

FDA Files

FDA looks behind the counter

BY STEVEN NILES

FDA held a public meeting Nov. 14 to obtain comments regarding behind-the-counter availability of drugs. This proposed new category of products would allow certain drugs to be available without a prescription, but only after intervention by a pharmacist. Statins, birth-control pills, and migraine drugs are examples of the types of products that may be appropriate for behind-the-counter status.

Proponents of such a strategy suggest that the availability of certain drugs behind the counter could increase patient access to medications that may be underused, particularly by patients without health insurance, because these medications otherwise would be available only with a prescription. These proponents believe that because pharmacists have the training and knowledge to provide certain interventions, they may be able to ensure that patients meet the conditions for use and educate patients on appropriate use of the drug product.

If such a policy were to go into effect, marketing of pharmaceuticals would likely shift as a result. The consumer and the pharmacist would receive more emphasis in the marketing mix than they currently do, according to Lorraine Pastore, president of healthcare ad agency **LifeBrands** (lifebrandsusa.com).

"Education would play a larger role to ensure proper use of these drugs and to ensure that patients know at what point to involve their physician," Ms. Pastore told *Med Ad News*. "That said, classic marketing efforts aimed at physicians would still need to be done. We are not yet at the point where patients would go to pharmacists when they feel ill."

Variations of a behind-the-counter status are already in effect in other countries, including Australia, Can-

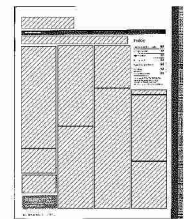
ada, France, New Zealand, the United Kingdom, Denmark, Germany, Italy, the Netherlands, Sweden, and Switzerland. The United Kingdom has a "pharmacist-only" class of drugs, while the other countries have more than three classes.

"Given that this so-called third class of drugs has been in effect in Europe for quite some time, we can glean some direction from marketing efforts there," Ms. Pastore says. "Physicians are still a critical target priority, but pharmacists receive more emphasis than they do here."

The criteria foreign countries use for switching a drug from prescription to intermediate class include indications suitable for self-medication with the intervention of a pharmacist and a low potential for side effects or overdose where an intervention by a pharmacist could minimize these risks. Other considerations include: abuse potential, patient choice and accessibility, and public-health issues. With the pharmacy-only classification, typically the pharmacist is required to ensure the patient meets certain criteria before dispensing, and to provide education on proper use and monitoring.

A behind-the-counter drug policy will help pharmacists realize their potential to guide patients' drug choices, according to David E. Williams, co-founder and principal, **MedPharma Partners LLC** (mppllc.com), and author of the **Health Business Blog** (healthbusinessblog.com). He notes that pharmacists have six years of training and are highly trusted by consumers, yet mainly spend their time counting pills.

"I'm always surprised that pharmacists, who really know more about drugs than doctors do, play such a minor role," Mr. Williams told *Med Ad News*. "It's a real shame because the accessibility of



pharmacies, if not pharmacists themselves, is very high ... this is something that will actually encourage the pharmacist to get more involved, and I'm hopeful that once that happens, it will key the pharmacist themselves and the consumers into the idea that the pharmacist should be a real partner with the patient in terms of what drugs they're taking."

Pharmacists, however, may have reason to be skeptical of the plan. "If you are dealing with the statin drugs, those are drugs you should have some checks done by your doctor on your liver, so getting those over the counter would really scare me," says Joel D. Shpigel R.Ph., CEO and co-founder of **Focus Express Mail Pharmacy** (focuspharmacy.com) and **Rx Meds Support** (rxmedssupport.com). "Unless the pharmacist is allowed to do a blood test and check on the function and see if it is OK every six months or so, and then get paid for it too, that would be good. That would be great for the pharmacist."

