The Pharmacist Activist

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Editorial

Express Scripts and Medco
A Fallen Giant OR a Bigger Monster?

It was only two months ago that my editorial was on the topic of mail-order pharmacy programs (www.pharmacistactivist.com; May 2011 – "Mail-Order Pharmacy Programs – Limitations, Inequities, and Deception"). However, the implications and concerns regarding the recent announcement that Express Scripts plans to buy Medco for $29.1 billion warrant further consideration of this topic.

Some background

The administration of prescription benefit programs has been dominated by three pharmacy benefit managers (PBMs) – Medco being the largest and followed in size by CVS Caremark and Express Scripts. Although it usually would not be expected that a smaller company would be in a position to acquire the largest company, Medco has recently lost three huge contracts including one with the insurer United Health Group (which now plans to manage its own prescription program) that accounts for approximately 17% of Medco's business. One suggested explanation underlying the planned acquisition is that Medco, rather than risking a further weakening of its position and unable to rule out the possibility of CVS Caremark selling its PBM to Express Scripts, identified to Express Scripts that it was receptive to being purchased. The proposed name for the combined company is Express Scripts Holdings Company and the current chairman and chief executive of Express Scripts will retain both his titles.

The potential for the new company to control the PBM marketplace in an anticompetitive manner has raised antitrust concerns and expectations of some that the acquisition will not be approved by the Federal Trade Commission (FTC). Others anticipate that the FTC will provide approval based on the reasoning that CVS Caremark, United Health, and smaller PBMs can provide sufficient competition in the marketplace.

Cost savings?

The executives of Express Scripts and Medco are promoting approval of the acquisition based, in large part, on their contention that the combined company will have sufficient influence to reduce the cost of prescription medications. Needless to say, a claim that a company can reduce the cost of any component of health care immediately attracts interest from government agencies, employers, unions, and others. However, before such a claim can be considered credible, important questions must be evaluated.

For a number of years the PBMs have operated in an essentially unregulated manner through which they have attained substantial influence, revenues, and growth. The first question that must be asked is: What has happened to the cost of prescription medications during this period of time in which the PBMs have had such a strong influence? The answer is that the cost of prescription drugs has markedly increased. Although some will quickly blame these increases on the pharmaceutical companies, why were the PBMs not able to reduce, or at least control, the costs of prescription medications in the recent past

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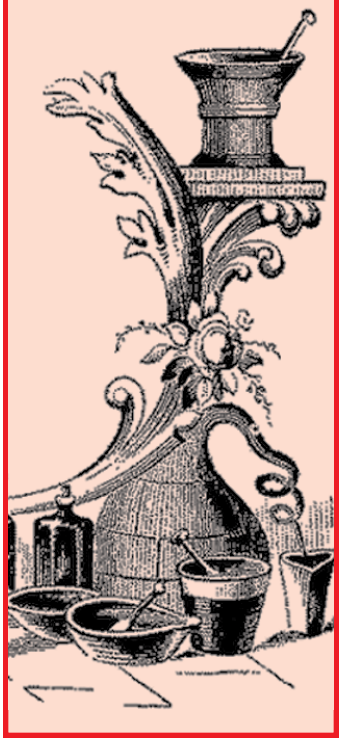

when they suggest they will be able to do so in the future if they are permitted to become bigger?

How will a combined Express Scripts and Medco be able to reduce the cost of prescription medications? The answer is that they will use their greater size and influence to obtain greater rebates from pharmaceutical companies and negotiate lower fees with chain pharmacies. And the independent pharmacies for which the PBMs dictate "take it or leave it" terms will be at an even greater disadvantage than they are now. The challenges that exist even now for independent pharmacies as a consequence of the PBMs' anticompetitive programs and policies should be reason just by itself for the FTC to reject the plan of Express Scripts to acquire Medco.

As unlikely as a reduction in overall costs of prescription medications would seem to be, some anticipated and unprecedented changes in the marketplace suggest that such a change could occur during the next several years. This is because there will be a large number of widely-prescribed and expensive medications (e.g., Lipitor, Plavix, Zyprexa, Lexapro, Seroquel) for which patent protection will expire and much less expensive generic formulations will become available. However, these opportunities for reduced costs of important medications will result regardless of whether Express Scripts and Medco exist as two companies or one company. Indeed, it will be very interesting to observe whether the PBMs pass on the savings to clients when they experience sharply reduced costs for these generic products.

If a reduction in the cost of prescription medications is attained as Express Scripts and Medco propose, who will be the beneficiaries of the savings? Most certainly these PBMs will retain as much of the savings as they can, and perhaps pass some of it on to their clients. If patients/consumers/the public experience any reduction in the cost of their prescription medications, it will be a very small fraction of the amount saved.

