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Stakeholders Weigh In on Growing Battle Over Drug 'Price Gouging'

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By [Patrick Connole](#), Managing Editor
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Between two Democratic presidential hopefuls' proposals to combat rising drug prices and reports of several staggering cost increases, a mounting public debate over drug pricing practices reached new heights in September and highlighted the increasing demand for greater transparency into drug pricing practices.

The New York Times on Sept. 20 reported that Turing Pharmaceuticals, a startup company founded by 32-year-old former hedge fund manager Martin Shkreli, had just acquired the oral antiparasitic agent Daraprim (pyrimethamine) and raised its price "overnight" from \$13.50 to \$750 per pill. An instant backlash to the story played out, with Shkreli defending his actions to multiple news outlets and taking a beating on Twitter, where even the Pharmaceutical Research and Manufacturers of America (PhRMA) declared that Turing "does not represent the values" of its member companies. Shkreli, who argued that the increase was necessary in order to finance development for a safer, more effective version of the drug, ultimately agreed to drop the price by an undisclosed amount.

PhRMA may have called Shkreli an outlier, but the debacle recalled another recent controversy: When Valeant Pharmaceuticals in February acquired two heart medications — Isuprel and Nitropress — it immediately raised their prices by 212% and 525%, respectively. And a Deutsche Bank analysis found that Valeant also increased the prices of 54 other medications by an average of 65.6% this year, reports FiercePharma.

Lawmakers Pursue Answers

Sen. Bernie Sanders (I-Vt.) and Rep. Elijah Cummings (D-Md.) have been pressing Valeant to explain its price hikes, to no avail. And on Sept. 28, all 18 Democratic members of the House Committee on Oversight and Government Reform — of which Cummings is ranking member — sent a letter to Committee Chairman Jason Chaffetz urging him to (1) issue a subpoena that would force Valeant to "turn over documents the company is withholding from Congress relating to massive price increases" for those drugs, and (2) ask Valeant CEO J. Michael Pearson to testify at an October hearing at which Shkreli's presence is also requested. The letter accused both firms of "engaging in the same business model of acquiring potentially life-saving drugs to maximize their own corporate profits." At press time, Chaffetz had not responded and no hearing date had been set.

Sanders, who is campaigning for the Democratic Party presidential nomination, on Sept. 10 introduced "The Prescription Drug Affordability Act of 2015" (S. 2023), which he co-authored with Cummings. The proposed legislation would, among other things, authorize the HHS secretary to negotiate drug prices paid for by the Medicare Part D program, allow the importation of drugs from Canada and prohibit anti-competitive "pay-for-delay" deals between brand and generic drug manufacturers. Moreover, it calls for greater drug pricing transparency by requiring companies to disclose the total costs related to research and development; price information charged to federal payers; and prices, profits and sale information for treatments sold in other countries.

And after tweeting a promise to get at "price gouging" in the specialty drug market, presidential hopeful Hillary Clinton on Sept. 21 unveiled her own plan to lower prescription drug costs. That proposal included allowing

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drug importation from abroad, fully funding the FDA Office of Generic Drugs to clear out its backlog of pending generic approvals, shortening the exclusivity period for biologics from 12 to seven years and requiring insurers to cap monthly and annual out-of-pocket costs on prescription drugs for members with chronic and serious conditions.

“Clinton’s proposal mirrors action on the state-level, where activity is heating up on both sides of the debate,” observed Elizabeth Carpenter, vice president at Avalere Health LLC, in a Sept. 22 press release. “Several states have recently approved legislation to limit out-of-pocket costs for patients, while others are proposing additional transparency surrounding the factors driving drug costs.”

But Evercore ISI analysts suggested it’s highly unlikely Clinton’s proposals would lead to actual drug pricing regulation if she were to be elected president and that her stance on drug pricing was timed more to neutralize Sanders’ actions. “At the end of the day, if you’re going to have something that changes the trajectory of drug pricing in the U.S., it has to come from a grassroots constituent level from the people, not from politicians, because if you look at where drug costs are going, a lot of it is going to coinsurance and copays, so the individual is spending more of their income,” observed Ross Muken, senior managing director and partner, during the Sept. 22 webinar.

