The Pharmacist Activist

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Editorial

Understanding and Reducing Drug Prices Must Start with Transparency

The EpiPen pricing debacle has received such widespread media attention that I have not felt a need to address this topic in an editorial. However, the multitude and complexity of the issues exposed have created more confusion than clarity for many, and represent a cascade of events that are applicable to not only EpiPen, but also to the prices and availability of many other prescription medications.

This cascade of events includes, but is not limited to, the following:.

- A pharmaceutical company increases the price of a medication.
- The pharmacy wholesaler and pharmacy benefit manager (PBM) are provided increased discounts/rebates from the pharmaceutical company.
- Insurance companies, PBMs, and other payers increase premiums for prescription benefit plans.
- Patient copays for prescription medications increase.

Although concerns about the prices of prescription medications are not new, they have received unprecedented attention during the last year through examples such as the Turing Daraprim ripoff, the Valeant/Philidor fiasco, and, the Mylan/EpiPen debacle. This latter situation has resulted in a torrent of recent criticism regarding not only the prices for individual prescription medications, but also numerous other stories, deals, and ramifications related to drug prices that include the following themes:

- The list price for EpiPen was approximately $100 when it was acquired by Mylan in 2007 but is more than $600 now.
- Mylan provides substantial rebates for EpiPen to PBMs.
- EpiPen has limited competition.
- Some healthcare organizations and patients have resorted to using much less expensive vials of epinephrine and syringes/needles because EpiPen has become unaffordable (which results in the loss of precious time in the management of an emergency).
- Mylan does not reduce the cost for EpiPen but indicates it will make a generic equivalent product available for approximately $300.

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- For EpiPen, Mylan provided the federal government the 13% rebate for generic drugs instead of the 23% rebate for brand-name drugs.
- Mylan agreed to pay $465 million to the federal government to settle allegations that it had inappropriately provided the lower rebate.
- The prices of many medications have been increased multiple times within a year.
- The prices of certain older medications that are only available from one company have skyrocketed.
- Pharmaceutical companies provide coupons for their more expensive brand-name medications to maintain and increase the number of new and refill prescriptions for these products (which results in higher total drug costs).
- Pharmaceutical companies spend more than $2 billion a year for direct-to-consumer advertising of prescription drugs.
- Pharmaceutical companies have spent approximately $100 million to defeat Proposition 61 in California that addresses concerns regarding the prices of prescription medications.
- PhRMA is increasing dues for member companies by 50% to greatly increase its resources to defend against criticisms of high drug prices and legislative initiatives to address them.
- PBMs are profiting greatly from higher drug prices while at the same time claiming that they are holding down drug costs. The combined operating profit for Express Scripts, CVS/Caremark, and OptumRx, the three largest PBMs, was $10.1 billion in 2015, up 30% from 2013.
- PBMs obtain rebates and "rebate administration fees" from pharmaceutical companies and fees from pharmacies that must participate under the terms of "take it or leave it" agreements.
- PBMs usually retain a significant percentage of the rebates they receive rather than providing these "savings" to their clients.
- PBMs require rebates from pharmaceutical companies for placement of a company's product on its formulary or in a preferred tier in its formulary.
- PBMs are accused of charging patients with prescription copays that are higher than the actual cost of the medications
- PBMs blame pharmaceutical companies for the high cost of drugs.
- Pharmaceutical companies blame PBMs and insurance companies for the high cost of drugs.
- The Department of Justice and several state Attorney's offices have issued subpoenas to Express Scripts requesting information regarding its relationships with pharmaceutical companies, and its relationship with patient assistance programs and the specialty pharmacies that dispense the prescriptions.
- Shareholders in pharmaceutical companies, PBMs, and drug wholesalers are concerned that the criticism and investigations regarding drug prices will reduce the value of their investments.
- Huge corporations consider collaboration to reduce the costs of medication and health care services.

The pharmaceutical companies have destroyed the credibility of any drug pricing system because of the large number of different prices it charges different purchasers for the same medication. The PBMs have plundered the drug distribution system and have extracted huge profits for themselves, while not contributing anything to the quality and scope of care needed to provide optimum drug therapy. The agreements between the pharmaceutical companies and PBMs are secretive and described as "proprietary" for self-serving competitive reasons. The result is a chaotic, deceptive, and often corrupt prescription "benefit" system that even many health professionals, human resources directors, and other healthcare benefits decision makers do not fully understand and are unable and/or unwilling to try to fix them. If this situation exists for individuals who are expected to be knowledgeable about these programs, it is certainly understandable that consumers, legislators, and other policy makers are neither aware of, nor can anticipate, the ways in which prescription plans and drug prices can be

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New Drug Review

Insulin degludec (Tresiba – Novo Nordisk)

Antidiabetic Agent

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 to improve glycemic control in adults with diabetes mellitus.

Comparable drugs:

Insulin detemir (Levemir), insulin glargine (Lantus).

Advantages:

- Has a longer duration of action and does not have to be administered at the same time each day;
- May be less likely to cause nocturnal hypoglycemia.

