **awareness** of the risk. A sharp knife, for example, represents a reasonable risk, since consumers are generally aware of the nature of the risk involved. Consequently, statutory interpretation requires that more weight be given to regulating a hidden hazard.

Once the Commission determines that a product constitutes an unreasonable risk, it must still determine whether the particular rule under consideration is **"reasonably necessary"** to reduce or eliminate this unreasonable risk. Again, this requires a three-step analysis. Here, the courts' have indicated that the Commission, "has a duty to take a hard look" at and weigh:

- 1) The **"nature and severity"** of the risk;
- 2) The **"potential the [rule] has for reducing the severity or frequency of the injury"**, and
- 3) The effect the rule would have on the **"utility, cost or availability of the product"**; a cost/benefits analysis.

Such an analysis is not discretionary upon the Commission; rather, it is mandatory. Caselaw has also indicated how some of these factors ought to be evaluated, although it is unnecessary to elaborate upon this here.

It should be noted that, in 1981, Congress amended the Consumer Product Safety Act, to specifically require that the Commission determine that the anticipated benefits of a rule bear a **"reasonable relationship"** to its expected costs. This, of course, constitutes only one aspect of the Commission's analysis. It should also be noted that the Commission must terminate a rulemaking proceeding and defer to an existing voluntary standard under certain express conditions.

As is apparent, members of this Commission may not rely upon subjective or speculative reasoning in evaluating the propriety of issuing a rule. Sound considerations of public policy demand that such a determination be based upon objective evidence.

I can tell you that, personally, I have devoted many long hours in applying these factors to each of the proposals currently before us -- as I am certain has been the case with each of my colleagues. To repeat, this has not been an easy task.

Having established the legal criteria upon which this Commission is compelled to base its decision-making, we are now ready to proceed.

**Statement of  
Chairman Jacqueline Jones-Smith  
On Children's Choking Hazards**

**March 18, 1992**

On June 26, 1990, the Commission published, in the Federal Register, four related Advanced Notices of Proposed Rulemaking (ANPRs) addressing alleged choking hazards associated with toys and other children's articles. Specifically, these ANPRs dealt with balloons, marbles, small balls and toys with small parts intended for children between the ages of three to five. After having analyzed the extensive public commentary it received on these proposals, staff conducted four separate briefing sessions covering these respective issues.

In each instance, staff recommended that the Commission proceed further with specific rulemaking proposals. Each of these proposals recommended mandating certain labeling standards and, also, advocated aggressive information and educational campaigns. In addition, with respect to small balls, staff recommended that the Commission require a minimum diameter of 1.68 inches for all balls intended for children under the age of three.

Today, the Commission voted on these recommendations. The Commission declined to adopt any of these staff recommendations and voted to terminate each rulemaking proceeding. In the case of balloon's, however, the Commission affirmatively directed the staff to work with the appropriate ASTM committee to attempt to modify its current labeling standard.

I agreed with my colleagues in voting to terminate further rulemaking with respect to marbles, small balls and toys with small parts intended for children between three and five years of age and, ultimately, in directing staff to work with ASTM to modify its current balloon standard. I strongly disagreed with my colleagues, however, as to the propriety of proceeding with rulemaking on labeling standards for balloons. My reasoning in each instance is explained below.

When the Commission voted in March 1990 to publish these ANPRs, it directed staff to address the disproportionate number of choking incidents, among children, associated with certain toys and children's articles. The ANPR stage of the rulemaking process is, in essence, a preliminary fact-finding procedure. While this may acknowledge the existence of a possible hazard, it would be inaccurate to characterize the Commission, in issuing an ANPR, as serving notice to the public that a product in fact poses an "unreasonable risk of injury", or that it is "reasonably necessary" for it to issue rules. This would be premature, since such findings constitute the ultimate conclusions that the Commission must reach, after analyzing all the evidence, including comments

solicited from the public, in order to issue a final rule.

As noted in my opening statement, in order to make these crucial findings, the Commission must apply a rigorous and objective legal analysis, as prescribed by its governing statutes and interpretive caselaw. I have done so with respect to the proposals advanced in each ANPR.

### BALLOONS

While it may be premature to suggest that a final rule ought to be promulgated, I believe that a compelling case has been made by staff to require that this Commission go forward and publish a Notice of Proposed Rulemaking (NPR) with respect to certain mandatory labeling standards for latex balloons sold in packages. I believe that the risk associated with choking on balloons is fundamentally different from the other hazards before this Commission. What is the basis for this conclusion?

In order to issue a final rule under the Federal Hazardous Substances Act, the Commission must first determine that an article presents a "mechanical hazard" posing an "unreasonable risk of personal injury or illness". To do so it must weigh three factors: Severity, likelihood of occurrence and a risk/utility analysis.

Clearly, the risk posed by ingesting whole or fragments of balloons registers on the highest scale of "severity". According to information collected by the Commission, at least 76 children, between January 1980 and July 1991, choked to death on balloons.

