



## U.S. CONSUMER PRODUCT SAFETY COMMISSION

4330 EAST WEST HIGHWAY  
BETHESDA, MARYLAND 20814-4408

### Record of Commission Action Commissioners Voting by Ballot\*

Commissioners Voting:      Chairman Inez M. Tenenbaum  
   Commissioner Nancy A. Nord  
   Commissioner Anne M. Northup  
   Commissioner Robert S. Adler

### ITEM:

Notice of Proposed Rulemaking: PPPA Rule Requiring Child-Resistant Packaging for Imidazolines  
(Briefing package dated January 11, 2012)

### DECISION:

The Commission voted unanimously (4-0) to approve publication of the draft proposed rule in the *Federal Register*. Pursuant to the Poison Prevention Packaging Act of 1970 ("PPPA"), the proposed rule would require child-resistant packaging for any over-the-counter or prescription drug product containing the equivalent of 0.08 milligrams or more of an imidazoline (tetrahydrozoline, naphazoline, oxymetazoline and xylometazoline) in a single package. Commissioner Adler issued the attached statement regarding this matter.

For the Commission:

A handwritten signature in black ink, appearing to read "Todd A. Stevenson".

Todd A. Stevenson  
Secretary

\* Ballot vote due January 18, 2012  
Attachment: Statement of Commissioner Adler



U.S. CONSUMER PRODUCT SAFETY COMMISSION  
4330 EAST WEST HIGHWAY  
BETHESDA, MD 20814

**STATEMENT OF COMMISSIONER ROBERT S. ADLER  
REGARDING THE NOTICE OF PROPOSED RULEMAKING  
REQUIRING CHILD-RESISTANT PACKAGING FOR IMIDAZOLINES**

**January 19, 2012**

The Poison Prevention Packaging Act of 1970 (PPPA), 15 U.S.C. 1471 et seq., has been one of the great successes in the history of the Consumer Product Safety Commission (CPSC) evidenced by the 84% decrease in pediatric poisoning fatalities since 1972.<sup>1</sup> Accordingly, I was pleased to recently vote to approve a Notice of Proposed Rulemaking that would require child-resistant packaging on products containing Imidazolines equivalent to 0.08 milligrams or more. In my opinion, the data provided by CPSC staff provides a solid basis for a preliminary finding that such packaging is technically feasible, practical, and appropriate. This, I believe, will greatly protect children from serious injury or illness from handling, using, or ingesting Imidazolines.

To avoid future confusion, however, I find it important to comment briefly on the "Preliminary Economic Analysis"<sup>2</sup> of the proposed rule as presented by the CPSC staff. While I have long believed in the value of thoughtful cost-benefit analysis, I am not sure of its usefulness in the context of this PPPA rulemaking for several reasons.

First, in 2008, Congress, by overwhelming majorities, went out of its way to amend the PPPA by adding the following to section 3 of the Act:

(e) Nothing in this Act shall be construed to require the Consumer Product Safety Commission, in establishing a standard under this section, to prepare a comparison of the costs that would be incurred in complying with such standard with the benefits of such standard.<sup>3</sup>

In other words, Congress went out of its way to remind the Commission that while cost-benefit analysis was not forbidden, it was not necessary. This is not to say that such an

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<sup>1</sup> CPSC Report on Pediatric Poisoning Fatalities 1972-2008 (December 2011) available at: <http://www.cpsc.gov/library/foia/foia12/os/pppa2011.pdf>. The last year for which reliable data is available is 2008.

<sup>2</sup> Notice of Proposed Rulemaking: PPPA Rule Requiring Child-Resistant Packaging for Imidazolines, Tab D, "Economic Analysis," at page 67.

<sup>3</sup> CPSIA § 233 (2008).

analysis will never be needed or welcome in a PPPA rulemaking, but that it shall never be required.

To me, the addition of this language to the PPPA is perfectly logical given the extensive findings that must be made in order for the Commission to move forward on any PPPA rulemaking. Specifically, prior to the CPSC establishing any standards for the “special packaging” of any household substance, the Commission must find that:

(1) the degree or nature of the hazard to children in the availability of such substance, by reason of its packaging, is such that special packaging is required to protect children from serious personal injury or serious illness resulting from handling, using, or ingesting such substance, **and** (2) the special packaging is technically feasible, practicable, and appropriate for such substance.<sup>4</sup>

In other words, the Commission *must* consider a host of factors before moving forward with PPPA rulemaking, including the reasonableness of the proposed standard, the available scientific, medical, and engineering data, the manufacturing practices of affected industries, and the nature and use of the specific household substance in question.<sup>5</sup> Although these findings do not constitute a formal cost-benefit analysis, they cover much of the same terrain, and do so in a way best designed for the type of regulation envisioned in the PPPA. They are comprehensive requirements for the Commission to meet prior to proposing or finalizing a safety rule. As more than three decades of data demonstrate, the law, and the Commission’s implementation of it, have been successful both in protecting consumers and meeting industry’s needs.

Moreover, although it is not explicitly noted in the staff’s economic analysis, the Commission must, as a matter of law under the Regulatory Flexibility Act (RFA), review proposed rules for their potential economic impact on small entities, including small businesses.<sup>6</sup> To me, this coupled with the findings required by the PPPA, satisfies our obligations to assess the impact of our actions in the market. Unless some good reason is shown for further economic analysis, I find it difficult to justify expending scarce Commission resources to reach conclusions that are apparent without such analysis.

While I look forward to comments on this proposed rule, I urge caution regarding the use of our limited resources in this manner in future rulemaking proceedings.

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<sup>4</sup> PPPA, 15 U.S.C. § 1472 (3)(a)(1) (emphasis added).

<sup>5</sup> PPPA, 15 U.S.C. § 1472(3)(b).

<sup>6</sup> 5 U.S.C. §§ 601–612. This required analysis appears at section “X” of the proposed rule’s preamble, at pages 20-21. The RFA’s focus on the most vulnerable of our businesses, small businesses, is always an appropriate and worthwhile use of time in my opinion.