The Pharmacist Activist

Volume 3, No. 6 • June 2008

Editorial

A Mail-Order MYTH

Many third-party prescription drug benefit programs include a mail-order component with provisions that are extremely unfair to local pharmacies. Some programs require participants to obtain certain medications from a mail-order pharmacy if all or most of the cost is to be covered by the program. Many programs provide a financial incentive to use a mail-order pharmacy rather than a local pharmacy, typically by permitting them 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.

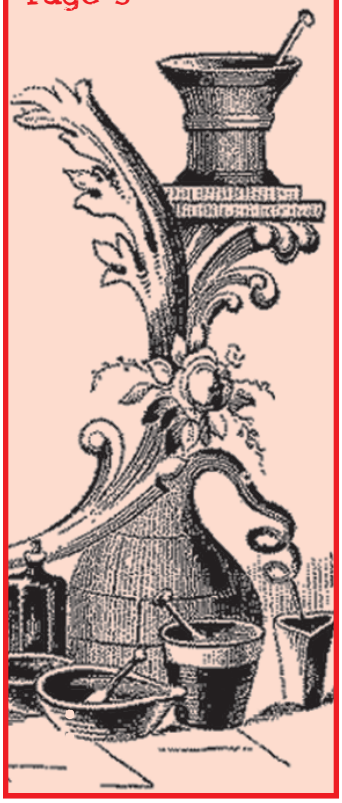
Pharmacists have challenged the inequitable provisions of these programs, but with only limited success. In my state of Pennsylvania, pharmacists are once again pursuing the approval of legislation that would permit local pharmacies to participate in prescription drug benefit programs in the same manner in which mail-order pharmacies do (i.e., "leveling the playing field"). As before, the mail-order pharmacies and their association, as well as the large insurance companies, have mounted strong opposition to this legislative effort. Much of the information they provide is disingenuous at best, but they make one allegation that I consider to be particularly egregious. This is the allegation that mail-order pharmacies make fewer errors and are, therefore, safer than local pharmacies. Not only is this an unprofessional characterization of pharmacists in another practice setting, but there is not credible evidence to support the allegation. After reading such comments in several recent letters sent by mail-order pharmacies and insurance companies to Pennsylvania legislators, I am even more determined to expose the myth that mail-order pharmacies are safer.

The studies

In one of the letters to some Pennsylvania legislators, an executive of a large insurance company states that "...studies have demonstrated that they (mail-order pharmacies) make fewer errors." No additional information or reference citations are provided regarding these "studies," so the hope of the letter writer is that the recipients will accept this statement as "fact."

Studies of dispensing errors in pharmacies have been conducted and published; however, these studies do not permit a reliable comparison of error rates in different pharmacy practice settings (e.g., mail-order pharmacies vs. local community pharmacies). Information that is available regarding errors that have occurred in mail-order pharmacies is essentially limited to one study that was conducted in a highly-automated, mail-order pharmacy and was designed by individuals employed by the pharmacy using study parameters that they selected (an example of a parameter that was not evaluated is the timeliness of the receipt of prescriptions in the mail-order pharmacy and the subsequent receipt of the prescriptions by patients, something that can be pretty much assumed in community and hospital pharmacies). The study was not conducted by "outside" researchers or other individuals who did not have a vested interest in the results. In contrast, the studies of errors in community and hospital pharmacies have typically been conducted by individuals who are not employed by the pharmacies being studied and who are in a position to objectively evaluate and report on the findings.

Contents



Those who claim that mail-order pharmacies "make fewer errors" appear to base their statement on this single study. However, even the authors acknowledge limitations of their study including "because mail-service pharmacies differ in their operation and degree of automation, these findings cannot be generalized to mail-service pharmacies as a class."

Another limitation of this study is that the authors attempt to compare their findings with those of studies in community pharmacies. This is a flawed comparison as the study was designed to determine the rate of errors in a particular mail-order pharmacy, and did not include a direct comparison with the experience in community pharmacies. To suggest or imply that the findings of this study can be appropriately compared with the results of other studies conducted in community pharmacies by impartial investigators is like comparing apples with oranges.

