The Pharmacist Activist

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Editorial

Mail-Order Pharmacy Programs – Limitations, Inequities, and Deception

Like many within our profession, I was more of an observer than a critic of mail-order pharmacy during the early years of its development. However, as it subsequently experienced a period of rapid growth, its limitations and problems were exposed and its proponents resorted to tactics that I consider to be anticompetitive and a disservice to patients. It is these tactics that have been primarily responsible for my becoming a strong critic of mail-order pharmacy programs that have mandated or provided incentives for their employees/clients to participate in these programs. Sometimes, however, the almost exclusive focus on these tactics and their consequences precludes a broader awareness and concern regarding the scope and quality of the health care for patients and the professional services they should be able to expect from pharmacists. It is the purpose of this commentary to address the larger range of implications and consequences associated with the provision of prescription medications through the mail.

Implications for Patients

Freedom of choice may be denied. Some prescription benefit programs mandate the use of a mail-order pharmacy for certain medications if patients are to receive financial coverage. These patients are being denied the opportunity to obtain these medications from the pharmacist with whom they have had a valued and longstanding professional relationship. Many patients consider this relationship with their local pharmacist to have a value equal to that of their relationship with their personal physician.

Mail-order pharmacy is not personal. Patients are denied the opportunity to meet with the invisible and unidentified pharmacist who is providing their medications from a mail-order pharmacy. The benefits of a face-to-face discussion can not be provided in a patient package insert or telephone conversation. I am convinced that it is not possible to provide optimal health care and optimal drug therapy and outcomes, and also to avoid drug-related problems, without the personal services and "touch" of caring pharmacists and other health professionals (please see my editorial in the March 2011 issue of *The Pharmacist Activist* regarding the need for a personal touch; www.pharmacistactivist.com). There has been extensive recent attention to the provision of "personalized medicine." It is contradictory and regressive that mail-order pharmacy is depersonalizing the provision of medication and denying access to a personal pharmacist in a manner that commonly exists in a local community pharmacy.

Mail-order pharmacy fragments the provision of medications and services. Prescription benefit programs that require or provide financial incentives to obtain certain medications from a mail-order pharmacy increase the complexity and potential for confusion and error with respect to the availability and use of medications. The

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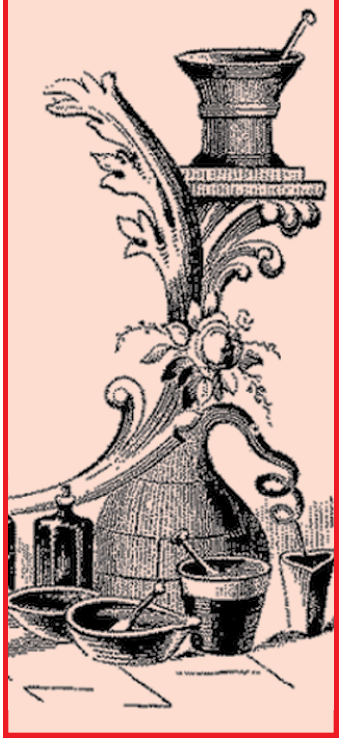

involvement of two or more pharmacies makes it more difficult and, sometimes, impossible, for any of the pharmacists to have a complete record of the medications a patient is using.

Mail-order pharmacies increase the risk of drug-related problems. Even when the mail-order pharmacy is owned by the pharmacy benefit manager (PBM) that administers the prescription benefit program and is thought to have a complete record of a patient's prescription medications, the involvement of multiple pharmacies increases the risk of drug interactions and other drug-related problems. For example, a PBM and its mail-order pharmacy is not likely to be aware of prescriptions for which a patient pays cash in response to promotions such as a 30-day supply of a generic medication for $4.00 or free prescriptions for generic antibiotics. Likewise, a mail-order pharmacy is not aware of nonprescription medications that a patient is using that may interact with prescription medications. The approach that provides the best opportunity to assure the most effective and safest use of medications is one in which a patient obtains all of their prescription and nonprescription medications at one local pharmacy.

Mail-order pharmacies can not meet many patient needs for medications. There are many medical problems for which it is important to start treatment as soon as possible. Examples include infections that should be promptly treated with an antibiotic and acute pain for which rapid relief of symptoms is needed. The inherent limitations of a mail distribution system preclude a mail-order pharmacy from being able to provide many of the medications that patients need on a timely basis. This situation reflects an underlying philosophy of limiting the scope of medications and "services" to those that will provide maximum profit for the mail-order pharmacy, rather than providing a full range of medications and services that are in the best interest of patients.

Mail-order pharmacies can not provide medications in a timely manner. Even the fastest mail distribution system has inherent delays both in receiving prescriptions and sending the completed prescriptions. Other operational and unanticipated delays add to the time that elapses from the time that a patient requests a prescription and the time that it is received. Every local pharmacy has received multiple requests from patients for small quantities of their prescription medications to hold them over until the supply from the mail-order pharmacy arrives.

