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UNDERSTANDING THE HIDDEN VILLAIN OF BIG PHARMA: PHARMACY BENEFIT MANAGERS

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PHARMACEUTICAL COMPANIES

In the past few months, four bills have been introduced in Congress calling for transparency in prescription drug pricing. These bills—[HR 1038](#), [HR 1316](#), [S.3308](#) and, earlier this week, one called [C-THRU](#)—largely concern pharmacy benefit managers (PBMs), a heretofore largely unrecognized component of the pharmaceutical industry.

PBMs quietly became an integral part of the pharmaceutical supply chain—that is, the path a drug takes from the manufacturing facility to a bathroom medicine cabinet—following the passage of the Medicare Modernization Act in 2003. In recent years, PBMs have become a cause for alarm because, these bills allege, they drive up drug prices and interfere with patients' access to medications. In 2015, Express Scripts, the largest PBM-only company in the U.S., reported a profit of more than \$660 million, from sales exceeding \$25 billion.

But even as drug prices and access have become increasingly at the mercy of PBMs, how they operate has remained mostly hidden. Earlier this year, Community Oncology Alliance, an advocacy organization for community-based cancer care practices, commissioned a report exposing how PBMs work and the damage they are causing. *Newsweek* spoke with COA Executive Director Ted Okon about what many health care experts believe is Big Pharma's latest villain.

Why did COA decide to examine the role that PBMs are playing in drug access and pricing?

Community-based oncology practices provide nearly 60 percent of the cancer care in the U.S. Often, these small practices have their own pharmacies or drug-dispensing facility. Many cancer drugs, particularly the newer, oral medications, are very expensive and won't be stocked by the typical corner pharmacy. Plus, because of how cancer care works, it's ideal if the medication is available right at the practice.

In the past few years, however, PBMs have played a more aggressive hand in cancer care. These companies are shaping what drugs a physician may prescribe and how patients access medications. Such problems have been increasing, leading us to investigate exactly how PBMs operate.

What are PBMs and how did they originate?

PBMs arose in the early 2000s, after the Medicare Modernization Act was passed into law in 2003. MMA included the creation of Medicare Part D, which handles benefits associated with prescription drugs. PBMs are companies that fulfilled a need created by Part D: a middleman between the insurer, including Medicare, and the pharmacy. The idea behind PBMs was that they could identify eligible patients, reduce the administrative burden on the benefits provider and negotiate drug prices with pharmaceutical manufacturers. Keeping this intermediary role in the private sector was supposed to help with all this.

The new treatments for hepatitis C are a good recent example. A curative drug was approved a few years ago but was incredibly expensive. When a second curative treatment emerged, Express Scripts told the first manufacturer that it would not put its drug on Express Scripts formulary unless the company lowered the price to that of the second drug. The PBM advertised this negotiation as an example of its benefit to patients.

How do PBMs negotiate prices with pharmaceutical companies?

From their inception, PBMs were able to negotiate prices through both upfront discounts and rebates following sales. PBMs created formularies—lists of preferred drugs—and insisted on certain discounts off the manufacturer's price of a medication in order to have it included on

the formulary. Without inclusion in formularies, insurers won't cover the drug and physicians won't prescribe it, so they provide quite a bit of leverage for negotiating prices. Medicare does not maintain its own formulary, which gave the lists created by these companies more power.

Is there competition among PBMs?

At first, there were several different PBMs actively providing these intermediary services. But over the years, these companies consolidated. Now, three firms control an estimated 80 to 85 percent of the market, possibly even more. Some companies focused on other areas of pharmaceuticals created their own PBM, such as CVS Caremark. The insurance company United Healthcare has its own PBM, called OptumRx. Express Scripts is a stand-alone PBM. These three companies control most of the market.

So how do PBMs cause drug prices to increase?

This issue is a murky one, mainly because PBMs lack transparency. I have heard these companies emphasize the importance of transparency except for *their* interactions with drug companies. PBMs assert that these interactions are the "secret sauce" that enables them to keep prices down. But I have come to the conclusion that this lack of transparency is actually driving prices up.

What is happening behind the scenes?

Let's say a manufacturer assigns a list price of \$10 to a given drug. The PBM then tells the company that it will not list the drug on its formulary unless it receives a discount. The willingness of the manufacturer to discount the drug, and the extent of that discount, is guided by a few factors: the power of the PBM, which the consolidation of companies has increased; how many other competitive products exist; and also the size of the pharmaceutical company.

The pharmaceutical company offers the PBM a discounted price of \$8. If the PBM does not accept that price, then the company may offer a rebate of an additional \$2 if sales of the drug reach some designated amount. The more powerful a PBM is, the greater discount they can demand—and the fact that three PBMs control the vast majority of the market makes these three companies very powerful.

But how does this negotiating practice lead to higher drug prices?

PBMs want to make money. To do so, they charge fees to pharmacies, whether it's a retail business or a community oncology practice. At community oncology practices, these fees have increased dramatically in recent years, from 3 percent up to 11 percent. Cancer medications are already expensive, and now PBMs are imposing an additional fee calculated as a percentage of the cost of that pricey drug.

In light of these practices, PBMs make more money from paying closer to the list price and receiving a rebate rather than an upfront discount. The higher the price of the drug, the higher the PBM fee at the pharmacy. So they don't have an incentive to drive upfront prices down as much as they can. They are taking fees based on the list price, but the net price that the PBM is paying for the drug is much lower than that because of rebates.

In addition, pharmaceutical companies now anticipate steep discounts and rebates when they set their list prices. As a result, they set list prices higher so that the eventual negotiated price will be as high as possible.

How does this approach affect patients?

Patients are being affected in many ways. In terms of cost, patients are now paying copays to their insurers for medications, and they are paying, directly or indirectly, the PBM fee. And all these fees are based on the list price, which is not really what the PBM is paying.

The more patients on Medicare pay for prescription drugs, the faster they enter the so-called "doughnut hole," when they are responsible for all their health care costs. And the faster they enter the doughnut hole, the faster they leave it, which increases taxpayer-funded Medicare costs.

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Are patients affected beyond cost?

Yes. Sometimes, health care providers must call the PBM before prescribing a drug. The PBM may require that the drug be delivered to the patient by its own specialty pharmacy rather than through the practice's own pharmacy, leading to delays. Sometimes a PBM refuses to cover a drug, leaving a physician to jump through hoops in order to obtain it for a patient. All of this then leads back to cost, because the copay ends up higher, sometimes by hundreds of dollars.

Are PBMs providing any benefits currently?

I think we have come to a point where not only are PBMs not doing anything good, they are actually doing the opposite. Delays, problems with access and higher prices are all resulting from how PBMs are operating. They are pushing drug prices higher and placing extreme

pressure on pharmacies because they want to steer that business toward themselves. PBMs used to be the sheriff. But they've become sheriff, jury, judge and executioner, all wrapped into one.

Do you think the current legislation could change this situation?

I do think that the current four bills could come together in some way to place some tight restrictions on PBMs.

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