The Pharmacist Activist

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Editorial

Deception and Hypocrisy
from Mail-order Pharmacies

Having devoted two recent editorials to the topic of mail-order pharmacies (please see the May and July issues at www.pharmacistactivist.com), I would much prefer to now address other subjects. However, recent comments by the CEOs of Medco and Express Scripts are too deceptive to be ignored.

CEO Insults Medco Pharmacists

At a meeting earlier this month, the CEO of Medco is reported to have stated that Medco's "robots" are "twenty-three times more accurate" than human pharmacists with respect to errors in dispensing prescriptions. Why is the "leader" of a pharmacy company even suggesting that robots and pharmacists can be compared, particularly when the comparison he states is so demeaning to pharmacists? His statement is most insulting to his own Medco pharmacists because these are the only pharmacists whose accuracy Medco is in a position to determine. Medco pharmacists must be furious! Only several months ago it was announced that Medco had agreed to be acquired by Express Scripts. If the acquisition is approved, there is every reason to believe that the CEO of Medco will become even wealthier than he is now as his "reward" for facilitating the acquisition. At the same time, however, many Medco pharmacists and other employees face the uncertainties of whether their positions will be eliminated or whether they may have to relocate to retain their positions. Then, to add insult to injury, Medco's CEO lauds the accuracy of its robots. However, someone had to program the robots. Could it have been Medco pharmacists that their CEO somehow overlooked?

But perhaps the Medco CEO was attempting to compare the Medco robots with pharmacists in local pharmacies. To my knowledge, there is no study that directly compares mail-order pharmacies and local pharmacies with respect to accuracy rates in dispensing prescriptions. So where does the Medco CEO's allegation that his robots are twenty-three times more accurate come from? Did Medco conduct a study that they have not published or otherwise made available? Or is this yet another extrapolation of a study done years ago that was designed by Medco personnel using study parameters that they selected, and that was conducted by individuals having a vested interest in the results. There were no local pharmacies included in this study. However, that did not stop the Medco personnel from attempting to compare the results of their "study" with the results of a different study in local pharmacies conducted by objective

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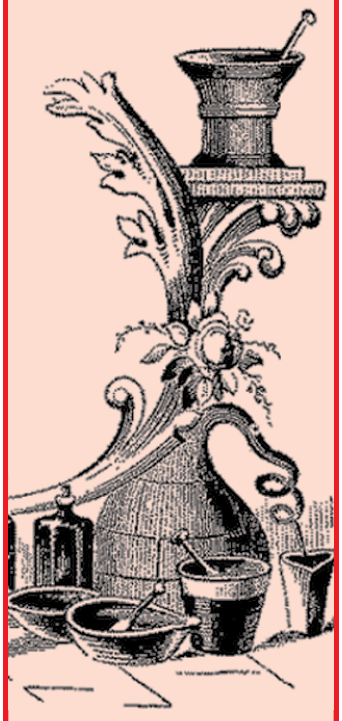

researchers. Medco and other mail-order pharmacies have attempted to use their data to claim that their pharmacies make fewer errors. However, this is blatant deception! Even the Medco authors of the paper they published regarding their study acknowledge that "…because mail-service pharmacies differ in their operation and degree of automation, these findings cannot be generalized to mail-service pharmacies as a class." I agree with this acknowledgement. However, if the study findings can't even be considered applicable to other mail-order pharmacies, there is absolutely no credibility to the claims of Medco and others that these findings can be considered applicable to local pharmacies.

Dissing Retail Pharmacy

In the same meeting in which the comment about the robots was made, the Medco CEO made the observations about retail pharmacy that "…there's a fiction that a pharmacist comes out and dialogues with you. …In reality, a high school student hands you a script from the shelf." He prefaced these comments by noting "I'm not dissing retail [pharmacy]…" However, this contradictory disclaimer can in no way diminish his outrageous denigration of community pharmacy practice. I will acknowledge that there are some local pharmacies in which there is no communication between the pharmacist and patient, and little or no professional service provided. I am critical of these pharmacies – but at least prescriptions are provided on a timely basis and a pharmacist is quickly available to respond to questions. How can the Medco CEO make such demeaning remarks about the profession of pharmacy from which his company has derived huge profits? How can he be so critical of community pharmacy practice and completely ignore the limitations and failures of the mail-order pharmacy for which he has responsibility?

