Support Grows for a Third Class of “Behind-the-Counter” Drugs

Robert I. Field, JD, MPH, PhD

A proposal was made to the Food and Drug Administration (FDA) that would allow for the creation of a new class of drugs, which would be sold “behind the counter” (BTC). This class of drugs would be more accessible than prescription-only drugs, but less accessible than over-the-counter (OTC) drugs. The idea is to allow for the sale of drugs that are too dangerous for direct patient purchase, but not as dangerous as prescription-only drugs. The proposed solution is to create a new class of drugs, which would be sold in a small bottle that would be kept in the back of the store. The FDA would be responsible for deciding which drugs would fall into this new category.

Prescription-only and over-the-counter drugs: the legal distinction

In 1951, Congress formalized the distinction between prescription-only and OTC drugs in the Durham–Humphrey Amendment to the Food, Drug, and Cosmetic Act. This law directed the FDA to distinguish between drugs that were too dangerous for use without professional supervision and those that were safe on an OTC basis with adequate directions and warnings on the label.

Although there are exceptions, the OTC class generally includes (1) drugs that are intended to treat ailments that are self-diagnosing for which no medical monitoring is needed for safe use and (2) drugs that are not habit-forming or toxic. Drugs that are initially approved for prescription-only status can be moved to OTC status if experience on the market indicates that these conditions have been met. Manufacturers commonly request such switches when drug patents near their expiration date in order to broaden the potential market. This was the case with Mevacor®.

The requirement for prescription status stems from the concept of the “learned intermediary” in professional settings. In technical fields, such as medicine and law, lay consumers generally lack the expertise needed to make decisions about purchasing goods and services. The law provides that licensed professionals with relevant training mediate the process. In the case of pharmaceutical agents, this means that a licensed physician must intervene before a patient can make a purchase. The physician must also determine the identity of the product, the dosage, and the duration of therapy. By implication, the physician is responsible for doing so in accordance with the applicable standard of care and can be held accountable for lapses through professional discipline and malpractice lawsuits.

Adding a third drug class: pros and cons

Proponents of adding a third class of drugs wonder whether physicians are the only health care professionals qualified to serve as learned intermediaries in terms of the use of drugs. Pharmacists are thoroughly trained in the uses and risks of the medications they dispense, and they often render detailed advice to patients on both prescription and OTC products. Some states already recognize other non-physician professionals as being qualified to supervise prescription drug use under limited circumstances, including nurse practitioners, physician assistants, and psychologists. Pharmacists seem well suited to mediate purchases of medium-risk products, and they are routinely ranked in polls as among the most trusted of professionals.

Opponents of the BTC idea warn that creating a third class of drugs might limit the availability of some OTC medications and might result in higher prices. The opponents contend that when a drug does not meet the criteria for prescription-only restrictions, it should be as accessible as possible. In addition to restricted access within a retail establishment, BTC drugs would be available only at pharmacies, whereas most OTC drugs can be purchased at a range of outlets, from supermarkets to convenience stores. The Consumer Healthcare Products Association estimates that creating a third drug class would reduce the number of available sources from 750,000 to 55,000.

The American Medical Association would be involved in the decision-making process, which would be different from the current system where the FDA is the sole decision-maker. The American Medical Association supports the idea of creating a new class of drugs, as it would allow for the sale of drugs that are too dangerous for direct patient purchase, but not as dangerous as prescription-only drugs. The idea is to create a new class of drugs, which would be sold in a small bottle that would be kept in the back of the store. The FDA would be responsible for deciding which drugs would fall into this new category.
HEALTH CARE AND LAW

(AMA) opposes BTC sales for a different reason. The AMA is concerned that some drugs that should remain prescription-only will be sold with a reduced level of outside supervision.

Proposals for a third class of drugs first surfaced in 1974, when several pharmacy organizations promoted the idea in response to an FDA review of OTC antacids. The idea has re-entered public discussion periodically since that time, as the number of drugs approved for OTC sale has steadily grown. In 1995, for example, the National Association of Boards of Pharmacy called for a third class of drugs that would not necessitate a prescription but that would require counseling. The Mevacor® decision brought the debate renewed attention, because statins are logical candidates for such treatment. They present greater risks than most available OTC drugs, but they also have widespread potential therapeutic benefits in treating cardiovascular disease.

EXISTING EXPERIENCE WITH PHARMACIST INTERVENTION

If the U.S. were to create a class of BTC drugs, it would not be the first nation to do so. Other countries already using this mechanism include the United Kingdom (UK), Canada, Australia, New Zealand, and Singapore. Simvastatin (Zocor®), another statin manufactured by Merck, was approved for nonprescription use in the UK as part of such a “pharmacist-only” class. However, the effectiveness of pharmacist intervention in drug purchasing in these countries is not at all clear. A 1995 report on experience in 10 countries by the General Accounting Office (GAO, now called the Government Accountability Office) found that safeguards against abuse are easily circumvented and that actual counseling of patients by pharmacists is infrequent and incomplete.1

Opponents of BTC drugs wonder whether experience in the U.S. would be any different. In fact, the state of Florida initiated an experiment in 1985 under the Pharmacist Self-Care Consultant Law to permit pharmacists to prescribe a limited number of drugs without physician supervision. The GAO Report found that the authority was rarely used. When it was used, the law’s record-keeping requirements were seldom followed.

WOULD A THIRD CLASS OF DRUGS SUCCEED?

The success of a third class of BTC drugs in the U.S. would depend on the active participation of pharmacists. If they respected their enhanced role as educated intermediaries and provided meaningful advice and counseling before offering products from behind the counter, the approach could achieve its goal. If they merely handed over the requested medications, it would not.

The involvement of pharmacists would depend on two factors. First, pharmacist education would have to include training in retail patient counseling, which—for the most part—is currently lacking. Second, pharmacies would have to grant their pharmacists time away from dispensing drugs to meet with patients. Their willingness to do so would probably depend on the availability of reimbursement for patient counseling from insurance or other sources. At this time, there is none.

Calls for a BTC class of drugs, however, are not likely to fade, and several forces may, in fact, cause them to intensify in the coming years. A growing number of drugs are falling into the gray area in which experience demonstrates relative safety but remaining risks indicate a continuing need for a degree of professional oversight. Statins will probably be only the first of this type. Moreover, the new Medicare prescription benefit, scheduled to take effect under the Medicare Modernization Act on January 1, 2006, is likely to result in increased drug use by the elderly and thereby heighten public concern about access.

Any alterations to the drug classification system would require action by Congress to amend the Durham–Humphrey Act, because the existing dichotomy is rooted in this federal law. As a result, change will probably not come quickly. However, as the nature and use of pharmaceutical products continue to evolve, the classification of drugs will almost certainly face pressures to adapt along with it.

REFERENCE