The Pharmacist Activist

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Editorial

THE CORPORATE DESTRUCTION OF HEALTH CARE: Part 2

In Part 1 (July, 2018) of this two-part series, I voiced strong concern that the authority that health professionals have for the decisions they are in the best position to make on behalf of their patients has been severely limited by corporation executives, health insurance companies, and government agencies. Experiences pertaining to the use of prescription medications were identified as typical of the challenges for the entire healthcare system, and certain policies of pharmacy benefit managers (PBMs; e.g., restrictive formularies, prior authorizations) and chain pharmacy executives (e.g., metrics, quotas, staffing levels) were considered. The resultant practice environment and working conditions in many pharmacies are characterized by decreased personal communication with and services for patients and an increased risk of medication errors and other drug-related problems. This editorial will primarily focus on the influence of pharmaceutical companies and insurance companies, as well as PBMs, on the provision and use of prescription medications.

Pharmaceutical companies

Pharmaceutical companies deserve great credit for their research programs and other initiatives that have resulted in the development of medications that are life-saving (e.g., antibiotics, certain anticancer agents), symptom-relieving, and otherwise improve the quality of life for patients with a wide range of illnesses. Vaccines have been of great value in the prevention of many illnesses, some of which are life-threatening. These companies and their founders/leaders at one time were accorded great respect and appropriately so. However, current discussions of pharmaceutical companies are most often in the context of public outrage regarding the cost of medications. The extent and intensity of this criticism is all the more noteworthy because most prescriptions are for lower-cost generic medications and most individuals only pay out-of-pocket a small fraction of the cost of their medications and they have no idea of what the actual costs are, because most of the expense is covered by insurance and government programs.

In the early years of my pharmacy experience, there were health insurance programs (e.g., Blue Cross/Blue Shield) that covered much of the cost of physician visits and hospitalization. Although there were some medications that were expensive, most were considered affordable and there was not a need for insurance programs to cover the cost of prescriptions. Today, however, prescription benefit programs are considered by most to be essential. There are many reasons for the dramatic increases in the cost of prescription medications that have resulted in the outrage that exists, and these reasons have their origins within the pharmaceutical companies that develop and market the drugs.

Most individuals understand and can accept the explanations for high prices for certain medications. Examples include

medications for rare disorders that will be needed by only a small number of patients, medications that are very complex and require sophisticated technology and skills to prepare, formulate, and/or administer, and medications that will cure or control problems such as infections and cancers that could otherwise be fatal. However, situations that individuals do not accept and are increasingly unwilling to tolerate are frequent and substantial price increases, greedy exploitation of the marketplace (e.g., Daraprim, the Valeant/Philidor debacle), strategies to prevent or delay generic competition, excessive, expensive, and often inappropriate marketing and advertising (e.g., billions of dollars for direct to consumer advertising), rebates/discounts/kickbacks, restricting the availability of many medications to specialty pharmacies, and disingenuous explanations for the high cost of medications.

It is the pharmaceutical companies, and only these companies, that establish the list prices for which medications are sold. There are no price controls for medications in the United States, resulting in pricing decisions made by the companies that are perceived by many as "charging as much as the market will bear." A common scenario is one in which a company markets a new drug and announces the list price that results in strong criticism that the price is too high. The company responds that no one actually pays the list price, and attempts to deflect the criticism towards "middlemen" (e.g., insurance companies, PBMs) which insist that the companies provide substantial discounts/rebates. However, when asked to identify the actual lower price resulting from the rebates, both the pharmaceutical companies and middlemen insist that this information can't be provided because others in a competitive marketplace would use it to their advantage. This lack of transparency leads to a situation in which each participant is determined to make the best deal for itself, chaos in the marketplace, and the conclusion on the part of those not involved in the secretive pricing decisions, that there is no valid justification for the high prices being charged and that those involved in determining them are self-serving and deceptive. The middlemen such as insurance companies and PBMs deserve the strong criticism directed against them, and this will be discussed later. However, it is the pharmaceutical companies that have the sole responsibility for establishing the list prices for their drugs, and they could decline to participate in the rebate games if they chose to do so. Thus, the outrage directed against them is self-inflicted.

