The Scott and White (S&W) Health Plan, which covers more than 50 counties in central, east, and west Texas, owns 12 drugstores that are part of the health plan network. This network also includes 2,400 physicians, 30 hospitals, and another 400 independent community pharmacies. Twelve pharmacists shuttle between the 12 company-owned S&W drugstores each day to perform their duties because of a collaborative practice agreement that they and one of the health plan’s physicians signed. Each pharmacist has completed either a 12-month, postdoctoral training program in ambulatory pharmacy practice or a special certification program. The 12 pharmacists saw 500 diabetic patients in 2011. Each patient agreed to an initial 1-hour visit with one of the pharmacists and 15- to 30-minute follow-up monthly visits. For agreeing to participate in the diabetes-control program, health plan members were relieved of copays and were given other concessions.

The agreement—blessed by the Texas state medical and pharmacy boards—allows the pharmacists to do for these patients what pharmacists traditionally do not do: adjust and even prescribe preselected medications, including insulin, which is not usually subjected to pharmacist intervention in any state. The pharmacists also have leeway to adjust medications for comorbidities such as hypertension and hyperlipidemia.

With all of these unconventional, extra responsibilities, the rumor is that the 12 pharmacists at the S&W pharmacy wear a cape with an “S” engraved on the back. In this case, however, the S stands not for Superman but for Savings.

Paul Godley, PharmD, Director of Clinical Pharmacy Services at S&W Health Plan, says the 12 pharmacists saw about 6,000 patients in 2011. The health plan reimbursed the pharmacists an average of $70 per visit ($105 for the initial visit and $55 for monthly follow-up visit). However, the plan saved $1,800 per patient in the diabetes program compared with a control group. Given that 500 health plan members participated, the annual savings to the S&W plan was $900,000. Patients in the intervention group also demonstrated an improvement in medication adherence and a trend toward lower glycosylated hemoglobin (HbA₁c) values.

The S&W program and the collaborative practice agreement that allowed the program to go forward resonate loudly in the current discussion about whether the FDA should create a new class of over-the-counter (OTC) drugs that would be available to patients only with “conditions of safe use” (CSU) in place. In some instances, the pharmacist would be required to interact with patients who wanted to buy an “OTC with CSU” (OTC/CSU) drug and would be paid for time spent helping patients decide whether such a drug was appropriate, entering the drug into a patient’s medical record, and performing other administrative and counseling tasks.

In February 2012, the FDA announced that it was considering this new paradigm for switching more prescription drugs to the OTC category. On March 22 and 23, the agency held a two-day public meeting at its White Oak headquarters in Silver Spring, Md. The idea was to increase access to prescription drugs that might not otherwise be approved for OTC status, minus the CSU that the FDA would attach to drugs in this new OTC class.

The FDA is also considering whether the same drug could be available simultaneously as both a prescription and a nonprescription OTC product. If the FDA decides to proceed, pharmacists and pharmacies would play an important role in the success of this new paradigm. The discussion led to numerous questions from 12 FDA panelists about collaborative practice agreements and their potential application to the new paradigm.

Reclassifying drugs that are “prescription only” as less expensive OTC/CSU drugs would be an important step, especially for the poor and uninsured; this move would also improve compliance for many other patients and would provide additional benefits such as easing the burden on emergency departments, reducing the impact of the shortage of primary care physicians, and lowering the costs of both private and federal health plans (e.g., Medicare and Medicaid).

Types of medications that might fit in this new OTC/CSU class, according to the American Society of Health System Pharmacists (ASHP), include statins for cholesterol; inhaled corticosteroids and beta-2 agonists for asthma; vaccines; and drugs for hypertension, osteoporosis, and diabetes.

A recent study by Booz & Company reported that 240 million people buy OTC medications each year; an estimated 60 million of these consumers do not otherwise seek treatment. OTC drugs save the U.S. health care system $102 billion annually. The study also notes that for every dollar spent on OTC drugs, the health care system saves $6 to $7.