A recent experience prompts me to question the nature of the errors that would be counted in this particular mail-order pharmacy. I was asked to serve as an expert witness in a lawsuit on behalf of a patient who was harmed as a result of an error involving a prescription that was dispensed by this pharmacy. The error involved a medication that has a well-recognized potential to cause serious adverse events, and it was prescribed in an excessive dosage. The pharmacist who first reviewed the prescription correctly identified the error in dosage and put a "hold" on the prescription. However, another pharmacist overrode the hold and dispensed the prescription with instructions for the patient that resulted in an excessive dosage and harm to the patient. Even though the record of this experience clearly shows that a pharmacist recognized the error and initiated an intervention, the pharmacy responded by denying that it had any responsibility for the error and the ensuing harm to the patient. This response was a major factor in my agreeing to participate in this case. Although I do not like to be on the opposite side of a pharmacist or pharmacy in a lawsuit, I considered the pharmacy's response to be inappropriate and unfair to the patient who was harmed. The response also sends a message that pharmacists have essentially no responsibility for assuring the safety of medications and that, when errors occur, they are the fault of the physician or some other party.

Following depositions and lengthy "negotiations," this case was settled out of court. As is often the situation when litigation is settled out of court, the pharmacy defendant admitted to no wrongdoing. Because no wrongdoing was acknowledged, a question exists as to whether this pharmacy would have considered this experience to be an error that would be counted in a study of the type it conducted.

Although some who would want individuals to believe that mail-order pharmacies make fewer errors refer to studies (in the plural) that show this, I am aware of only the one study discussed above that is identified to support this claim. Have the other mail-order pharmacies conducted studies of their error rates? If so, what are the results? If not, why not?

Questions that need to be asked

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

Have studies of errors been conducted in the mail-order pharmacies you are using/promoting? If so, who conducted the studies (e.g., the pharmacy's own employees) and what parameters were evaluated in the studies?

What are the results of these studies (e.g., error rates) in these mail-order pharmacies?