Secondly, while the annual incidents of such deaths -- about 7 or 8 per year -- does not rise to epidemic proportions, it does, in my opinion, demonstrate a sufficiently high "likelihood" of occurrence; especially since each reported incident is a death. This number represents 40% of all known choking deaths of children under the age of ten, caused by children's products.

Caselaw on this point further bolsters my position. It establishes that even where the likelihood of injury is relatively low -- or even "remote" -- a mitigating factor is whether consumers are "unaware of either the severity, frequency, or ways of avoiding the risk." In this case, tests with so-called "focus groups", clearly established that parents are generally unaware of the severity, or even the existence, of the risk posed by young children -- both under and over the age of three -- putting balloons in their mouths.

The consequences of a child's swallowing a balloon are unforeseen to most adults. The unique, rubbery composition of balloons produces a choking hazard quite distinct from that of a typical "small part". When swallowed, it clings and conforms to

the child's esophagus, making it almost impossible to expel, even with assistance. Parents do not perceive this danger.

In other words, balloons represent a hidden hazard. Whatever deficiencies there may be in understanding or predicting the impact of labeling in effectively reducing risks, proper labeling, at a bare minimum, will certainly heighten people's awareness of the nature and existence of such a risk of injury or death.

Finally, there is no controversy at all about the relatively inexpensive and burdenless nature of package labeling; particularly since there already is a voluntary standard -- albeit, a legally inadequate one -- that simply needs to be modified.

Thus, on balance, through application of the requisite statutory formula, I must conclude that the possibility of small children choking on balloons represents an "unreasonable risk of personal injury."

The second question that must be answered by the Commission in finding that the staff's recommended balloon labeling standard ought to be issued as a final rule is: Whether that specific rule is "reasonably necessary" to effectively address the identified hazard? Here, the one additional issue that must be addressed is: Whether the rule has the "potential" for "reducing the severity or frequency of the injury"?

There need not be statistical certainty as to the impact of the rule; merely that it has the "potential" of mitigating the hazard. I believe that the hidden nature of this hazard governs the Commission's legal obligations in this instance. The caselaw is clear and supportive on this point.

The law instructs us that the Commission need not "cite empirical data in support of its finding that the particular requirement [is] likely to reduce the risk of injury" and, further that "it may exercise considerable discretion in determining an appropriate remedy". What we do need to demonstrate, I believe, in the case of such a hidden hazard, is that the rule under consideration provide a clearly effective means of heightening the awareness of the targeted audience as to the nature and severity of the hazard. This alone, logically, would create the "potential" for effectively reducing deaths and injuries.

Would the staff's specific proposal accomplish this? The evidence to date, including economic data on the marketing of balloons for consumer use, leads me to believe it would do so; however, it is this issue that I would have staff, and the public, further address upon issuing an NPR.

This then is the basis of my vote to adopt the staff's recommendation to go forward with publishing an NPR. I am

disappointed that my colleagues reached a contrary conclusion. Nonetheless, inasmuch as the Commission did vote to terminate this rulemaking proceeding, I subsequently cast my ballot in favor of directing the staff to work with ASTM to improve the existing voluntary standard.

I am certainly hopeful that this activity will produce a positive outcome. However, despite recent communications from industry indicating that it is willing to work with the staff on such modifications, to date, industry has not been especially cooperative.

I might note in this regard that the Commission is unanimous in its conclusion that the current ASTM standard is legally inadequate. Were it otherwise, we would have been required to defer to the voluntary standard and terminate our proceedings. This was not the case. I was personally displeased that the ASTM committee suspended work on improvements to the balloon labeling standard. Industry's sudden interest in re-opening this forum does not alter the fact that it would have been far more productive to have resolved this matter long ago.

Still, with a good faith effort on the part of industry, there is always the potential, both of producing an adequate labeling standard and agreeing to an extensive information and educational campaign. Success in these two areas could well work to increase consumer awareness of the hazard posed by balloons and to prompt consumers to take actions that would lead to a reduction in injuries and deaths.

#### MARBLES

I voted to terminate further rulemaking proceedings on alleged choking hazards associated with marbles. In my opinion, the evidence submitted to the Commission was legally insufficient to warrant any further proceedings on the staff's proposals. My reasoning is as follows.

First, the severity of the risk posed by swallowing or ingesting marbles is identical to that of balloons -- that is, death -- and, thus, must be given considerable weight. Here, however, the likelihood of a choking incident is both relatively remote and, unlike balloons, foreseeable.

The data shows less than one such incident annually. This does not mean that the problem should be dismissed. No, certainly not! Commission is obligated to investigate whether there are other, tempering factors that may act to elevate the nature of the underlying hazard.

According to information obtained from focus groups, parents

seem to recognize that marbles do present a choking hazard. Whereas parents will, on the one hand, readily give the youngest of children an inflated balloon, they understand that marbles are not intended for small children and that they pose a choking hazard. Thus, marbles do not present a hidden hazard. They pose the same generic risk as any other "small part".

