

**Testimony of Sumit Dutta, M.D., Chief Medical Officer, OptumRx**  
**Before the United States House of Representatives**  
**Energy & Commerce Subcommittee on Oversight and Investigations**  
**“Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin”**  
**April 10, 2019**

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, I am honored to be here today on behalf of OptumRx. Our company has 28,000 dedicated employees – including 5,000 pharmacist and pharmacy technicians – working every day to improve the quality of pharmacy care services, simplify the health care experience, and ensure that the individuals we are privileged to serve have affordable access to the drugs they need.

**1. OptumRx’s pharmacy care services approach is achieving better health outcomes for patients, lowering costs for the system, and improving the health care experience for consumers.**

OptumRx helps deliver pharmacy care services to 250,000 patients each day. These services help improve health outcomes for patients and reduce costs in the system. Here are some examples:

- We communicate with patients and their physicians about how to take their medications, avoid harmful drug interactions, and access convenient home-delivery services.
- We provide drug infusion services directly in patients’ homes, so that they do not need to visit a hospital to obtain the same, high-quality care. These in-home services help improve medication adherence and reduce costs.
- We have more than 450 pharmacies embedded in community mental health centers to serve the behavioral health medication needs of patients where they receive their care. Our ability to deploy those on-site services has helped improve medication adherence, reduced emergency room visits and hospitalizations and reduced overall costs by \$700 per patient.
- We provide special assistance for patients who need help managing their chronic conditions, including real-time video consultations with pharmacists.
- We are helping to address the opioid crisis by implementing evidence-based programs that help prevent overprescribing by physicians and detect suspected opioid misuse, as well as offering medication-assisted treatment to patients with opioid use disorder. Our customers who have adopted our opioid management program have achieved a 96 percent adherence rate by prescribers with the Centers for Disease Control and Prevention’s prescribing guidelines.

Our pharmacy care services approach is doing important work to improve health outcomes and lower costs. We are not stopping with those efforts. We are also developing consumer-friendly tools to make the health care experience more satisfying and effective for patients and providers. For example, one of these tools, PreCheck MyScript®, is a digital platform that simplifies the drug prescribing experience by showing the prescribing physician what the patient’s true out-of-pocket cost would be while the patient is still in the physician’s office. PreCheck MyScript® has helped lower consumer out-of-pocket costs by an average of \$135 per prescription filled. This platform is just one of the ways we are working to simplify the system.

## **2. OptumRx negotiates better prices with drug manufacturers for our customers and consumers.**

OptumRx delivers value for our customers and the consumers we serve through a number of services, including negotiating lower drug costs. And approximately 98 percent of the discounts we negotiate from manufacturers go to our customers. Historically, our customers have used these discounts to reduce the costs of drugs, help keep premiums stable and help ensure access to drugs for consumers.

We have heeded the call for change by taking direct action to ensure that the discounts we obtain directly lower consumers' out-of-pocket costs at the pharmacy counter. Last year, we implemented a point-of-sale discount solution at scale for fully insured group customers so that consumers receive the benefit of discounts at the pharmacy counter. This action has already made nearly six million consumers eligible for point-of-sale discounts. Eligible consumers filling prescriptions on discounted brand drugs are seeing average savings of \$130 per eligible prescription. We believe it will also improve prescription drug adherence by as much as 16 percent. By the end of 2019 we expect more than nine million consumers will be eligible for these point-of-sale discounts. Last month, we announced a decision to expand this point-of-sale discount solution to all new employer-sponsored plans beginning in January 2020.

It is important to recognize that pharmacy benefit managers are the only stakeholders in the prescription drug supply chain working to reduce costs for their customers and the only ones able to effectively negotiate with drug companies.

OptumRx manages pharmacy benefits on behalf of customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and federal and state government employee plans. In that role, we promote use of clinically effective, lowest net-cost prescription drugs for consumers when medications are needed.

This work starts with an independent, clinically based formulary design process. OptumRx's Pharmacy & Therapeutics (P&T) Committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an unbiased and evidence-based way. The P&T Committee meets regularly, and its deliberations are open and transparent to OptumRx's customers and prospective customers.

A drug's cost plays no role in the P&T Committee's clinical review. Cost only becomes relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered. If there is more than one drug in a particular class, OptumRx gives preferable placement on its formulary to the drug with the lowest overall cost to our customer. For about 90 percent of prescriptions processed, OptumRx can identify a low-cost generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug.

Unfortunately with insulin, there are no true generic alternatives. Because branded insulin products within each class (short-acting and long-acting) are therapeutically equivalent, we have been able to negotiate with competing brand manufacturers to obtain significant discounts off list prices, allowing plans to place the drug with the lowest overall cost to the customer in a preferred position on the formulary. But the solution that will benefit everyone who uses insulin is true generic and biosimilar competition which will drive down list prices.

