The Pharmacist Activist

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Editorial

Mail-order Pharmacy

Threatens the Role of Pharmacists as Health Professionals

The comment I hear most often from independent pharmacists regarding the financial challenges they face is: "I can compete with the chain pharmacies in my community. It is the mail-order prescription programs and their unfair incentives that steal my patients that are the greatest threat to the survival of my pharmacy."

The pharmacy benefit managers (PBMs) and insurance companies that are the primary advocates for mail-order pharmacy have been successful in perpetuating what I consider to be a myth that obtaining prescriptions from mail-order pharmacies is less expensive than obtaining prescriptions from local pharmacies. Because it is only the PBMs and insurance companies that have the pertinent data (designated as proprietary to avoid providing it to others) and dictate the financial terms of prescription benefit programs, they are in a position to manage/manipulate this information to their advantage. Advocates for local pharmacies have had only very limited success in refuting this message.

An issue for our entire profession

Many within pharmacy consider mail-order pharmacy to be an issue that only affects community pharmacy. I contend that it is of importance for our entire profession for reasons that go beyond the fact that community pharmacy is by far the largest area of pharmacy practice and, therefore, is the experience through which most of the public relate to and identify the profession of pharmacy.

Mail-order pharmacy promotes the message that it is not necessary or important for a patient to meet face-to-face with a pharmacist when they obtain prescription medications. Individually and collectively, pharmacists take great pride in our role and services as health professionals. But is not a personal relationship and communication with patients the very foundation of the role of individuals considered to be health professionals? Can anyone imagine a physician, dentist, or nurse in practice responsibilities fulfilling their role as health professionals without actually

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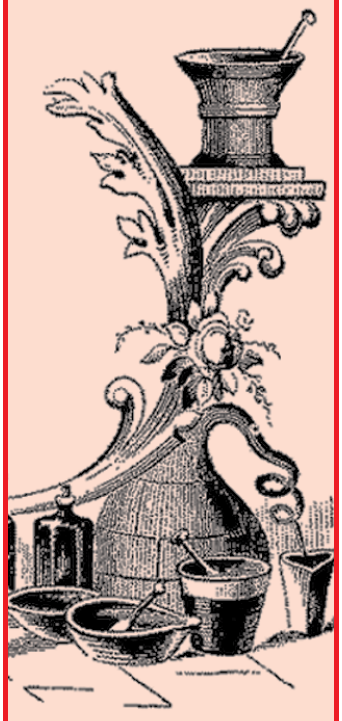

seeing patients? However, the owners and advocates for mail-order pharmacies have equated the dispensing of prescription medications to the sale of commodities in a manner that demeans and threatens the role of pharmacists as health professionals. This must be considered of great importance for our entire profession. Our profession is currently giving a very high priority to efforts to obtain "provider status" for pharmacists. These efforts are very important and should be strongly supported. However, to what extent is our profession taking action, or even voicing concern, about the threat to our recognition as health professionals represented by mail-order pharmacy?

In addition to promoting mail-order pharmacy, some PBMs are taking steps to limit the number of local pharmacies that are included in their "networks." These PBMs allege that certain legislative initiatives would require them to include in their networks pharmacies that "overcharge," without acknowledging that differences in charges may result from differences in services that could reduce the costs associated with the occurrence of drug-related problems. They further contend that permitting all interested pharmacies to participate in their programs is inefficient and increases costs. They attempt to justify decisions to exclude certain pharmacies from their networks and the resulting inconveniences for patients by suggesting that there are so many pharmacies that patients should not be inconvenienced. The president of the Pharmaceutical Care Management Association (PCMA), the organization that represents PBMs, has stated: "The United States has more pharmacies than it has McDonalds, Burger Kings, Pizza Huts, Wendys, Taco Bells, Kentucky Fried Chickens, Domino Pizzas, and Dunkin Donuts combined."

Pharmacy's political strength (or lack thereof)

The PCMA president's comment about the number of pharmacies was intended to promote the interests of the PBMs to the disadvantage of pharmacies that would be excluded from the PBM networks. I was surprised that the number of pharmacies is higher than all those fast food organizations combined. But I am not going to count them and I will take his word for it. However, I will urge that we use the number of pharmacies to our profession's advantage.

The profession of pharmacy needs to organize and mobilize the large number of local pharmacists and others who support them to attain political strength that will result in actions and programs from which our patients, communities, and profession will all benefit. All of the national, state, and local organizations of pharmacists that are committed to protecting and advancing the professional role of pharmacists should be active participants in this effort and support it with staff and resources.

The profession of pharmacy is not even close to attaining its potential with respect to political strength and influence. This situation must change!

Additional strategies

In addition to developing and enacting legislation that will protect patient choices in selecting a pharmacy and protect pharmacies from restrictive and coercive programs imposed by PBMs, additional strategies must also be pursued. I recommend the following:

1. We must determine the number of prescriptions that residents in a particular state are receiving from a mail-order pharmacy in another state, and the estimated dollar value of those prescriptions. The largest mail-order pharmacies are located in a small number of states with the result that prescriptions with a total value of many millions of dollars are being sent out of most states each year. In addition to this data, the loss of tax and other revenues that a state experiences when pharmacies close, as well as the reduction or lack of growth in the number of employees in pharmacies because of the extent to which prescriptions are sent out of state, must be included in the financial analysis of the impact of mail-order pharmacy programs on a state's economy.

2. We must strive to determine (to the extent possible in what are typically highly confidential transactions) the terms under which PBMs and mail-order pharmacies have established agreements for prescription programs with employers, unions, and government agencies. Rumors of kickbacks or other inappropriate payments or incentives must be investigated by the appropriate authorities. Individuals who are aware of illegal or

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New Drug Review

Dimethyl fumarate (Tecfidera – Biogen Idec)

Agent for Multiple Sclerosis

New Drug Comparison Rating (NDCR) = 4

(significant advantage[s]) in a scale of 1 to 5 with 5 being the highest rating

Indication:
Treatment of patients with relapsing forms of multiple sclerosis (MS).