Implications for Communities and States

I have often heard pharmacy owners make the observation that they anticipate and can successfully contend with competition at the local level. However, they find it extremely difficult, and sometimes impossible, to compete with programs that include unfair and non-negotiable terms, and require patients to obtain certain prescriptions at a mail-order pharmacy or provide a financial incentive to do so. These circumstances may cause or contribute to the closure of a local pharmacy, with the result that people in the community have less convenient access to medications and services of a pharmacist. The closure of a pharmacy also results in a loss of jobs for residents of the community

At the state level there is a loss of tax and other revenues when a pharmacy closes and jobs are lost. In addition, there is also a high probability that the millions of dollars generated from prescriptions dispensed by mail-order pharmacies are going to another state rather than being retained within the states where the patients reside when they obtained these prescriptions in local pharmacies. Mail-order pharmacy has become a huge business with most of the revenues and jobs being concentrated in the small number of states in which the highly-automated, high-capacity pharmacies and office facilities are located. An example of the financial implications is included in a recent press release from Express Scripts in which it is announced that it generates about $1 billion in economic benefits each year for the state of Missouri in which its headquarters and many of its facilities are based.

Inequities and Deception

The largest administrators (PBMs) of prescription benefit programs (CVS Caremark, Express Scripts, Medco) have their own mail-order pharmacies. Their profits are highest when they are not only paid for administering a program, but also receive revenues when prescriptions are dispensed by the mail-order pharmacies they own. Many local pharmacies would be satisfied with a peaceful co-existence with mail-order pharmacies if the terms of participation were the same for all pharmacies and if patients had the freedom to choose the pharmacy they wished to use. However, this is not the case.

PBMs have conflicts of interest. The PBMs determine the terms and conditions of prescription benefit programs unilaterally without an opportunity for pharmacists to be involved in the planning of the programs. The terms, conditions, and compensation are non-negotiable and presented to pharmacies on a take it or leave it basis. Because these PBMs have their own mail-order pharmacies, the terms and conditions are constructed to favor these pharmacies and to restrict, or even exclude, the participation of other pharmacies. The PBMs get away with this obvious conflict of interest because local pharmacies are restricted by federal antitrust legislation from working together or through professional organizations to negotiate the terms of a program.

Programs are anticompetitive and inequitable. Some prescription benefit programs require patients to obtain certain medications from a mail-order pharmacy if all or most of the cost of the prescription is to be covered by the benefit program. Many programs provide a financial incentive to use a mail-order pharmacy rather than a local pharmacy, typically by permitting the mail-order pharmacy to provide a 90-day supply of medication for one or two co-payments, whereas local pharmacies are restricted to providing a 30-day supply that would necessitate three co-payments over a 90-day period.

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New Drug Review

Ceftaroline fosamil
(Teflaro – Forest)
Antibiotic

New Drug Comparison Rating (NDCR) = 4

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

Indications:
Administered intravenously for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of *Staphylococcus aureus* (including methicillin-susceptible and –resistant isolates), *Streptococcus pyogenes*, *Streptococcus agalactiae*, *Escherichia coli*, *Klebsiella pneumoniae*, and *Klebsiella oxytoca*; also indicated for the treatment of community-acquired bacterial pneumonia (CABP) caused by susceptible isolates of *Streptococcus pneumoniae* (including cases with concurrent bacteremia), *Staphylococcus aureus* (methicillin-susceptible isolates only), *Haemophilus influenzae*, *Klebsiella pneumoniae*, *Klebsiella oxytoca*, and *Escherichia coli*.

Comparable drug:
Ceftriaxone (Rocephin).

Advantages:
- Is active against methicillin-resistant isolates of *Staphylococcus aureus* (MRSA);
- Less likely to be associated with symptoms of gallbladder disease or biliary problems.

Disadvantages:
- Labeled indications are more limited (ceftriaxone is indicated for numerous types of infections);
- Administered more frequently (every 12 hours whereas ceftriaxone is often administered every 24 hours);
- Dosage should be adjusted in patients with moderate or severe renal impairment;
- Use in pediatric patients has not been evaluated;
- More likely to cause direct Coombs' test seroconversion.

Most important risks/adverse events:
Serious hypersensitivity reactions, including anaphylaxis (use is contraindicated in patients who have experienced serious hypersensitivity to ceftaroline or other cephalosporins; caution must be exercised in patients with known hypersensitivity to other beta-lactam antibiotics [e.g., penicillins, carbapenems]); *Clostridium difficile*-associated diarrhea (should be considered in all patients who experience diarrhea following antibiotic use, including the period of time following completion of antibiotic therapy); seroconversion from a negative to a positive direct Coombs' test (hemolytic anemia should be considered if anemia develops).

Most common adverse events:
Diarrhea (5%), nausea (4%), rash (3%), positive direct Coombs' test (11%).

