

## 3 Key Issues To Watch As Pricing Probes Swamp Big Pharma

By **Jeff Overley**

*Law360, Washington (November 9, 2015, 8:00 PM ET)* -- The whirlwind of investigations into sky-high prescription drug prices has sucked in the world's largest drugmakers and cleared a path for legislation and regulation aimed at curbing costs, experts say.

Probes related to drug pricing have been launched in recent weeks by the Senate Special Committee on Aging and by Democratic members of the House Oversight Committee. In addition, the U.S. Department of Health and Human Services has given multiple indications that regulatory moves on drug prices may lie ahead.

Targets include Valeant Pharmaceuticals International Inc., Turing Pharmaceuticals Inc. and other companies criticized for jacking up the prices of old generics, as well as Gilead Sciences Inc., AbbVie Inc. and other manufacturers of expensive specialty medications for hepatitis C.

After years of outcry about drug prices but little in the way of action, the sudden wave of scrutiny suggests that a policy response may finally be looming.

"I think that the collective efforts here ... clearly can have an impact," Morgan Lewis & Bockius LLP partner Stephen Paul Mahinka said.

Here are three key issues to watch as the inquiries move ahead.

### **Medicare Negotiations Eyed Once Again**

Whenever drug prices make news, the immediate question is whether the time has come to let Medicare negotiate drug prices or let Americans reimport drugs from countries that bargain for cheaper prices on U.S.-made medications.

Many experts remain skeptical of the prospects for such dramatic changes, mainly because Republicans who control Congress tend to worry about sapping away money for research and development of innovative drugs.

"I don't see broad legislation on this for a while, if at all," Wilson Sonsini Goodrich & Rosati partner PC David M. Hoffmeister said.

However, that doesn't mean there won't be a conversation about systemic reforms. The 2016

campaigns will inevitably explore consumer pocketbook issues, and few of those issues gain headlines easier than alleged price gouging of sick Americans.

Democratic presidential candidates Hillary Clinton and Sen. Bernie Sanders of Vermont have recently endorsed letting Medicare negotiate drug prices. GOP candidate Sen. Marco Rubio of Florida has entered the fray as well, at least rhetorically, reportedly accusing drugmakers of "pure profiteering."

Joshua P. Cohen, a researcher at the Tufts Center for the Study of Drug Development, predicted that lawmakers will refuse to let Medicare negotiate drug prices or allow drug reimportation. But he also predicted that the race for the White House will return the issues to the spotlight.

"I do not think that Congress as currently constituted would pass such legislation," Cohen said in an email. "Nevertheless, these proposals will be revisited, as they have vocal proponents (several presidential candidates) and constituencies demanding lower prices."

### **Value-Based Drug Pay Gains Traction**

Even though the federal government doesn't directly negotiate drug prices in Medicare, it does benefit from surrogate negotiations by private insurance plans. Those negotiations set prices under Medicare Part D and can influence reimbursement that's set by statute under Medicaid.

In recent days, the Obama administration has expressed a keen interest in those negotiations, looking in particular at negotiation of pay-for-performance deals that link reimbursement to a drug's effectiveness.

For example, the Centers for Medicare & Medicaid Services on Thursday wrote to Gilead, AbbVie, Merck & Co. Inc. and Johnson & Johnson for information about how value-based arrangements with private insurers for hepatitis C drugs could affect Medicaid payments.

"CMS believes that some value-based purchasing arrangements may impact [Medicaid reimbursement] and would like more information regarding such programs in order to develop future guidance," the agency wrote.

In addition, HHS on Nov. 20 is holding a public forum with drugmakers about efforts to "develop innovative purchasing strategies and incorporate value-based and outcomes-based models into purchasing programs in both the public and private sectors."

There are limits on the extent to which Medicare Part D plans can tie drug coverage to value, but those limits could be loosened through regulation without any new authority from Congress, experts say.

"You could make changes on the CMS side ... to allow you to do more of this value-based contracting," Mahinka said.

And regardless of regulatory policies, the demand for value will impact prices under insurance policies that are offered by employers or sold directly to individuals outside of Medicare.

"The real action here isn't so much going to be a new federal rule," Mahinka said. "It's going to be innovative pricing strategies."

## Generic-Drug Prices Drive Debate

Surprisingly, much of the recent debate has been galvanized by surging prices for generic drugs that have traditionally been very cheap. Reports began emerging last year about skyrocketing charges for a number of basic products, including saline fluids, asthma drug albuterol and antibiotic doxycycline.

When it comes to specific generic-drug companies, Valeant has created steady controversy acquiring the rights to old generics with little competition and then steeply increasing prices. Turing took things to new heights recently when it acquired the rights to an old drug called Daraprim and raised the price to \$750 per pill from \$13.50 per pill.

As a sign of how bad the optics have become, trade group Pharmaceutical Research and Manufacturers of America recently distanced itself by likening Valeant to a hedge fund and declaring that Turing "does not represent the values" of its other members.

The actions of Valeant and Turing may have helped to build support for a little-noticed provision in Congress' budget deal late last month. Under the deal, lawmakers agreed to increase the Medicaid rebates paid by generic-drug companies, booking an estimated \$1 billion over the next decade.

That sort of modest action could repeat itself as the debate continues, allowing lawmakers to address public fury through baby steps without getting hung up on bolder, politically divisive proposals.

"They may be picking at it slowly," Hoffmeister said.

If Congress does move further to curb generic-drug spending, it could be a serious business threat for producers of truly inexpensive generics. That's because drugs that sell for only \$10 or \$20 per prescription can only lower costs so much more.

"Generic drugs really operate on a very thin margin, and that margin is really at risk," Hoffmeister said.

Nonetheless, experts say that bipartisan action will be easier on generics because the industry exists mainly to provide cheaper drugs, as opposed to innovative new products. If the industry doesn't deliver value in exchange for its streamlined approvals, Congress may force its hand.

"The generics market is supposed to be competitive and lower prices," Cohen said. "So, high-profile cases like Daraprim draw the ire of both Democrats and Republicans."

--Editing by Katherine Rautenberg and Patricia K. Cole.