The Pharmacist Activist

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Editorial

The Drug Pricing Blame Games

Which of the following has the greatest responsibility for establishing the prices for prescription medications?

a. Pharmaceutical companies
b. Pharmacy benefit managers
c. Health insurance companies
d. Hospitals
e. Federal government
f. Pharmacists
g. a, b, c, d, and e

If any of these answer choices can be quickly and unanimously ruled out as the correct answer, it is "f" – Pharmacists. However, this is of little consolation for the thousands of independent pharmacies and some chain pharmacies that are fighting for financial survival because of the non-negotiable policies and inadequate compensation provided for the medications and services of pharmacists. To add insult to injury, of the answer choices for the above question, it is Pharmacists who have the most important role in assuring that patients understand the appropriate use of the prescribed medications and in attaining positive therapeutic outcomes. Of the entities identified above, it is also only the Pharmacists who are personally known to patients, and whose accessibility requires them to devote the time, effort, and frustration to respond to patient questions, criticisms, and even anger, about drug prices.

Of the other choices to the question above, some will be inclined to choose "g," that includes all of the other choices except pharmacists. Although pharmaceutical companies, the federal government, health insurance companies, pharmacy benefit managers, and hospitals each has a significant role in the determination of drug prices, there are differences in the degree and importance of their responsibility/fault for the prices of drugs. However, the extent to which these entities blame each other for the prices of drugs would be almost comical if it wasn't so serious.

The correct answer to the question of which has the "greatest" responsibility for establishing drug prices is "a" – Pharmaceutical companies, with Pharmacy benefit managers (PBMs) having the second most important responsibility. In the following discussion, the roles of the different participants in the determination of drug prices are considered.

Pharmaceutical companies

It is *only* the pharmaceutical companies that have the opportunity to establish the "list price" of their medications and to determine whether they will provide discounts/rebates from the list prices and, if so, the amount of these deductions. The buck (billions of them) stops with them. When challenged about the high prices of prescription medications, they quickly respond that no one pays the list price. When asked to identify the amounts of discounts/rebates to PBMs and others, as well as the actual prices of medications, they refuse to provide this information with the explanation that their competitors could use it to their advantage. An opportunity for clarification is rejected and the secret deals result in suspicion and distrust.

Whereas the pharmaceutical companies and PBMs are enthusiastic partners with respect to the secret discounts/rebates, they are strongly critical of each other when questions are raised regarding the high cost of drugs. The pharmaceutical

companies insist that it is the "middlemen" (i.e., PBMs and health insurance companies) that are primarily responsible for the high costs because they "force" the companies to provide large discounts/rebates. The PBMs respond that their role is essential in lowering the prices pharmaceutical companies would otherwise charge. The sad irony is that, at the same time this blame game escalates, drug prices continue to increase as do the profits for the mutual benefit of the pharmaceutical companies and PBMs.

Pharmaceutical companies are also engaged in the blame game with hospitals. While hospitals voice criticisms of high drug prices, pharmaceutical companies respond with their research that approximately 17% of hospitals marked up drug costs by 700% or more and that, on average, hospitals increased drug costs by 479%.

The pharmaceutical companies spend hundreds of millions of dollars for direct-to-consumer (DTC) advertising of prescription drugs and their prescription coupon programs for which they are the primary beneficiaries. These programs contribute to increased drug prices and, although I would like to see both practices prohibited, I am not optimistic about restricting DTC advertising of prescription drugs because of freedom of speech protections for which I am an advocate for other reasons.

The pharmaceutical companies have also become increasingly critical of the present drug-payment system that they contend increases list prices from which other entities benefit. However, it is their pricing strategies and secret deals that are most responsible for the current debacle, and any negative consequences they might experience are self-inflicted.

PBMs

Although pharmaceutical companies have the greatest responsibility for establishing drug prices, it is the PBMs that have been the greatest financial beneficiaries of the current broken system of drug pricing. The pharmaceutical companies can at least be given credit for the development of important medications and publicly identifying the list prices for their medications. To the contrary, PBMs contribute nothing to the scope and quality of health care or the efficacy or safety of medications, and it is difficult to identify any aspect of their financial operations that is transparent and available for public review. If anything, they create barriers to the access and appropriate use of prescription medications.