The paradigm, if accepted, would shift some of the balance of power in drug prescribing from the physician to the pharmacist. The FDA has outlined a potentially broad role for pharmacists in this new paradigm. For example, some diseases might necessitate confirmation of a diagnosis or routine monitoring using a diagnostic test (e.g., a blood test for cholesterol levels or liver function) that could be available in a pharmacy. The pharmacist or patient could then use the results to determine whether a certain drug is appropriate.

The pharmacist might also determine whether the patient

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has any other conditions or risk factors that would contraindicate the use of a particular drug and might also help patients choose among various drug products. If a diagnostic test is required before a drug can be prescribed, creating a pathway for OTC use may spur industry to develop diagnostics suitable for use by the patient or a pharmacy professional.

Depending on how aggressive the FDA decides to be, changes for the pharmacy industry could be cataclysmic, in both positive and negative ways. The paradigm opens the door for pharmacists to achieve a long-term goal: the ability to perform a broad menu of medication therapy management (MTM) services and, importantly, to be paid for performing those services. Medicare, for example, pays for some MTM services for some Part D recipients. However, Medicare and a few private payers have only dipped a toe into that water, and it is a pinky toe at that. Any “new world order” would also impose considerable new administrative burdens on pharmacists, such as verifying the accuracy of a patient’s use of an algorithm designed to test a drug’s appropriateness, entering customer information into electronic health records (EHRs), sending data to the drug manufacturer, and more.

Just the prospect of pharmacists invading their turf has physicians in a tizzy. At the FDA meeting on March 22, Sandra Adamson Fryhofer, MD, MACP, who was representing the American Medical Association (AMA), answered an FDA official who had asked her what training pharmacists should receive in order to obtain broader authority to initiate drug intervention.

“They should go to medical school,” she answered. “By-passing physicians for chronic disease is a mistake,” she added. “It hurts patients and could threaten their lives.”

Yet pharmacists contend that they are already saving patients and the public large sums of health care dollars through MTM programs designed to serve patients with chronic diseases such as diabetes, asthma, and chronic heart failure. Many of these MTM programs, such as the S&W diabetes plan, function because of collaborative practice agreements, which are legal in 46 states. Such an agreement between a physician organization and a pharmacy allows pharmacists to make drug decisions for patients that a physician might customarily make. With these agreements, pharmacists are working at a higher level; they are performing the same roles that the FDA anticipates would be included in the services that would be required if the agency recategorized a prescription drug as an OTC drug under this new paradigm.

The new paradigm would also affect community retail pharmacies. Cynthia Reilly, BSPharm, of the ASHP, says that hospitals and health systems will be affected too—50% of hospitals have outpatient pharmacies. In addition, health systems often have numerous satellite clinics, some of which have pharmacies attached.

Ms. Reilly says, “Those pharmacies are in an ideal position to contribute to the new paradigm.” This is particularly true because pharmacists in hospitals and clinics are usually much closer to physicians geographically (and certainly operationally), given the health plan setting and the integration of health plan staff members. More and more, that integration is also electronic, as evidenced by the growing use of EHRs in health plans and hospitals.

Hospitals are also under increasing pressure to reduce re-admission rates. One way they could do that, explains Ms. Reilly, is by giving pharmacists in the outpatient setting broader access to OTC drugs targeted for chronic illnesses and a broader role in ensuring that discharged hospital patients either continue their regimens (e.g., with anticoagulants) or that they be switched to an alternative drug to ensure better compliance and fewer return trips to the hospital.

