The Pharmacist Activist

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Editorial

Reducing Drug Prices – By Increasing Competition, Increasing Self-care, and Eliminating PBM Fraud and Scams

Not a day goes by without the publication of the latest outrage regarding the high prices of prescription drugs, or the most recent specific example of exorbitant drug costs that patients can't afford and health insurance companies/pharmacy benefit managers (PBMs) won't pay. This situation is all the more remarkable in that the vast majority of patients, prescribers, legislators, and others could not come close in even guessing the actual price of medications they personally use. This is a consequence of the deceptive, confusing maze of coverage and information (or more accurately the *lack* of information/transparency) that characterizes the distribution of prescription medications. With the exception of the pharmaceutical companies, almost everyone agrees that prescription drug prices are too high. The President, Democrats and Republicans in Congress, employers, unions, health professionals, consumers/patients are in agreement, but decades of rhetoric have not resulted in a constructive course of action.

As I have urged in previous editorials, priority attention must be directed at the pharmaceutical companies that establish the list prices for prescription medications, and these efforts must be strengthened. However, there are also other initiatives that can be concurrently pursued that include the following.

Increasing competition

Many have voiced strong concerns regarding the acquisition of Aetna by CVS-Caremark. Although this acquisition has not yet been officially finalized, and the judge who must do so has criticized the companies for assuming he will "rubber-stamp" the recommendation, I anticipate that this acquisition will occur. The concerns are based on the expectation that the combination of the already huge chain pharmacy/PBM with the already huge health insurance company will have even greater influence and domination by reducing competition in the marketplace. These companies claim that their merger will not be anticompetitive and that they will be in a better position to provide insurance, medications, and services for patients more efficiently (i.e., at reduced costs). When requested to identify the strategies and financial projections that support their claims, they provide the response that we have heard so often we can recite it in unison: "That information is proprietary and can't be revealed because our competitors will use it for their advantage." It is no consolation that these companies know the meaning of competition but only view it with concern if it impacts their own self-interests and profits.

CVS-Caremark often boasts about the thousands of other chain and independent pharmacies in their networks in its deceptive efforts to suggest that competition has not been adversely influenced. However, it conveniently ignores and suppresses information about its egregious and anticompetitive policies and abysmal compensation that forces many of these other pharmacies to close or be sold (often to CVS).

The suggestion of CVS/Caremark and Aetna that their customers will be better served by the acquisition is vague and not supported by examples. Indeed, there is already information to indicate that

just the opposite will occur. From CVS pharmacists I have heard that technician hours in their stores have been reduced this month, and that the explanation provided by management is that it is a result of the financial implications of the CVS-Aetna deal. Even prior to now, many CVS pharmacists had little or no time to speak with patients about the appropriate use of their medications. The reduction in technician hours will result in further reduction of such communication.

If the CVS-Caremark acquisition of Aetna occurs, as most expect, it communicates the opinion of the government agencies/officials that permit it that competition will not be adversely affected. Although this may be a valid premise with respect to how CVS/Caremark, Cigna/Express Scripts, and United Health/Optum compete with each other, independent pharmacies and small chain pharmacies will have little or no remaining opportunity to be competitive with these giant corporations. There is, however, an important response – *Independent pharmacies should be exempt from antitrust laws!*

The huge companies like CVS/Caremark will scream their opposition to this initiative and state that independent pharmacies would expect higher fees and that this would increase prescription drug prices. TRUE and FALSE! It is true that independent pharmacists need and would receive higher fees. However, this initiative should DECREASE rather than increase drug prices because competition would be INCREASED and the secretive spreads/discounts/rebates and profits of the huge companies would be exposed. Even with a higher professional fee added to the cost of the medication, the resultant prices for many prescriptions will be considerably less at independent pharmacies than the manipulated prices the PBMs and insurance companies are currently receiving. Independent pharmacies that could operate without the restrictions of antitrust laws would become the fourth large entity in the marketplace that would increase competition with and be far more transparent than the existing three large companies.

