



**APhA**

**American  
Pharmaceutical  
Association**

2215 Constitution Avenue, NW  
Washington, DC 20037-2985  
(202) 628-4410 Fax (202) 783-2351  
<http://www.aphanet.org>

*The National Professional  
Society of Pharmacists*

**Statement of the  
American Pharmaceutical Association  
Before the Food and Drug Administration  
Center for Drug Evaluation and Research  
Over-the-Counter Drug Products  
Part 15 Hearing  
June 28, 2000**

Presented by Rebecca Chater, Pharmacist

Good morning. Thank you for the opportunity to present the views of the American Pharmaceutical Association (APhA), the national professional society of pharmacists. I am Rebecca Chater, a community pharmacist with Kerr Drugs in North Carolina. I completed a three-year term as a member of the APhA Board of Trustees in March of this year. APhA's more than 53,000 members are pharmacists providing care in all practice settings (such as community, hospital, long-term care, and hospice settings), pharmaceutical scientists and pharmacy students. In each of these settings, pharmacists help consumers manage and improve their medication use—including the appropriate selection and use of over-the-counter (OTC) products.

An important component of the discussions today is the site where the majority of our members practice: the pharmacy. Most OTC products are purchased at a pharmacy,<sup>1</sup> and this positions pharmacists well to interact with consumers at the point of decision-making and purchase. The pharmacist fulfills an essential role in the use of medications—helping consumers make medications work. While the Food and Drug Administration (FDA) ensures the safety and effectiveness of available products; manufacturers ensure the production of quality, contaminant-free products; and physicians and other prescribers diagnose and direct consumer interaction with the

<sup>1</sup> 61% of all respondents purchased OTCs at a chain or independent pharmacy. "Navigating the Medication Marketplace: How Consumers Choose", a joint survey from PREVENTION® Magazine and the American Pharmaceutical Association, 1997.

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health care system, pharmacists work with consumers to make the best use of the powerful technology we know as medications—whether classified as prescription medications, over-the-counter (OTC) products, or dietary supplements. In my practice—and in community pharmacies across the country—pharmacists serve as the bridge between consumer's self-care activities and interaction with the formal health care system. For example, we monitor for interactions between OTC products, dietary supplements and prescription medications, and for the development of adverse effects. My comments are based on the perspective of the pharmacist as medication use manager.

APhA has long supported activities and programs designed to assure the appropriate use of OTC medications for consumer self-care. Examples include publishing the *Handbook of Nonprescription Drugs* for more than 25 years, conducting consumer hot-lines for access to pharmacist consultation about OTC products, and participation in the *Partnership for Self Care*, an initiative designed to help consumers use OTC medications safely and effectively. The APhA House of Delegates has advocated for appropriate labeling of OTC drug products since 1978. APhA believes that an important component of the pharmacists' professional responsibility includes providing consultation to support drug selection, dosing and use of prescription and non-prescription medications and dietary supplements.

My comments today will focus on four of the many questions posed in the April 27<sup>th</sup> announcement for this meeting. Specifically, I will discuss the criteria FDA should consider in rendering decisions on OTC availability of drug products; a recommendation for assuring consumer understanding of OTC products through pharmacist-directed research; risks posed by consumer confusion resulting from brand-name line extensions; and the current structure for marketing OTC products.

#### *Criteria*

The number of products shifting from prescription-only to OTC status has increased markedly over the past several years, providing consumers more choices for self-care.

These products, however, are available in a myriad of environments, including environments that do not provide the consumer with convenient direct access to a health care professional. This lack of access to a pharmacist places greater responsibility on the consumer for interpretation and understanding of drug labeling and appropriate use of medications. As such, the decisions determining what products should be available in this environment must also be carefully considered.

The question of whether a product should be switched from prescription to OTC status must involve more than the traditional review of the clinical research information demonstrating safety and effectiveness of the product. While such information represents the core of information for considering a transition to OTC status, APhA recommends that the FDA criteria include an assessment of the environment surrounding the use of the product in question, as well as the environment of the disease or symptom at issue. The product-switch question must be animated by a review of existing therapies in the self care market, the degree of treatments sought in the existing self care system, and the risks and benefits of increasing access to the product at issue.

