Third Class of Drugs

Some in the pharmacy profession continue to call for a new class of drugs - a third class of OTC medicines that would only be sold only in pharmacies. CHPA and others believe this would restrict consumer access to medicines and lead to higher costs.

What You Should Know About A Third Class of Drugs

- The distribution of medicine in the United States is based on a two-class system: prescription and nonprescription. A nonprescription drug is one that the U.S. Food and Drug Administration (FDA) has found to be safe and effective for direct consumer use based on the label instructions and warnings. In the absence of physician supervision, FDA requires a wider margin of safety for nonprescription medicines than for prescription drugs.

- A third class of drugs would be available only through a pharmacist. Drugs in the third class would not be available in other convenient retail outlets, such as discount stores, grocery stores without a pharmacy, hotel gift shops, and convenience stores.

- The current two-class system of drug distribution empowers consumers with a widening choice of safe and effective medicinal options for self-care and makes nonprescription medicines widely available at convenient times and locations at competitive prices. This emphasis on consumer empowerment in matters of self health care directly serves two of the most fundamental demands of any workable health care system: access and affordability.

- The FDA has repeatedly rejected a third class or transition class of drugs. As recently as March 9, 1994, the FDA stated that it would be inappropriate to restrict the sale of OTC drugs to pharmacies because such a restriction would reduce the number of outlets (from 750,000 to 55,000 nationwide) where consumers could purchase OTCs, limit competition, and raise some OTC drug prices, with no attendant public health benefit. Diminished competition will also have a disproportionate impact on traditionally underserved populations in urban and rural areas of the country.

- The U.S. Justice Department and the National Association of Attorneys General have opposed a third class of drugs, calling such proposals anti-competitive and anti-consumer because they create a monopoly in the distribution of nonprescription drugs.

- At a time when health care reform efforts are trying to increase competition and reduce costs, it doesn't make sense to limit the distribution and availability of nonprescription drugs.

- Among the organizations opposing a third class of drugs are the American Medical Association, Interamerican College of Physicians and Surgeons, National Black Caucus of State Legislators, National League of Nursing, Food Marketing Institute, Consumer Alert, National Black Women's Health Project, National Coalition of Hispanic Health and Human Services Organizations, National Grange, National Council on Aging, Food Industry Association Executives, and many others.

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What Others Say

Leading Voices Against a Third Class of Drugs
For years, pharmaceutical interests have been trying to establish a third class of drugs that could be sold only in pharmacies. Quoted below are statements from just a few of the prominent individuals and groups that have voiced opposition to or rejected such proposals.

U.S. Food and Drug Administration
"The Commissioner has spent a great deal of time reviewing the comments and discussing [the issue of a third class] with various groups, both in and out of the profession of pharmacy. The Federal Food, Drug, and Cosmetic Act requires that OTC drugs be safe and effective for lay use. Although the act permits imposition of whatever limitations or restrictions are necessary to assure the safe use of any drug, including restrictions on the channels of distribution, no controlled studies or other adequate research data have been supplied to support the position that any class of OTC drugs must be dispensed only by pharmacists in order to assure their safe use. It would be inappropriate to restrict the sale of OTC drugs to pharmacies based on anything less than proof that a significant safety issue was involved." - Statement from antacid monograph, Federal Register, June 1974.

Jane E. Henney, M.D., Commissioner of Food and Drugs, FDA
"One last area that I know is of concern to your organization is the creation of a 'transition class' of pharmaceuticals that would be sold only under the supervision of a registered pharmacist, and only under certain conditions. First, it is a very good thing that we are constantly questioning the current system in an effort to find ways to increase patient access to medical products in a way that does not create unnecessary procedural hurdles, yet provides adequate safeguards for patients and consumers. However, weighing the balance, we do not believe that the creation of another class of drugs is needed since there is a formal process in place to establish when a prescription product is appropriate for OTC use." - Speech to the National Association of Boards of Pharmacy Executive Officers Conference, September 1999.

U.S. General Accounting Office (GAO)
"Other countries’ experiences do not support a fundamental change in the drug distribution of the United States such as creating an intermediate class of drugs, whether fixed or transition, at this time. The evidence that does exist tends to undermine the contention that major benefits are being obtained in countries with a pharmacist or pharmacy only class." - August 24, 1995, report, Nonprescription Drugs: Value of a Pharmacist-Controlled Class Has Yet to Be Demonstrated, requested by Rep. John Dingell (D-Mich.).

American Medical Association (AMA) Resolution
"Resolved, that the AMA support(s) the present classification of drugs as either prescription or over-the-counter items; and . . . oppose(s) the establishment of a third class of drugs." - 1984 resolution passed by the AMA House of Delegates.

For more information, visit the Press Room at www.chpa-info.org. Select A Third Class of Drugs Hurts Consumers under “Position Papers.”