



AMERICAN COLLEGE OF PHYSICIANS
INTERNAL MEDICINE | *Doctors for Adults*

November 15, 2007

Andrew von Eschenbach, MD
Commissioner, Food and Drug Administration
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, Maryland 20852

Re: Food and Drug Administration [Docket No. 2007N-0356], Behind the Counter Availability of Certain Drugs; Public Meeting

Dear Commissioner von Eschenbach:

The American College of Physicians (ACP), the nation's largest medical specialty organization representing 124,000 physicians and medical students, appreciates this opportunity to provide comments regarding the Federal Drug Administration's (FDA) consideration of implementing a behind-the-counter (B-T-C) category of drugs. The College supports the efforts of the agency to investigate and consider means of improving our current system of regulating medications—a treatment option that is becoming increasingly important due to pharmaceutical innovation and a U.S population that is aging and experiencing increased incidence of chronic illness.

The College understands that this new B-T-C drug category under consideration would make certain prescription-only drugs potentially available without a prescription; but only after the intervention of a pharmacist. The pharmacist would be expected to interact with the consumer (patient) in a way that would allegedly ensure safe and effective use of the drug product through such interventions as determining that the patient meets the conditions for use and educating the consumer on the appropriate use of the drug product. The College further understands that variations of this B-T-C drug category are utilized in other countries.

The College's believes that the current two-drug category system of prescription-only and over-the-counter (O-T-C) drugs formalized by Congress under the Durham-Humphrey's Amendment to the Food, Drug and Cosmetic Act is effective in ensuring safe and accessible medications to the population. The current system allows for the general availability within the O-T-C market of those drugs suitable for self-medication that also require no medical monitoring and have a low potential for significant adverse side-effects, overdose or abuse. Furthermore, it appropriately requires the intervention of a physician, specifically trained in the diagnosis and treatment of medical conditions, to serve as the intermediary prior to having access to medications that don't meet the O-T-C conditions.

The College believes that the B-T-C drug category under consideration offers little evidence of improving the current two-category system and poses increased patient-safety concerns.

More specifically, **the College opposes the implementation of a B-T-C drug category** for the following reasons:

- The pharmacist does not have the necessary training to serve as the intermediary to drugs that fall outside the current O-T-C requirements—Many of the medications being considered for potential inclusion in this B-T-C category (e.g. cholesterol-lowering drugs, drugs for the treatment of asthma) relate to conditions that require the taking of a skilled medical history, a physical exam, and the use of laboratory results to ensure that an accurate diagnosis is made and the most appropriate medication is used. The pharmacist, while skilled in areas of drug effects and interactions, does not have the adequate training to provide these diagnostic and treatment considerations.
- The pharmacist may not have time in their current schedule of activities to even perform limited counseling or educational expectations—The experience of many of our members is that most pharmacists are already having difficulties meeting their current drug dispensing demands. These increased demands are fueled by current demographics and the implementation of the Medicare Part D benefit. It is unclear whether the typical pharmacist would be able to adequately meet even minimal additional intervention requirements.
- The consideration of a B-T-C drug category raises a number of questions that must be addressed prior to any consideration of implementation—The FDA Notice of Comment includes a large number of questions that currently have no suitable answer regarding the potential implementation of a B-T-C drug category. These include questions pertaining to the criteria for a drug to be treated as a B-T-C, the appropriate role of the pharmacist and the training required, and the type of documentation that would be required. Additional issues not included in the Notice that need to be considered include the process by which the patient’s personal physician would be notified regarding this medication intervention to ensure appropriate subsequent care, the pharmacist’s responsibility to provide follow-up consistent with their intervention, and the extent the pharmacist would be legally liable for their actions during this encounter.
- There is no currently available data supporting the contention that a B-T-C drug category would safely increase access, lower cost, or generally effect improvement to our current two-category system—As you are aware, the most comprehensive study of this issue was a 1995 Government Accounting Office (now the Government Accountability Office) study ¹ that examined international (and the limited national) experience with a B-T-C drug category. The results reflected that there was no clear pattern of increased or decreased access, that the counseling conducted by pharmacists was infrequent and incomplete and that any safeguards provided to deter drug abuse were easily circumvented. The study concluded that “the evidence that is available tends to undermine the contention that major benefits are obtained in countries that have such a class.” The College is aware of no evidence in the current literature to refute this conclusion.

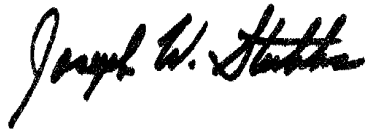
The College is not opposed to the FDA’s expanding of the limited number of drug exceptions to the two-category system that were recently implemented for non-medical reasons and require only an administrative intervention on the part of the pharmacist. Examples of this include the recent implementation of a proof-of-age requirement prior to the dispensing of a Plan B

¹ General Accounting Office. Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated. August 1995. Accessed at <http://www.gao.gov/archive/1995/pe95012.pdf> on 12 November 2005.

emergency contraceptive, which was motivated by social /legislative concerns and the signature requirement and quantity limitations coupled to the dispensing of drug products with pseudoephedrine, which was motivated by concerns related to its use as a key ingredient to the production of methamphetamine.

The College also is open to re-examining its position regarding the implementation of a B-T-C drug category once suitable answers to the many important outstanding policy questions are derived and research demonstrates that certain defined medications can be effectively and safely removed from the prescription-only drug category through this procedure.

Respectfully,

A handwritten signature in black ink, reading "Joseph W. Stubbs". The signature is written in a cursive, flowing style.

Joseph W. Stubbs, MD, FACP
Chair, Medical Service Committee
American College of Physicians