In addition, the information before the Commission indicates multiple sources of marbles sold for consumer use, some of which would not be covered under the proposed rule. The incident data reveals that the sources of the marbles are generally unknown. We can only try to guess whether they were originally sold in a package - and thus subject to this regulatory proposal -- or were part of a game for children over three, or were decorator marbles? This is simply unclear.

Finally, the fact that labeling costs appear to be low does not, by itself, overcome these other legal shortcomings. On balance, the case that marbles represent an "unreasonable risk" of injury is very marginal at best.

Furthermore, the weight of the evidence does not support the "reasonable necessity" of promulgating this particular rule. In the case of marbles, the rule's potential for "reducing the severity or frequency of the injury" is less so than in the case of balloons. The distinction, again, being that this is not a hidden hazard and that, in general, parents and consumer's are generally aware of the risk.

Thus, I do not find that marbles pose any unique risk justifying a specific labeling standard. Whatever minimal risk may be present is more consistent with that of any other "small part". This issue is addressed in more depth below.

#### SMALL BALLS

I voted to deny the staff's recommendation to continue rulemaking on labeling small balls for reasons virtually identical to those discussed in the above analysis of marbles. To reiterate, while on the one hand, the potential risk is severe, on the other hand, incidents, in legal terms, are rather remote and consumers appear to be aware of the hazard. The focus groups recognized the associated "small parts" choking hazard. Thus, on balance, the evidence before the Commission is insufficient to satisfy the requirements mandated under our statutory scheme.

The supplementary issue of whether the Commission ought to increase the minimum diameter of balls, intended for the use of children under the age of three, to a size greater than the current small parts' test cylinder also falls short -- well short -- of

satisfying the statutory criteria.

The proposal before the Commission is that the current minimum small ball diameter restrictions be increased from 1.25 inches to 1.68 inches. However, this recommendation does not even pass the most cursory evidentiary examination. Commission data indicates that over a eleven year span there were forty small ball choking incidents of children under ten years of age. Of these, only two incidents would be explicitly implicated by these proposals. These involved: Children under three, choking on balls known to be between 1.25 and 1.68 inches in diameter, and intended for the use of children under the age of three.

In addition, a recent staff investigation has determined that small balls between 1.25 and 1.75 inches in diameter constitute "less than 1 percent of all toy shipments intended" to be marketed to children under the age of three. These two sets of statistics suggest that the hazard such balls pose to the relevant age population is so de minimus, that a full statutory analysis of this alleged risk is unnecessary.

#### TOYS INTENDED FOR CHILDREN THREE TO FIVE YEARS OF AGE

Finally, staff recommends that safety labels be affixed to any toys or games, intended for children between the ages of three and five, that contain small parts. This recommendation, in my opinion, was a particularly difficult one to evaluate. It had much to commend it; but, on final analysis, I determined that there was insufficient evidence to justify continuing this rulemaking.

I should note that, in my view, small balls and marbles -- to the extent that they fail the small part's test -- must be regarded as analogous to other small parts. To the extent that such toys should be regulated it should be in the context of our general small part's regulations.

I do believe, personally, that warning labels on toys that contain small parts, but are intended for children aged three to five, would be beneficial for adults in their selection of toys for children. This is my own subjective evaluation. However, the evidence before this Commission simply does not comport with such a conclusion. Thus, my vote to terminate these proceedings.

The severity of choking on small parts requires the Commission to weigh this factor heavily in balancing it against other statutory considerations. Still, to conclude, in the first instance, that this hazard represents an "unreasonable risk of injury", the Commission must know something more definitive about the likelihood that such incidents will occur. The data is deficient on this score.

What the data shows is that over an eleven year span some sixty choking deaths to children under the age of ten have resulted from the ingestion of toys or children's products other than small balls, marbles and balloons. Yet, it could not be ascertained whether more than a few of these choking instrumentalities could be classified as "small parts", as per our regulations? If not "small parts", then they fall outside the remedial scope of this proposed regulation and are not relevant to this evaluation.

Many of the identified choking incidents involved pieces of broken toys or other "abused" articles. These are not "small parts", nor are they the types of hazards addressed by the proposed warning labels. Given this information, it is impossible to even guess what the "likelihood of occurrence" might be.

As to whether or not the proposed rule is "reasonably necessary", there is no reliable data to base a finding that it has the potential for "reducing the severity or frequency of the injury". This would be pure speculation. There is little objective evidence from which to base any evaluation of how consumers' buying habits or child supervisory practices might be modified by such precautionary labeling.

We are informed by many of those participating in our focus groups that they appreciate the safety message contained in a small parts warning. But the Commission can infer little about what impact this would have either upon their actual behavior, under real life conditions or, certainly, upon any reduction in choking incidents. This is also recognized by the staff.

