

Statement
of the
**American
Pharmacists
Association**

Submitted to the

**Food and Drug Administration
Joint Meeting of the Nonprescription Drugs
Advisory Committee and
the Pediatric Advisory Committee**

**on “Safety and Efficacy of Over-the-Counter Cough
and Cold Products Marketed for Pediatric Use”**

October 19, 2007



American Pharmacists Association
1100 15th Street, N.W.
Suite 400
Washington, DC 20005

(202) 628-4410
<http://www.pharmacist.com>

**Statement of the American Pharmacists Association
Winnie A. Landis, Pharmacist, President**

**Before the Food and Drug Administration
Joint Meeting of the Nonprescription Drugs Advisory Committee and
Pediatric Advisory Committee**

**Safety and Efficacy of Over-the-Counter Cough and Cold Products
Marketed for Pediatric Use**

October 19, 2007

Thank you for the opportunity to provide comments on the safety and efficacy of over-the-counter (OTC) cough and cold products marketed for pediatric use. I am Winnie Landis, President of the American Pharmacists Association (APhA). I am a pharmacist and a diabetes educator with CVS Pharmacy in Lafayette, Indiana. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the military.

Improving the public's health and safety with respect to medication use is the pharmacist's, and APhA's, highest priority. Pharmacists, the medication experts on the health care team, are the most accessible health care providers and the only health care provider available to interact and communicate with consumers at the point-of-sale for prescription and OTC products. As such, pharmacists play an important role in helping consumers manage and improve their medication use — including the appropriate selection and monitoring of prescription and OTC products.

APhA's comments will focus on the pharmacist's role in helping parents and caregivers select and use the appropriate OTC products for pediatric patients, specifically, we recommend the following:

- The need for complete, comprehensive, and understandable labeling information;
- Removing risks of the same brand-name or brand-name line extensions being used for OTC products containing different active ingredients;
- Including the statement on the OTC product "Ask your doctor or pharmacist about the directions for using this product" and also the statement "Do Not Use in children under two years of age";
- Standardization in the OTC dosing units;
- Improvements to OTC drug monograph information; and
- Pharmacist representation on FDA Advisory Committees that address OTC products.

Pharmacists rely on the Food and Drug Administration (FDA) to determine whether medications, including OTC products, are safe and effective for their patients. However, we applaud our colleagues at the nonprescription pharmaceutical product manufacturers for proactively responding to reports of improper use of these OTC products, some of which have led to overdoses.

Role of the Pharmacist

Pharmacists offer a value added component to OTC products — assisting in appropriate product selection, identifying potentially dangerous combinations of medications, and educating patients on the proper use of these products. The proximity of OTC products to pharmacists, along with the knowledge that pharmacists have, allows pharmacists to play a critical role in consumers selection and purchase of OTC products, or determining when the patient needs to be referred to another health care professional.

Especially for pediatric patients, pharmacists play a vital role in educating parents and caregivers on the proper selection, dosing, and administration of OTC products. They also calculate appropriate doses based on age, weight, symptoms and provide training on the proper use of measuring devices to be used with some medications. In some cases, pharmacists may recommend not to use certain products based upon the patient's needs. The absence of pediatric specific formulations and dosing guidance led to APhA's support of FDA's effort to require manufacturers to include more extensive studies in the pediatric population for both prescription and OTC products.¹

Product Labeling

A large portion of the issue we are discussing today reflects a need for clear and comprehensive information about the safe use of these products. The label on the package is the primary vehicle used by consumers to obtain information about using these products. We agree with the concern raised by the FDA and other stakeholders that improvements to the package labeling are necessary. APhA supports the use of labeling that includes complete, comprehensive, and understandable information that is not misleading. The label should also inform consumers of the potential benefits and risks of a product, especially if used in the pediatric population, as well as cautionary statements if used for specific pharmacological effects, such as intentional sedation. APhA does not support advertising or labeling for any prescription or OTC medication that is false or misleading, or any promotional efforts that encourage indiscriminate use of the medication. Product labeling should only reflect information that is supported by FDA's approval — that such a product is safe and effective for a given patient population and age group. We also recommend that the FDA clarify and improve current labeling for OTC products used for the pediatric population, given the recent challenges with misuse and dosing problems associated with pediatric cough and cold products reported to be due to misleading product labeling.