The PBMs are a relatively new industry that has exploited a vulnerable area of the drug distribution and payment system for their own benefit. They have grown rapidly to a size, profitability, and strength that even the largest pharmaceutical companies and chain pharmacies (e.g., Walgreens) have been unsuccessful in challenging the policies and financial terms they dictate. I would contend, however, that the largest PBMs with the most egregious prescription "benefit" programs are not needed and that much less costly programs for administering prescription claims can be used (please see my editorial, "Reducing Drug Costs – PBMs are Not Needed and Should Not be Used!" in the September 2018 issue of *The Pharmacist Activist*).

A recent initiative of some PBMs is to offer clients prescription plans at a lower cost, but that do not include coverage for certain very expensive medications for rare diseases. The promotion of such programs would emphasize a lower cost and a message that the excluded diseases/medications are so rare that it is unlikely that employees of the company/union are not likely to experience them. Because the cost of the prescription program is the most dominant factor in these decisions, little or no attention will be devoted to the implications of exclusion from coverage of a disease and medication of which most have no knowledge. If such prescription plans are permitted to be offered and purchased, we can anticipate an increasing number of heart-wrenching experiences of patients and families who thought their health insurance and prescription plans included such coverage, only to find it denied.

Health insurance companies

The complexity of health insurance programs including prescription plans creates a maze that most don't understand, and which gives rise to additional layers of administration (e.g., brokers, consultants) that increase the cost of healthcare services and costs. Health insurance companies themselves have been highly profitable, but their greatest culpability with respect to drug prices has been the extent to which they have enabled the utilization of PBM prescription plans and the growth of this industry.

Hospitals

I acknowledge that I do not review hospital bills for my wife and myself unless the amount I am personally charged reaches a level that I consider surprising and unreasonable. I also quickly realize that I do not understand the extent of the terms and coverage of the insurance programs, as well as how the charges have been determined, and I then seek clarification. This action sometimes only adds to the frustration when individuals at the institution who are employed in the office that

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New Drug Review

Erenumab-aooe

(Aimovig – Amgen; Novartis) *Agent for Migraine*

New Drug Comparison Rating (NDCR) = 4
(significant advantages)
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 drugs:
Beta-adrenergic blocking agents (e.g., propranolol).

Advantages:
- Is more effective in some patients;
- Has a unique mechanism of action (calcitonin gene-related peptide [CGRP] receptor antagonism);
- Is less likely to cause adverse events and interact with other drugs;
- Is administered less frequently (once a month).

Disadvantages:
- Is administered subcutaneously (whereas beta-blockers are administered orally);
- Effectiveness and safety have not been established in pediatric patients;
- Has not been directly compared with other medications in clinical studies;
- Is much more expensive.

Most important risks/adverse events:
Clinical studies excluded patients with medication overuse headache, as well as patients with myocardial infarction, stroke, transient ischemic attacks, unstable angina, coronary artery bypass surgery, or other revascularization procedures within 12 months prior to screening.

Most common adverse events:
Injection site reactions (6%).

Usual dosage:
Administered subcutaneously; 70 mg once a month; some patients may benefit from a dosage of 140 mg once a month, which is administered as two consecutive injections of 70 mg each.

Products:
Injection in single-dose prefilled syringes and prefilled autoinjectors containing 70 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 at least 30 minutes protected from direct sunlight).

Comments:
Patients who experience migraine attacks frequently are often candidates for preventive management to reduce the frequency and severity of attacks. Those who experience 4 to 14 migraine days per month (i.e., monthly migraine days [MMD]) are classified as having episodic migraines, whereas those with 15 or more headache days per month with at least 8 migraine days per month are classified as having chronic migraines. Certain beta-adrenergic blocking agents (i.e., propranolol, timolol) and certain antiepileptic drugs (i.e., divalproex sodium, topiramate) have labeled indications for migraine prevention, as does onabotulinumtoxinA (Botox; for patients with chronic migraine). Calcitonin gene-related peptide (CGRP) is a neuropeptide that is primarily distributed in the central and peripheral nervous systems and acts as a vasodilator. It is involved in the transmission of pain impulses and elevated concentrations have been associated with migraine attacks. Erenumab is a human monoclonal antibody that exhibits high affinity binding to the CGRP receptor and is the first of a new class of CGRP antagonists.