In the final analysis, the Commission is left with very little hard data. The Commission can not promulgate regulations based upon mere guesswork, subjective inferences or emotional reactions. Thus, I must conclude that there is no legitimate basis, within our statutory scheme, to proceed with this regulatory proposal.



U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D.C. 20207

**STATEMENT OF  
COMMISSIONER CAROL G. DAWSON  
U.S. CONSUMER PRODUCT SAFETY COMMISSION**

**THE COMMISSION DECISION TO TERMINATE RULEMAKING ON  
BALLOONS, MARBLES, SMALL BALLS  
AND CERTAIN TOYS AND GAMES  
MARCH 18, 1992**

One of the most successful activities undertaken by the Commission is its continuing effort to reduce choking incidents among children under three. This success can be attributed, in large measure, to the development of the small parts tester which is used to determine whether a product intended for a child under three has small parts. A children's product with a small part which fits fully into the small parts tester is banned. The result of this simple rule, in place since 1980, has been a dramatic decline in the number of injuries and deaths associated with toys and games intended for children under three.

The proposals which the Commission rejected today grew out of an earlier effort to re-examine the small parts tester and explore ways to reduce choking deaths even further. But, as with many efforts intended to fix things that are not broken, the staff-proposed remedies raised a number of serious questions. Of all the concerns that were raised, the most troubling was that there was little or no evidence that the proposed rules would have any impact at all on reducing deaths and injuries.

The Commission closely examined each proposal, being briefed on the proposed ban of marbles and balloons which fail to carry warning labels. The Commission also extensively reviewed the proposal to ban small balls (defined as less than 1.68 inches in diameter) in games and toys for children under three. Commission staff also proposed to ban all toys and games containing balls less than 1.68 inches in diameter which fail to carry an approved warning label. The final briefing of the Commission involved the staff proposal to ban toys intended for children ages three and four which contain small parts unless carrying a government-mandated warning label.

The staff proposals were based on the belief that warning labels are inexpensive, so even if they are largely ineffective, there is no harm in mandating them. The law, however, requires that the Commission make certain findings before it can issue a banning regulation under the Federal Hazardous Substances Act

(FHSA). Product bans issued under the FHSA have serious consequences, not the least of which is that a violation of the FHSA can be a federal crime.

In order to satisfy the statutory criteria for rulemaking, the Commission must be able to answer affirmatively certain pertinent questions before proceeding with the rule:

- o Does failure to place a warning label on a bag of marbles create an unreasonable risk of injury?
- o Is a label warning of the presence of a small ball in any game or toy reasonably necessary to justify the ban of products which fail to conform?
- o What is the potential effectiveness of a government-mandated warning label on a package of balloons to reduce choking deaths and injuries?

Any time a child chokes to death on a small object it is a concern to the Commission. The agency has an excellent record of responding with measures resulting in real reductions in injuries and deaths. After careful consideration and exhaustive inquiry into the data and the staff's rationale, however, it is clear to me that the current proposed remedies would simply not be effective. Moreover, the proposals are not fully supported by the data and other information provided. As I discuss further in greater detail, the injury data in each proposal is acknowledged to be very limited, and, as a consequence, seriously undermines the rationale of the proposed rules.

The American public expects federal agencies, such as the Commission, to set priorities, focus their resources on the greatest needs, and be able to show concrete results of their work. The Commission has an enormous mission, with jurisdiction over thousands of different products, many of which pose a greater risk to the public than marbles, balloons, small balls and small parts in certain toys. Consequently, I believe the Commission acted wisely in terminating rulemaking on these projects and turning its attention to more serious product safety issues. The Commission will continue to build on its past successes by vigorously enforcing existing standards, encouraging manufacturers to develop even safer products, and better informing the American public of how to ensure the safety of our children.

## BALLOONS

The Commission staff recommended that a Notice of Proposed Rulemaking be developed that would ban the sale of common

balloons in packages that fail to carry a government-mandated warning about the risk of choking to children under eight. The Commission sensibly rejected the proposed ban, which would have made a violation of the ban a federal crime, by a vote of 2-1, I voted with the majority.

Although I had voted for the Advance Notice of Proposed Rulemaking on this matter, in March, 1990. I believe that the information obtained during the notice and comment period demonstrates that there is insufficient evidence that balloons which fail to carry a choking hazard warning pose an unreasonable risk of injury. Moreover, I believe that the proposed rule fails to address even the relatively minor risk associated with balloon use.

Although there is much that we do not know regarding the circumstances surrounding choking incidents involving balloons, statistics indicate that such incidents occur very infrequently. Each year, 1.2 billion balloons are sold in the U.S. Balloons, on average, are associated with six choking incidents involving children under eight annually. In any given year, there are approximately 29 million children under eight in the United States. Staff indicates, therefore, that the rate of injury is about one in 200,000,000 balloons.

