The Pharmacist Activist

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Editorial

Many Prescription Medications Should be Available Without a Prescription from a Pharmacist

The *Federal Register* of Tuesday, February 28 (pages 12059 – 12062) included a notice from the Food and Drug Administration that it would hold a public hearing on March 22 and 23 to receive comments on the subject, "Using Innovative Technologies and Other Conditions of Safe Use To Expand Which Drug Products Can Be Considered Nonprescription." I was one of the participants in the hearing and presented the testimony provided below:

Food and Drug Administration Public Hearing
March 22, 2012

Comments provided by Daniel A. Hussar, B.S. (Pharmacy), Ph.D.
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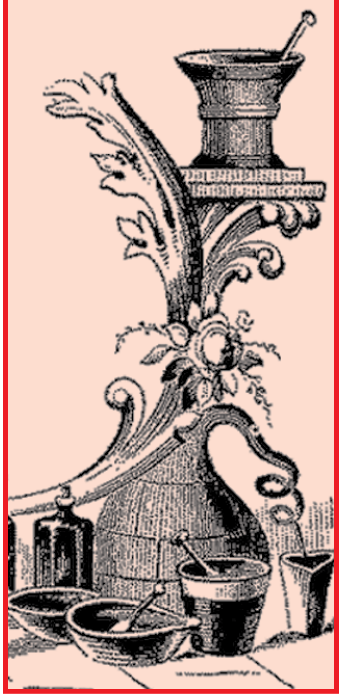
I commend the Food and Drug Administration (FDA) for convening this hearing to receive comments and opinions on a topic that I believe represents a very important opportunity to improve health care for millions of individuals. The perspectives and recommendations I am providing are based on my responsibilities as a pharmacist and faculty member at the Philadelphia College of Pharmacy that include teaching our required Nonprescription Therapeutics course, having taught every area of drug therapy, and having written and spoken about every new drug marketed in the United States in the last 40 years.

As stated in the *Federal Register* announcement of this public hearing, "Undertreatment of many common diseases or conditions in the United States is a well recognized public health problem." Millions of Americans do not see a physician or other prescriber unless they are experiencing symptoms they can no longer tolerate. Millions of Americans use unregulated herbal and other natural products, as well as dietary supplements, for which there is no evidence of effectiveness and safety. It is my strong conviction that there are actions that can be taken that will greatly increase access to, effectiveness, and safety

Contents



of a significantly larger number of medications. These actions will result in better health care that is provided in an efficient manner, and will also reduce the burden on emergency rooms and many physician providers.

The responsibilities of pharmacists currently include the assessment of the type and severity of symptoms described by patients, decisions whether to refer a patient to a physician/emergency department or to recommend the use of nonprescription medications, and, in the latter situation, to provide the counseling and monitoring needed to assure the appropriate management of the condition. Pharmacists have the knowledge and accessibility to assume a greatly expanded role in the appropriate use of medications. The topics being addressed at this hearing are particularly important and timely with respect to their relationship to the recent *Report to the Surgeon General, Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*.

My comments will primarily focus on the identification of medications that currently require a prescription, but which I would recommend for availability without a prescription in a pharmacy with the consultation of a pharmacist. The following medications are examples of those that I recommend for nonprescription availability from a pharmacist.

1. Epinephrine auto-injector for severe allergic reactions.

2. Albuterol for oral inhalation for acute asthma attacks.

3. Naloxone for narcotic overdosage.

Epinephrine, albuterol, and naloxone are used for the treatment of very serious and even life-threatening experiences. These events require emergency treatment and often occur in an area and/or at a time in which the local pharmacy is more accessible than a physician or a hospital.

4. Triptans (e.g., sumatriptan) for migraine headache.

Migraine attacks can be severe and disabling for some patients. The sooner the use of effective treatment can be initiated, the greater the likelihood of relieving symptoms on a timely basis and preventing worsening of the migraine attack.

5. Oseltamivir for influenza.

Oseltamivir is one of a very small number of medications that is effective for the treatment of influenza. However, for this drug to be optimally effective, it is very important that treatment be initiated as soon as possible following the onset of symptoms (within two days). Patients who experience influenza symptoms should be provided the fastest access possible to medication that might be of significant benefit.

6. Statins (e.g., atorvastatin, pravastatin, simvastatin) for hyperlipidemia.

Many individuals, rather than seeing a physician and receiving prescribed medications for high cholesterol concentrations, are purchasing dietary/nutritional supplements such as red yeast rice in which a statin is the primary active ingredient. These products have not been evaluated in clinical studies, there are little or no safety data, and there is often no assurance of standardization of active ingredients. In these situations, it is highly preferable to have nonprescription pharmacy availability of statins that have been extensively studied, have a known safety profile, and will be monitored by a pharmacist.

