Valeant, Philidor RX, and the Uninformed Attack on Specialty Pharmacy

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Yesterday, Valeant Pharmaceuticals finally explained its complex interactions with Philidor RX Services, a so-called "specialty pharmacy" that has a previouslyundisclosed financial relationship with Valeant. Click here to see the full 89-slide webcast deck. Valeant has been labeled the "Enron of the pharmaceutical industry," although I don't know if any of the alleged shenanigans are true.

Unfortunately, the controversy has tarred the entire specialty pharmacy industry along with manufacturers' legitimate specialty pharmacy relationships. Below, I explain why Philidor RX is not a specialty pharmacy. I also suggest what the Valeant-Philidor relationship could mean for payer surveillance of manufacturers' copay offset programs.



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I believe (hope?) that over time, everyone will recognize the differences between a true specialty pharmacy and a company such as Philidor. Meanwhile, expect greater scrutiny of manufacturers' specialty channel strategies. Smaller independent specialty pharmacies should also expect greater oversight, as manufacturers and payers work to validate the business operations of their trading partners.

OUCH!

Here's the inflammatory report, written by well-known short-seller Citron Research, that sent Valeant's stock tumbling last Wednesday: Valeant: Could this be the Pharmaceutical Enron? Subtle, right?

The stock market went bananas. Valeant's stock dropped by almost 50% last week, before rebounding slightly. As of yesterday's close, its stock is still down a whopping 38% in the past 6 trading days.

Alas, the controversy launched a slew of poorly researched news stories filled with anti-specialty-pharmacy rhetoric. Here's a small sample from last week:

- "...what's really at the heart of the accusations against Valeant is the use of a new, shadowy segment within the pharmaceutical industry: specialty pharmacies." (The Fraud Allegations Against Valeant Exposed An Industry Secret That's Going To Infuriate Washington, *Business Insider*
- "Use of specialty pharmacies seems to have become a new way of trying to keep the health system paying for high-priced drugs." (Drug Makers Sidestep Barriers on Pricing, *The New York Times*)
- "A short-selling research firm has accused Valeant of using Philidor and other specialty pharmacies to orchestrate fraudulent transactions and thus inflate its financial results." (Valeant's Disclosure: Why Now?, *The Wall Street Journal*)
- "Specialty pharmacies are a valuable part of the system ... but they also open up yet another loophole with the potential for conflicts of interest." (The bad boys of pharma: Investors love them — until cracks in the model appear, *Financial Post* ACRUX DDS PTY LTD. et al. EXHIBIT 1530

Loophole? Fraudulent? Shadowy segment?!? Yikes!



also imply—inaccurately—that every pharmaceutical manufacturer utilizing a specialty pharmacy networks is trying to game the system or trick payers. Oy.

Late yesterday afternoon, the National Association of Specialty Pharmacy (NASP) emailed a statement to the few thousand people on its email list. But the damage is done.

More bad news keeps coming. In the past few days, journalists have unearthed even more alleged problems at Philidor. Check out this troubling *Wall Street Journal* investigative article: Valeant and Pharmacy More Intertwined Than Thought. It alleges that Valeant employees used bogus email names while secretly working at Philidor. On yesterday's call, Valeant announced that a new Board committee would be reviewing the company's relationship with Philidor Rx Services and other pharmacies.

MY \$0.02: PHILIDOR IS NOT A SPECIALTY PHARMACY

Philidor Rx is a manufacturer-controlled mail pharmacy that dispenses primarily Valeant products. It was founded in 2013 and now employs more 600 people. Philidor also provides copay card administration services for Valeant.

This brief description should be sufficient to disqualify Philidor RX from being designated a "specialty pharmacy." But given the media's uninformed perspective, we must stipulate precisely why Philidor Rx is not part of the specialty pharmacy industry.

1. Products. Most people in healthcare understand that specialty pharmacies focus on self-administered specialty drugs covered under a patient's pharmacy insurance benefit. Specialty drugs are almost always highly differentiated brand-name drugs for patients undergoing intensive therapies for such chronic, complex illnesses as cancer, rheumatoid arthritis, multiple sclerosis, and HIV.