Comparable drugs:
Fingolimod (Gilenya), teriflunomide (Aubagio).

Advantages:
- Has a unique mechanism of action (activates the nuclear factor [erythroid-derived 2]-like 2 pathway);
- Less risk of cardiac adverse events (compared with fingolimod);
- Less risk of hepatotoxicity and teratogenicity (compared with teriflunomide);
- Is rapidly metabolized and excreted (compared with teriflunomide).

Disadvantages:
- Is administered more frequently (twice a day, compared with once a day with fingolimod and teriflunomide);
- Many patients experience flushing.

Most important risks/adverse events:
Decreased lymphocyte counts (increased risk of infection; a recent [within 6 months] complete blood count [CBC] is recommended before initiating therapy, and a CBC should be determined annually, or more frequently, during treatment; in patients who develop a serious infection, interruption of treatment should be considered); flushing (e.g., redness, warmth, itching, burning).

Most common adverse events:
Flushing (40%), abdominal pain (18%), diarrhea (14%), nausea (12%), lymphopenia (2%).

Usual dosage:
Administration with food may reduce the incidence of flushing; initially, 120 mg twice a day; after 7 days, the dosage should be increased to the maintenance dose of 240 mg twice a day.

Products:
Delayed-release capsules – 120 mg, 240 mg; capsules should be swallowed whole, and should not be crushed or chewed, or the contents sprinkled on food; capsules should be stored in the original container and, once opened, any remaining contents of the container should be discarded after 90 days.

Comments:
Dimethyl fumarate (DMF) is the third drug to be effective following oral administration to be marketed in the last 3 years for the treatment of patients with relapsing forms of MS, joining fingolimod and teriflunomide. Following oral administration, DMF undergoes rapid presystemic hydrolysis by esterases to its active metabolite, monomethyl fumarate (MMF). DMF is not quantifiable in the plasma, and its pharmacologic activity is attributed to MMF. Both DMF and MMF activate the nuclear factor [erythroid-derived 2]-like 2 pathway, which is involved in the cellular response to oxidative stress. MMF has been demonstrated in vitro to have nicotinic acid receptor agonist activity.

DMF was evaluated in two placebo-controlled studies. The primary endpoint of one study was the proportion of patients who experienced relapse within 2 years. Of patients treated with DMF, 27% experienced relapse compared with 46% of those receiving placebo. The drug also was demonstrated to be more effective in attaining additional endpoints, including annualized relapse rate and time to confirmed disability progression. In the second study, the primary endpoint was the annualized relapse rate at 2 years, at which time these rates were 0.224 and 0.401 for DMF and placebo, respectively. In both studies, the drug also was demonstrated to have a significant effect on magnetic resonance imaging endpoints (i.e., a lower number of new or newly enlarging lesions).

DMF is extensively metabolized by esterases to MMF before it reaches the systemic circulation. Further metabolism of MMF occurs through the tricarboxylic acid cycle. The primary route of elimination is exhalation of carbon dioxide, that accounts for approximately 60% of the dose of the drug.

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other inappropriate actions should consider being a whistleblower if the situation enables participation in that capacity.

3. Engage others in the community in developing and promoting programs that encourage "buying local." I recently read the book, *Switch – How to Change Things when Change is Hard* (Chip Heath and Dan Heath; Broadway Books, 2010). It was very thought-stimulating and enjoyable, and I highly recommend it. One of the experiences that the authors described was especially intriguing. It involved a small town and surrounding county in South Dakota in the mid-1990s. The population was declining; many of the residents were elderly and, when the young people were old enough, they left and didn't return. A high school teacher and his business class decided to analyze the situation. They constructed a survey to which members of the community responded and one of the findings was particularly noteworthy – one-half of the residents were doing significant shopping outside the county, driving for as long as an hour to go to larger stores. The class developed a plan around the theme of buying local that they presented to community leaders and residents. They estimated that if residents would spend 10% more of their disposable income at home, they would increase the local economy by $7 million. The community was energized and enthusiastically participated in various phases of the program. After one year, the amount of money spent in the county had increased by $15.6 million. The improved economy provided more tax revenue that the community could commit to support other needs and programs.

   Thousands of communities throughout the country are experiencing similar situations. Pharmacists are well positioned to provide leadership in developing initiatives such as this one that will be of benefit for the entire community and, of course, will also keep prescriptions local.

4. The national pharmacy organizations should provide a prescription drug benefit program for their employees that will serve as such a positive model that other organizations will want to consider a similar program for their employees. The program should include medication therapy management (MTM) and the full range of other professional services that pharmacists are in a position to provide. If such a prescription benefit program is not presently available in the communities in which the employees of our professional organizations reside, our organizations should provide the financial support and leadership to establish such programs. It is imperative that this be done. If our organizations that are the primary advocates for the provision of comprehensive services by pharmacists are not assuring such services for their own employees, how will we convince other organizations/employers that they should do this for their employees?

5. The profession of pharmacy must establish our own prescription benefit program that will compete with the programs of the PBMs and insurance companies. We have the expertise and motivation to establish the best program that will provide the greatest benefit for patients in assuring optimum therapeutic outcomes and avoiding drug-related problems. I also believe that this program can be financially competitive with other programs and, very possibly, be even more cost effective because of the extent to which drug-related problems and associated costs will be substantially reduced. This action is very important for our entire profession and all of our national organizations that have a commitment to increase the role of pharmacists in providing services and care for patients should be participants. It will be a major step in recapturing control of our destiny.

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