Let me explain. A review of existing therapies in the self-care market is important to explore what products are being used for self-care in the current environment. If existing alternatives for self-care are less safe—due to potential for interactions with other therapy or risk of negative side effects—the relative safety of the product in question for transition may increase and the risk-benefit analysis shift in favor of the transition to OTC product. If, however, a broad array of safe and effective products with minimal side effects is available for self-care, this component of what I will call the “environmental scan” may not affect the risk/benefit analysis. If existing alternatives for self-care are limited to dietary supplements, other problems may exist. Numerous studies have documented problems with product content and release of the active ingredient in dietary supplement products<sup>2</sup> and consumers in this scenario are

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<sup>2</sup> Four of nine melatonin products studied did not disintegrate within the thirty-minute limit of the guideline. Huigeong Hahm et al., *Comparison of Melatonin Products Against USP's Nutritional Supplements Standards and Other Criteria*, 39 J. AM. PHARMACEUTICAL ASS'N 27 (1999).

limited to products whose content may not match the claims on the label. Again, the relative safety of the product in question for transition may increase.

Another component of this environmental scan or analysis should be a review of the degree to which consumers are choosing self-care treatment for the disease or condition at issue. Assessment of the use of self-care treatments, such as OTC products, dietary supplements or other alternative therapies, could provide valuable information about consumer's interest in self-care treatment for the condition at issue. Such an assessment may provide information about how consumer's use those products, including whether consumers seek health care advice when symptoms persist after using available self-care treatments.

The risks and benefits associated with increasing access to the product must also be evaluated in this environmental scan. Specifically, the FDA process should evaluate the use of the product in the prescription-only environment to assess prescribing patterns, etc. that may be consistent with an increasingly consumer-driven use of the product. The provision of the product by pharmacists under the purview of collaborative practice agreements may, for example, support the expanded availability of a product. (Generally, collaborative practice agreements authorized by state law allow pharmacists and physicians to develop a protocol detailing the conditions under which a pharmacist will initiate or modify a patient's drug therapy. For example, a woman seeking emergency contraception may be referred to an appropriately trained pharmacist operating under such a protocol for evaluation and subsequent prescribing and dispensing of the product, if suitable.) Limited use of a medication, by contrast, or prescribing by a limited number of specifically trained physicians may not support expanded access as an OTC product.

#### *Assuring Consumer Understanding of OTC Products*

Consumer understanding of proposed OTC product labeling is essential to support the transition from prescription-only to over-the-counter status. APhA supports methods to assess consumer understanding of proposed labeling that involves the site where most

OTC products are purchased (the pharmacy) and the health care professional most accessible to respond to questions about OTC products (the pharmacist).

In a recent multi-center clinical trial, pharmacists acted as principal investigators to evaluate compliance and persistence by consumers self-selecting to receive a product being considered for transition to OTC status. In this study, data was gathered at more than 50 pharmacies—gathered at the site where most OTC products are expected to be purchased, and overseen by the health care professional most likely to help consumers choose a product and answer questions about how to use the product appropriately. Studies such as this provide valuable information to support the transition from prescription-only to OTC status.

Pharmacists, if widely utilized in Phase IV and post-marketing surveillance clinical trials such as what I have just described, can play a valuable role in assessing (and influencing through pharmaceutical care where appropriate) medication use in the uncontrolled, real-world setting of self-care and health care. In this system, pharmacists will ultimately provide contributions to our knowledge base regarding the effectiveness of various medications in the population at large.

*Risks Posed by Consumer Confusion Resulting from Brand-name Line Extensions*

As APhA has expressed to the FDA many times, pharmacists continue to have significant concerns about the presence and proliferation of the use of the same brand name (or minor variations of the same brand name) to identify products with different active ingredients. Just as "Kleenex" is now a universal name for facial tissues, consumers and health care professionals correlate product brand names with active ingredients of OTC medications. Consumers and perhaps even some health professionals may also assume that a consistent brand name on an over-the-counter drug product refers to consistent active ingredient(s). This is *not* the current situation, given the proliferation of over-the-counter brand name line extensions. The APhA is concerned that this practice may cause significant confusion.

Recently, I was made aware of a cough and cold product where the children's suspension formulation is significantly different from the pediatric drop formulation: one product contains an additional decongestant. The parent, directed by her pediatrician to use the brand name product—but with no direction as to “which” brand name product—was left standing in the pharmacy trying to choose among products with different formulations and active ingredients. Interaction with a pharmacist helped this parent resolve the situation, but one must ask how many times this situation is repeated, and how much confusion could be prevented by avoiding or limiting use of the same or similar brand names for products with different active ingredients.