Usual dosage:
600 mg every 12 hours administered by intravenous infusion over a period of 1 hour; duration of therapy should be guided by the site and severity of the infection, as well as the patient's progress, but is usually 5-14 days for the treatment of ABSSSI and 5-7 days for the treatment of CABP; dosage should be reduced in patients with moderate renal impairment (400 mg every 12 hours), severe renal impairment (300 mg every 12 hours), or end-stage renal disease (200 mg every 12 hours).

Products:
Single-use vials – 400 mg, 600 mg (should be stored in a refrigerator); contents of a vial should be constituted with 20 mL of Sterile Water for Injection, and this solution should be further diluted in a volume of at least 250 mL of 0.9% Sodium Chloride Injection or other appropriate vehicle.

Comments:
Ceftaroline fosamil is a water-soluble prodrug that is converted to its active form, ceftaroline, during intravenous infusion. Ceftaroline is a cephalosporin antibiotic that, like its predecessors, exhibits a bactericidal action by inhibiting penicillin-binding proteins and inhibiting bacterial cell wall synthesis. It is active against numerous Gram-positive and Gram-negative bacteria and is the first cephalosporin to be approved for an infection caused by methicillin-resistant isolates of *Staphylococcus aureus* (MRSA). In the studies in patients with ABSSSI, ceftaroline was compared with a regimen of vancomycin plus aztreonam, and the two regimens were considered comparable in effectiveness. In the studies in patients with CABP, ceftaroline was compared with ceftriaxone, and the two agents were considered comparable in effectiveness; however, effectiveness against MRSA was not evaluated in these studies because few of the patients had pneumonia caused by MRSA, and ceftriaxone is not effective against MRSA.

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Attempted justification is disingenuous and deceptive. The attempts of the PBMs to justify the terms and restrictions in their programs usually focus on two claims, both of which are unsupported and deceptive:

Claim # 1: The cost of dispensing prescriptions from a mail-order pharmacy is less than from local pharmacies, and the cost of the prescription benefit program would be much greater if there were not requirements/incentives to use the mail-order pharmacy.

When asked for the data and other information to support this claim, the PBMs respond that they cannot provide it because the data is proprietary and they can't risk having it become known to their competitors. In the few situations in which limited information is available, the data that is made available has been selected by the PBM and provided in a format and manner that supports its position. The claim and the information can not be independently verified. To my knowledge, there is no study that has been conducted by independent researchers who have full access to pertinent information that supports the claim that a mail-order pharmacy program is less costly than a program in which prescriptions are provided through local pharmacies.

Some suggest that mail-order pharmacies should be able to operate more efficiently because of the greater discounts attained when purchasing large quantities of medications needed for their high prescription volume, as well as the use of highly automated equipment to process and prepare prescriptions. However, these efficiencies could be offset by the costs incurred in mailing the prescriptions, the wastage of medications that are often very expensive because of the emphasis in dispensing 90-day supplies (only to have the prescriber change the dosage or discontinue the medication), and the cost of the automated equipment.

If the claim that mail-order pharmacy programs are less expensive is valid, I have to think that credible, independently-verified documentation would be quickly provided. It has not been and I can not accept the claim.

Claim # 2: Mail-order pharmacies make fewer errors and are, therefore, safer than local pharmacies.

Information that is available regarding errors that have occurred in mail-order pharmacies is essentially limited to one study that was conducted by Medco. The study was designed by Medco personnel using study parameters that they selected (that did not include, for example, whether the initiation of treatment was delayed because the medication did not reach the patient via the mail on a timely basis). The study was not conducted by "outside" researchers or other individuals who did not have a vested interest in the results. The results of this study have been widely cited by the PBMs with mail-order pharmacies. However, they conveniently ignore the following limitation of this study that the authors acknowledge in the published paper – "because mail-service pharmacies differ in their operation and degree of automation, these findings cannot be generalized to mail-service pharmacies as a class."

Although these authors indicate that their results cannot be generalized to other mail-order pharmacies, they attempt to compare their findings with those of studies in community pharmacies. This is a flawed comparison as their study did not include a direct comparison with the experience in community pharmacies.

When individuals or organizations claim that mail-order pharmacies make fewer errors or are safer than community pharmacies, the following questions should be asked in response:

- *Have studies of errors been conducted in the mail-order pharmacy you are using/recommending? If so, who conducted the studies (e.g., the pharmacy's own employees) and what types of errors were included in the study parameters?*
- *What are the results of these studies (e.g., error rates) in this mail-order pharmacy, and what other data are available regarding errors?*
- *How many lawsuits alleging errors (including those settled out of court) have been filed against this mail-order pharmacy?*

I have asked these questions on several occasions. No responses have been forthcoming. The claims that mail-order pharmacies are less costly and safer than local pharmacies are flawed and deceptive. They must be rejected.

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