Different Venue–Different Message

The planned acquisition of Medco by Express Scripts has raised numerous concerns that are being addressed by the Federal Trade Commission (FTC) and Congressional committees. Those opposing the acquisition are concerned that the merger of two of the three largest pharmacy benefit managers (PBMs) will result in a dominant and anticompetitive influence in the marketplace that will force an even larger number of consumers to obtain their prescriptions from the mail-order pharmacies that these PBMs own. Many local pharmacies will not be able to survive financially and the provision of medications and professional services on a timely basis for patients will be diminished.

The testimony provided by the Medco CEO before the FTC has strikingly different content and tone when compared with his comments identified earlier. His comments include: "More than 85% of prescriptions filled for Medco customers are filled through our networks of more than 60,000 retail pharmacies. Medco is dependent on the continued existence of strong independent retail pharmacies." Can these comments be provided by the same individual who speaks so disparagingly about the accuracy of pharmacists compared with his robots? The message clearly depends on the audience and, for the FTC, the message is that there are tens of thousands of local pharmacies on whom Medco is dependent and a competitive marketplace will continue. Compared with the other comments of the Medco CEO and the actions of Medco in the marketplace, this message is hypocritical.

The Express Scripts Message

At a hearing of a House subcommittee that is examining the planned acquisition of Medco, the CEO of Express Scripts noted that the acquisition would result in "safer and more affordable" drugs. I have already refuted the allegation that mail-order pharmacies are safer than local pharmacies. One response to the claim that drugs will be more affordable if the acquisition is permitted is the following question: What has happened to the cost of prescription drugs during the period of time in which the number of prescriptions dispensed by mail-order pharmacies has greatly increased? The answer is that the cost of prescription drugs has also greatly increased. If these PBMs were not able to make drugs more affordable during the period in which their size, power, and influence have markedly increased, why would they be able to do this if they were permitted to merge? The answer is they can't and they won't. This issue is addressed in greater detail in the editorial in the July issue of *The Pharmacist Activist* – "Express Scripts and Medco – A Fallen Giant or a Bigger Monster?"

When the CEO of Express Scripts was asked at the House subcommittee hearing to identify the best way to reduce prescription drug costs, his response was by reducing waste, fraud, and abuse. This is a laudable goal but his response invites attention to the most important reasons for the waste of medications and the resultant costs. The most frequent explanation is the large quantities of medications received from mail-order pharmacies that are not used.

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New Drug Review

Ticagrelor
(Brilinta – AstraZeneca)

Antiplatelet Agent

New Drug Comparison Rating (NDCR) = 4

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

Indications:
To reduce the rate of thrombotic cardiovascular events in patients with acute coronary syndrome (ACS) (unstable angina, non-ST elevation myocardial infarction [NSTEMI], or ST elevation myocardial infarction [STEMI]); in patients treated with percutaneous coronary intervention (PCI), it also reduces the rate of stent thrombosis.

Comparable drugs:
Clopidogrel (Plavix), prasugrel (Effient).

Advantages:
- More effective in reducing cardiovascular death and myocardial infarction (compared with clopidogrel; has not been directly compared with prasugrel in clinical studies);
- Action is not changed by genetic influences that reduce CYP2C19 activity or by the concurrent use of CYP2C19 inhibitors (e.g., omeprazole) (compared with clopidogrel);
- Broader labeled indications (compared with prasugrel);
- Is the first in a new chemical class of antiplatelet agents;
- May be less likely to cause thrombotic thrombocytopenic purpura (compared with clopidogrel).

Disadvantages:
- Is administered twice a day (whereas clopidogrel and prasugrel are administered once a day);
- More likely to cause bleeding adverse events (compared with clopidogrel) (boxed warning);
- Effectiveness may be reduced by the use of maintenance doses of aspirin greater than 100 mg a day (boxed warning);
- More likely to cause dyspnea;
- Labeled indications are more limited (compared with clopidogrel for which the labeled indications also include patients who are to be managed with coronary artery bypass graft [CABG] surgery, and to reduce atherothrombotic events in patients with a history of recent myocardial infarction, recent stroke, or established peripheral arterial disease);
- More likely to interact with CYP3A4 inhibitors and inducers;
- May be more likely to cause adverse events in patients with hepatic impairment (compared with clopidogrel).

