The Pharmacist Activist

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Editorial

Prescription Drug Prices –

Billions for Pharmaceutical Companies, Insurance Companies, and PBMs, but Pennies for Pharmacies

Concerns regarding the prices for prescription drugs continue to generate criticism and anger, and are prominent in the news. Much of the criticism is directed against the pharmaceutical companies which typically respond in a manner that invites further criticism. A common scenario is for a company to respond to a criticism of a high price for a drug by saying that the publicized price is not the "real" price, and that the actual price is much lower because of discounts and rebates. When further questioned about the amount of the discounts and rebates, companies respond by saying that information is proprietary and can't be disclosed. Consumers, legislators, and others then conclude that not only are drug prices excessive, but they are also determined in secret negotiations with purchasers.

There was a time when the average wholesale price (AWP) represented the exact or a close approximation of the cost of a medication purchased by a pharmacy, and could be appropriately used as a fair basis for reimbursing the cost of drug products to pharmacies. Today, AWP is designated by some as "ain't what's paid," reflecting the chaos that exists with respect to drug prices and efforts to determine what might be considered as equitable costs for patients and equitable compensation for pharmacists dispensing the medications. Because of their pricing strategies, deals, discounts, and secrecy in charging vastly different prices to different purchasers for the same medication, pharmaceutical companies are most responsible for the lack of credibility of explanations regarding the cost of medications. The resultant damage to their image is self-inflicted.

It is to the credit of some pharmaceutical companies, however, that many of their billions in revenue are committed to research programs that result in the development of new medications that represent very important advances in the treatment of disease. Notwithstanding the continuing debate about the cost of medications, these companies make a very important contribution to the scope and quality of health care through their discovery of new drugs. It is essential that such innovation continues.

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Insurance companies and PBMs

There is no question that insurance programs are needed by most individuals to obtain healthcare services and products. However, insurance companies focus exclusively on the economics of health care and the management of benefits. The same is true for pharmacy benefit managers (PBMs). I would contend that insurance companies and PBMs contribute nothing to the quality of health care for individual patients and society as a whole. Indeed, one could argue that their policies and actions actually delay and/or compromise the provision of healthcare services and products to patients, and thereby reduce the timeliness and quality of care. For their "services," the large insurance companies and PBMs receive billions of dollars in revenues. A recently filed lawsuit provides a perspective on the huge amount of funding that is received by these companies.

Anthem is one of the largest health insurance companies in the country, and it will become even larger if its plan to acquire Cigna for approximately $54 billion is approved. Express Scripts is the largest PBM in the country. Anthem has a 10-year contract with Express Scripts to administer its prescription benefit plans that continues through 2019. Express Scripts negotiates with pharmaceutical companies regarding the costs of their drugs in discussions that lack transparency and are subject to numerous allegations. It claims that these negotiations result in "savings" and lower drug prices. But who benefits from these savings? The easy answer is that it is not patients nor pharmacies that are benefiting from these savings. That leaves, in this situation, Anthem and Express Scripts and the dispute is whether or how the savings should be shared.

Anthem has sued Express Scripts for $15 BILLION, alleging that the PBM is not providing it with what it considers to be its share of the savings that have resulted from negotiations with the pharmaceutical companies. Anthem contends that it is being overcharged for the drugs and notes in a news release:

> "Under the agreement, Express Scripts is obligated to negotiate in good faith to ensure Anthem is receiving competitive benchmark pricing. Anthem has worked hard for more than a year to try to get Express Scripts to engage in such good faith negotiations, but Express Scripts has failed to do so."

Express Scripts has responded:

> "Express Scripts has consistently acted in good faith and in accordance with the terms of its agreement with Anthem. We believe that Anthem's lawsuit is without merit."

It is significant that the amount of $15 billion being considered does not represent what is the much larger cost of the medications, but rather the "savings" that have been negotiated from what were presumably already steeply discounted prices. The battle is between two huge companies that contribute nothing to the quality of patient care but that extract billions of dollars from the extensive funding that is committed for the provision of health care.

Ordinarily such disagreements would be settled in private discussions, and it is unusual that this situation has reached the point that a lawsuit is filed. However, the matter has now received extensive publicity and should be cause for great concern on the part of the clients of Anthem and Express Scripts, patients in these prescription benefit plans, and participating pharmacies, none of whom can expect to experience any benefit from the billions in savings that Anthem and Express Scripts wish to add to their profits.

I do not have confidence that either Anthem or Express Scripts is acting in "good faith" as they claim. There is an irony that these two huge companies can negotiate with each other but if two small pharmacies worked with each other to try to negotiate payments from a PBM, they would be in jeopardy of violating antitrust laws.

The best thing that could happen from this lawsuit would be that the records and specifics of the secret negotiations of drug prices could be obtained through the discovery process. Subsequent publicity of this information would help expose the deals and manipulation of drug prices for

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New Drug Review

Eluxadoline (Viberzi – Allergan)

Agent for Irritable Bowel Syndrome with Diarrhea

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
in a scale of 1 to 5 with 5 being the highest rating

Indication:
Treatment of adult patients with irritable bowel syndrome with diarrhea (IBS-D).

Comparable drug:
Alosetron (e.g., Lotronex).

Advantages:
- Has a unique mechanism of action (is a mu-opioid receptor agonist and a delta-opioid receptor antagonist);
- Labeled indication is not restrictive (whereas alosetron is indicated only for women with severe IBS-D);
- Less risk of serious gastrointestinal adverse events (whereas the labeling for alosetron includes a boxed warning regarding the risk of ischemic colitis and serious complications of constipation);
- Prescribing is not restricted (whereas prescribers of alosetron must be enrolled in a Prescribing Program and patients must understand and comply with the provisions of a Patient Acknowledgement Form).