Some within pharmacy will respond that pharmacists have previously sought exemption from antitrust laws and were unsuccessful. However, the present situation is very different. The outrage about drug prices and the determination to increase competition that would reduce prices is unprecedented. This is the best time for the profession of pharmacy to aggressively pursue legislative changes and/or Federal Trade Commission/Department of Justice approval to exempt independent pharmacies from current antitrust restrictions.

Increasing self-care

Medications that are available without a prescription are usually much less expensive than most prescription medications. I would contend that there are numerous medications that currently require a prescription that are safe enough to be available without a prescription. Some of these medications should be available in an unrestricted manner without a prescription (i.e.,over-the-counter [OTC]), whereas the nonprescription use and safety of certain medications would be optimized by the assessment, guidance, and monitoring of pharmacists (i.e., behind-the-counter [BTC], third class of drugs, pharmacist-only class of drugs).

The FDA classifies medications as prescription or nonprescription drugs, and has repeatedly refused to consider departures from this classification to which it feels its authority is restricted, or initiatives to change the existing system. Some pharmacists and pharmacy associations have recommended additional options in which nonprescription drugs can be classified, but have been similarly timid in initiating actions that would result in beneficial revisions.

If revision of existing legislation or new legislation is considered necessary to increase the nonprescription availability of certain medications that currently require a prescription, the support for such an action by the FDA, as the federal agency with expertise and authority in this area, would be a very positive initial step that would be strongly supported by pharmacists, consumer groups, and others. Successful efforts to make progressive legislative changes would greatly increase the availability of beneficial medications for individuals who might not have ready access to prescribers or for other reasons do not make appointments with health professionals.

The increased availability of medications without a prescription, whether OTC or with the advice of a pharmacist, will also result in a reduced cost of many medications. Because prescription benefit plans typically do not include nonprescription medications, some will view this as a disincentive for consumers to use a nonprescription medication rather than one that is prescribed. However, prescription benefit programs should not only support, but also provide coverage for nonprescription options at a lower cost than what they would have covered if the same medication remained available only on prescription. This issue of coverage of cost must also be considered in the context of consumers paying billions of dollars each year out-of-pocket for dietary supplements, herbal products, etc. The greater nonprescription availability of medications that have been evaluated in comprehensive clinical studies and a rigorous approval process would also be expected to reduce consumer expenditures for products that have not been thoroughly studied and for which there are unresolved questions about effectiveness and safety.

Eliminating PBM fraud and scams

The numerous deceptive and self-serving practices and strategies

(Continued on Page 4)

New Drug Review

Galcanezumab-gnlm
(Emgality – Lilly)

Agent for Migraine

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:
Administered subcutaneously for the preventive treatment of migraine in adults.

Comparable drug:
Erenumab (Aimovig), fremanezumab (Ajovy).

Advantages:
- Product does not contain latex derivatives (compared with erenumab).

Disadvantages:
- Is administered more frequently (compared with fremanezumab that may be administered once every 3 months);
- May be more likely to cause hypersensitivity reactions (compared with erenumab).

Most important risks/adverse events:
Hypersensitivity reactions; clinical studies excluded patients with a history of stroke, myocardial infarction, unstable angina, percutaneous coronary intervention, coronary artery bypass grafting, deep vein thrombosis, or pulmonary embolism within 6 months of screening.

Most common adverse events:
Injection site reactions (18%, compared with 13% with placebo).

Usual dosage:
Administered subcutaneously; loading dose of 240 mg (administered as two consecutive injections of 120 mg each), followed by 120 mg once a month.

Products:
Injection in single-dose prefilled pens and prefilled syringes containing 120 mg of the drug per mL (products should be stored in a refrigerator and, prior to administration, should be allowed to sit at room temperature for 30 minutes protected from direct sunlight).

Comments:
Calcitonin gene-related peptide (CGRP) is a neuropeptide that is involved in the transmission of pain impulses, and elevated concentrations have been associated with migraine attacks. Galcanezumab is a human monoclonal antibody that binds to CGRP ligand and blocks its binding to its receptor. It is the third CGRP antagonist approved for the preventive treatment of migraine, joining erenumab and fremanezumab.

