The Pharmacist Activist

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Editorial

Express Scripts Almost Discovers Conscience - But Fails To Do So!

Express Scripts has recently sued the large accounting firm Ernst & Young and one of its former employees (one of the accounts of the story appears in the February 19 issue of *The Wall Street Journal*, page B2). Ernst & Young was retained by Express Scripts to provide consultant services at the time it was acquiring Medco, and the lawsuit alleges that the Ernst & Young employee had been sneaking into Express Scripts' headquarters and stealing confidential and proprietary information in at least 20,000 pages of documents. Specifically, the lawsuit alleges the "...theft of trade secrets, misappropriation of confidential and proprietary information, and unauthorized access and tampering with Express Scripts' computer systems and electronically stored information."

The lawsuit includes a statement that "...the Court should award substantial punitive damages..," based on the allegation that Ernst & Young and its employee "were possessed with an evil motive, and their conduct shocks the *conscious* (emphasis added)..." It is not a surprise to most community pharmacists to learn that Express Scripts is able to recognize evil motivation. While stopping short of suggesting that Express Scripts invented evil motivation, many pharmacists would contend that evil motivation underlies the Express Scripts' prescription benefit programs that are inequitable for pharmacists and a disservice to patients.

It is, however, the allegation that "their conduct shocks the conscious" that suggests varying interpretations. I have to think that "conscience" is the word that was intended rather than "conscious." "Conscience" is defined in my dictionary as "the faculty of recognizing the difference between right and wrong with regard to one's conduct coupled with a sense that one should act accordingly." But many pharmacists would contend that there is no evidence of conscience in Express Scripts' prescription benefits programs, thereby inviting the question of whether Express Scripts recognizes the existence of conscience. Has "conscience" escaped its understanding and vocabulary, as well as its programs and actions?

An alternative explanation is that the word "conscious" was used in error in the lawsuit. However, Express Scripts and Medco have gone to great lengths to try to convince their clients and patients that they rarely make errors and that their mail-order pharmacies make fewer errors than local pharmacies (claims that in my opinion are false). Therefore, it becomes even more difficult to imagine that Express Scripts would make an error in something as important to it as a lawsuit alleging evil motivation and crimes and requesting punitive damages.

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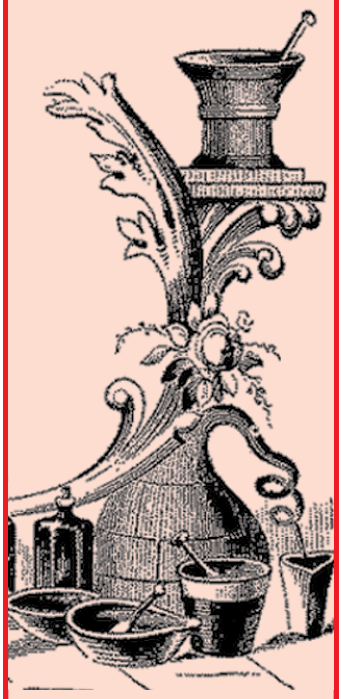

I am not trying to defend Ernst & Young and its employee and, if Express Scripts' allegations of theft, tampering, etc. are accurate, the defendants should receive the appropriate consequences. However, it is apparent that Express Scripts has not discovered conscience.

Strength and influence

Regardless of the outcome of Express Scripts' lawsuit, it is appropriate to consider the impact this organization has had on the profession and practice of pharmacy. Less than a year ago, Express Scripts acquired Medco, its largest competitor, for $29.1 billion. Walgreens, with more than 8,000 pharmacies, declined to continue its working relationship with Express Scripts because it did not believe that the terms of the proposed contract were adequate. However, in the opinion of most, Express Scripts won this battle of giants and, after a number of months, the two organizations reached an agreement. I commend Walgreens for its willingness to take a strong stand in addressing the important concerns regarding Express Scripts' prescription benefit programs. Regrettably, other large chain pharmacies have essentially been silent regarding these issues, and chains like CVS and Rite Aid responded to Walgreens' challenge to Express Scripts by stealing patients from Walgreens.

