

**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.