Most important risks/adverse events:
Bleeding events (boxed warning; contraindicated in patients with active pathological bleeding or a history of intracranial hemorrhage; use should not be started in patients planned to undergo urgent CABG surgery; treatment should be discontinued at least five days prior to any surgery if possible; risk of bleeding is increased by the concurrent use of anticoagulants and the chronic use of nonsteroidal anti-inflammatory drugs); effectiveness may be reduced by daily maintenance doses of aspirin greater than 100 mg (boxed warning); contraindicated in patients with severe hepatic impairment and caution must be exercised in patients with moderate hepatic impairment; dyspnea; is a substrate for CYP3A4 and concurrent use with a strong CYP3A4 inhibitor (e.g., clarithromycin) or a CYP3A4 inducer (e.g., rifampin) should be avoided; concurrent use with digoxin should be closely monitored; when used in patients treated with lovastatin or simvastatin, the dosage of the statin should not exceed 40 mg a day.

Most common adverse events:
Bleeding (12%), dyspnea (14%), headache (7%), cough (5%), dizziness (5%).

Usual dosage:
Initial loading dose of 180 mg, followed with a dosage of 90 mg twice a day; regimen also includes aspirin in an initial loading dose (usually 325 mg), followed by a daily maintenance dosage of 75-100 mg (usually 81 mg); patients for whom antiplatelet treatment was started with clopidogrel can be switched to ticagrelor without interruption of the antiplatelet effect.

Product:
Tablets – 90 mg.

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The Drug Enforcement Administration (DEA) has held three National Drug Take-Back Days – in September, 2010, April, 2011, and on October 29, 2011. On the first two of these days, more than 309 tons of medications were collected. If a study was done of randomly selected quantities of the collected medications (while preserving the confidentiality of the patients who turned in the medications), my expectation is that the medications supplied by mail-order pharmacies would represent a disproportionately high percentage.

Actions

The National Community Pharmacists Association and the National Association of Chain Drug Stores, as well as a number of consumer organizations, have mounted strong opposition to the acquisition of Medco by Express Scripts. Individual pharmacists, particularly those in local pharmacies, must join this effort. Owners of pharmacies should individually assess their participation in prescription benefit programs in which there are non-negotiable, take-it-or-leave-it terms of participation, inadequate compensation, abusive audits, and insulting criticism from those administering the programs.

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New Drug Review (cont.)

Comments:

The benefits and risks of ticagrelor are most similar to those of clopidogrel and prasugrel. The three agents exhibit antiplatelet activity and are used primarily to reduce the risk of cardiovascular complications in patients with acute coronary syndrome. Their mechanism of action involves binding with P2Y12 adenosine diphosphate receptors on platelets and inhibiting platelet activation and aggregation. Clopidogrel and prasugrel are thienopyridine derivatives that are converted to active metabolites following administration. Ticagrelor is in a new chemical class and is designated as a cyclopentyltriazolopyrimidine. It is converted to an active metabolite that is approximately equipotent with the parent drug, and both agents reversibly interact with platelet P2Y12 receptors. The new drug is used in a regimen that also includes aspirin in a maintenance dosage of 75-100 mg (usually 81 mg) a day.

The effectiveness of ticagrelor was demonstrated in a large study in which it was compared with clopidogrel and in which patients received either agent plus aspirin and standard therapy. A combined endpoint of cardiovascular death, myocardial infarction, and stroke was used in the study and ticagrelor was more effective than clopidogrel in reducing the endpoint (9.8% v. 11.7% at 12 months representing a 16% relative risk reduction). The difference in treatments resulted from a reduction in death and myocardial infarction, with no difference being observed with respect to the occurrence of stroke. In patients treated with PCI, ticagrelor also reduced the rate of stent thrombosis. The daily maintenance dosage of aspirin used in conjunction with ticagrelor should not exceed 100 mg because higher doses may reduce the action of the new drug.

Bleeding is the most important risk associated with the use of ticagrelor and was experienced by 12% of the patients in the clinical studies. Almost all patients who underwent CABG surgery experienced bleeding regardless of whether they were treated with ticagrelor or clopidogrel. The new drug should not be started in patients who are to undergo urgent CABG surgery. The frequency of non-CABG related bleeding events was higher in patients treated with ticagrelor (8.7% total; 4.5% major) than in those treated with clopidogrel (7% total; 3.8% major). If possible, bleeding events should be managed without discontinuing ticagrelor because stopping the drug increases the risk of subsequent cardiovascular events.

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