

Statement
of the
**American
Pharmacists
Association**

**Submitted to the
Food and Drug Administration**

**Behind-the-Counter Availability
of Certain Drugs**

November 14, 2007



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**Statement of the American Pharmacists Association (APhA)
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To the Food and Drug Administration (FDA)

**Behind-the-Counter Availability of Certain Drugs Public Meeting
November 14, 2007**

Good morning. Thank you for the opportunity to provide pharmacists' perspective on various issues related to the FDA's interest in behind-the-counter availability of certain drugs. I am Michael Moné, a pharmacist and a lawyer and currently serve as the Director of Regulatory Compliance for Medicine Shoppe International. I am here today as a representative of the American Pharmacists Association (APhA), the first established and oldest professional organization for pharmacists that represents more than 60,000 members in all practice settings.

Improving the public's health and safety with respect to medication use is 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 patients at the point-of-sale for prescription and over-the-counter (OTC) medications. As such, pharmacists have demonstrated that we successfully assist patients to manage and improve their medication use.

APhA applauds the FDA's recognition that pharmacists are in a unique position to provide the oversight needed to improve medication use outcomes of certain medications used to treat patient-identified conditions or symptoms. BTC medications that require a pharmacist clinical intervention would facilitate more pharmacist-patient communication that would ultimately lead to improved medication use outcomes and improved public health.

APhA received feedback from more than 600 responders to a recent poll about the questions posed in the Federal Register meeting notice. More than 80% indicated that they support the concept of BTC status for certain drugs and would be willing to provide additional information to patients related to BTC medications.

APhA supports FDA classification of certain drugs being available without a prescription but only after intervention by a pharmacist. This public health initiative will be successful only if it is designed around a collaborative pharmacist-patient health care encounter, not solely a retail transaction. The patient and the pharmacist will jointly assess the patient's condition to determine if the BTC medication is appropriate or whether the patient requires a referral. This pharmacist-patient encounter will result in improved public health, enhanced patient access to medications, and will facilitate safe and appropriate use of medications.

APhA relies on the FDA to determine drug status and to establish those market factors that would ensure viability of this initiative. APhA's support of certain drugs being available without a prescription, but only after an intervention by pharmacist, is based upon four key principles:

- *Principle One: A pharmacist-patient clinical intervention is essential;*
- *Principle Two: The FDA must base its BTC categorization decisions on science;*
- *Principle Three: The processes for drug availability without a prescription must be uniform; and*
- *Principle Four: Pharmacists must be able to bill and be paid for the clinical services provided.*

Principle One: A pharmacist-patient clinical intervention is essential

- BTC will be successful when a BTC medication is only available after a patient receives assessment, consultation, and clinical evaluation from a pharmacist and patients may not waive this requirement by signing an opt-out form;
- BTC will be successful when a BTC medication is identified as appropriate for treatment based upon:
 - A patient's self-identified condition or symptoms for which the patient is seeking care; and
 - A pharmacist's clinical assessment confirms that the condition for which the patient is seeking care can be addressed appropriately with an available BTC medication.

Pharmacist interventions to determine the clinical appropriateness of a BTC medication has the potential to increase appropriate patient access to medications that would otherwise be available only by prescription. This pharmacist-patient interaction is particularly relevant for patients with no health insurance and for other underserved populations who do not have ready access to health care providers. A benefit of certain drugs being available without a prescription but only after intervention by a pharmacist may offer an opportunity for the FDA to preserve access to certain medications in the rare case when the primary concern with that medication is preventing inappropriate use or misuse. In such a case, transition of a product from OTC to BTC could allow the medication to remain available in the marketplace with the patient care oversight provided by a pharmacist that would be required for its safe and effective use.

Pharmacists' clinical intervention in providing a BTC medication would also serve to increase compliance with medication therapy. An additional value to the health care system of certain medications being available without a prescription, but only after intervention with a pharmacist, will be the identification of patients that require no treatment, those that can be treated with a BTC medication, or those that require referral to a physician. In all case, more patients would receive higher quality health care. Studies, such as the Asheville Project, have demonstrated that referrals to physicians increase when pharmacists are actively engaged in clinical interventions with the patient. These studies further document that pharmacists assist patients to manage their prescription medications, increase patient compliance, improve patient safety, and the patient's health outcomes improve significantly.^{1,2}

Principle Two: The FDA must base its BTC categorization decisions on science

- *BTC will be successful when FDA relies on clinical evidence of medication safety and efficacy when determining which products to include as BTC medications;*

- *BTC will be successful when* FDA designates a product as BTC when clinical evidence exists that a particular drug product can be used safely with the intervention of a pharmacist; and
- *BTC will be successful when* a defined standardized process is created by the FDA for BTC product designation and for movement among Rx, BTC, and OTC.

Opportunities for increased pharmacist-patient interactions will improve safe medication use and outcomes. A pharmacist's intervention will include an assessment of a patient's symptoms to confirm that a BTC medication is an appropriate therapy option for the patient. A pharmacist may review, conduct, and/or assess patient screening outcomes, which may include laboratory testing data, and provide patient risk assessment, counseling and education on the safe and effective use of the BTC medication.

Principle Three: The processes for drug availability without a prescription must be uniform

- *BTC will be successful when* standardized administrative and clinical processes are created to ensure an effective pharmacist-patient clinical interaction; and
- *BTC will be successful when* pharmacists are able to access and share as appropriate required patient medical information in a timely and efficient manner.

A pharmacist-patient interaction would also mean that, when appropriate, the pharmacist and patient could arrange for follow-up monitoring. The pharmacist would maintain a standardized, electronic patient record to document the intervention, and upon consent, communicate relevant data and information to a known primary care provider.

Principle Four: Pharmacists must be able to bill and be paid for the clinical services provided

- *BTC will be successful when* a standardized mechanism is established and in place for pharmacists to bill and be paid for the services provided - either by the patient, a third-party payer, or others; and
- *BTC will be successful when* payment for related clinical services is separate from payment for the BTC product.

Conclusion

We are pleased that the FDA is recognizing the clinical value of pharmacists and their ability to address a growing health care concern related to medication use. APhA firmly believes that pharmacists are a valuable and readily accessible resource to help meet patients health care needs regarding access to and the safe and appropriate use of medications. As consumers become more aware of product risks and benefits, pharmacists can play a valuable role in patient's self-care decisions. Providing patients with safe and appropriate medications after consultation and clinical intervention by a pharmacist will increase patient access to medications; enhanced patient education; and improve medication use.

As the Agency moves ahead with this concept, APhA recommends that the Agency incorporate these key principles:

- *One: The pharmacist-patient clinical intervention;*
- *Two: Science-based decision making;*

- *Three: Uniform administrative and clinical processes; and*
- *Four: The ability for pharmacists to bill and be paid for the clinical services provided.*

APhA offers its support and assistance to the Agency in future discussions and meetings about this important public health initiative.

Thank you for the opportunity to present the views of the nation's pharmacists.

¹ The Asheville Project: Long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma. *J Am Pharm Assoc.* 2006;45(2):133-147.

² Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia. *J Am Pharm Assoc* 2000;40:147-65.