7. Diuretics (e.g., hydrochlorothiazide) for edema and high blood pressure.

8. Tamsulosin for benign prostatic hyperplasia.

9. Agents for overactive bladder (e.g., tolterodine).

10. Celecoxib for pain and inflammation.

11. Cyclobenzaprine for musculoskeletal symptoms.

12. Ramelteon for insomnia characterized by difficulty in falling asleep.

13. Corticosteroids (e.g., fluticasone propionate) for intranasal administration for allergic rhinitis.

14. Montelukast for allergic rhinitis.

15. Agents for smoking cessation (nicotine nasal spray, nicotine inhalation system, varenicline).

(Continued on Page 4)

New Drug Review

Fidaxomicin
(Dificid – Optimer)

Antibiotic

New Drug Comparison Rating (NDCR) = 4

(significant advantages) in a scale of 1 to 5 with 5 being the highest rating

Indication:
Treatment of *Clostridium difficile*-associated diarrhea in adult patients.

Comparable drug:
Vancomycin (e.g., Vancocin).

Advantages:
- More effective in preventing recurrence of infection;
- Administered less frequently (twice a day whereas vancomycin [oral] is administered four times a day);
- Less risk of nephrotoxicity or ototoxicity.

Disadvantages:
- Dosage recommendations are not provided for patients less than 18 years of age;
- Labeled indications are more limited (vancomycin [oral] is also indicated for the treatment of enterocolitis caused by *Staphylococcus aureus* including methicillin-resistant strains).

Most important risks/adverse events:
Should not be used for systemic infections; should only be used to treat infections that are proven or strongly suspected to be caused by *Clostridium difficile* (to reduce the possible development of drug-resistant bacteria).

Most common adverse events:
Nausea (11%), vomiting (7%), abdominal pain (6%), gastrointestinal hemorrhage (4%), anemia (2%), neutropenia (2%).

Usual dosage:
200 mg twice a day for 10 days.

Product:
Film-coated tablets – 200 mg.

Comments:
Fidaxomicin is a macrolide antibacterial drug that has a narrow spectrum of action and is primarily active against species of clostridia, including *C. difficile*. It inhibits RNA synthesis by RNA polymerases and is bactericidal against *C. difficile*. Fidaxomicin and its active metabolite act locally in the gastrointestinal tract, are not absorbed to an appreciable extent, and should not be used for the treatment of systemic infections.

The effectiveness of fidaxomicin was demonstrated in two studies in which it was compared with orally administered vancomycin. The primary efficacy endpoint was the clinical response rate at the end of the 10-day course of treatment. The clinical response rate for the patients treated with fidaxomicin was 88% in both studies, a rate that was considered noninferior or similar to the rate in the patients treated with vancomycin. An additional efficacy endpoint was sustained clinical response 25 days after the end of treatment (i.e., without proven or suspected *Clostridium difficile*-associated diarrhea recurrence through 25 days beyond the end of treatment). With respect to this endpoint, fidaxomicin was superior to vancomycin, with rates of sustained response of 70% and 72% in the two studies, compared with 57% and 57% with vancomycin. However, in one of the studies among a subset of patients who were infected with a more virulent strain of C. difficile, the sustained response rates for the two drugs were similar.

Daniel A. Hussar

More than 440,000 Americans die each year as a result of smoking-related illnesses. Although some smokers have been successful in quitting with the use of nonprescription nicotine replacement therapy (gum, lozenge, patch) or other strategies, others have not had a successful experience with these products. There are many smokers who want to quit but who will not set up an appointment with a physician to discuss other options. For these individuals, the nonprescription availability from a pharmacist of nicotine nasal spray, nicotine inhalation system, and varenicline will provide a pharmacist-monitored opportunity for a successful effort to stop smoking. It is an unacceptable irony that only proof of age is required to purchase a dangerous product like cigarettes whereas a prescription is required to obtain certain of the products that will help individuals stop smoking.

Attention should also be given to revision of the labeling of the nicotine replacement therapy formulations that are currently available without a prescription. For example, the labeling for these products contains the statement, "Do not use if you continue to smoke..." Although the goal is for the individual to not smoke at all, some are not able to resist the craving to smoke but do so on a less frequent basis. Because they have not followed the specific instructions, they may conclude that the treatment has not been successful and discontinue it. However, a substantial reduction in the number of cigarettes smoked should also be considered a positive result and a source of encouragement to stop smoking completely. The labeling for the nonprescription nicotine replacement therapies also includes a statement that individuals should not use a second nicotine-containing product concurrently. However, this statement may actually preclude the use of what, for some individuals, may actually be the best strategy to stop smoking, that is to use the patch to provide a sustained low concentration of nicotine and the lozenge or gum to provide a prompt, but brief, action when cravings to smoke are experienced.

In addition to these examples, there are also other prescription medications that can be considered for nonprescription availability from a pharmacist. With certain of the agents identified, there will be a need for specific parameters and guidelines to assure appropriate use and these will vary depending on the medication. However, this should not be reason to delay consideration of medications for which a change in status can be made quickly.

The increase in the number of nonprescription medications that are available from a pharmacist will not only result in increased patient access to helpful medications, but will also make them available on a more cost-effective basis. I also anticipate that there will be increased communication, collaboration, and referrals between pharmacists and prescribers as they fulfill their individual responsibilities for the patients being served.

Neither the FDA nor the public should tolerate "turf battles" among the health professions as these issues are addressed. There is much more to be done in improving the scope and quality of health care and preventing drug-related problems than all of the health professions are doing now. We can and must do much better. The opportunities that the FDA is considering are ones in which all participants can "win," and I urge your bold and prompt action.

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