Medications are, of course, not the only costly products that consumers purchase. But medications are unique in the marketplace in that much of the cost is paid by insurance companies or government agencies (e.g.,Medicaid, Medicare), notwithstanding the fact that most consumers support these programs through premiums and taxes. However, even with this advantageous situation, pharmaceutical companies have made decisions that incur the wrath of consumers, legislators, and others. It is difficult to imagine that consumer opinions could be worse if the companies sought that outcome.

The situation described would be bad enough if it "just" involved high drug costs and criticisms. However, the initial decisions regarding list prices and willingness to engage in rebate games trigger a very costly cascade of events that involve health insurance companies, insurance brokers, PBMs, auditors, and others. By the time each of these participants in this downward spiral of events has extracted its compensation and profits, there are insufficient funds to provide patients with prescription plans and options that permit them to choose their physicians and pharmacies, and to provide equitable compensation for the services of pharmacists. In addition, pharmacists are the only participants in the drug distribution process who are personally known and accessible to patients, and who commit the time to respond to questions regarding restrictive formulary options, prior authorizations, and co-pays, and are often the recipients of patient criticisms for decisions over which they have no control. The abysmal compensation provided to pharmacists adds insult to injury. A pharmacist friend recently voiced his frustration about the number of prescriptions for which his actual cost for the medications was more than the amount he was compensated. He further observed that for many of the other prescriptions, the slight financial return he receives is less than the Dunkin Donuts down the street makes in selling one donut.

The consequences of the present drug distribution "system" and the decisions that perpetuate it, are that many inadequately compensated pharmacists have little or no personal communication with patients, and provide minimal information and professional services with respect to the appropriate use of medications. The very busy and stressful workplace environment that exists in many pharmacies results in an increased risk of errors and other drug-related problems, many of which I believe are attributable to what I have characterized as the corporate destruction of health care.

The highest priorities in the use of medications should be to provide patients with positive therapeutic outcomes with the lowest possible risk. Patients would experience the greatest benefit, and pharmacists would derive the professional and personal fulfillment of significantly contributing to the improvement and maintenance of the health of those whom they

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New Drug Review

Betrixaban
(Bevyxxa – Portola)

Anticoagulant

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

Indication:
Prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE.

Comparable drugs:
Apixaban (Eliquis), edoxaban (Savaysa), rivaroxaban (Xarelto).

Advantages:
- Is the first orally-administered anticoagulant to be demonstrated to be effective for VTE prophylaxis for in-hospital and extended-duration use in acutely ill medical patients;
- Is as effective or more effective than enoxaparin for VTE prophylaxis in acutely ill medical patients.

Disadvantages:
- Labeled indications are more limited (comparable drugs are indicated for reducing the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation, and for the treatment of deep vein thrombosis [DVT] and pulmonary embolism [PE]; apixaban and rivaroxaban are also indicated for reducing the risk of recurrence of DVT and PE, and for the prophylaxis of DVT in patients undergoing hip or knee replacement surgery).

Most important risks/adverse events:
Contraindicated in patients with active pathological bleeding; risk of epidural or spinal hematomas in patients receiving neuraxial anesthesia or undergoing spinal puncture (boxed warning); risk of bleeding (risk factors include the concomitant use of other medications that may be associated with bleeding events [e.g., aspirin and other antiplatelet agents, other anticoagulants, nonsteroidal anti-inflammatory drugs]; concurrent use of another anticoagulant should be avoided); risk of bleeding events is increased in patients with severe renal impairment, and patients being treated with a P-glycoprotein (P-gp) inhibitor (e.g., amiodarone, azithromycin, clarithromycin, ketoconazole, verapamil); use should be avoided in patients with hepatic impairment.

Most common adverse events:
Clinically relevant non-major bleeding events (2.45%), urinary tract infection (3%), constipation (3%), hypokalemia (3%).

Usual dosage:
Initial single dose of 160 mg, followed by 80 mg once a day, with doses administered at the same time of day with food; recommended duration of treatment is 35 to 42 days; in patients with severe renal impairment, or who are being treated with a P-gp inhibitor, the dosage should be reduced to an initial single dose of 80 mg, followed by 40 mg once a day with food.

Products:
Capsules – 40 mg, 80 mg.

