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For the first time, drug makers and PBMs must jointly face an insulin price fixing lawsuit

By Ed Silverman @Pharmalot

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A federal judge ruled that a Texas county can proceed with a lawsuit accusing several drug makers and pharmacy benefit managers of conspiring to fix prices for insulin, the first time these companies will have to collectively defend their role in the rising cost of the life-saving diabetes medicine.

In a lawsuit filed last year, Harris County officials claimed taxpayers were "fraudulently overcharged" for ongoing and drastic price hikes for a medication that has not substantively changed in many years. From 2013 to 2018, the county maintained it paid $27.5 million for insulin due to an allegedly misleading pricing scheme involving both drug companies and the biggest pharmacy benefit managers, or PBMs.

This is not the first lawsuit to accuse insulin makers of price fixing. Over the past two years, the attorneys general in Minnesota and Kentucky have filed lawsuits alleging the companies — Novo Nordisk (NVO), Sanofi (SNY), and Eli Lilly (LLY) — conspired to fix prices. And several groups of consumers have filed their own lawsuits alleging conspiracies.

Until now, though, none of the lawsuits had also made similar allegations against the big PBMs – OptumRx, Express Scripts and CVS Caremark. As a result, consumer advocates and policy makers have argued that litigation provided an incomplete picture of the opaque nature of pricing for insulin, which has become a poster child for the rising cost of prescription medicines.

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Trump claims his policies made insulin 'so cheap, it's like water.' But for most people, it costs just as much as before [13]

"The truth is that both groups of companies have been working together to create an artificial pricing system, and so anyone purchasing insulin is being harmed by this conspiracy by two dominant market actors," said Joanne Cicala, an attorney who represents Harris County. She noted the companies now face civil racketeering and fraud claims.

"It's a perfect storm. There's no competition, you have three manufacturers dominating the supply chain and, mostly, three pharmacy benefit managers that have dominated the form of reimbursement for approximately 250 million Americans. The combined market power is really extraordinary… So you've got to talk about the PBMs, too, because they're the ones that create the incentive structure."

This is how the county alleged the scheme worked: To maintain or increase sales, the county maintained there was a "quid pro quo" arrangement between drug makers and pharmacy benefit managers. The drug makers "artificially" raised prices to win placement on formularies, the lists of medicines compiled by pharmacy benefit managers to determine insurance coverage.

From there, the drug makers issued "secret payments" in the form of rebates, fees, and discounts to the pharmacy benefit managers. Meanwhile, the pharmacy benefit managers separately negotiate with pharmacies to reimburse them at a lower price than what health plans, such as those run by Harris County, pay for insulin. The PBMs allegedly pocket the difference, and also use the inflated prices to profit when selling insulin through their own mail-order pharmacies.

We asked the drug makers and PBMs for comment and will update you accordingly.

More than 29 million Americans, or 9.3% of the U.S. population, have some form of diabetes, and about 7.4 million use insulin. However, a recent study[16] found that among adults who were prescribed a diabetes medication in the past 12 months, 13.2% skipped dosages, took fewer dosages, or delayed filling a prescription in order to save money. And 24.4% asked their doctor for a lower-cost alternative.

Consequently, more diabetics are rationing the medicine or traveling to Canada to purchase lower-cost insulin. Seizing on the issue as the presidential re-election nears, the Trump administration is pursuing a plan to allow reimportation of insulin from other countries and also began a program to lower out-of-pocket costs for which Medicare beneficiaries pay $35 a month for insulin, but this is only available to a fraction of seniors enrolled in certain pricey private insurance plans.

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Drug makers sue to block Minnesota law making it cheaper to get insulin in emergencies [17]

At the same time, a growing number of states are pursuing their own ideas, notably, passing laws that cap the monthly cost of insulin. In Minnesota, for instance, the state recently enacted a law that would provide residents,

who would otherwise forgo their insulin, to immediately pick up a 30-day supply of the drug from a pharmacy for $35. Drug makers are forced to provide insulin for free or face hefty fines. The pharmaceutical industry trade group filed a lawsuit[18], though, claiming the law is unconstitutional.

The interplay between drug makers and PBMs, by the way, has also gained the attention of congressional committees that have launched investigations[19] into insulin pricing.

The mounting scrutiny has put drug makers on the defensive.

Over the past year or so, the companies have pursued various tactics[20] to generate goodwill. These include offering free insulin for a limited time during the Covid-19 pandemic, selling lower-cost authorized generics and resetting monthly co-pay cards. Consumer advocates, however, complain these are effectively band-aids and prices should simply be lowered.

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