APhA also shares the public's concern about the increasing number of OTC products and the appropriate use of these products. Consumers are challenged to decipher the labeling information and choose from a myriad of products. The complexity is compounded by some products whose active ingredients have changed, but the product name remains the same, or products with the same ingredients but with different labeling. To help consumers make better informed choices, APhA supports disclosure of all therapeutically active ingredients of an OTC product to the public and discourages the use of the same brand-name or brand-name line extensions for OTC products containing different active ingredients.^{2, 3}

¹ APhA Policy: Use of Representative Populations in Clinical Studies. JAPhA NS30(6):46 Jun 1990 (JAPhA NS45(5): 559 September/October 2005).

² APhA Policy: Non-prescription Drug Advertising. JAPhA NS20(7):62 July 1980 (Reviewed 2004) (Reviewed 2006).

We also recommend that the FDA require labeling on OTC packaging to say “Ask your doctor or pharmacist about the proper directions to use this product,” especially when used in pediatric populations. APhA also supports the recommendation by the Consumer Healthcare Products Association (CHPA) to change the labeling on all OTC cough and cold products to read “Do Not Use in children under two years of age.”⁴

Education

In addition to providing consumers clear labeling information, more needs to be done to educate consumers about medication use in general. Consumers must be reminded that any medication, including OTCs, has the potential to cause harm if used incorrectly. Patients may unintentionally exceed the recommended dose by taking the wrong dose of a medication or taking multiple products with the same active ingredients. For the pediatric population, this can occur when parents or caregivers accidentally give the wrong dosage because they use a measuring device incorrectly, or determine the dose based on the child’s age rather than weight, or when they are not aware of the similarities among products. Many products, especially those with multiple-ingredients, are particularly challenging for consumers to self-manage. To address this problem, parents or caregivers must be encouraged to read product labeling, to understand how to give the medication correctly, and to be aware of the possible side effects and what to avoid while administering the medication. Again, pharmacists are available to help consumers learn how to appropriately select and use OTC products — a key to reducing product overdosing and related adverse events — and equally as important, when not to use OTC products, a common recommendation for a pediatric patient.

Unfortunately, despite a recommendation from a physician or pharmacist not to use a cough or cold product in children under six, parents do give such medications out of desperation to do something to address their child’s health care needs. This is a patient safety issue which may be more common than we might like to admit. Improvement in OTC labeling would better educate parents and caregivers on how to appropriately use OTC products for the pediatric population. Another improvement would be to eliminate the use of different dosing units on OTC packaging. For example, some products use the unit teaspoon, while others may cause confusion by using the unit mL or cc. APhA recommends that the FDA consider standardizing dosing unit terminology to reduce confusion that may contribute to product dosing misuse.

In addition to educating consumers, we encourage the FDA to continue developing ways to better educate all stakeholders, including product manufacturers, pharmacists and physicians about the appropriate use of OTC products. To this end, APhA supports efforts to reevaluate and improve patient safety information provided in all OTC drug monographs.⁵ In addition, we also urge FDA to consider pharmacists for appointment to FDA Advisory Committees that address OTC medications. Finally, we are looking forward to working with the Consumers Healthcare Products Association (CHPA) to educate pharmacists and consumers on the safe and effective use of OTC medications.

³ APhA Policy: Brand-Name Line Extension. JAPhA NS36(6):396 June 1996 (Reviewed 2004) (Reviewed 2006).

⁴ CHPA Briefing Information Executive Summary. Accessed online at <http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4323b1-00-index.htm>.

⁵ Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (CCABADP) in 21 CFR Part 341

Conclusion

In conclusion, we recommend that the FDA consider ways to improve OTC labeling by requiring full disclosure of all active ingredients in OTC products, by taking steps to reduce name and ingredient confusion, and by requiring language that these products should not be used in children under the age of two. We also recommend standardization of OTC dosing units, improving OTC drug monograph information, and the importance of having a pharmacist on FDA Advisory Committees related to OTC products. Again, pharmacists are available to help consumers use medications appropriately and safely in order to reduce product misuse. APhA has increased communications to its members regarding this issue and we offer our support and assistance in helping the FDA and other stakeholders to educate the public on this important issue.

Thank you for your consideration of the views of the nation's pharmacists.