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February 2016 Issue [Download PDF format]

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EDITORIAL:

Is Walgreens Valeant's New Philidor?

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Valeant Pharmaceuticals has grown in size by acquiring other pharmaceutical companies and their products. However, in comparison to most large pharmaceutical companies, its investment in research and related programs to develop new drugs has been very small. To many pharmacists, Valeant is best known for dramatic price increases and very high prices for its products, including some that are not available from other sources. As examples, in early 2015 Valeant acquired two drugs that have been marketed for many years – Isuprel injection (isoproterenol hydrochloride) and Nitropress injection (sodium nitroprusside) – and promptly raised their prices 525% and 212%, respectively. The attempted justification for these increases is the observation of their outside consultants that the previous prices for the drugs do not reflect their "true value." Concerns have also been raised regarding the high prices for many of Valeant's dermatology (e.g., Jublia, Luzu, Solodyn) and ophthalmology products. In the financial community, however, Valeant was viewed as a very attractive investment – until October.

Philidor

Philidor was a "specialty" pharmacy that was unknown to most prior to October 2015. In a short period of time it had grown to the point that it had hundreds of employees. Its growth apparently was attributable to its "specialization" in dispensing Valeant products. However, from information learned from internal documents and former employees, serious questions exist about its operations. It is alleged that Philidor employees used strategies to dispense high-priced Valeant products (e.g., hundreds of dollars for a 60-gram tube of Luzu) instead of much less expensive equivalent products. The strategies were designed to obtain maximum reimbursement from PBMs and insurance companies with explanations such as prescribers had insisted that the brand-name Valeant product be dispensed as written. Prescription

NEW DRUG REVIEW:

Mepolizumab (Nucala – GlaxoSmithKline) *Antiasthmatic Agent*

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

Indications:
Administered subcutaneously for the add-on maintenance treatment of patients aged 12 years and older with severe asthma and with an eosinophilic phenotype; Is not indicated for the treatment of other eosinophilic conditions, or for the relief of acute bronchospasm or status asthmaticus.

Comparable drugs:
Omalizumab (Xolair).

Advantages:

- May increase the effectiveness of treatment of patients with severe asthma and with an eosinophilic phenotype;
- May permit a reduction in dosage of oral corticosteroids;
- Has a unique mechanism of action (is an interleukin-5 [IL-5] antagonist);
- Less risk of anaphylaxis (labeling for omalizumab includes a boxed warning regarding this risk);
- Is not likely to be associated with the occurrence of eosinophilic conditions.

Disadvantages:

- Labeled indications are more limited (indications for omalizumab include patients with moderate to severe allergic asthma, as well as chronic idiopathic urticaria).

Most important risks/adverse events:
Hypersensitivity reactions (e.g., rash, pruritus, angioedema, bronchospasm; treatment should be discontinued if reactions occur); should not be used to treat acute bronchospasm or status asthmaticus; reduction in dosage or discontinuation of systemic or inhaled corticosteroids (if appropriate, dosage should be reduced gradually under the supervision of a physician, to avoid systemic withdrawal sym

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co-pays were discounted or waived for patients as an incentive to have them use Philidor's mail-order pharmacy, and prescription refills were provided without being specifically requested by patients. The following example provides further insights regarding the strategies employed.

> Luliconazole (Luzu) cream is a topical azole antifungal agent that was approved by the FDA in late 2013 for the treatment of interdigital tinea pedis, tinea cruris, and tinea corporis. One of Valeant's statements in promoting the product is, "Luzu is the only topical azole antifungal approved to treat athlete's foot between the toes with once-daily, 2-week treatment." This statement is accurate but conveniently ignores the availability of other topical antifungal agents such as terbinafine (Lamisil AT) that is used for this condition once-daily for just 1 week. When I reviewed luliconazole as a new drug, it was one of a very few drugs to which I have given the lowest rating of 1 (important disadvantages) on a scale of 1 to 5 in my New Drug Comparison Rating system. I remember wondering to myself who would use this prescription product when terbinafine is at least equally effective, is available without a prescription, is used for a shorter treatment period, and is much less expensive. I didn't have to wait long to find out from the following experience shared by a patient.
>
> The patient was prescribed Luzu for athlete's foot but was surprised that the prescriber suggested that he obtain the prescription from a mail-order pharmacy (Philidor) that would cover the co-pay for the first prescription. The prescription was delivered and several weeks later the patient received a call from Philidor offering to waive his co-pay for all his remaining refills. The patient observed that he probably would not have needed or ordered the refills if he would have been charged a co-pay. He now has "a few years' supply of athlete's foot cream" and is also suspicious of what incentives the prescriber may have received, as well as the relationship between Valeant and Philidor.