Disadvantages:

- Has not been evaluated in pediatric patients (whereas insulin detemir is indicated in children with type 1 diabetes as young as 2 years of age, and insulin glargine is indicated in children with type 1 diabetes as young as 6 years).

Most important risks/adverse events:

Not recommended for use in patients with diabetic ketoacidosis; contraindicated during episodes of hypoglycemia; hypoglycemia (monitoring should be increased when changes are made in insulin dosage, co-administered glucose-lowering medications, meal patterns, and/or physical activity, and in patients with hepatic or renal impairment); hypersensitivity reactions; hypokalemia (potassium concentrations should be monitored in patients at risk); fluid retention and heart failure with concurrent use of a thiazolidinedione (e.g., pioglitazone); risk of hypoglycemia may be increased by the concurrent use of other antidiabetic agents, and medications such as ACE inhibitors and angiotensin II receptor blocking agents; blood glucose lowering effect may be reduced by the concurrent use of medications such as corticosteroids, diuretics, antipsychotic agents, and oral contraceptives; activity may be altered by the concurrent use of alcohol or beta-blockers; signs and symptoms of hypoglycemia may be blunted by anti-adrenergic drugs (e.g.,beta-blockers, clonidine, guanethidine, reserpine).

Most common adverse events:

Hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema, weight gain, nasopharyngitis, upper respiratory tract infection, headache, sinusitis, gastroenteritis.

Usual dosage:

Administered subcutaneously once a day at any time of day; dosage must be individualized based on the patient's metabolic needs, blood glucose monitoring results, and glycemic control goal; recommended starting dose in insulin-naïve patients with type 1 diabetes is approximately one-third to one-half of the total daily insulin dose (as a general rule, 0.2 to 0.4 units of insulin/kg can be used to calculate the initial total daily insulin dose); remainder of the total daily insulin dose should be administered as a short-acting insulin and divided between each daily meal;
recommended starting dose in insulin-naïve patients with type 2 diabetes is 10 units once a day;
recommended starting dose in patients already on insulin therapy is the same unit dose as the total daily long or intermediate-acting insulin unit dose.

Products:

Prefilled pens – 100 units/mL (U-100; 3 mL), 200 units/mL (U-200; 3 mL); should be stored in a refrigerator; "in-use" pens should not be refrigerated but should be kept at room temperature for up to 8 weeks;
also approved in a combination formulation with the rapid acting analog insulin aspart (Ryzodeg 70/30).

Comments:

Insulin degludec is the third long-acting human insulin analog, joining insulin glargine and insulin detemir. It is prepared using recombinant DNA technology and, following subcutaneous administration, forms multi-hexamers that result in a depot of the drug and delayed absorption from the subcutaneous tissues. Its duration of action is approximately 42 hours, compared with a duration of action of approximately 24 hours for insulin glargine and insulin detemir. A new formulation of insulin glargine (Toujeo) has a duration of action that continues slightly beyond 24 hours. The delayed absorption and elimination may provide a more consistent response. Although patients should be encouraged to administer insulin products at the same time each day, insulin degludec may be administered at any time of the day, unlike the other long-acting insulin analogs.

The effectiveness of insulin degludec was demonstrated in multiple clinical studies in which it was determined to be noninferior to insulin glargine and insulin detemir in lowering HbA1c concentrations. It was more effective than sitagliptin in lowering HbA1c concentrations, but also caused more episodes of hypoglycemia.

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manipulated. Frustration is further increased when, following identification of a drug pricing abuse, there is public outrage and congressional hearings, but no action results and the incident is soon forgotten, at least until the next drug pricing abuse is exposed.

Drug prices and prescription benefit plans are so complex that there is not a single strategy for establishing a system on a timely basis that would be effective, efficient, and equitable. Some have advocated price controls but such an action is controversial for many reasons, would take many years to accomplish, and should only be considered as a last resort. There are, however, changes that can be made but must be initiated with a requirement for transparency regarding drug prices. Pharmaceutical companies and PBMs will not provide this information voluntarily, so legislation will be necessary.

Transparency

The public, payers for prescription benefit plans (i.e., government agencies, employers), legislators, and health professionals must insist on the provision of the following information for each medication:

1. The manufacturer's list price (i.e., selling 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 amount 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 amount of the rebate (and rebate administration fees) provided for the 5 largest PBMs;

6. The amount of the copay for patients in the 5 largest prescription benefit plans;

7. The fee provided to pharmacists for dispensing and other services provided in the 5 largest prescription benefit plans;

8. The terms and procedures for any company-sponsored patient assistance programs;

9. Any other information regarding discounts, rebates, fees or other financial data that is pertinent to the cost of the medication.

The information identified above can be quickly provided by the pharmaceutical companies, PBMs and other pertinent organizations. The legislation that will require the provision of this information must include a section on fines/penalties for failure to provide the information on a timely basis or actions that circumvent the intent of the legislation. Other actions that should also be considered include prohibiting 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 alternatives are available.

Although pharmaceutical companies and PBMs will continue to strongly oppose transparency with respect to drug prices, their abuses of the current system must no longer be tolerated. They have forfeited their right to confidentiality of information that they manipulate for their benefit and to the disadvantage of others.

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