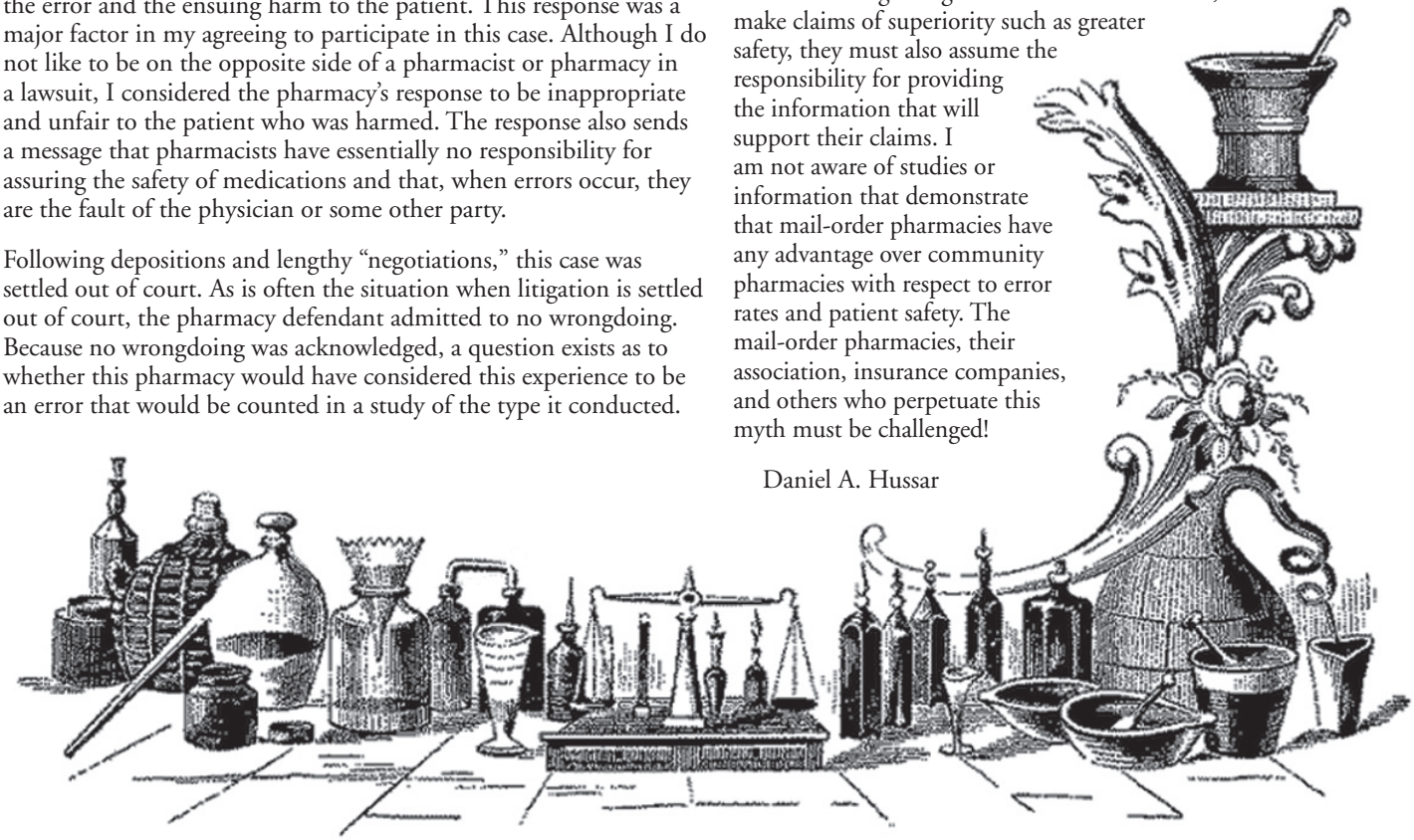
How many lawsuits (including those settled out of court) have been filed against these pharmacies?

What is the average number of days/weeks that elapse between the day that a prescription is written and the day it is received by the patient in the mail?

What is the basis for your claim that mail-order pharmacies make fewer errors than community pharmacies?

In most circumstances, pharmacies should not be expected to provide information regarding their error rates. However, when some choose to make claims of superiority such as greater safety, they must also assume the responsibility for providing the information that will support their claims. I am not aware of studies or information that demonstrate that mail-order pharmacies have any advantage over community pharmacies with respect to error rates and patient safety. The mail-order pharmacies, their association, insurance companies, and others who perpetuate this myth must be challenged!

Daniel A. Hussar



New Drug Review

Sinecatechins (Veregen – Bradley)

Agent for Genital Warts

New Drug Comparison Rating (NDCR) = 2

(significant disadvantages)

in a scale of 1 to 5, with 5 being the highest rating

Indication:

Topical treatment of external genital and perianal warts in immunocompetent patients 18 years and older.

Comparable drugs:

Self-applied medications for genital warts: imiquimod (Aldara), podofilox (Condylox).

Advantages:

- Different mechanism of action;
- May be less likely to cause systemic adverse events (compared with imiquimod);
- Does not have a limitation on the area of wart tissue to be treated or the amount of formulation used (compared with podofilox).

Disadvantages:

- Has not been directly compared with other agents in clinical studies;
- Labeled indications are more limited (compared with imiquimod that also has labeled indications for actinic keratosis and superficial basal cell carcinoma);
- Must be applied more frequently (three times a day compared with three times a week with imiquimod and twice a day for three consecutive days in each weekly cycle with podofilox);
- May weaken condoms and vaginal diaphragms;
- May stain clothing and bedding.

Most important risks/adverse events:

Use on open wounds should be avoided.

Most common adverse events:

Erythema (70%), pruritus (69%), burning (67%), pain/discomfort (56%), erosion/ulceration (49%), edema (45%), induration (35%), vesicular rash (20%).