The effectiveness of galcanezumab was demonstrated in three placebo-controlled clinical studies, two of which were conducted in patients with episodic migraine (i.e., 4 to 14 migraine days per month [MMD]) for a period of 6 months. Patients treated with galcanezumab experienced, on average, two fewer MMD than those on placebo, and 62% and 59% of patients, respectively, experienced at least a 50% reduction from baseline in MMD, compared with 39% and 26% of those receiving placebo. The third study was conducted in patients with chronic migraine (i.e., 15 or more headache days per month with at least 8 MMD) for a period of 3 months. Patients treated with galcanezumab experienced, on average, two fewer MMD, than those receiving placebo. Twenty-eight percent experienced at least a 50% reduction from baseline in MMD, compared with 15% of those receiving placebo.

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of many PBMs have been the subject of many previous editorials in The Pharmacist Activist. If there is any encouragement, it is that, in addition to pharmacists, many others are now recognizing and criticizing the PBM actions and profits that are responsible for a large component of the high prices for prescription medications. But just when I think there may not be any more ways in which PBMs can exploit the "system," I hear of another.

The January 5-6, 2019 issue of *The Wall Street Journal* has a front-page story (Joseph Walker and Christopher Weaver) titled: "Medicare Overpaid Insurers Billions: CVS, Humana and others managing Part D drug plans pocketed $9 billion in extra revenues." Excerpts from this article are noted below.

> "Each June, health insurers send the government detailed cost forecasts for providing prescription-drug benefits to more than 40 million people on Medicare.
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> No one expects the estimates to be spot on. After all, it is a tall order to predict the spending for the following year for the thousands of members in each plan.
>
> However, year after year, most of those estimates have turned out to be wrong in the particular way that, thanks to Medicare's arcane payment rules, results in more revenue for the health insurers, a Wall Street Journal investigation has found. As a consequence, the insurers kept $9.1 billion more in taxpayer funds than they would have had their estimates been accurate from 2006 to 2015, according to Medicare data obtained by the Journal.
>
> Those payments have largely been hidden from view since Medicare's prescription-drug program was launched more than a decade ago, and are an example of how the secrecy of the $3.5 trillion U.S. health-care system promotes and obscures higher spending."
>
> "After the year ends, Medicare compares the plans' bids to actual spending. If the insurer overestimated its costs, it pockets a chunk of the extra money it received – sometimes all of it – and this can often translate into more profit for the insurer, in addition to the profit built into the approved bid. If the extra money is greater than 5% of the original bid, it has to pay some of it back to Medicare.
>
> For instance, in 2015, insurers overestimated costs by about $2.2 billion, and kept about $1.06 billion of it after paying back $1.1 billion to the government, according to the data reviewed by the Journal."
>
> "If those big insurers were aiming to submit accurate bids, the probability that they would have overestimated costs so frequently and by such a large amount is less than one in one million, according to a statistical analysis done for the Journal by researchers at Memorial Sloan Kettering Cancer Center, who study pharmaceutical pricing and reimbursement."
>
> "A CVS official said it is to be expected that companies would be 'biased' toward overestimating costs 'because we can't have years where we lose money'."

Even after reading this comprehensive and detailed report, I don't fully understand how this situation was implemented, and has been exploited for years. But CVS, Humana, and others sure figured out how to exploit it. I am outraged that my tax dollars have contributed to the further enrichment of executives of CVS and other companies! We should all be outraged! Why are the government officials who have the responsibility for these programs allowing this situation to continue to exist? Where is the accountability? I commend the Wall Street Journal reporters who have exposed this scam. However, government officials whom we pay should not have let this situation occur in the first place. I will refrain from describing my reaction to the comment of the CVS official other than to say it is typical of previous actions of CVS management that doesn't care if they put patients at risk or force others out of business, as long as CVS doesn't lose money.

Even if what has occurred is somehow legal, it is wrong and a blatant abuse of taxpayer funds. Each of us should take a copy of this article to our legislators and demand that this situation be corrected. The President and the Congress should first give high priority to resolving the matters that contribute to high drug prices over which the federal government has control. These actions should include prohibiting the continued participation of CVS, Humana and the other companies that have egregiously exploited the government's (i.e., the people's) prescription and other health programs.

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