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Washington Health Policy Week in Review

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Lawmaker Anticipates Delivery of Drug-Price Report Within Weeks

By Kerry Young, *CQ Roll Call*

August 12, 2016—A sweeping report on the prices that federal agencies pay for prescription drugs could be made public within weeks, providing new fodder for the intensifying debate about the rising costs of medicine in the United States, according to the office of the lawmaker who requested it.

Rep. Marcy Kaptur, D-Ohio, used her post as an appropriator to attach a mandate for this report to the fiscal 2016 spending package (PL 113-114). Congress ordered the Department of Health and Human Services, in consultation with the Department of Veterans Affairs, to present an analysis of drug spending including the changes they have seen in prices since 2003. Kaptur told *CQ HealthBeat* that she is seeking to learn how these agencies have been affected by the spikes in the cost of medicines that consumers have reported.

"There isn't a day that goes by that I am not approached by a constituent who brings up the issue of escalating prescription drug prices," Kaptur said. "They have seen medications that they've taken for years double, even triple in price, and they don't understand why. And neither do I."

Public concern about the cost of drug is forcing the issue into the center debates about health policy. Both Donald Trump and Hillary Clinton have pointed to the problems many Americans face paying for medicines. The Pharmaceutical Research and Manufacturers of America has shaken up its staff and ramped up lobbying efforts in recent months, anticipating a closer congressional examination of the issue in the next session.

"Voters have made this their number one concern in health care," said John Rother, the president and chief executive of the National Coalition on Health Care, which is leading a campaign addressing high drug costs. "The dollars involved are getting to be painful and are squeezing out other high-priority items."

Spending on medicines in the United States rose by 8.5 percent to \$310 billion last year, according to consultant IMS Health, while the inflation rate as measured by the Consumer Price Index was little changed. In defending rising costs of drugs, the pharmaceutical industry has continually pointed to the significant investment needed to discover new medicines and bring them to market.

Yet, people in Rep. Kaptur's district are sometimes struggling to afford a bedrock medicine of the pharmaceutical industry that's been sold since the 1920s. Insulin costs are straining the budgets of many senior citizens even though they have Medicare Part D coverage, said Tina Elmlinger, health care advocate trainer and affordable medications coordinator for Sandusky, Ohio-based

Serving Our Seniors, which advocates for older adults and their ability to maintain their independence.

"They are getting sticker shock," she told *CQ HealthBeat*.

Indeed, the cost of insulin appears to be helping drive some older consumers into what's called the donut hole, or a temporary gap in coverage in the Medicare Part D drug insurance. The mean price of insulin increased from \$4.34 per milliliter in 2002 to \$12.92 in 2013, according to research published in the Journal of the American Medical Association in April.

Biotech Insulin

Companies such as Eli Lilly & Co. and Sanofi argue that they have made great strides with insulin, a product initially derived from the pancreas glands of pigs. They've created long-acting biotech versions of insulin, a critical protein that helps escort glucose into cells to serve as a kind of fuel. Innovations with insulin include the development of so-called pens for easier delivery, an advantage for older people who may struggle with syringes.

But prices have been rising for even well-established insulin products that have been on the market for a while, such as Sanofi's Lantus franchise, according to Medicare. The Food and Drug Administration approved long-acting Lantus in 2000 and the SoloStar pen version of it in 2007.

There was a 41 percent increase in the average cost per unit for Lantus in 2014 from the previous year, and a 27 percent on for the SoloStar version, according to Medicare's drug spending dashboard. The tool is being used by the agency to address concerns about the affordability of medicines. Lantus SoloStar cost Medicare's Part D drug

insurance program \$2.02 billion in 2014, while the original version of the cost it \$1.73 billion.

Competition could heat up soon for Lantus in the United States, with Lilly allowed to launch its long-acting Basaglar in December. Copycat versions of biotech drugs in general, though, have not generated the kinds of steep savings seen with pills, with the difficulties of producing these protein-based medicines limiting entrants to the market.

When asked for a comment on the Lantus price increases reported by Medicare, Sanofi responded by raising issues about insurers. It said its rebates to these firms and pharmacy-benefit managers increased significantly in recent years. Sanofi also noted that many consumers are paying a large share of their drug costs directly due to changes in insurance plans.

"Recent cost-shifting to the consumer by insurers through insurance design changes should be a key element of any discussion about the affordability of pharmaceuticals for the patient," Sanofi said in a statement.

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