While the rate of injury is low, had the staff been able to suggest a remedy that would result in the actual reduction or elimination of injuries, federal intervention might have been warranted. No claim was made, however, that the staff-proposed warning label would reduce any of the injuries or deaths. The staff indicated that, having worked backwards, it concluded that a warning label was justified on the basis that if it were only one percent effective, the cost of labeling would compare favorably to the benefits. Absent supporting data, staff then concluded that it is reasonable to assume that the proposal would be at least one percent effective. There is no dispute that the information could equally support the belief that the government warning label would be totally ineffective in reducing injuries and deaths.

The proposal to ban balloons sold without warnings would also apply to those balloons sold by retail stores in bins or containers. This proposal would, however, apply to only 64 per cent of all the balloons sold in the United States. Balloons which are sold or distributed individually such as in malls, fairs, conventions, other public places and for commercial use would not be banned for failure to carry a warning label. A rule resulting in the labeling of all balloons, staff indicated, would be very costly and difficult to justify under the statutory criteria that the costs bear a reasonable relation to the benefits.

The proposal to exempt balloons sold individually causes considerable concern. The staff was unable to determine in most of the choking incidents where and how the child obtained the balloon. In the three choking incidents that staff recounted, the balloon was one which would have come under the exemption of this proposal. While the rule proposes to ban some balloons but not others, there appears to be no logical basis in the injury data to warrant making such a distinction.

Furthermore, while the warning label is directed primarily at parents and caretakers, there is no data indicating that they would be the ones most likely see the warning, read it, and follow the instructions. Because the warnings would be printed on packages and bins where balloons are sold, the labels would not remain with the product, making their effectiveness in warning the parent or caretaker very uncertain.

Although the staff has identified a safety risk associated with balloons, it has not proposed a remedy that would actually reduce the risk of injury. Considering the low rate of injury, the doubtful effectiveness of the warning label, and the application of the rule to only 64 per cent of the total number of balloons distributed in the United States, I believe the case for government intervention on this matter has not been made.

#### MARBLES

The Commission staff recommended that a Notice of Proposed Rulemaking be developed that would ban the sale of marbles in packages and games that fail to carry a government-mandated warning about the risk of choking to children under three, and reminding other children to keep marbles out of their mouths. The Commission sensibly rejected the proposed ban, which would have made a violation of the ban a federal crime.

Statistics indicate that choking incidents involving marbles are a rare occurrence. Each year, 1.5 billion marbles are sold in the U.S. Marbles, on average, are associated with less than one choking incident involving children three and under each year. In the past 11 and one-half years, the Commission knows of nine choking deaths associated with marbles. In any given year, there are approximately 11 million children under three in the United States. Staff indicates that the rate of injury is approximately one in 500,000,000 marbles, based on annual marble sales, and the rate is even less if the average useful life of a marble is taken into consideration.

Of the nine incidents associated with marbles, the staff has indicated that it has detailed information on only one death, which involved a three and one-half month old infant. Although

the staff knows that the infant was in a daycare center at the time of the incident, other aspects of the incident are unknown such as how the infant obtained the marble, the type of marble, etc.

No claim is made that the staff-proposed warning label would result in actual reduction of any injuries or deaths. The rule is being advanced on the basis of its estimated low costs. It is argued that, if any benefits at all are achieved, the rule would be justified. The staff has described this approach as having worked backwards from a cost/benefit analysis. Rather than approaching the problem by identifying a remedy that would either eliminate or adequately reduce the risk of injury, staff apparently proceeded by assuming the need for a government mandated label, and estimating the cost of compliance. The cost was then compared with the number of lives needed to be saved to justify the cost. Staff asserts that if one life were saved in 100 years because of the rule, the costs would compare favorably with the benefits. It was concluded that, indeed, one life would be saved in 100 years. This conclusion was reached without independent supporting data, based on an assumption that the conclusion was reasonable. Because of the absence of data, it is equally reasonable to assume that the proposed rule might result in no reduction at all of injuries or deaths.

The proposal to ban marbles sold without warnings would also apply to marbles sold by retail stores in bins or containers. This proposal would, however, apply to only 30 per cent of all the marbles sold in the United States. Decorative marbles, industrial marbles, and others which are not sold or distributed in games or packages, would not be banned for failure to carry a warning label. Moreover, it is not certain what products would be encompassed by the definition of a marble, because it appears that the staff definition could encompass small balls, beads and other small round objects.

The proposed ban would apply only to 30 per cent of all marbles distributed in the United States, which amounts to approximately 450-500 million marbles. This limited application causes considerable concern, given that staff does not know where and how the marbles involved in the choking incidents were obtained or whether the proposed rule would apply to marbles involved in the choking incidents. It is difficult to find a rational basis in the data to warrant making such a distinction.

Furthermore, while the proposed warning is directed primarily at parents and caretakers, there is no data indicating that they would be the ones who would most likely see the warning, read it, and follow the instructions. Because the warnings would be printed on packages and bins where marbles are sold and on games containing marbles, the labels, for the most

toys intended for children under three they will be banned. If they are sold in games, toys or bins intended for anyone over three, they will have to carry a warning label.