### 3. Insulin costs too much already, yet manufacturers keep raising prices.

Multiple independent studies have shown that the list price of insulin has skyrocketed in recent years. The Health Care Cost Institute (HCCI), for example, found that manufacturers doubled the price of insulin between 2012 and 2016.<sup>1</sup> The Journal of the American Medical Association (JAMA) published research that found insulin prices went up 197 percent between 2003 and 2013.<sup>2</sup> Addressing the high cost of insulin is a crucial part of reducing the overall cost of treating diabetes for our customers and consumers alike. We recognize that when the cost of insulin is too high for patients, they may be forced to make unhealthy choices like rationing their doses, or going without insulin altogether. This practice can lead to complicating health consequences and put patients at risk.

Manufacturers are increasing insulin prices for one simple reason: there is a lack of meaningful competition. In the absence of competition, manufacturers often set exceptionally high prices. Moreover, manufacturers appear to have raised the list prices of competing insulin formulations in tandem over the last decade or more.<sup>3</sup>

A driving factor behind this challenge is that manufacturers have been able to exploit loopholes in a U.S. patent system that is designed to reward investment in innovation. Insulin has been used to treat diabetes for nearly 100 years, and manufacturers have not introduced any significant new innovations in decades. Yet they continue to drive list prices higher and extend their patents.

For years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition.<sup>4</sup> Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products.

All of this legal maneuvering has led to a lack of competition from true generic alternatives, the introduction of which would have a significant and beneficial impact on list prices. This problem is particularly acute when it comes to insulin.

Manufacturers have blamed pharmacy benefit managers, health plans, and hospitals for high drug costs. They contend that the discounts or rebates we negotiate with them are the root cause of the problem. That is simply untrue.

In fact, drug prices are rising the fastest in the area of specialty drugs, where due to the importance of the drug and the lack of a clinical alternative, manufacturers are unwilling to negotiate a discount. It is no surprise, then, that the Centers for Medicare and Medicaid

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<sup>1</sup> Binek & Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, Health Care Cost Institute, January 21, 2019 (available at <https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices>).

<sup>2</sup> Hua, Carvalho, Tew, Huang, Herman, and Clarke, Research Letter: *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*, Journal of the American Medical Association, Volume 315, Number 13 (April 5, 2016) (available at <https://jamanetwork.com/journals/jama/fullarticle/2510902>).

<sup>3</sup> Binek & Johnson, *supra* note 1 at 7-8; see also Ramsay, "There's something odd about the way insulin prices change," Business Insider, September 17, 2016 (available at <https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9>), citing data from Truven Health Analytics.

<sup>4</sup> I-MAK, *Overpatented, Overpriced Special Edition: Lantus*, October 30, 2018 (available at <http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf>).

Services (CMS) recently reported that in 2016 and 2017 drug manufacturers raised prices the most on those drugs that have no discounts.<sup>5</sup>

Drug manufacturers also have responded to criticisms of the high prices they set for their products by introducing so-called “authorized generic” versions of their higher-priced brand products.

OptumRx promotes the use of true generics to drive costs lower through competition. That’s why almost 90 percent of the prescriptions we administer are for generic drugs.

“Authorized generics” are not generic drugs. The marketing and production of “authorized generics” is exclusively controlled and directed by brand drug manufacturers. They do nothing to promote competition. In fact, drug manufacturers generally make more money per “authorized generic” script. In our experience, these “authorized generics” often result in net prices higher than the brand drugs they replace. “Authorized generics” are just another tactic for drug manufacturers to improve profitability.

For years, manufacturers have engaged in such tactics to extend their control over a drug, limit competition, and maximize profits at the expense of consumers. The promotion of “authorized generics” is of a kind with patent “ever-greening” and pay-for-delay deals that work to keep true generics – and real competition – out of the market.

As an example, consider a hypothetical brand manufacturer that has set the list price for its brand drug at \$100. OptumRx has successfully negotiated a \$70 discount off that list price, resulting in a net overall cost of \$30 for the brand drug. If the brand manufacturer announces a so-called “authorized generic” at a list price of \$50, the list price may be lower, but the overall net price of the “generic” is \$20 higher than the brand drug. This situation may result in a lower cost-sharing obligation for some plan members in the short-term, but in the long-term it will be more expensive for plans and lead to higher overall drug costs for everyone, benefiting no one other than the manufacturers.

