

Editorial

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Dear Legislator

btaining equitable compensation for professional services and the medications dispensed continues to be one of the most frustrating challenges for the profession of pharmacy. In my state of Pennsylvania, the Pharmaceutical Assistance Contract for the Elderly (PACE) has been one of the fairest third-party prescription programs for pharmacists. However, unfortunately, changes have been proposed (but which must be approved by the legislature) that would drastically reduce the compensation for the cost of drug products.

Throughout the country pharmacists are facing similar challenges and it is imperative that we communicate our concerns to our legislators with sufficient persuasion that they will support our position. The following is a letter that I sent to my representative about our PACE program. Although the specifics differ among the myriad of prescription programs, some of the issues are the same. My hope in including it in this issue of *The Pharmacist Activist* is that some of the sections may be helpful in letters that you send to your legislators and may save you time in writing them. If any of the content of this letter would serve these purposes, please feel free to use any parts of it (verbatim if you wish) in your own letters. Attribution is not necessary.

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April 13, 2009

Dear Representative xxxxxx:

Thank you for meeting with me and several other pharmacists and pharmacy students on March 25. I voiced concern about possible changes in the PACE prescription program and I am now following up with respect to a memorandum you have received from Representative xxxx xxxxxxx.

Representative xxxxxx has contacted members of the House of Representatives regarding legislation that he is proposing that would amend the PACE program. This proposal would be devastating financially for the community pharmacies in the Commonwealth. I strongly urge you to NOT be a co-sponsor of this legislation and, if it is introduced, to be a leader in speaking against it.

In the memorandum from Representative xxxxxx, he notes that "this legislation will generate \$41.5 million in savings to the Commonwealth." ALL of this amount would be derived from a reduction in payments to community pharmacists. Although the proposal provides an increase in dispensing fees for pharmacists, this is very misleading as the drug product cost to be reimbursed to pharmacists would be reduced by such a large amount that it not only offsets the increase in dispensing fees but results in a net reduction to pharmacists of \$41.5 million.

Approximately 80% of the cost of prescriptions in the PACE program represents the monies received by the pharmaceutical companies that supply the drugs. The compensation that pharmacists receive represents only a very small fraction of the total cost of the prescriptions. Pharmacists have not received increases in compensation in the PACE program and, in fact, the compensation for pharmacists has decreased because of reductions in the reimbursement for the cost of the medications. In sharp contrast, pharmaceutical companies increase the cost of their medications whenever they choose to, sometimes several times a year. In addition, these companies have created chaos in the marketplace by selling their products at different prices to different purchasers in a manner that makes it essentially impossible to establish a system that equitably identifies the cost for prescription medications.

If it is necessary that savings be extracted from the PACE prescription program, there are other ways of doing it that focus on the component of the program that has, by far, the largest financial impact. I am providing the following specific recommendations:

- 1. The rebates provided by pharmaceutical companies for their medications that are dispensed in the PACE program are much lower than the rebates they provide in the Medicaid program. The rebates in the PACE program should be increased.
- 2. Some of the medications provided in the PACE program are much more expensive than other medications that are equally effective and safe. A formulary should be established that will limit the use of higher-priced medications when less expensive products are available that do not compromise effectiveness and safety. I can provide specific examples of how this can be accomplished.
- 3. Price increases from pharmaceutical companies should not be permitted during the next budget year. If a pharmaceutical company decides to raise the price of its medications during this time period, they must reimburse to the PACE program the difference between the price at the beginning of the year and the price to which it has been increased. Compensation for pharmacists has not been increased but, in fact, has been decreased; therefore, it is grossly unfair that pharmaceutical companies are permitted to raise their prices for medications at will.

I realize that some, but not most, pharmaceutical companies have their headquarters in Pennsylvania and that they have considerable political influence. However, <u>every</u> community pharmacy that participates in the PACE program is located in the Commonwealth. I trust that you and your colleagues in the House of Representatives will recognize that the legislation proposed by Representative xxxxxx is inequitable and unacceptable for community pharmacies.

Thank you for your consideration of my concerns. I will contact you next week to discuss these issues with you further.

Sincerely,

Daniel A. Hussar

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In my subsequent telephone conversation with my Representative, he responded that he will not support the proposed legislation that would reduce compensation for pharmacists. In the meantime, it was learned that one of the state Senators had been asked to be the primary sponsor in the Senate for the same proposal. Several pharmacists contacted this senator's office to voice pharmacy's concerns. Later that same day, this Senator responded to say that she would not be a sponsor of this legislation. Other Pennsylvania pharmacists have also been contacting their legislators but we have a formidable challenge.

I have often heard an observation to the effect that "every legislator has a pharmacist." This statement suggests that pharmacists should be highly influential and effective in initiating and amending legislation. Although there have been some pharmacist-influenced legislative accomplishments, the unfortunate fact remains that, overall, pharmacy has not been effective in addressing legislative issues that have a major impact on expanding the professional role of pharmacists and in obtaining equitable compensation for pharmacists' services.