Mr. Williams believes that pharmacists will need to be reimbursed in some way for their counseling services under a behind-the-counter drug scenario. "Where I think things may go is that maybe more automation within the pharmacy is in order to fill the prescriptions," Mr. Williams says. "The pharmacist may be freed from the role that they have now and can act more as counselors. It may just be a shift of role as opposed to something that's an additional income source to them. The cost may need to be built into the price of the product."

According to Mr. Williams, making more drugs available behind the counter will increase access to medications. Products that FDA might be reluctant to switch from prescription to over the counter may pass as behind the counter drugs.

"All else being equal, an OTC or a BTC drug should be less expensive than a prescription drug, so it should increase access to the products," Mr. Williams says.

The time may be right for a behind-the-counter drug policy, according to Richard Meyer, senior manager of global e-marketing, **Medtronic Diabetes** (min-

imed.com). The U.S. health-care system is heavily overburdened, and people are looking for ways to reduce costs.

"With consumers today, time is a new currency, and it is really difficult to take time out of your schedule to continually have to go back to the doctor and get a prescription refill on things like allergy medication, erectile-dysfunction medications, and even some statin medications," Mr. Meyer says. "What better way to take costs out of the health-care system than to take some top products like statins, allergy medications, erectile-dysfunction medications, move them behind the counter, and basically just have consumers go and choose whatever program or drug they want to choose."

A major shift that could potentially result from the creation of a behind-the-counter drug category is that pharmaceutical companies may begin to market directly to pharmacists, even detailing them as they do with physicians. According to Mr. Williams, this opens new marketing opportunities for pharmaceutical companies, but has the potential to bias the judgment of pharmacists and undermine the public's trust in them. Whether pharmacists would be interested in receiving visits from pharmaceutical reps is also an open question.

"The pharmaceutical companies would definitely be very interested in a new channel where they can have an impact," Mr. Williams told *Med Ad News*. "If they do so, they would also probably like to ride on the coattails of the pharmacists' trustworthiness and popularity with patients. They would very much like to influence somebody who is a trusted person, a trusted advisor to the patients. Pharmacists have that role."

With a behind-the-counter drug category in place, direct-to-consumer marketing would increase in importance. "With direct to consumer advertising for prescriptions, it's more of an indirect process," Mr. Williams says. "It counts on the patient to go to the doctor and ask for the drug. In this case, it just counts on the patient to go to the pharmacist and ask for the drug. It's not so clear the pharmacist will have a reason to say no if the patient is actually asking for the drug. So, this should be

a pretty good return on investment for direct-to-consumer advertising on this kind of product.”

FDA will need to address what fair-balance information would look like in a behind-the-counter drug ad. “If we do not need fair balance ... it will be very easy for [pharmaceutical marketers] to develop new ad campaigns,” Mr. Meyer says. “Then it’s going to come down to who has the best brand positioning and who has the best pricing.”

Mr. Meyer believes that a behind-the-counter drug category would be a benefit to the pharmaceutical industry while also presenting its own challenges. “Pharmaceutical companies are not good when it comes to competing head to head,” Mr. Meyer told *Med Ad News*. “If the drugs go [behind the counter], then pharmacy companies are going to have to compete a lot more. It’s going to come down to shelf space, it’s going to come down to packaging, it’s going to come down to their DTC budgets.”

FDA has already taken a step in the direction of behind-the-counter drugs with the August 2006 approval of dual-label **Plan B** emergency contraceptive. For consumers 18 years old and older,

Plan B is available behind-the-counter. Consumers must go to the pharmacy counter, ask a pharmacy staff member for help, and show a government issued ID. For women 17 years old and younger, Plan B is only available with a prescription from a health-care provider.

Following the approval, marketer **Duramed Pharmaceuticals Inc.**, a subsidiary of **Barr Pharmaceuticals Inc.** (barrlabs.com), launched the Convenient Access Responsible Education Program. This comprehensive education program is for health-care professionals and consumers.

Plan B’s unusual approval status has created unique challenges for the product’s marketing team. For more information on how Duramed is meeting those challenges by focusing on education, see the story on page 32.