Cynthia Reilly says that any FDA approvals of switches to the OTC/CSU category should be performed on a drug-by-drug basis, not on a drug-class-by-drug-class basis. Beyond that, the ASHP has four OTC/CSU definitions that it would like the FDA to adopt:

- The prescription drug meets many of the criteria currently used to reclassify it to OTC status. Examples would include a drug product with a well-established benefit-to-risk ratio and a wide safety margin. The drug would not be a systemic or an anti-infective agent that might raise concerns about emerging bacterial resistance.
- The drug has been marketed as a prescription product for a sufficient length of time and has been used in sufficiently large numbers of patients so that any serious adverse effects have already been reported.
- The drug shows evidence of effectiveness and safety at the dose and regimen that would be available without a prescription.
- The drug can be used to treat a disease, symptom, or condition that can be readily detected or diagnosed by a patient, a pharmacist, or a health care practitioner. Further, if a drug is used for a condition that requires laboratory or other medical monitoring, the pharmacist should be able to perform or obtain the results.

Because the new paradigm would mean switching some of the balance of power from the physician to the pharmacist and potentially open up new sources of payment, pharmacy groups are enthusiastic about the new paradigm. Thomas Menighan, BSPharm, MBA, Executive Vice President of the American Pharmacists Association (APhA), said:

We view the new drug paradigm concept being considered by the FDA as an exciting opportunity to utilize this open access to pharmacists to safely increase the availability of certain medications and to optimize the important role [that] pharmacists play in improving public health.

In one sense, it is a bit surprising that pharmacy organizations would be enthusiastic about a new class of OTC drugs that would demand more attention from pharmacists. The CSU that the FDA would attach to this new OTC category sounds a lot like the Risk Evaluation and Mitigation Strategies (REMS) that Congress in 2007 authorized the FDA to require of important new prescription drugs that might not have otherwise been approved. The REMS that drug companies did produce have come in different sizes and colors, making life difficult for pharmacists, mainly because the FDA has not yet established a standard format.

The drug companies themselves haven’t been much happier
with the FDA’s unfocused administration of its REMS authority. That has led to industry pressure on Congress to rewrite the REMS provisions in the 2007 law as it reauthorizes the Prescription Drug User Fee Act (PDUFA), which was first passed in 1992. The REMS provision was inserted into PDUFA IV, which was passed in 2007. However, the resemblance of the proposed OTC/CSU category to REMS has caught the eye of some pharmacy groups.

Anita Ducca, Vice President of Regulatory Affairs at the Healthcare Distribution Management Association, notes that REMS, such as the iPledge program, require wholesale distributors to verify the status of eligible pharmacies and requires manufacturers to maintain registries of qualified dispensing sites. iPledge also requires physicians and pharmacists to take steps to confirm that female patients taking an isotretinoin product, such as Accutane (Roche), Sotret (Ranbaxy), or Amnesteem (Mylan), do not become pregnant. Pharmacists who fill a prescription must verify through the iPledge Web site or by telephone that all criteria have been met, and they must obtain authorization before dispensing isotretinoin.

Anita Ducca explains:

We have found through experience with REMS programs that variations in the elements of data to be communicated among these organizations increase the complexity of the data sharing. This complexity would only be magnified if, as with REMS, drugs in this class experience varying restricted distribution data, requirements, and components.

Pharmacy associations certainly have some qualms about workflow burdens that may be imposed by a new OTC/CSU category, not to mention concerns about whether payment for added responsibilities would be forthcoming and sufficient. However, they cite a somewhat more telling piece of history as they look on the bright side of the potential new OTC class. That would be the shift of flu immunization from the physician’s office to the pharmacy.

Of course, the states, not the FDA, passed the necessary laws to expand the pharmacist’s scope of practice to allow that shift; however, the APhA says that about 175,000 pharmacists have completed a certification training program that permits them to administer vaccines. In the 2010–2011 influenza season, pharmacists administered approximately 20 million influenza vaccinations.

The “APhA believes that the new paradigm being considered can build on the successful immunization public health model,” states Thomas Menighan.

But Dr. Adamson Fryhofer, Chair-Elect of the AMA’s Council on Science and Public Health, a faculty member of Emory University, and a primary care physician in Atlanta, argues that the immunization model doesn’t apply to chronic disease. She explains:

“Treating chronic disease is much different. Other co-morbidities might evolve or a different therapy might be needed.”

