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Valeant risks clash with insurers amid scrutiny

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Governments, businesses and insurers are already grappling with the mounting costs of prescription medications and the sustainability of payment systems.

Now, with tensions over those issues running high, Valeant's revelations this week about its pharmacy partners has added fuel to the debate over drug pricing. The company is under investigation by U.S. regulators, including prosecutors in Massachusetts and New York, and it could soon encounter resistance from insurers and drug benefit plan managers.

At the centre of the growing controversy is Philidor RX Services LLC. The Hatboro, Pa.-based registered pharmacy, which has ties to Valeant, processes prescriptions and sends medications by mail through 45 states – shipping is free and the company has projected its daily dispensing will surpass 12,000 prescriptions by the end of the year.

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.

Some have questioned how long insurers will tolerate that approach.

"While management naturally wants to maximize shareholder value, we worry that this strategy may not be sustainable as the insurers could stem costs by raising patients' co-pays (deductibles), denying coverage for certain Valeant drugs and/or stop doing business with specialty pharmacies involved in Valeant's [alternate fulfilment] program," Dimitry Khmelnitsky, investment analyst at Veritas Investment Research, wrote in a note to clients.

Valeant revealed its relationship with Philidor on Monday after a noted short seller raised the issue. That prompted a selloff of the company's shares, which dropped 32 per cent over the course of the week on the Toronto Stock Exchange. Valeant has called accusations by the short seller, Citron Research, "erroneous."

Valeant maintains that Philidor will dispense generic products "as specified in the patient's prescription or as requested by the patient." But some reports suggest that Philidor primarily dispenses Valeant drugs and pushes customers to renew prescriptions.

Private insurers that back workplace benefit plans are already under pressure as new drugs increasingly come to market with shocking prices. The first $1-million drug claim hit a Canadian insurer in 2009 and, since then, employers have been rethinking their benefit plans and looking for ways to cut costs. That includes raising deductibles, pushing employees toward generic versions of drugs and getting employees to cover premiums.

In the U.S., high drug prices have also become a hot-button issue and some politicians are calling for new regulations to rein in costs.

This month, Valeant received subpoenas from prosecutors requesting more information on its drug-pricing decisions, patient assistance programs and distribution methods, among other things.

Customers have an incentive to use Philidor because the company is able to reduce or waive the portion of the costs that they would pay out of pocket. The pharmacy fills the prescriptions quickly and Valeant takes on the risk that the private insurer will pay the rest of the expense. Since many workplace health benefit plans allow employees to choose their medications, insurers usually pay. Other pharmaceutical companies also use these kinds of pharmacies, but Valeant says it has the contractual right to buy Philidor and this kind of controlling interest is an unorthodox arrangement.

Efforts to get closer to the end customer were abandoned by several large pharmaceutical companies more than a decade go.

In 2003, Merck & Co. Inc. completed its spinoff of Medco Health Solutions Inc., a prescription benefit plan management company that filled or processed approximately 548 million prescriptions a year at the time. The sale put an end to the appearance of a conflict of interest, since benefit plan managers' incentives and restrictions play a role in determining what medications patients take. The U.S. government's scrutiny of Medicare patients' drug coverage at the time added to the pressure. Other drug companies also dabbled in, and abandoned, the pharmaceutical services business.

Most pharmaceutical manufacturers aren't "playing any games" and now primarily just acquire other drug makers as consolidation sweeps through other facets of the health care industry, said Edith Rosato, chief executive officer of the Academy of Managed Care Pharmacy, a national professional association of pharmacists and health care practitioners in the U.S.

"I've seen drug wholesalers, like Cardinal Health – they own pharmacies, and have specialty pharmacies, and they also own a home infusion company, and they recently purchased a medication therapy management company," she said. "I'm seeing some integration in other components of the health care system." She added that there could likely be regulatory issues with pharmaceutical manufacturers buying up health insurers or drug wholesalers.

Valeant calls Philidor a "specialty pharmacy" and the company says that – as with many U.S. pharmaceutical companies – more of its revenue is coming through its specialty pharmacy channels.

That caused confusion, since the label of "specialty pharmacy" is a term commonly used for those that transport, store and distribute specialty drugs, such as "biologics" – treatments made from living cells. These medicines have been on the rise in recent years to treat conditions from cancers to rare genetic diseases. They are often administered by injection, need to be kept at cool temperatures and have a shorter shelf life. In Canada, both Shoppers Drug Mart and Rexall have developed specialty pharmacy networks with services such as IV infusion clinics.

On top of dealing with specialty drugs, specialty pharmacies have unique ways of dealing with patients – educating them, managing their medications and making sure good health outcomes are being achieved for patients. Research shows that many patients do not take their medications correctly, so there are often services in place to boost adherence to prescriptions.

These kinds of pharmacies can actually save money by cutting waste out of the system, which insurers like. Insurers have also increasingly been forming preferred pharmacy networks where they can negotiate volume discounts and help make sure that expensive drugs are being used properly and where they are needed most.

None of Canada's more than 9,000 pharmacies – specialty or otherwise – are known to be owned or controlled by drug manufacturers, according to Denise Carpenter, CEO of the Neighbourhood Pharmacy Association of Canada, which represents many of the country's largest pharmacy operators.

It's not only the ethics of a drug maker owning a pharmacy that are raising questions. There's also the mystery swirling around another specialty pharmacy in California called R&O Pharmacy LLC, which operates as part of the Philidor pharmacy network in California, where Philidor was denied a licence in 2014. Philidor and R&O have a call-centre phone number in common and Philidor says it has the right to purchase its affiliated pharmacies such as R&O in the future.

Court documents indicate that R&O got a letter from Valeant's general counsel demanding $68.9-million (U.S.) as payment for drugs sold through its network. R&O says it has never before done business with Valeant and suggests both companies might be victims of a "massive fraud." Valeant said it would show in court how it is owed the money. Analysts were perplexed by this legal action, given the seemingly close ties of the three companies.

"Over all, while we do not have all the pieces to this puzzle yet, we find Valeant's apparent control over Philidor, and Philidor's alleged activities with other pharmacies such as R&O, as aggressive, unusual and questionable," Alex Arfaei, an analyst with BMO Nesbitt Burns, said in a note to clients. He estimates that 10 per cent of Valeant's revenue come from specialty pharmacies.

Valeant said it would hold a call with investors Monday morning that would address "incorrect interpretations of facts," among other things. But neither Valeant nor Philidor responded to requests for details or clarification from The Globe.

In the meantime, Quebec's securities regulator, the Autorité des marchés financiers, said it is watching the situation closely, although it was not yet ready to comment on the details. "These allegations are however worrying and our goal is to make sure that there was no negligence regarding our securities regulation," the AMF said.