Plans Call for More Transparency

AHIP President and CEO Marilyn Tavenner, meanwhile, issued a statement calling for “market-based solutions” to promote a more affordable prescription drug market. “[R]ecent proposals that would impose arbitrary caps on insurance coverage or force government negotiation on prescription drug prices will only add to the cost pressures facing individuals and families across the country,” griped Tavenner on Sept. 22. “We strongly believe that greater transparency around drug pricing and more competition in the market are critical to support sustainable, private-sector solutions that deliver the best value for patients and the health system. We are committed to working with all policymakers to achieve those goals.”

Health plan-supported solutions identified by AHIP include: alternative payment and incentive models for new drugs and technology; a shorter exclusivity period for biologics to promote greater price competition and bring lower-cost specialty drugs and biosimilars to market sooner; and increased transparency on prescription drug research, development and pricing.

And while not directly in response to the Shkreli matter or the candidates’ proposals, Albany, N.Y.-based nonprofit health plan CDPHP on Sept. 22 rolled out a well-timed education and advocacy initiative aimed at consumers and legislators that is focused on drug price inflation. The new educational campaign, “Inside Look: A Call for Rx Transparency” (www.chphp.com/RxCosts), aims to shed light on pricing for all prescription drugs. On the website, people can show their support for the campaign and sign up to receive information on drug price trends, as well as legislative efforts to control costs.

In an interview with *DBN* sister publication *Health Plan Week*, CDPHP President and CEO John Bennett, M.D., explains, “We think that this has reached an almost crisis stage in that people can’t afford their medicines. And insurers have been and are required to pass along premium increases that we don’t want to pass along on the basis of [drug price] increases.”

Bennett points to examples like the popular asthma drug Albuterol, which experienced a 4,000% price increase from October 2013 to April 2014, resulting in an additional \$3 million in costs to CDPHP.

“It is those kinds of things that are just going to bankrupt our entire system,” he continues. “We all know about the issue of [new hepatitis C drug] Sovaldi and some of these drugs for some very serious diseases, but one of the things we want to educate people about is the fact that this is occurring across a broad swath of drugs. It is not only the Sovaldis and this drug that was in the press the last two [weeks]. This is insulin. Insulin. Insulin has gone up suddenly from about \$120 per vial to \$270 per vial.”

Plans Must Evaluate Cost vs. Value

CDPHP is eyeing legislation in other states, such as Massachusetts, where a proposal (S. 1048) in the state legislature is seeking to place a first-of-its-kind price cap on some drugs and require pharmaceutical companies to justify their prices by revealing how much they spend on research, production and marketing, along with the prices they charge for the same drug overseas. Some expensive drugs would then be assigned price caps, if deemed necessary.

As for Hillary Clinton’s plan and others that would cap cost sharing for patients, Bennett says that will be a big win for drug manufacturers because it does not get at the heart of the issue. “They will be high fiving all the way to the bank with that,” since the price for the drug will be paid on the back end via premiums, setting up insurers to take the blame.

Mary Jo Carden, vice president of government and pharmacy affairs at the Academy of Managed Care Pharmacy, says the recent reports of price increases illustrate the “growing importance” of the debate over

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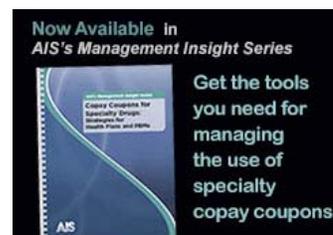
cost vs. value. “It’s always been important to managed care, but it’s really the question of the day for everyone to ask,” she suggests to *DBN*.

“If a drug provides actual value, then it could be worth it for a specific patient or a specific subset of patients,” she continues. “If the overall value of the drug is low and the cost is high, then that’s where managed care seeks to look for alternatives. So it’s really all about value and assessing quality of life, incremental comparative effective research, etc. and looking at that type of data to determine what really is the value of a product. Because as far as costs are concerned, it’s still all a relative figure.”

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