As I was writing this editorial, I received a communication from John Buck, the Editor-in-Chief of NEWS-Line Publishing, the organization that publishes *The Pharmacist Activist*. He is preparing a commentary regarding the proposed acquisition for another NEWS-Line publication, and shared the following observation:

> "In searching for news and opinions about the merger, I found more articles on how to profit from it or on Wall Street's reaction to it, than its effect on the consumer, healthcare, or community pharmacies. That is just sad."

His comments are absolutely on target! The quality and scope of the services provided patients by pharmacists, as well as the timely availability and affordability of medications for patients, should receive the highest priority. However, these issues are rarely mentioned in the media coverage. Lest I also be considered guilty of an excessive focus on the economic issues, please also read my May 2011 editorial.

Some responses

As noted earlier, one of the ways in which the combined Express Scripts and Medco would expect to reduce the costs of medications is to reduce the compensation to participating community pharmacies. Therefore, not surprisingly, the National Community Pharmacists Association (NCPA) and the National Association of Chain Drug Stores (NACDS) were among the first to respond to the announcement of the planned acquisition with a statement that reads, in part:

> "Today's announcement that Express Scripts will buy Medco creates a middle man that is too big to play fair, and will have immense power to unfairly dominate the market. This combination will monopolize control of the supply line for brand and generic prescription drugs, threaten access to pharmacy patient care, and is a bad deal for America for healthcare plans, for pharmacies, and – most notably – for patients."

I fully concur with this statement. The characterization of "too big to play fair" also invites the observation that these two companies, as well as CVS Caremark, have been viewed by many as being unfair and worse even as separate entities. This is reflected, in part, by their payment of hundreds of millions of dollars to settle claims of fraud and deceptive practices so that these companies can avoid acknowledging any wrongdoing and escape further prosecution. The anticipated consequence of permitting these companies to become bigger and wield more influence would be a further abuse of their power.

It is appropriate that NACDS has taken a strong position against the proposed acquisition. Even though individual chains can negotiate program terms and compensation with the PBMs, most are in a weak bargaining position when dealing with a huge PBM. It is noteworthy that the immediate past chairman of the Board of Directors of NACDS is the president and CEO of CVS Caremark, the strongest competitor of Express Scripts and Medco. The vice chairman of the NACDS Board is the president and CEO of Walgreens. Walgreens recently announced that it would not accept the terms of a new contract (with estimated revenue of more than $5 billion) offered by Express Scripts to participate in its prescription programs. In the face of the implications of the proposed acquisition of Medco, it will be very interesting to observe whether Walgreens stands its ground against Express Scripts or whether it reaches an agreement as it did last year when it threatened to discontinue participation in programs administered by CVS Caremark.

There has been very little comment regarding the proposed acquisition from the pharmaceutical companies that the combined and more powerful PBM will expect to provide greater rebates for their medications. It is ironic that the same pharmaceutical companies that initially caused the chaos regarding the pricing of pharmaceuticals may now be victims of the giant PBMs to whose growth the companies' pricing policies significantly contributed.

No opportunity to respond

There is another important group who either do not have a forum in which they can respond or there is not enough interest on the part of their company, the media or others in

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New Drug Review

Vilazodone hydrochloride (Viibryd – Forest)

Antidepressant

New Drug Comparison Rating (NDCR) = 2

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

Indication:
Treatment of major depressive disorder in adults.

Comparable drugs:
Other selective serotonin reuptake inhibitors (SSRIs; escitalopram [Lexapro] is the specific agent to which comparisons are made).

Advantages:
- In addition to SSRI activity, also acts as a partial agonist at serotonergic 5-HT_{1A} receptors (however, it is not known whether this latter action contributes to the antidepressant activity).

Disadvantages:
- Has not been directly compared with other antidepressants in clinical studies;
- Labeled indications are more limited (escitalopram is also indicated for the treatment of generalized anxiety disorder, and fluoxetine, paroxetine, and sertraline have multiple additional labeled indications);
- Has not been evaluated in patients less than 18 years of age (whereas escitalopram is indicated for the treatment of depression in adolescent patients aged 12-17 years);
- Dosage titration is needed.