Disadvantages:
- Has a greater risk of sphincter of Oddi spasm and pancreatitis;
- Is a controlled substance (Schedule IV).

Most important risks/adverse events:
Contraindicated in patients with known or suspected biliary duct obstruction, or sphincter of Oddi disease or dysfunction, or a history of pancreatitis or structural diseases of the pancreas, including known or suspected pancreatic duct obstruction (with respect to the risk of sphincter of Oddi spasm and pancreatitis, patients without a gallbladder should be monitored for new or worsening abdominal pain, or acute biliary pain with liver or pancreatic enzyme elevations; treatment should be discontinued if these symptoms develop); contraindicated in patients with severe hepatic impairment, severe constipation or sequelae from constipation, or suspected mechanical GI obstruction; contraindicated in patients with alcoholism, alcohol abuse, alcohol addiction, or in those who drink more than 3 alcoholic beverages/day; potential for misuse/abuse (included in Schedule IV); is a substrate for organic anion-transporter polypeptide (OATP)1B1 and dosage should be reduced when an OATP1B1 inhibitor (e.g., cyclosporine, gemfibrozil) is used concurrently; action may be increased by the concurrent use of a strong CYP inhibitor (e.g., clarithromycin, paroxetine); concurrent use with drugs that may cause constipation (e.g., alosetron, anticholinergics, opioid analgesics) should be avoided (loperamide may be used occasionally for the acute management of severe diarrhea but chronic use should be avoided); may increase the action of rosuvastatin (Crestor) and the lowest effective dose of rosuvastatin should be used; may increase the action of CYP3A substrates with a narrow therapeutic index (e.g., cyclosporine, fentanyl).

Most common adverse events:
Constipation (8%), nausea (7%), abdominal pain (7%).

Usual dosage:
100 mg twice a day with food; dosage should be reduced to 75 mg twice a day with food in patients who do not have a gallbladder, have mild or moderate hepatic impairment, are concurrently taking an OATP1B1 inhibitor (e.g., cyclosporine, gemfibrozil), or who are unable to tolerate the 100 mg dose; treatment should be discontinued in patients who develop severe constipation for more than 4 days.

Products:
Tablets – 75 mg, 100 mg.

Comments:
IBS-D is a functional bowel disorder that is characterized by chronic abdominal pain and frequent diarrhea (loose or watery stools at least 25% of the time). Loperamide may help control diarrhea but does not provide adequate relief of symptoms in many patients. Alosetron is a serotonin (5-HT3) receptor antagonist that may be effective, but its labeled indication is limited (i.e., women with severe IBS-D who have not responded to conventional therapy) and it may cause serious GI adverse events. Rifaximin (Xifaxan) was previously available for the treatment of certain types of travelers' diarrhea and to reduce the risk of overt hepatic encephalopathy recurrence. Rifaximin and eluxadoline were approved for the treatment of IBS-D on the same date. Eluxadoline has mixed opioid receptor activity; it acts as an agonist at mu receptors and kappa receptors, and as an antagonist of delta receptors. Its effectiveness was demonstrated in two placebo-controlled studies in which it was more effective than placebo in reducing abdominal pain and improving stool consistency over 26 weeks of treatment.

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the purpose of increasing profits for insurance companies and PBMs.

Pharmacies

While the pharmaceutical companies, insurance companies, and PBMs are battling for billions, pharmacies are receiving only pennies in comparison for their services in dispensing a prescription. With respect to the reimbursement of the cost of a medication, pharmacists pay more for some medications than the amount that the PBM is willing to provide. As one egregious example that was recently shared with me, the actual cost for a medication requested on prescription was approximately $1,500, but the PBM would only provide reimbursement of $1,100.

Another strategy that PBMs are pursuing for the alleged purposes of "savings" and "efficiency" is to reduce the size of their network of pharmacies. A friend recently shared her experience in being pressured by her prescription benefit plan to obtain her prescriptions from CVS. However, she values the services of her local independent pharmacist so much that she has resisted the pressure to use a different pharmacy, even though she is paying more for her prescriptions because of the terms of her benefit plan. Although she is in a position to assume an additional cost, most others are not. But, most importantly, insurance companies and PBMs that care only about the money must not be permitted to dictate which pharmacy a patient must use to obtain their prescriptions and related advice and services.

Can anything be done?

Some would suggest that the insurance companies and PBMs are so large and have such vast resources that nothing can be done to influence their decisions. I would respond that the issues are so important, for patients as well as pharmacists, that the profession of pharmacy must not give up in its efforts to make positive changes. I recommend the following actions:

1. Efforts to have pharmacists exempted from antitrust legislation must be strengthened. This would permit pharmacists to work together to negotiate the terms of prescription benefit programs. Our profession has been trying to do this for so long that some have lost hope. Although this will take years to accomplish through legislation, we must give this effort a higher priority while also developing the following initiatives.

2. The American Pharmacists Association, the National Community Pharmacists Association, and other interested pharmacy associations should develop a Model Prescription Benefit Plan.

3. These associations should support and conduct a pilot program in which the Model Prescription Benefit Plan would be provided through participating pharmacies for employees of selected collaborating organizations. I anticipate that such a pilot program in which prescription medications are accompanied by comprehensive advice and services of pharmacists will be highly valued by patients, can be cost-effective, provide equitable compensation for pharmacists, and provide a model that can be expanded to include many more patients, employers, and pharmacists.

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