Usual dosage:

A strand of ointment (approximately 0.5 cm) is applied three times a day to all external genital and perianal warts, leaving a thin layer of the ointment on the warts; treatment should be continued until the warts have completely cleared, but not for a period longer than 16 weeks; treated areas should not be covered or wrapped as to be occlusive.

(Continued on Page 4)

Free Subscription

Go to www.pharmacistactivist.com to sign-up for a FREE subscription.

The Pharmacist Activist will be provided FREE via e-mail to interested pharmacists and pharmacy students who request a complimentary subscription by providing the information below. The opportunity to provide this newsletter without charge is made possible by the generous support of individuals who are committed to the provision of objective and unbiased information regarding new drugs, as well as editorial opinion about important issues facing the profession.

It is important that the development and distribution of *The Pharmacist Activist* be as cost efficient as possible. Therefore, we prefer to send the monthly issues to you via e-mail.

Sign-up online at:
www.pharmacistactivist.com

To assure that you will receive *The Pharmacist Activist*, sign-up online or complete this form and mail to address noted below.

☐ YES, I would like to receive a FREE subscription to The Pharmacist Activist

Name: _____

E-mail: _____

Home Address: _____

City/State/Zip: _____

Work Address: _____

City/State/Zip: _____

Job Title/Student: _____

Employer: _____

Educational Facility/School: _____

Signature (required): _____ Date: _____

Mail this subscription form to:
The Pharmacist Activist
661 Moore Rd., Suite 100, King of Prussia, PA 19406

Author/Editor
Daniel A. Hussar, Ph.D.
Philadelphia College of Pharmacy
University of the Sciences in Philadelphia

Publishers
Christopher J. Polli • G. Patrick Polli II

Assistant Editor
John Buck

Publications Director
Jeff Zajac

Graphic Artist/Designer
Joe Monte

The opinions and recommendations are those of the author and do not necessarily represent those of his full-time employer or the publisher.

The Pharmacist Activist
661 Moore Rd., Suite 100
King of Prussia, PA 19406
610-337-1050 • Fax: 610-337-1049
E-mail: pharmacistactivist@news-line.com

News, Information and Career Opportunities
NEWS - Line PUBLISHING

New Drug Review (cont.)

Product:

Ointment – 15%; should be stored in a refrigerator prior to dispensing.

Comments:

Genital warts (condyloma acuminata) are caused by the human papillomavirus (HPV). HPV infection is highly contagious and is one of the most common sexually-transmitted diseases. Epidemiologic data also identify an increased incidence of cervical cancer associated with the virus. Sinecatechins is a botanical product that is a partially purified fraction of an extract of green tea leaves that contains a mixture of catechins (a class of polyphenols) and other green tea components. Catechins constitute 85 to 95% of the total drug substance which includes more than 55% of epigallocatechin gallate. The product has been approved for the topical treatment of external genital and perianal warts; its mechanism of action has not been specifically identified although it has demonstrated antioxidant activity in vitro.

The effectiveness of sinecatechins ointment has been demonstrated in two studies in which it was compared with the ointment vehicle. Complete clearance of warts was experienced by 54% of patients, compared with 35% of those who received the vehicle. The median time to complete clearance of the warts was 16 weeks and 10 weeks in the two studies. The rate of recurrence of warts 12 weeks following completion of treatment in patients with complete clearance was 7% for those treated with sinecatechins and 6% for those treated with the vehicle. The product has not been evaluated for the treatment of urethral, intra-vaginal, cervical, rectal, or intra-anal HPV disease, or in immunosuppressed patients.

Approximately two-thirds of the patients treated with sinecatechins experienced either a moderate or severe adverse reaction that resulted in discontinuation or interruption of treatment in 5% of patients. The ointment may weaken condoms and vaginal diaphragms, and concurrent use, as well as sexual contact while the ointment is on the skin, is not recommended. The ointment may stain clothing and bedding.

Daniel A. Hussar