How many state pharmacy associations can identify one or more pharmacists in each legislative district who personally know the representative and senator serving that district? If this information is not available now, we must give a very high priority to identifying these pharmacists and preparing them in a manner that will provide a rapid and authoritative pharmacy response on important legislative issues.

At the Annual Meeting of the National Association of Chain Drug Stores held this month, Chairman of the Board Andy Giancamilli (CEO of Snyders Drug Stores) made the following observation regarding the public policy battles that are crucial to retail pharmacy: "We can't just do things, we need to win things." I fully concur. We have experienced too many losses. We can win and we must win!

Daniel A. Hussar

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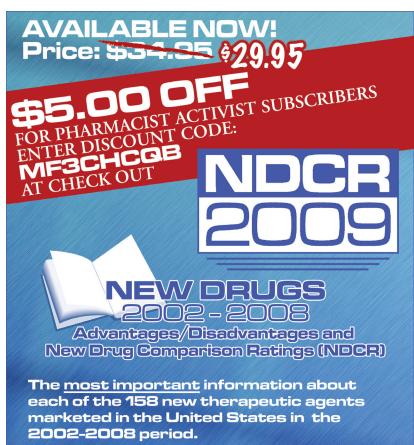
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Comparisons with previously-marketed drugs with specific advantages and disadvantages identified.

Ratings for each new drug based on comparisons with related agents.

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New Drug Review

Febuxostat (Uloric - Takeđa)

Agent for Gout

New Drug Comparison Rating (NDCR) = 3

(no or minor advantages/ disadvantages) in a scale of 1 to 5, with 5 being the highest rating

Indication:

Chronic management of hyperuricemia in patients with gout.

Comparable drug: Allopurinol (e.g., Zyloprim).

Advantages:

- Has not been reported to cause dermatologic/hypersensitivity reactions with serious complications;
- Dosage titration is less complex;
- Is administered once a day throughout the dosage range (compared with allopurinol for which dosages above 300 mg daily should be administered in
- Dosage reduction is not necessary in patients with mild or moderate renal impairment.

Disadvantages:

- Labeled indications are more limited (allopurinol is also indicated for the management of patients with leukemia, lymphoma, and malignancies who are receiving cancer therapy which causes increased uric acid concentrations, and for the management of patients with recurrent calcium oxalate calculi);
- Is contraindicated in patients who are being treated with xanthine oxidase substrates (azathioprine [e.g., Imuran], mercaptopurine [e.g., Purinethol], theophylline); (labeling for allopurinol includes a warning about these interactions and recommendations for dosage reductions to decrease the risk of concurrent use);
- May be more likely to cause cardiovascular thromboembolic events;
- Not indicated in patients less than 18 years of age.

Most important risks/adverse events:

Contraindicated in patients being treated with azathioprine, mercaptopurine, or theophylline (the metabolism of these xanthine oxidase substrates is inhibited, resulting in increased concentrations and a risk of serious toxicity); increased gout flares; cardiovascular thromboembolic events; liver function test abnormalities (transaminase [ALT and AST] elevations; should be monitored at two months and four months, and periodically thereafter).

Most common adverse events:

Nausea (1%), arthralgia (1%), rash (1%), transaminase elevations (6%).

Usual dosage:

Initially, 40 mg once a day; in patients who do not achieve a serum uric acid concentration less than 6 mg/dL after two weeks with the initial dosage, the dosage should be increased to 80 mg once a day.

Products:

Tablets – 40 mg, 80 mg.

Comments:

Febuxostat is the first new treatment option for patients with chronic gout in more than 40 years. Like allopurinol, it is classified as a xanthine oxidase inhibitor. Xanthine oxidase is responsible for the breakdown of the purine base, hypoxanthine, to xanthine, and then to uric acid. Hyperuricemia is a precursor to gout. By inhibiting xanthine oxidase, febuxostat and allopurinol reduce uric acid production and lower elevated serum concentrations of uric acid. Neither febuxostat nor allopurinol is recommended for the treatment of asymptomatic hyperuricemia.

In the largest clinical study, febuxostat in a dosage of 80 mg once a day was more effective than allopurinol in a dosage of 300 mg once a day (or 200 mg once a day in patients with moderate renal impairment) in lowering serum uric acid concentrations to less than 6 mg/dL at the final visit (67% vs. 42% of patients, respectively). However, the results with febuxostat in a dosage of 40 mg once a day (45% of patients) were similar to those with allopurinol. It cannot be concluded that the new agent is more effective than allopurinol because the 300 mg/day dosage of the latter agent that was used in the clinical studies is considerably less than the maximum dosage (800 mg/day).

Following initiation of febuxostat or allopurinol treatment, gout flares may be experienced because of the mobilization of urate from tissue deposits. When initiating treatment, flare prophylaxis with a nonsteroidal anti-inflammatory drug (e.g., naproxen, 250 mg twice a day) or colchicine (0.6 mg once or twice a day) may be beneficial for up to six months.

Daniel A. Hussar