Of the nine incidents, one involved an eight year old who choked on a ball measuring 1.73 inches in diameter, which clearly falls outside the scope of the proposal. Of the remaining eight incidents, three involved high-bounce balls, two involved balls given as cereal premiums, one involved a ball contained in a game and the other three were unknown.

A major difficulty with the staff proposal is that we know so little about how the ball was actually marketed in the above eight cases, except that two came from vending machines, one from a package that carried a warning that it was intended for children over five, and the cereal premiums. Since the proposed remedy to the hazard differs on how the product is marketed, it is essential to know the target age groups of the products containing the balls involved in the choking incidents. Such information is critical for establishing the rationale for the rule. In other words, the Commission must be able to answer the question: How will the proposed rule prevent at least some similar choking incidents from happening again?

Other questions remain, such as the availability of data to support a determination that the maximum diameter should be set at 1.68 inches. The proposal seems to encompass all games and toys that include small balls, including those that are clearly adult products. It is unclear what is included in the term "ball." Questions concerning the effectiveness of the labeling provisions are similar to those that are present in the balloon and marbles proposal. The sheer numbers of small balls (less than 1.68 inches in diameter) sold in this country each year, which is on the order of 150-175 million units, their useful life, and the relatively low rate of injury, are also causes of concern.

Moreover, when this proposal and the staff proposals for labeling small parts in games and toys intended for children three and four years old are applied in concrete situations, anomalous results can occur. For example, a game intended for a five or six year old that has many small parts which would fail the small parts test would not have to be labeled even under the new staff proposals. However, if this particular game also contained a ball 1.67 inches in diameter, a warning label would be required. The result, I believe, could mislead American consumers regarding the relative risks associated with the particular game.

part, would not remain with the product, making their effectiveness in warning the parent or caretaker very uncertain.

Although the staff has identified a problem associated with marbles, it has not proposed a plan that would actually reduce the risk of injury. Considering the low rate of injury, the doubtful effectiveness of the warning label, and the application of the rule to only 30 per cent of all marbles distributed in the United States, I believe the case for government intervention on this matter has not been made.

### SMALL BALLS

As part of the Commission effort to examine the risk of choking to children, the staff considered hazards associated with small balls. The staff proposed a ban of small balls sold in games and toys intended for children under three, if they were less than 1.68 inches in diameter. The sale of such balls in any game, toy or bin intended for those over three years old would be banned unless accompanied by the staff-proposed warning label. The Commission found the proposals inadequate and voted to discontinue rulemaking.

The staff based its proposal on the fact that there have been 40 choking incidents involving children under 10 in the past eleven and one-half years associated with small balls. On closer inspection, little else is known about those 40 incidents. The staff indicated that of the 40 incidents, it knew the actual diameter of the ball in only 13 cases. Significantly, in four of the 13 cases, the ball was 1.25 inches in diameter or less. CPSC regulations already ban small parts which would include balls 1.25 inches in diameter or less if they are contained in products intended for children under three.

The incident data is important for assessing whether the proposed rule rationally relates to the hazard. The staff provided very little data to determine whether the four incidents which involved a ball that was 1.25 inches in diameter would be addressed by the current proposal. If such balls were contained in a game or toy intended for a child under three, the product is already banned under the small parts test. The staff indicated that one incident appeared to involve a ball from a game of jacks, and in the others, the origin of the ball was unknown. The children involved two under the age of one, a fourteen month old and a three year old.

The other nine incidents involve balls larger than 1.25 inches but smaller than 1.68 inches in diameter. The staff proposal intends to treat such balls in two different ways, depending on how they are marketed. If they are sold in games or

## TOYS AND GAMES INTENDED FOR CHILDREN BETWEEN AGE THREE AND FIVE

As part of its examination of choking hazards, the Commission staff proposed a rule which would ban toys and games intended for children ages three and four which contained small parts unless they carried a commission-approved warning. The proposal was designed to warn parents and others purchasing a toy or game intended for children ages three and four for a child under three that the product contained small parts. The Commission carefully considered the proposal and declined to continue with it, basing its decision in part on serious concerns regarding the need for the rule, the rationale for, and the effectiveness of the remedy.

Each year, 370 million toys and games are purchased for three to five year olds. Staff estimates that approximately 50 per cent of these toys and games contain small parts. The National Bulk Vendors Association (NBVA), which claims to represent 100 per cent of the manufacturers and importers in the vending industry, indicates that most, if not all, of their annual sales of 480,000,000 would qualify as small parts.

Currently, Commission regulations prohibit the sale of any product intended for children under three which contain small parts as defined in the regulations. The staff contends that products intended for children over three are often labeled by the manufacturers in a way that fails to indicate that they contain small parts. Furthermore, the staff contends that parents and others may buy a toy for a child under three which is intended for older children because they mistakenly believe that the manufacturer's label only indicates child-development appropriateness.