Thomas Menighan answers that broader pharmacist involvement in a new OTC category would improve, not hinder, care coordination (as Dr. Adamson Fryhofer had implied); he says:

It is widely known in pharmacy, but often not well documented, that pharmacists routinely refer patients to an appropriate provider and improve care coordination everyday. The new paradigm being considered should not segment or silo patient care activity in the pharmacy but, rather, provide for redirecting undertreated patients back into care to reduce morbidity and decrease costs.

That, of course, is what the FDA hopes to accomplish by establishing the new category. It believes that the requirement to obtain a prescription for appropriate medication may contribute to the undertreatment of some common medical conditions, including hyperlipidemia, hypertension, migraines, and asthma. Some medications require routine monitoring through the prescribing practitioner (the physician), such as blood tests to assist in diagnosis, to determine whether a medication is working, or to adjust the dose. With the new paradigm, patients might need to make an initial visit to a physician, who might approve a certain number of refills beyond those that would normally be authorized without a return visit under a specialized CSU. This paradigm might be useful for some rescue medications (e.g., inhalers used to treat asthma or epinephrine for allergic reactions) that patients need to keep on hand for emergencies.

It is unclear whether the FDA has the authority to establish a new OTC/CSU category without a congressional blessing. Janet Woodcock, Director of the FDA Center for Drug Evaluation and Research, said that Congress could give the FDA the authority when it reauthorizes PDUFA this year. The FDA made a PDUFA V proposal to the Congress in January, but it did not include a request for OTC/CSU authority.

The FDA may approve a switch of a prescription drug to an OTC drug if it is convinced that all of the necessary safety information to be conveyed to consumers is included in the Drug Facts label that appears on the package. The label is a limiting factor, and it has stood in the way of FDA approval of some switches (as in the case of statins). For example, three FDA advisory panels rejected Merck’s Mevacor Daily (lovastatin) for OTC use. In that instance, FDA officials were left wishing they had additional tools for helping patients decide whether a statin was appropriate to treat their hypercholesterolemia.

Drug manufacturers have been testing algorithms that are consumer-friendly in an effort to rectify the Mevacor problem. At the March 22 FDA meeting, David Schlifkowitz, Vice President, Wellness Category, Global Regulatory and Quality, at GlaxoSmithKline Consumer Healthcare, walked the audience through an algorithm that his company has developed for bisoprolol (Cardior, Merck), a prescription beta blocker. However, he had to field some probing questions from the 12 FDA officials sitting as “inquisitors” at the dais. He could not explain how the FDA could be assured that a patient had actually completed an algorithm correctly, whether at a kiosk, at a home computer, or on a cell phone. He admitted that the proliferation of kiosks in drugstores, as well as other venues, such as convenience stores, would pose a problem. Asked whether senior citizens would be able to navigate algorithms, he responded, “It would be up to the designers to make the algorithms as simple as possible.”

Whether it would have helped Merck to have a high-quality continued on page 305
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algorithm in place back in 2007 when Mevacor failed to meet the FDA’s OTC hurdle remains to be seen. It is clear, however, that the FDA has been most hesitant to approve switches of prescription medications to OTC status. There were no switches in 2010, two in 2009, and none in 2008 (2011 data are not yet posted on the FDA’s Web site). The FDA did approve the switch of fexofenadine (Allegra, Chattem/Sanofi) in 2011, but that change was hardly path-breaking, given the approval of the same switch for loratadine (Claritin, Schering) a decade ago.

Cindy DiBiasi, a partner at 3D Communications LLC, says:

While FDA has been very tough on switches in recent years—like everything at FDA—the pendulum continues to swing. I think what’s most promising of all is that there seems to be a lot of interest, motivation, and activity from both the FDA and industry on switch—and sometimes it just takes that type of momentum to get things moving again.

REFERENCE