Comments:
Betrixaban is the fourth orally-administered anticoagulant that acts by inhibiting Factor Xa activity, joining rivaroxaban, apixaban, and edoxaban. However, its labeled indication is different than those of the comparable drugs and it is the first orally-administered anticoagulant demonstrated to be effective for in-hospital and extended-duration prophylaxis of VTE in patients with acute medical illnesses whose mobility is significantly restricted. Its effectiveness was demonstrated in a study of approximately 7,500 patients that compared extended duration betrixaban (35 to 42 days) with short duration enoxaparin (administered subcutaneously for 6 to 14 days). Efficacy was based on the composite outcome up to the Day 35 visit of the occurrence of asymptomatic proximal DVT, symptomatic proximal or distal DVT, non-fatal PE, or VTE-related death. Betrixaban reduced the composite outcome compared with those taking enoxaparin plus placebo (4.4% vs. 6.0%). Symptomatic events were reported in 0.9% and 1.5%, respectively, in patients treated with betrixaban and enoxaparin, and VTE-related death occurred in 0.3% and 0.5% of patients, respectively. The incidence of major bleeding (e.g., intracranial bleeding) was 0.67% in patients treated with betrixaban and 0.57% in patients treated with enoxaparin.

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serve. If there was a commitment to these priorities on the part of the pharmaceutical companies, I believe that there would be a much greater understanding and appreciation of the value of their medications, and respect for and trust in the companies. But this raises a question as to the type of prescription benefit programs that pharmaceutical companies provide for their own employees. The answer is that they use the same or similar broken programs for which costs, rather than the quality and extent of health care for patients, are the almost exclusive focus. A wonderful opportunity for the development of a model prescription benefit programs has been ignored or rejected.

Insurance companies and PBMs

Health insurance including coverage for prescription medications is considered essential by most Americans. However, insurance companies, PBMs, and other corporate entities with interrelated functions (e.g., insurance brokers), have used their extensive resources and influence to inappropriately assume authority for decisions regarding health care that should be made by prescribers, pharmacists, and other health professionals who are personally involved in the care of patients. Some of the policies and restrictions imposed by PBMs are identified in my first editorial on this topic in the July issue of *The Pharmacist Activist*. Health insurance companies have enabled the growth and markedly increased role of PBMs with respect to the use of medications. Health insurance and PBM programs were initially developed to facilitate the management of the financial and administrative aspects of the provision of healthcare services and products to patients. However, as they have grown, they have seized excessive authority for decisions that they are not in a position to make with respect to the care of patients. Their priorities have been to extend their own growth and profits, rather than the quality of services for their clients. This situation will only worsen if the proposed acquisitions of Aetna by CVS and Express Scripts by Cigna are permitted to occur.

Notwithstanding my earlier criticisms of pharmaceutical companies, these companies have developed medications that have great value in curing potentially fatal illnesses and extending and improving the quality of life for millions of individuals. I would contend that health insurance companies and PBMs contribute nothing to the improvement of the quality and scope of healthcare services and products for patients and, indeed, interfere with and compromise the services of health professionals. Yet these companies extract many billions of dollars from resources that could be used for much greater benefit.

Actions needed

The healthcare system is broken and the rapidly escalating costs are unsustainable. It is unrealistic to expect that progressive changes can be made quickly. However, some actions can be initiated and I recommend the following with respect to prescription benefit programs.

1. A task force of patient advocates, pharmacists, and prescribers with pertinent expertise should be convened and provided the responsibility of developing a model prescription benefit program with the priorities of optimal drug therapy outcomes and patient safety. This program should be presented to the appropriate officials at pharmaceutical companies with the request that they provide financial and other support for implementation.

2. Every organization that has a mission and/or activities in areas of health care and drug therapy should provide the model prescription benefit program for their employees. These organizations would include but not be limited to pharmaceutical companies, pharmaceutical wholesalers, health insurance companies, hospitals and other healthcare institutions, professional associations of pharmacists, physicians, and other health professionals, and universities with pharmacy, medical, and/or other health professions colleges.

I anticipate that a model prescription benefit program can be developed that will be more comprehensive, effective, safer, and efficient that the ones available now. Once it is successfully implemented by the organizations identified above, other employers and government programs will also adopt it.

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