Most important risks/adverse events:
Risk of suicidal thinking and behavior in children, adolescents, and young adults to 24 years (boxed warning [has not been evaluated in patients less than 18 years]); serotonin syndrome and neuroleptic malignant syndrome (NMS)-like reactions (risk is greater in patients who are also being treated with other agents having serotonergic activity [e.g., other SSRIs, serotonin-norepinephrine reuptake inhibitors (SNRIs; e.g., venlafaxine), triptans, tramadol], or antidopaminergic activity [e.g., antipsychotic agents]); contraindicated in patients being treated with a monoamine oxidase inhibitor (MAOI) or who have taken an MAOI within the preceding 14 days (an interval of at least 14 days should elapse following discontinuation of vilazodone before starting treatment with an MAOI); concurrent use with a serotonin precursor such as tryptophan is not recommended; activation of mania/hypomania; seizures; hyponatremia; abnormal bleeding (risk is increased in patients being treated with an anticoagulant, aspirin, or a nonsteroidal anti-inflammatory drug); may cause central nervous system (CNS) effects (e.g., dizziness) and patients should be cautioned about engaging in activities such as driving and operating machinery until they have determined how the medication may affect their alertness and judgment; patients should be advised to avoid drinking alcoholic beverages while using the drug; Pregnancy Category C (risk of complications has been reported to be increased if used during the third trimester); action may be increased by the concurrent use of a strong CYP3A4 inhibitor (e.g., clarithromycin) and the dosage of vilazodone should be reduced; action may be reduced by the concurrent use of a CYP3A4 inducer.

Most common adverse events:
Diarrhea (28%), nausea (23%), vomiting (5%), dizziness (9%), insomnia (6%), sexual dysfunction.

Usual dosage:
Administration with food (high fat or light meal) significantly increases bioavailability and should be administered with food; recommended maintenance dosage – 40 mg once a day; dosage should be titrated starting with a dosage of 10 mg once a day for 7 days, followed by 20 mg once a day for an additional 7 days, and then an increase to 40 mg once a day; dosage should be reduced to 20 mg once a day in patients who are also being treated with a strong inhibitor of CYP3A4; if treatment is to be discontinued, the dosage should be gradually reduced.

Products:
Film-coated tablets – 10 mg, 20 mg, 40 mg.

whether they have a response. This group includes the Medco pharmacists and other employees. When a deal valued at $29 billion is planned and implemented, company stock holders are expected to benefit and the highest level executives are provided substantial additional compensation and/or other benefits. Little or no attention is given to the welfare of the employees whose dedication and efforts have significantly contributed to the growth of a company to the point that it motivates another company to acquire it.

As strongly as I feel that the type and scope of pharmacy practice that I advocate can not be provided through a mail-order pharmacy program, I have a genuine concern for the Medco pharmacists and other employees whose lives will be affected by a decision that they probably did not know was even being considered. They have been sold out by their executives. Uncertainties regarding closing of facilities and loss of jobs or need for relocation are challenging at any time but particularly during the current economic climate that includes a tightened employment market for pharmacists.

Actions

Although the proposed acquisition of Medco by Express Scripts would have the largest impact on pharmacy practice and patient care in the community setting, it has important implications for the entire profession of pharmacy. Accordingly, the associations of pharmacy practitioners should object to the acquisition in a unified and strong voice to the FTC and our legislators. However, this should be viewed as a short-term intervention to prevent a bad situation from becoming worse.

The prescription benefit programs that are currently available have serious flaws, are a disservice to patients with respect to their limitations in quality and scope, and are inequitable for pharmacists. The profession of pharmacy must design better prescription benefit plans that give the highest priority to the provision of optimal drug therapy for patients by pharmacists who meet with and participate in the direct care of patients.

I am convinced that better programs can be developed that will also be cost-effective. The flawed programs administered by PBM "middlemen" are extracting billions of dollars from the health care system without participation in direct patient care and contributing nothing to the overall quality of pharmacy services. These resources must be redirected to programs that will attain positive outcomes.

The profession of pharmacy can not expect that the government, insurance companies, or PBMs will develop prescription benefit programs that will fully utilize the expertise and scope of services of pharmacists for the benefit of patients. As a profession, we must accept the responsibility for the development of a model prescription benefit program and secure the resources to evaluate it on a pilot basis. I am optimistic that a model program can be so successful and cost-effective that the wisdom of using it for much larger programs will be quickly recognized and embraced.

Daniel A. Hussar

New Drug Review (cont.)

Comments:

Vilazodone is a selective serotonin reuptake inhibitor (SSRI) with properties that are most similar to those of citalopram, escitalopram, fluoxetine, paroxetine, and sertraline. It differs from its predecessors by also acting as a partial agonist at serotonergic 5-HT_{1A} receptors; however, it is not known whether this partial agonist action contributes to the antidepressant effect of the drug. The effectiveness of vilazodone has been demonstrated in two 8-week, placebo-controlled trials. It has not been directly compared with other antidepressants in clinical studies, and there are no data to suggest that it is more effective than other SSRIs in the treatment of depression. Most other SSRIs have multiple labeled indications; however, depression is the single labeled indication for vilazodone at the present time.

The drug-related problems associated with the use of vilazodone are generally similar to those for the other SSRIs. Although vilazodone was not observed to cause a significant change in body weight during the 8-week period of the clinical studies, data are insufficient to determine if increases in weight occur over longer periods of treatment, such as have been associated with the continued use of other SSRIs.

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