When choosing or recommending OTC therapy, consumers and health professionals are likely to see only the prominent brand name and assume that this correlates with active ingredient consistency. Consideration of the risks of confusion with brand name line extensions must be a component of FDA's review of consumer understanding. Reviewing product names and brand name line extensions fits within a concept I discussed previously: the “environmental scan” component of the transition from prescription to OTC status. A brand name, considered in isolation, may appear clear and understandable—but when placed on a pharmacy shelf with five other products with similar names, may lose much of that clarity. Or more concerning, the clarity may be lost when consumers try to recall their OTC therapy when consulting with a pharmacist about appropriate medication use. Without being able to accurately identify the active ingredients in a product, checks for drug interactions and other potential problems are severely limited.

#### *Current Structure for Marketing OTC Products*

Finally, I will address the Agency's question about the adequacy of the marketing structure for OTC products in the United States. Generally, FDA's existing structure for marketing both prescription and OTC products could be improved by an expanded recognition of the role of the pharmacist in ensuring appropriate medication use. We are each aware of the steadily mounting evidence of morbidity and mortality attributable to underuse and misuse of prescription pharmaceuticals. This evidence has

recently spilled over from its historical confinement in the pages of medical journals to play out in the lay media. The media, with the public not far behind, are demanding more accountability of manufacturers, physicians, and pharmacists.

With prescription medications, part of the problem is the fact that health professionals are unfortunately being pushed by economic pressures into spending less time with each patient. With OTC products, consumers must navigate the self-care system without the assistance of a health care provider, unless they choose to ask for assistance. These marketplace trends make it difficult for prescribers, pharmacists and consumers alike to remain alert to the risks of every drug they prescribe and dispense, or in the consumer's situation, purchase and use.

The FDA could help this situation considerably by enhancing the use of the pharmacist in managing medication use. Pharmacist consultation can be valuable in ensuring appropriate medication use,<sup>3</sup> reducing adverse events,<sup>4</sup> and ensuring consumer persistence and compliance with therapy.<sup>5</sup> Additionally, pharmacists can be valuable sources of information about medication use in "real life"—providing additional information about the use of prescription and OTC medications and dietary supplements. As I described earlier, pharmacist participation in research activities in the community pharmacy can provide valuable information about consumer comprehension of labeling and the appropriateness of medication use without the traditional health care professional intervention involved in the prescription medication use system.

Should the Agency be presented with a situation where the appropriateness of OTC classification is questionable, however, the use of a system of marketing products through pharmacists should be considered. Such availability would expand access

<sup>3</sup> 60.5% of patients reached and were maintained at their National Cholesterol Education Program goals in project where pharmacists worked collaboratively with patients and physicians to promote patient persistence and compliance with prescribed dyslipidemic therapy. Benjamin Blumi et al. *Pharmaceutical Care Services and Results in Project ImPACT: Hyperlipidemia*, 40 J. AM. PHARMACEUTICAL ASS'N 157 (2000).

<sup>4</sup> Incorporation of a pharmacist on rounds as a member of a medical intensive care unit patient care team resulted in a 66% decrease in the number of preventable adverse drug events caused by prescribing errors. Lucian Leape et al, *JAMA*, July 21, 1999.

beyond the traditional system, while maintaining health professional interaction. Additionally, data gathered from the experience of expanded access through pharmacists could be used to support the transition from prescription to full-OTC availability.

It is important to recognize that APhA is not asserting that every product considered for switch to OTC status must flow through a transition class. Rather, APhA is recommending an alternative distribution system for use when the data are insufficient to support a transition to full OTC status, but expanded access to the product is necessary to support quality self-care.

Over-the-counter medications are valuable part of consumer self-care and our health care system. The FDA must assure that OTC products are accompanied by labeling to support appropriate use and coordination with the health care delivery system. The belief that over-the-counter drug products are helpful is true, but the belief that they are risk-free is dangerous. The FDA's hearing today about the agency's approach to regulating OTC products is an important step in assuring quality OTC products for consumers' use in self-care, and pharmacists' interaction as the bridge between self-care and health-care.

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

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<sup>5</sup> See note 3.