The current small parts regulation also bans products intended for children under three that have small parts as a result of breaking away during "use and abuse" testing. The staff proposal would exempt toys intended for children ages three and four from "use and abuse" testing.

In a period between January 1980 and July 1991, CPSC raw data indicates that 60 children under 10 died as a result of choking on small parts other than balloons and small balls. The raw data can be misleading if not closely examined. As a result of our questions, the staff narrowed the incident data and was able to identify only eight deaths that might have been covered by the proposal. The products were identified: wheels from a toy vehicle; a paper weight stopper; a toy jewelry box knob; a hinge pin from a toy make-up case; the suction cup from a "jump-up" toy; a metal "basketball" from a key ring; and, two game pieces. Upon further questioning, the number was reduced to two as a result of applying the criteria of the proposed rule, such as it

being applicable to only toys and games, not other products, intended for children ages three and four, and the exemption of such products from "use and abuse" testing. In addition, since the rule is not directed to accident scenarios involving infants, injury data including infants is not particularly relevant.

The injury data simply does not support the rationale of the rule, which is to warn parents of children under three from buying toys for them which are intended for children ages three and four. Although there appears to be merit in the criticism of some manufacturers labels, such as those marked "three and up," for failure to communicate the presence of small parts, the data does not support the contention that such labeling leads to children being injured. In addition to concerns about the rationale for the rule, I am very concerned about the difficulties in determining what is "intended for children ages three and four" for both those seeking to comply with the law and for Commission enforcement purposes. Consequently, the Commission properly terminated rulemaking on this proposal.



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

**STATEMENT OF COMMISSIONER MARY SHEILA GALL  
DECISION TO TERMINATE RULEMAKING ON  
BALLOONS, MARBLES, SMALL BALLS  
AND CERTAIN TOYS AND GAMES**

**March 18, 1992**

**SUMMARY**

On March 18, 1992, the Consumer Product Safety Commission met to consider options to address choking hazards associated with (1) balloons, (2) marbles (3) small balls and (4) toys and other articles with small parts intended for children aged three to approximately six years. I voted to terminate rulemaking on all four proposals and withdraw the Advance Notices of Proposed Rulemaking (ANPRs). In my judgment, the evidence presented to the Commission does not meet the statutory criteria of the Federal Hazardous Substances Act (FHSA).

**BACKGROUND**

In 1979, the Commission issued a small parts regulation (under the FHSA) to ban certain toys and other articles intended for children younger than 3 years of age. The test cylinder specified by the regulation is used to determine if a toy has small parts which present a choking hazard.

In 1988, the Commission considered a revision of the small parts regulation and concluded that the existing regulation was very effective in reducing choking incidents.

In 1990, four separate ANPRs were published to address specific choking hazards to children. The ANPRs examined balloons, marbles, small balls, and toys and other articles intended for use by children 3 to 6 years old.

After analysis and consideration of public comments, the Commission staff has recommended four separate actions:

- \* mandatory labels for balloons sold in packages and bins, warning of choking hazards in children up to 8
- \* mandatory labels of marbles sold in packages and bins warning of choking hazards and reminding children not to put them in their mouths
- \* a ban of small balls less than 1.68 inches in diameter marketed for children under three, along with mandatory warning labeling on all games and toys with balls less than 1.68 inches in diameter
- \* mandatory warning labels of toys containing small parts intended for children ages 3 and 4.

#### **FEDERAL HAZARDOUS SUBSTANCES ACT**

Under the Federal Hazardous Substances Act, the Commission must consider whether a hazard presents an "unreasonable risk of personal injury or illness" and whether the proposed remedy is "reasonably necessary" to justify a mandatory regulation. "Unreasonable risk of injury" requires a balancing of the severity and frequency of the injuries and the costs and benefits of the proposed remedy. The Commission must also determine whether the proposed remedy is "reasonably necessary" to reduce the risk of injury. Again, the Commission must weigh the severity and the frequency of the injury, the costs and benefits of the proposed remedy and its effectiveness in reducing or eliminating the risk.

#### **BALLOONS**

There are approximately 37 million children under 10 in the United States. From January 1980 to July 1991, there were 76 fatalities (for children under 10) involving balloons, an average of 7 deaths per year. One billion, two hundred million balloons are sold in the United States each year. Considering the number of children, the number of available balloons, and the number of fatalities, the risk is low. Because the product is so familiar and not perceived to be hazardous, label effectiveness is questionable. Failure to warn was not shown to cause an unreasonable risk of injury. Though the costs were low, the proposed remedy was not shown to be effective in reducing the risk.

Of the 1.2 billion balloons sold each year in the United States, the proposed labeling would apply to 64%. The remaining 400 million sold individually or distributed at fairs, conventions, public gatherings or for commercial use would be exempt. Evidence does not indicate how the balloons involved in the fatalities were obtained. It is not known if they would have been labeled (under the proposal) or if they would have been exempt because they were promotional handouts or meant for decorative display.

