FDA Watch

Behind-the-Counter Drug Access

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Late in 2007, the U.S. Food and Drug Administration (FDA) held a public meeting chaired by Dr. Randall Lutter, Deputy Commissioner for Policy, and Dr. Douglas Throckmorton, Deputy Director for the Center for Drug Evaluation and Research, to discern the prevailing thought on the possibility of developing a behind-the-counter (BTC) status for drug access in the United States. Similar to over-the-counter (OTC) status, BTC would allow a patient to access medications at the pharmacy without seeing a doctor. Unlike OTC, however, access would not be allowed without the intervention of a learned intermediary. But, unlike a prescription medication, BTC would allow a patient to access drugs after an assessment and decision by a pharmacist.

BTC is currently a practice in several European nations, Canada, and Australia. In the United States, there is a limited version of BTC with a very narrow set of drugs, including cold remedies containing pseudoephedrine and Plan B oral (morning after) contraceptives; however, proponents of BTC status are quick to point out that there is a real difference between these types of drugs that involve the pharmacist in a policing action, where the pharmacist's role is to check age and intention, over a pharmacist's role as a true learned intermediary where there would be evaluation and counsel.

The event of a meeting held by the FDA suggests at least an openness of thought to the concept of BTC status, but the realities, as revealed in the course of the FDA's meeting, may be far different. It was the third time the FDA has met to discuss BTC, the first time being in the 1970s and the second in 1995.

There is ample reason for continued interest in a BTC status for the United States. One driver for drugs to switch from (prescription) Rx to OTC status is naturally that of access. OTC status opens the way for those without traditional access to healthcare channels to be able to access medications that they otherwise might not be able to obtain. Another obvious driver is cost, which also affects access, allowing for many (though not all) patients to access medications for far less than they would otherwise pay, unless that access were subsidized by an insurance program.

But a cornerstone criterion for the switch is that the patient can self-diagnose and self-treat the condition for which treatment is sought and use the compound safely. Some drugs just miss that call.

For example, in 2007 Merck attempted to switch Mevacor, a statin, from Rx to OTC status for the third time and failed. There have been some medical professionals who are such strong advocates of widespread statin use, that they have jokingly made statements that statins, like fluoride, should be in our drinking water.

One of the reasons for the statin Rx to OTC switch failure, however, is that because patients cannot self-diagnose or self-monitor high cholesterol, the drug does not meet switch criteria. But is a physician necessary to assess, diagnose, and monitor the patient?

The landscape is further complicated when considering the fact that "ready-clinics"—stripped down instant healthcare available in many retail establishments—are increasingly common and seen as a way to cut costs and improve access.

The FDA meeting involved 6 panels designed to represent various stakeholder groups, ranging from pharmacy organizations to educational institutions to consumers, retailers, and manufacturers. Noticeably absent were payors, despite the fact that reimbursement for pharmacists emerged as a major issue that would define the success or failure of a BTC initiative.

Of the panelists, the split between those who support a BTC designation and those who opposed was largely predictable, divided along lines of pharmacist groups being in favor of BTC status, and most physician-based groups, such as the American Medical Association, unequivocal in their opposition. Consumer groups and some professional societies fell in between, expressing some limited support for BTC, particularly to save consumers money, but offering caution as well on several points.

There have been and remain many barriers to the institution of a BTC class that do not appear poised to be resolved anytime soon, particularly when considering the overwhelming and growing regulatory burden and challenge that the FDA is facing for 2008 and beyond.

For example, for a pharmacist's transformed role, it is clear that there also needs to be a mechanism for reimbursement, which does not exist now. If a pharmacist takes time to evaluate and counsel a patient beyond today's standards, how will the pharmacist be paid for that service? Currently, there is no mechanism on either the public or private side. Reimbursement

would need to address not only the time of the pharmacist, but the increased liability that is being assumed in the role of prescriber.

Reimbursement is also a factor when it comes to the patient. How will BTC drugs be reimbursed, if at all? Currently most OTC drugs are not reimbursed, though they may be covered by a patient's flexible payment system through their employer to use pretax dollars for purchase. Most Rx drugs are reimbursed by public and private plans. And if products are not reimbursed, how does that affect the increased patient access that is one of the primary goals of a BTC system? Where would BTC drugs fit into the reimbursement scheme?

There are a myriad of other issues as well, including that most pharmacies are not equipped to provide examinations, blood draws, and room for private, confidential counseling and record-keeping, and would need to be revamped to accommodate a new role for the pharmacist as an evaluator and prescriber. Finally, although many younger pharmacists may be trained in patient evaluation, many older pharmacists might not be. To bring pharmacists into a new role, there must be a new standard of training and licensing that would require time and money to construct.

Although BTC may continue to be an aspiration for some, it became clear in the course of the FDA meeting that any movement to transform the current 2-tier system to a 3-tier system would require significant commitment on the part of many stakeholders to put into place the mechanisms and safeguards that ensure that the existence of a BTC status would in fact reach the goals set for it—to increase patient access and to reduce costs. ■

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