Other questions also exist regarding Philidor's operations and the Philidor - Valeant relationship. At least some of Philidor's employees were asked by the company to sign agreements that they would not discuss the company's operations. Philidor moved to acquire or open pharmacies in other states for the apparent purpose of having multiple pharmacies from which to submit claims to PBMs and insurance companies. To the credit of the California Board of Pharmacy, it denied issuing a license because of questions regarding the ownership and operations of Philidor.

Philidor is Valeant (or not?)

The more that is learned about Philidor, the stronger the allegations become. It has been alleged to be a "phantom pharmacy" that existed to increase the sales of Valeant products using questionable practices. Its business and accounting practices have been questioned. It has been alleged to be owned by or operated under the direction of Valeant. For many months there had not been a general awareness of a relationship between Valeant and Philidor. However, it is now known that Philidor accounted for about 7% of Valeant's revenue. Valeant has reported that in late 2014 it paid $100 million for an option to buy Philidor.

conditions previously suppressed by systemic corticosteroid therapy); opportunistic infections (risk of herpes zoster infection and, if appropriate, varicella vaccination should be considered prior to starting treatment); helminth infections (should be treated prior to starting treatment; if a helminth infection develops during treatment and does not respond to anti-helminth treatment, mepolizumab should be discontinued until the infection resolves).

Most common adverse events:
Headache (19%), injection site reactions (8%), back pain (5%), fatigue (5%).

Usual dosage:
100 mg every 4 weeks administered subcutaneously into the upper arm, thigh, or abdomen.

Products:
Single-dose vials – 100 mg of lyophilized powder for reconstitution; should be reconstituted and administered by a healthcare professional; contents of a vial should be reconstituted with 1.2 mL of Sterile Water for Injection; reconstituted solution should not be shaken to avoid foaming and/or precipitation; product labeling should be consulted for specific recommendations for reconstitution and administration.

Comments:
Many patients with asthma do not experience adequate reduction of symptoms and associated complications with available treatments, and there are more than 400,000 asthma-related hospitalizations each year in the United States. Multiple cell types, including eosinophils, and mediators (e.g., cytokines) are involved in the inflammatory process that occurs in the airways of the lungs. Interleukin-5 (IL-5) is the major cytokine that is responsible for the growth and differentiation, recruitment, activation, and survival of eosinophils. Mepolizumab is an IL-5 antagonist that reduces the production and survival of eosinophils. It has been approved for use in conjunction with other maintenance treatments for patients with severe asthma and with an eosinophilic phenotype.

The effectiveness of mepolizumab was demonstrated in three placebo-controlled trials in which either the new drug or placebo was added to an existing treatment regimen (e.g., oral and/or inhaled corticosteroids). In one of the studies, the primary endpoint was the percent reduction of the oral corticosteroid dose during weeks 20 to 24 compared with the baseline dose, while maintaining asthma control. Twenty-three percent of the patients treated with mepolizumab had a 90% to 100% reduction in their oral corticosteroid dose, compared with 11% in the placebo group. Additionally, 54% of patients treated with the new drug achieved at least a 50% reduction in the daily prednisone dose compared with 33% of those receiving placebo. Mepolizumab did not provide consistent improvements in mean change from baseline in mean forced expiratory volume in 1 second (FEV_1).

