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Inaccurate Views of Specialty Pharmacies Tarnish Industry

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By [Angela Maas](#), Managing Editor
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Media reports about Valeant Pharmaceuticals International Inc. and the business practices of pharmacy Philidor Rx Services LLC have put specialty pharmacies in the spotlight — but not in a good way. And while information is still coming out about the allegations, it's important to note that while reports refer to Philidor as a "specialty pharmacy," it really isn't one, and this characterization is doing a disservice to those companies that are providing a complex array of services to multiple stakeholders.

"Since we don't know all the details still, it's hard to determine too much other than there were a lot of inappropriate relationships in play that are not typical of specialty pharmacies," says F. Randy Vogenberg, Ph.D., partner at Access Market Intelligence. "We also know that this was not your typical specialty pharmacy that has been referred to as dealing with specialized drug therapies that are costly and requiring additional clinical/patient support services in accordance with" definitions by the National Association of Specialty Pharmacy or the Academy of Managed Care Pharmacy.

According to Bill Sullivan, founder of and principal consultant for Specialty Pharmacy Solutions LLC, "none of the products manufactured by Valeant and dispensed/distributed through Philidor were specialty products. The media inaccurately seized on the term 'specialty pharmacy,' and the perception that Philidor was a real specialty pharmacy is simply inaccurate. They never handled a true specialty product at any time. The fact that at least one of their products was high-cost does not qualify it as a specialty drug according to the SP industry definition." In fact, says Sullivan, Valeant's product portfolio contains only one drug — Diastat (diazepam) for epilepsy — that could be considered a specialty drug.



"A key concern is market confusion," contends Elan Rubinstein, Pharm.D., principal at EB Rubinstein Associates. He points to one article that says Valeant's specialty pharmacy arrangement is typical in the pharmaceutical industry. "This is not true," he asserts. "A specialty pharmacy is not captive of a pharmaceutical manufacturer, where (1) the manufacturer encourages physicians and patients to preferentially submit prescriptions to the specialty pharmacy, (2) where a key business purpose of the specialty pharmacy is to maximize a manufacturer's product sales, and (3) where the specialty pharmacy dispenses no other manufacturers' products." Instead, he tells *SPN*, Philidor "should be considered a mail-order pharmacy."

"Valeant/Philidor co-opted the specialty pharmacy model of providing patient support services including prior-authorization and financial assistance (e.g., co-pay cards). These are routine components of the specialty model; however, no clinical or cognitive services were ever provided to patients, which are hallmarks of the specialty model," Sullivan explains.

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“Specialty pharmacies play a vital role in supporting access to complex biologics and related therapies,” contends Stephen Cichy, founder of and managing director for Monarch Specialty Group, LLC. “Specialty pharmacies offer a unique platform of services that other distribution channels are unable to effectively provide. Depending on the needs of a specific manufacturer, these services may include inventory management, access to knowledgeable pharmacist staff, compliance monitoring, coordination of patient care including clinical management of disease specific programs, medical benefit management and billing/reimbursement expertise.”

“Philidor’s business practices appear to be at the heart of the allegations,” he continues. “Alleged insufficient licensure, faulty accounting practices, unclear association with affiliated pharmacies and questionable communication tactics with its patients have all been implicated. While Philidor’s operation as a closed-door pharmacy or even its role as a sub-contracted business partner to a manufacturer isn’t unusual, its business practices with its customers and employees are in question. For example, it’s not extraordinary for a state-licensed pharmacy to fill prescriptions on behalf of another pharmacy, but in all cases it must be clearly documented to patients that the state-licensed pharmacy is the one providing the medication.”

Clear Policies ‘Ensure Ethical Practices’

In addition, says Sullivan, “Most payer contracts prohibit a pharmacy from dispensing a drug unless the patient meets their financial liability,” but Philidor allegedly provided drugs for free when it couldn’t obtain prior authorization. “Manufacturers can run free-drug programs, but the patient must apply and meet eligibility criteria before receiving a free drug,” a process that “Philidor apparently side-stepped,” according to reports. “Whether Valeant promoted this practice remains to be seen. A manufacturer whose product costs little to manufacture but is priced very high has the margin to generate a lot of profit that can be utilized by giving away free product and maintain/grow their market share.”

Sullivan explains that “all specialty pharmacies need to have clear, unambiguous policies and procedures in place to ensure ethical practices. Specialty pharmacy accreditation clearly mandates that pharmacies not only develop such P&Ps but also detailed standard operating procedures and training to ensure that staff adheres to the policies. A specialty pharmacy that wants to retain their accreditation needs to conduct regular internal audits to validate adherence to the policies.”

Moving forward, Vogenberg says it will be interesting to see what kinds of actions that federal and state regulators, as well as the U.S. Department of Justice and state attorneys general, may take with respect to Philidor and potentially Valeant. In addition, he says, “Given the post-ACA [i.e., Affordable Care Act] focus on patient outcomes and population health, how can manufacturers work more effectively with other stakeholders, including health plans, to create a win-win opportunity instead of another Philidor?”

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