The effectiveness of erenumab was demonstrated in three placebo-controlled clinical trials, two of which were conducted in patients with a history of episodic migraine. The largest of these studies was conducted over a 6-month period using erenumab in dosages of 70 mg once a month and 140 mg once a month. Patients treated with erenumab experienced, on average, one to two fewer MMD than those on placebo, and 43% and 50% of patients, respectively, experienced at least a 50% reduction from baseline in MMD, compared with 27% of those receiving placebo. The third study was conducted in patients with a history of chronic migraine and, over the course of 3 months, patients treated with erenumab experienced, on average, 2.5 fewer MMD, with dosages of 70 mg and 140 mg once a month, than those receiving placebo. Forty percent and 41%, respectively, experienced at least a 50% reduction from baseline in MMD, compared with 24% of those receiving placebo. Erenumab has not been directly compared with other agents that have been used in the prevention of migraine. However, it has been used effectively in some patients who have experienced an inadequate response to or have not tolerated other therapies, or were not candidates for treatment because of the risk of using other medications.

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is supposed to provide clarification and resolution of questions do not themselves interpret the policies accurately and provide conflicting information. The manner in which hospitals determine the charges to patients and their insurance plans for medications is unknown to most, even the pharmacists who work at the hospital. The pharmaceutical companies have valid reasons for raising questions about drug charges that are alleged to be marked up 700%. Hospitals should be accountable for explaining how the charges for medications and services are determined.

Federal government

I have been an advocate for a competitive and lightly-regulated marketplace that provides freedom for organizations and individuals to establish fair prices for their products and services, in contrast to the concept of having a single payer (i.e.. government) determine the financial parameters. Having a competitive marketplace is the basis for which the federal legislation pertaining to prescription medications in the Medicare program includes a provision that the government will not engage in the negotiation of drug prices. However, the current system has been exploited by corporations and some individuals, and the continuing rising costs of prescription medications and healthcare services in general are unsustainable. Our current programs and policies must be re-examined.

The federal government has proposed a regulation that will require pharmaceutical companies to include the list price of drugs they promote in television advertisements. The rule would apply to drugs with a cost of more than $35 a month that is paid for by Medicaid or Medicare. The pharmaceutical companies are opposing this proposal and have responded that they will include information in their TV ads that will direct consumers to websites where they can obtain information about list prices. Unlike drug prices, this strategy is clear as most would agree that very few consumers will go to the websites. I do not anticipate that the proposed regulation will attain its intended goal of reducing drug prices. However, I support this action because I consider it very important that consumers and others know the initial list prices for medications, and have a better awareness of the implications of these costs. I also view this as a first step that will result in transparency of the discounts, rebates, and other subsequent changes that affect drug prices.

Recommendations

The following information should be available to interested parties for each medication:

1. The manufacturer's list price for the medication in the most commonly supplied quantities (e.g., 30, 100, 1,000 tablets);
2. The amount of discounts for volume purchases (e.g., 10,000, 100,000 tablets);
3. The cost of the drug to the 5 largest pharmaceutical wholesalers;
4. The amounts of discounts and/or rebates provided for purchasers such as:
    a. government agencies (e.g., Veterans Administration, Medicare, Medicaid, prescription programs for the elderly);
    b. hospitals;
    c. specialty pharmacies.
5. The amounts of the rebates (and rebate administration fees) provided for the 5 largest PBMs;
6. The amounts of the copays for patients in the 5 largest prescription benefit plans;
7. The fees provided for pharmacists for dispensing and other services provided in the 5 largest prescription benefit plans;
8. The terms and procedures for pharmaceutical company-sponsored patient assistance programs;
9. Any other information regarding discounts, rebates, fees, or other financial data that is pertinent to the cost of a medication;
10. In addition to the information identified above, actions should be taken to prohibit companies from increasing the price of a medication more than once a year, and prohibiting the provision of coupons or other incentives that would result in the use of higher priced medications when lower priced acceptable alternatives are available.

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