



American Academy of Pediatrics



**TESTIMONY OF DAVID BROMBERG, MD, FAAP
ON BEHALF OF THE
AMERICAN ACADEMY OF PEDIATRICS**

before the
JOINT MEETING OF THE FOOD AND DRUG ADMINISTRATION
NONPRESCRIPTION DRUGS ADVISORY COMMITTEE
AND
PEDIATRIC ADVISORY COMMITTEE

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**Department of Federal Affairs
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Thank you for the opportunity to provide comments to the Pediatric Advisory Committee and the Nonprescription Drugs Advisory Committee of the Food and Drug Administration.

My name is Dr. David Bromberg and I am a pediatrician with 36 years of clinical experience treating children in a private practice in Frederick, Maryland. It is in this practice that I care for children with coughs and colds on a daily basis and address the issues of cough and cold medications with my patients and their families. I am here today in an official capacity representing the American Academy of Pediatrics (AAP).

Coughs and colds bring a lot of children to medical attention either in the office or over the phone. Parents want to know what they can do to give their children relief. The conversation quickly turns to one of the multitude of commercially available cough and cold preparations.

These compounds were never studied in children prior to approval. Rather, efficacy data in adults were extrapolated to children. When these drugs were approved, that was the standard practice. This extrapolation was based on the assumption that children are little adults. But since that time, our understanding of the physiology of children and how they absorb, metabolize, excrete and react to medications has evolved to the point where we have ample evidence to state that children are in fact not little adults. The data generated from the implementation of the Best Pharmaceuticals for Children Act (BPCA) and the Pediatric Research Equity Act (PREA) humble us on a regular basis. There is much we still do not understand about the difference between children's and adult's drug metabolism and action.

Although cough and cold products were originally approved based on data extrapolated from adults and applied to children, subsequent studies have found these products to be ineffective in children under six years of age. Based on the evidence available in peer-reviewed literature, these medications, either singly or in combination, do not work to relieve cough and cold symptoms in this population.

Reports that have been received by the FDA point to a possible risk of death and other adverse events from the use and misuse of cough and cold products in children, especially in, but not limited to, children younger than two years of age. The American Academy of Pediatrics urges the FDA to pursue further studies to determine whether or not cough and cold products have any beneficial role in the treatment of what is in fact a self-limited disease in children, the common cold.

Simply labeling these products with a warning against use in children under age two years is part of the solution, but not the whole solution. While it is important to limit the use of these products in this especially vulnerable population, such labeling does not go far enough or address the use of cough and cold medications in older children. Why not label these products with what we actually know? In children under six years there is direct evidence that cough and cold products do not work and some indirect evidence that cough and cold products present a risk. AAP advises that appropriate and consistent labeling regarding the lack of efficacy and the potential side effects for cough and cold products be developed and adopted by all manufacturers of these products.

AAP proposes the following labeling language:

This product has been shown to be ineffective in the treatment of cough and cold in children under six years of age. Serious adverse reactions, including but not limited to death have been reported with the use, misuse and abuse of this product.

With this type of labeling in place, the American Academy of Pediatrics would urge the FDA to pursue further studies to determine whether or not cough and cold products have any beneficial role in the treatment of the common cold and the simple cough. The Academy would urge the study of single ingredient formulations first followed by studies of any proposed or marketed combination product. The AAP has spoken with a single voice for over 30 years regarding the importance of studying medicines in children. If a medicine will be used in children, it should be studied in children. Cough and cold medications should not be exceptions to this rule.

While troubling to parents and children, cough and cold symptoms are usually benign and self-limiting. The available data show cough and cold products to be ineffective for children under six years with cough and cold symptoms. In the absence of evidence of efficacy, any risk associated with these drug therapies is unacceptable. The current labeling of these products is therefore inadequate, inaccurate and dangerous. With labeling that follows the Academy's recommendation, pediatric data can continue to be generated and the wording of the labels can then be modified to reflect increased understanding of both the safety and efficacy of cough and cold products.

On behalf of the American Academy of Pediatrics, I thank you for your attention.