There is an ASTM voluntary standard warning label for balloons. An estimated 93% of balloons presently sold in packages carry some form of warning label.

After consideration of all the facts, I voted with the majority to direct the staff to draft a Federal Register Notice to terminate the rulemaking proceeding for balloons and to withdraw the Advance Notice of Proposed Rulemaking published in 1990.

As noted above, evidence established that the risk of injury is low. This was sufficient in my judgment to decide against mandatory action. However, the staff identified the hazard of the conforming nature of the latex material when it obstructs the windpipe. It is not easily removed. Though 93% of balloon packages sampled carried warning labels, the text and application was inconsistent. Accordingly, some improvements to the voluntary standard may be warranted. Therefore, I proposed a motion directing the staff to continue efforts with ASTM on improving the voluntary standard for balloons. This motion passed.

## **MARBLES**

There are approximately 37 million children under 10 in the United States. There are 11 million children under 3. From January 1980 to July 1991, there were 10 deaths associated with marbles, an average of one death per year. All of the 10 deaths were children 3 and under. There are 1.5 billion marbles sold in the United States each year. Given the number of children, the number and long life of the product and the number of fatalities, the risk is low.

Of the estimated 1.5 billion marbles sold each year, approximately 30% are intended for games and play use. The remainder would be exempt from the proposed label requirements. We do not know the source of the marbles involved in the 10 fatalities. We cannot conclude the proposed labeling would have applied in these cases.

Evidence acknowledges that consumers are familiar with the hazards associated with marbles and they know that marbles are not intended for very young children. Warning labels on familiar products cannot be shown to be an effective way to reduce the risk of injury. Nor can data prove that the absence of warning labels creates an unreasonable risk of injury. Mandatory labeling cannot be shown to predict that adults who purchase the product will remind older children to keep marbles out of their mouths. And, though the cost is low, evidence cannot support the effectiveness of the remedy in reducing the risk of injury.

Though the ASTM has not included marbles in their voluntary standards, we have found that a significant number of marbles marketed in packages intended for play do have warning labels.

I voted with my colleagues to direct the staff to draft a Federal Register Notice to announce the Commission's decision to terminate the rulemaking proceeding for marbles and to withdraw the Advance Notice of Proposed Rulemaking published in 1990.

### **SMALL BALLS**

There are approximately 37 million children under 10 in the United States. Eleven million children are under the age of 3. From January 1980 to July 1991 there were 40 fatalities (children under 10), an average of 3 deaths per year. An estimated 150 to 175 million small balls (diameter less than 1.68 inches) and an additional 60 to 70 million toys and games containing small balls are sold each year. Considering the number of children, the number of available products, and the number of fatalities, the risk is low.

Small balls intended for children under the age of 3 come under the small parts standard, which bans balls with diameters of 1.25 inches or less. A recent survey of products intended for use by children under 3 years of age indicates that less than 1% of these products contain small balls larger than 1.25 inches but less than 1.75 inches. More than 99% of the products intended for children less than 3 already meet the proposed requirements. This further highlights that the risk is low.

Consumers are familiar with the hazards of small balls. Because the products are familiar, labeling of products that contain small balls with diameters of 1.68 inches or less cannot be shown to effectively reduce or eliminate the risk of injury. Again, data fails to indicate that a failure to warn of choking hazards creates an unreasonable risk. Though the cost is low, the suggested remedy cannot be shown to reduce the risk of injury.

Because the evidence presented cannot meet all of the requisite findings required by law to show that a rule is necessary to reduce the risk of injury it is my judgment that mandatory action is not appropriate with regard to either the minimum size requirement or the labeling.

I voted with my colleagues to direct the staff to draft a Federal Register Notice to announce the Commission's decision to terminate the rulemaking proceeding for small balls and to withdraw the Advance Notice of Proposed Rulemaking published in 1990.

### **SMALL PARTS IN TOYS AND GAMES FOR CHILDREN 3 AND 4 YEARS OF AGE**

There are approximately 7.3 million children aged 3 and 4 in the United States. Approximately 185 million toys containing small parts are sold each year intended for children 3 and 4 years of age. From January 1980 to July 1991, there were 60 choking deaths (children under 10) associated with children's products. In 17 of the deaths in children under 3, the products identified appeared to be intended for children over the age of 3. But only 1 of these products (small game pieces) might have been subject to the proposed labeling requirement.

Considering the number of children, the number of products and the number of fatalities, the risk is low. Failure to warn cannot be proven to create an unreasonable risk of injury. Again, labeling cannot be shown to be effective in reducing or eliminating the risk because these are familiar products. Though the costs are low, mandatory labeling cannot be shown to reduce the risk of injury.

I voted with my colleagues to direct the staff to draft a Federal Register Notice to announce the Commission's decision to terminate the rulemaking proceeding for toys and games for 3 and 4 year olds and to withdraw the Advance Notice of Proposed Rulemaking published in 1990.