Finally, manufacturers assert that their net profits on insulins are going down even as list prices go up. For a drug that is 100 years old and has seen no significant innovation in decades, their profits should go down. At the same time, the FTC has recognized that in the PBM market, “competition for accounts is intense, has driven down prices, and has resulted in declining PBM profit margins.”<sup>6</sup>

#### **4. OptumRx is working on behalf of its customers and consumers to mitigate the impact of insulin manufacturers’ price increases.**

OptumRx is working to mitigate the impact of the high and rising price of insulin set by insulin manufacturers for our customers and consumers.

**First**, we negotiate substantial discounts from insulin manufacturers on behalf of our customers, and approximately 98 percent of those discounts go to our customers.

**Second**, we are leading the way to ensure that the discounts we negotiate on insulin directly benefit consumers.

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<sup>5</sup> Sarah Karlin-Smith, Sarah Owerhohle and Janie Boschma, “Drugs with a single manufacturer drive Medicare, Medicaid spending increases, CMS says.” Politico, March 14, 2019.

<sup>6</sup> See, e.g., [https://www.ftc.gov/sites/default/files/documents/public\\_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express/120402expressscripts.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express/120402expressscripts.pdf).

- As noted above, for more than a year we have implemented a point-of-sale discount solution to ensure that consumers directly benefit from our negotiations with drug manufacturers. By the end of 2019 we expect more than nine million consumers will be eligible for these point-of-sale discounts, and beginning January 1, 2020, we will expand this point-of-sale discount solution to all new employer-sponsored plans.
- Seventy-six percent of the consumers we serve who need insulin pay zero at the pharmacy or have a fixed copay, most commonly about \$35.
- OptumRx has placed insulin on its Preventive Drug List, leading by example for many of our customers to do the same. This approach takes insulin out of the deductible structure entirely for consumers in those plans.
- On average, out-of-pocket costs for the consumers we serve who need insulin are about \$41 per month, which is about eight percent of the list price of the drug.

**Third**, we understand that paying for insulin is just one of the many hurdles diabetics must overcome to treat their disease. Comorbidities associated with diabetes like hypertension, obesity, and high cholesterol levels often also require treatment through medication. OptumRx works to reduce the costs of these drugs as well, encouraging the use of low cost generics or lower cost, therapeutically equivalent brand drugs when they are available. We also employ thousands of licensed pharmacists and pharmacy technicians who, in addition to being available by phone 24 hours a day, 7 days a week, provide face-to-face or virtual consultations and coaching to help consumers manage chronic conditions. And where possible, we use data and analytics to identify opportunities to engage consumers on health actions that help improve outcomes and lower total cost of care.

## **5. Sensible policy reforms will help make drugs more affordable.**

The actions described above have significantly blunted the impact of rising list prices for many of the consumers we serve, and we will continue to find creative and fair solutions to this problem for those who might still be vulnerable to high list prices. But absent more competition in the insulin market, we expect to see manufacturers continue to increase their prices.

An effective intellectual property environment plays an indispensable role in both promoting drug discovery and ensuring innovations are affordable and sustainable. Today's intellectual property system does not work as intended. The most important step Congress can take to address the high cost of prescription drugs is to modernize the intellectual property system. Several reforms can help eliminate drug manufacturers' ability to manipulate the patent and regulatory system and thereby prevent lower-cost generics and biosimilars from reaching consumers more quickly. Specifically, Congress should:

- Pass the bipartisan CREATES Act to end the manipulation by drug manufacturers of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generic competition;
- Prohibit "pay-for-delay" settlements between manufacturers that delay the market entry of lower-cost alternatives;
- Restrict "ever-greening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, to extend the patent exclusivity period;

- Reduce the exclusivity period for brand and specialty drugs; and
- Continue FDA reforms to promote greater uptake of biosimilars, which is even more important with FDA's recent guidance to treat insulin as a biosimilar beginning in 2020.

If the Administration intends to finalize the Proposed Safe Harbor Rule, it should prevent the disruption of the existing and proven supply chain and ensure that pharmacy benefit managers are explicitly authorized to facilitate discounts at the point of sale for seniors. Today, pharmacy benefit managers administer point-of-sale discounts, including for Medicare Part D, through proven, stable, secure, and highly efficient systems that have evolved through three decades of investment, innovation, and partnership with key stakeholders. Unless pharmacy benefit managers facilitate point-of-sale discounts, existing, negotiated drug discounts will be jeopardized, net prices could increase, and consumers will experience disruption.

We appreciate the opportunity to address the Committee today, and share with you the meaningful solutions we are advancing to deliver value for patients and bring down the cost of insulin. We are committed to doing our part to make insulin more affordable for people and sustainable for the country. I would be pleased to answer any questions you have.