The CEO of Express Scripts has made public comments that are insulting and demeaning to pharmacists and the profession of pharmacy, most notably, "At the end of the day...Nexium is Nexium, Lipitor is Lipitor, drugs are drugs, and it shouldn't matter that much who's counting to 30." Notwithstanding a broader context in which this comment was made, his remarks reflect negatively on all pharmacists including those employed by Express Scripts, and ignore the value of the services pharmacists provide. However, with the exception of the National Community Pharmacists Association and several others, this comment was essentially unchallenged.

These situations make it strikingly clear that Express Scripts has the strength and influence to have an enormous impact on how pharmacy is currently practiced and how it may be practiced in the future. The following questions must be addressed:

> Does the Express Scripts' system for providing prescription medications and pertinent pharmacist services best meet the needs of patients with respect to their use of medications?
>
> Does the Express Scripts' system for providing prescription medications and pertinent services make the best use of pharmacists' abilities and services?
>
> Does the Express Scripts' system for providing prescription medications demonstrate the knowledge and professional role of pharmacists and advance the profession of pharmacy?

My response to these three questions is an emphatic "NO!" and most pharmacists would agree. And now the questions become:

> Does any national pharmacy association or coalition of national pharmacy associations have the strength and influence that exceed or match that of Express Scripts?
>
> What is the profession of pharmacy doing to address the concerns pertaining to Express Scripts' prescription benefit programs?

Actions

Some might conclude that the profession of pharmacy is not strong enough to effectively contend with the situations described above, as well as the legislative and economic changes that have a major impact on health care. However, the risk that these circumstances may result in a reduction in the quality and safety of health care is so important that we must persevere and further strengthen efforts to assure that the standards of health care are enhanced and not compromised. Actions in this direction must include the following:

1. We must develop an organizational structure that best meets the needs of the profession of pharmacy and serves the public interest with respect to the effective and safe use of medications.

2. The profession must develop more programs that document the benefits and value of pharmacists' professional services.

3. Pharmacists must establish effective communication and working relationships with their legislators.

4. Pharmacists must be committed to exercise their conscience for the benefit of our patients and our profession.

Express Scripts' executives may have wealth and influence, but pharmacists have conscience and the commitment to provide professional services in a caring and compassionate manner that is personalized for their patients.

Daniel A. Hussar

New Drug Review

Teriflunomide
(Aubagio – Sanofi)

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 drug:
Fingolimod (Gilenya).

Advantages:
- Has a unique mechanism of action (pyrimidine synthesis inhibition);
- Less risk of cardiac adverse events (e.g., bradycardia, prolongation of QT interval);
- Treatment may be initiated easily (whereas first-dose monitoring is needed with fingolimod).

Disadvantages:
- May be less effective in reducing MS relapses (based on data from separate studies of the two agents);
- Labeled indication is more limited (indication for fingolimod includes the statement "to reduce the frequency of clinical exacerbations and to delay the accumulation of physical disability");
- Risk of teratogenicity (Pregnancy Category X);
- Is very slowly eliminated (accelerated elimination procedure is required in certain situations).