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Current or former Valeant employees using fake names were alleged to be involved in the operations of Philidor.

As the concerns of investors and others intensified and Valeant's stock value plunged, Valeant decided to end the relationship with Philidor. A letter dated November 2, 2015 from the CEO of Valeant to physicians and other healthcare professionals includes the following statement:

> "We know many doctors and patients were concerned about the recent allegations surrounding Philidor's business practices, and so were we. Given those questions, we decided it was appropriate to terminate our relationship with Philidor."

The CEO of Valeant has also stated that "Operating honestly and ethically is our first priority…" Both Philidor and Valeant announced that Philidor would be shutting down its operations.

The more that is learned about the Valeant - Philidor relationship and their business practices, the questions and suspicions become even stronger that there is much more still to be learned. As an important example, how could Valeant pay $100 million for an option to purchase Philidor and now try to claim that it was unaware of its business practices?

Valeant and Walgreens

On December 15, 2015 Valeant and Walgreens jointly announced 20-year fulfillment agreements involving the two companies that are "designed to help enhance patient care through expanded services and lower out-of-pocket expenses." The announcement notes that Valeant will reduce prices by 10% for all its dermatological and ophthalmological products distributed through more than 8,000 Walgreens retail outlets. It is further noted that Valeant plans to further extend distribution of these products to "additional participating independent pharmacies" (editor's note: Independent pharmacies beware!).

The announcement also identifies a separate agreement that states:

> "Valeant will also distribute certain branded products, that have generics available, in the dermatology, ophthalmology, gastrointestinal and neurology/other therapeutic areas through Walgreens at generic prices; an expected average price decrease of more than 50 percent."

Glumetza (metformin extended-release tablets) is one of the products included in this separate agreement. Valeant raised the price of Glumetza by 800% in 2015, resulting in harsh criticism from the patients who suddenly had to pay much more for the drug, as well as many others. Express Scripts has announced that when generic versions of Glumetza become available this month that it will block reimbursement for Glumetza. The chief medical officer of Express Scripts has also indicated that every claim for Valeant products will be getting "extra scrutiny" to be sure that the PBMs rules are being followed.

The Valeant – Walgreens agreements warrant investigation, if in fact it will be possible to learn the specific terms and

financials of the agreements. However, just based on the statements noted above, it can be concluded that when a discount of 10%, 50%, or some other percentage is deducted from an outrageously high price, the discounted price will still be very high and may still be much higher than that of other products that are equivalent in effectiveness and safety.

Numerous questions exist. It has been suggested that the Valeant – Walgreens agreements may result in "savings" by avoiding the middlemen (i.e., wholesalers). If Express Scripts and other PBMs will not cover Valeant products like Glumetza, Jublia, and Luzu, will Valeant/Walgreens provide alternative prescription benefit coverage for patients for whom these products are prescribed, thereby avoiding the PBM middlemen? If so, will the prescription benefit coverage for patients for these products be similar to or better than their previous coverage? Will Walgreens receive fees from Valeant for dispensing prescriptions for these products that are higher than the fees that would be expected from a PBM? Is it true that Walgreens will receive Valeant drugs on consignment, thereby enabling it to reduce inventory costs? What financial incentives are being provided to Walgreens that have resulted in its participation in long-term agreements with a company whose drug prices and business practices have been so strongly criticized? Is Walgreens Valeant's new Philidor? Can Walgreens withdraw from the agreements?

And more questions

When concerns about Philidor's operations and its relationship with Valeant became public in the fall of 2015, Valeant appointed an Ad Hoc Committee of the Board of Directors to review the company's relationship with Philidor and related matters. On February 23, it was announced that there has been a preliminary identification of certain sales to Philidor (approximately $58 million of net revenues) that should have been recognized when products were dispensed to patients rather than on delivery to Philidor. The questions regarding the accounting practices are likely to necessitate a restatement of Valeant's earnings. But will the review of this Committee go beyond the evaluation of accounting practices? For example, will the allegation that current or former employees of Valeant were involved in the operations of Philidor be investigated? The questions continue!

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