Philidor Rx, however, focuses on Valeant's comparatively undifferentiated traditional drug portfolio. According to Valeant, Philidor's dispensing activity focused primarily on Valeant's own dermatology products such as Retin-A-Micro and Solydyn. For Valeant's Jublia toe fungus medicine, 44% of revenues flowed through Philidor.

2. Revenue Recognition. Manufacturers usually recognize revenues when a product is sold to a pharmacy or to a wholesaler for resale to a pharmacy. Before December 2014, Valeant accounted for its sales to Philidor in this way.

In December 2014, however, Valeant executed a purchase option and began consolidating Philidor's revenues. That's why Valeant doesn't recognize revenue until the product is dispensed, at which point Valeant books the net prescription revenues. Valeant also consolidates the revenues of other, unnamed pharmacies in Philidor's "network of pharmacies" located in California, Florida, New Jersey, South Carolina and Texas.

Valeant also revealed that Philidor dispenses Valeant medications before adjudication of the reimbursement is finalized, so Philidor takes on risk for non-reimbursement. As far as I know, unaffiliated pharmacies always require the payer's confirmation of coverage and payment before dispensing a prescription.

3. Sources of Pharmacy Profits. A pharmacy earns the majority of its profits from the spread between (1) the drug's acquisition cost and (2) the reimbursement from the payer or consumer. Pharmacies may also receive a minority of their profits from dispensing fees charged to payers and services fees charged to manufacturers. By contrast, Philidor Rx is now effectively operating a direct-selling pharmacy for Valeant products, so the concept of spread does not apply.

4. Ownership. No other pharma manufacturer owns or operates a significant specialty pharmacy. Instead, the pharmacies that dispense specialty drugs are owned and operated by such organizations as pharmacy benefit managers, health plans, independent pharmacies, retail drugstore chains, health plans, pharmaceutical wholeselers, physician practices, and heapital systems. See Section 3.3. (page 44) of our 2014 15 Economic Penert

On page 16 of its slide deck, Valeant calls out AbbVie's Pharmacy Solutions business as an example of a manufacturer-owned specialty pharmacy. The Pharmacy Solutions website, however, clearly states that it is an AbbVie company. Last week, AbbVie felt compelled to remind analysts that "revenue from Pharmacy Solutions is less than 0.2% of our total U.S. sales." Other manufacturers also issued statements clarifying that they use only unaffiliated pharmacies.

REIGNITING THE COPAY OFFSET CONTROVERSY

Valeant Risks Clash With Insurers Amid Scrutiny, from Toronto's *The Globe and Mail*, provides a reasonably concise summary of how Philidor and Valeant worked:

"Philidor helps boost Valeant's profit in part by filling its brand-name drug prescriptions, where an independent pharmacy might substitute a less expensive alternative or generic drug, analysts say."

Put another way, it appears that Valeant used Philidor Rx to support its very aggressive copay offset programs.

As regular Drug Channels readers know, PBMs and third-party payers generally hate copay offset programs for nonspecialty drugs. They argue that copayment offset programs interfere with benefit plan design, reduce generic substitution, and raise plan sponsors' costs. Four years ago, I highlighted the controversy in Wake-Up Call for Copay Cards and PBMs Launch a New Attack on Copay Cards.

At the same time, payers are figuring out how to exploit manufacturers' copay programs, by:

- Offering benefit designs with pharmacy deductibles, so that pharmaceutical manufacturers end up paying fullprice for their own products. See How Pharmacy Benefit Deductibles Stimulate Manufacturer Copay Program Spending.
- Using high coinsurance rates for fourth-tier specialty drugs, thereby forcing manufacturers to cover patients' large out-of-pocket costs. See How the Fourth Tier Coinsurance Boom Drives Copay Offset Programs.

Valeant's approach, however, will create greater payer scrutiny for copay cards associated with Valeant products. I'm sure that prescription claims from Philidor and other Valeant pharmacies will also be examined much more closely by third-party payers. Going forward, that scrutiny may end up having the biggest impact on Valeant's future sales growth.

In the meantime, specialty pharmacies and their manufacturer partners should definitely care about their bad reputation.