Most important risks/adverse events:
Hepatotoxicity (boxed warning; contraindicated in patients with severe hepatic impairment; liver function tests should be determined within 6 months before initiating treatment, and alanine aminotransferase [ALT] concentrations should be monitored at least monthly for 6 months after starting treatment); teratogenicity (boxed warning; Pregnancy Category X; contraindicated in pregnant women or women of childbearing potential who are not using reliable contraception; drug is detected in semen and male patients should use reliable contraception); concurrent use with leflunomide (e.g., Arava) is contraindicated; reduction of white blood cell and platelet counts (complete blood cell count should be obtained within 6 months before starting treatment and further monitoring conducted as indicated); immunosuppression/infection (use is not recommended in patients with severe immunodeficiency, bone marrow disease, or severe, uncontrolled infection; patients with an active acute or chronic infection should not start treatment until the infection is resolved; patients should be screened for latent tuberculosis before initiating therapy; immunization with live vaccines is not recommended during treatment); hypertension (blood pressure should be determined before starting treatment and periodically thereafter); acute renal failure and hyperkalemia (renal function and potassium concentrations should be monitored in patients at risk); peripheral neuropathy; severe dermatologic reactions (e.g., Stevens-Johnson syndrome); interstitial lung disease; inhibits the CYP2C8 metabolic pathway and may increase the action of substrates such as repaglinide (Prandin) and pioglitazone (Actos); may reduce the action of medications that are metabolized by the CYP1A2 pathway (e.g., duloxetine [Cymbalta], theophylline); may decrease the international normalized ratio (INR) in patients treated with warfarin.

Most common adverse events:
Diarrhea (18%), nausea (14%), alopecia (13%), influenza (12%), paresthesia (10%), increased ALT (14%).

Usual dosage:
7 mg or 14 mg once a day.

Products:
Film-coated tablets – 7 mg, 14 mg.

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New Drug Review (cont.)

Comments:

The medications that have been used most often in the treatment of MS include interferon beta-1a (Avonex, Rebif), interferon beta-1b (Betaseron), and glatiramer acetate (Copaxone). However, these agents must be administered parenterally and many patients experience adverse events. In 2010, fingolimod was marketed as the first orally-administered medication to be approved for the treatment of patients with relapsing forms of MS. Teriflunomide is an immunomodulatory agent with anti-inflammatory activity, and is the second drug to be approved for oral use in the treatment of relapsing forms of MS. The new drug is the principal active metabolite of leflunomide, a drug that has been available for many years for the treatment of rheumatoid arthritis.

Teriflunomide has a unique mechanism of action among the agents used for the treatment of MS, and acts by inhibiting dihydroorotate dehydrogenase, a mitochondrial enzyme involved in de novo pyrimidine synthesis. This is thought to result in a reduction in the number of activated lymphocytes in the central nervous system. Its effectiveness was demonstrated in a placebo-controlled study conducted over 108 weeks. The relapse rate for the patients treated with teriflunomide was approximately 31% lower than in those receiving placebo. Fifty-seven percent of the patients treated with the new drug (dosage of 14 mg once a day) remained relapse-free at week 108, compared with 46% of those receiving placebo. In magnetic resonance imaging evaluations there was a reduction in the number of active lesions and total lesion volume in patients treated with teriflunomide. Although some data suggest that teriflunomide may delay disability progression, this has not yet been conclusively demonstrated.

Teriflunomide is eliminated very slowly from the plasma and, following discontinuation of treatment, it may take as long as 2 years in some patients for the plasma concentration to decline to less than 0.02 mg/liter. The drug is eliminated primarily through direct biliary excretion of unchanged drug, and an accelerated elimination procedure using cholestyramine or activated charcoal should be employed in patients for whom the persistence of the drug in the system is associated with unacceptable risk. For example, women being treated with teriflunomide who wish to become pregnant should discontinue the drug and undergo an accelerated elimination procedure, which includes verification of plasma concentrations less than 0.02 mg/liter, a concentration considered to have minimal risk.

Two procedures have been used to accelerate the elimination of teriflunomide. One uses cholestyramine in a dosage of 8 grams every 8 hours for 11 days. If this dosage is not well tolerated, a dosage of 4 grams 3 times a day can be used. The second procedure involves the administration of 50 grams of activated charcoal every 12 hours for 11 days. If either of these procedures is poorly tolerated, treatment days do not have to be consecutive unless there is a need to reduce plasma concentrations rapidly.

Daniel A. Hussar

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