Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Dr. Sumit Dutta, Senior Vice President and Chief Medical Officer, OptumRx

The Honorable Michael C. Burgess (R-TX)

1. **One thing that has constantly come up in our conversations about drug pricing is that high deductible plans have become increasingly common. When did high-deductible health plans start to become more common?**

RESPONSE: The Kaiser Family Foundation has studied the market share of various types of employer health plans over the years. It reports that in 2006, 4% of covered workers were in High-Deductible Health Plans (HDHPs). That number rose to 13% by 2010; 24% by 2015, and 29% in 2018.[1]

2. **As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. We've heard that some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans.**

    a. **What kinds of drugs are commonly included on preventive drug lists?**

RESPONSE: As a general matter, HDHP preventive drug lists are developed based on a clinical evaluation of whether a drug is able to prevent a disease or condition, as opposed to treating an existing illness or condition. These lists are intended to comply with the HDHP safe harbor outlined in § 223(c)(2)(C) of the Internal Revenue Code. That section states, in relevant part:

> [a] plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1871 of the Social Security Act, except as otherwise provided by the Secretary).

A HDHP may, therefore, provide preventive care benefits, including certain prescription drug benefits, without a deductible or with a deductible below the minimum annual deductible. There is, however, no requirement that a plan *must* provide those benefits. Different plans might reach different conclusions about the preventive nature of a drug, and therefore make different determinations about whether a particular drug should be included on the preventive drug list so as not to affect the plan's tax status.

[1] *See* Kaiser Family Foundation, *2018 Employer Health Benefits Survey*, October 3, 2018, (https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-5-market-shares-of-health-plans/)

Nevertheless, HDHP preventive drug lists commonly include medications such as those that prevent blood clots and reduce the risk of a stroke; prevent heart disease and reduce high blood pressure; and prevent osteoporosis. As noted below, OptumRx includes insulins (and non-insulin products used to treat diabetes) on its template preventive drug list for members on HDHPs.

3. **One chart from Express Scripts' 2018 Drug Trend Report shows that the out-of-pocket cost for patients in a high-deductible plan per 30 day adjusted Rx in 2018 was $40.69 when insulin was on a preventive drug list, compared to $105.16 when insulin was not on a preventive drug list. Given preventive medications can help people avoid many illnesses and conditions, and the aforementioned chart shows that having a drug, such as insulin, on a preventive drug list can save the patient money – do each of you have data that shows the savings to the patient as well as the overall health care system as a result of having a medication, such as insulin, on a preventive drug list?**

RESPONSE: In large part because OptumRx has insulin on its HDHP preventive drug list, and encourages its customers to do the same, we have helped our customers keep Out-of-Pocket (OOP) costs low for insulin products. Indeed, 76% of our customers' enrollees who need insulin pay nothing at the pharmacy counter, or pay only a fixed co-pay. Due to policy terms, including the fact that insulin is on OptumRx's HDHP preventive drug list, the average OOP costs for a 30-day supply of insulin are approximately $41 per month for our commercial plan and Medicare enrollees, which is less than 8% of the average list price for major insulin products.

   a. **I have a similar question for you. During a briefing with Committee staff, Express Scripts said that your company makes preventive drug lists with first dollar coverage available to your clients but that preventive drug lists are not widely used.**

      i. **Do you recommend that your clients include insulin on their preventive drug lists?**

RESPONSE: Yes.

      ii. **How long have you recommended that your clients include insulin on their preventive drug list?**

RESPONSE: OptumRx has recommended that our customers include insulins on their HDHP preventive drug list – either by adopting OptumRx's list as their own, or including it on a list they develop – since the list was established in 2011.

      iii. **Do you know how many of your clients use preventative drug lists, and have insulin on their preventive list? What percentage of your clients is that?**

RESPONSE: As suggested above, preventive drug lists benefit members in HDHPs, who constitute only a portion of the members OptumRx serves. Currently, 459 customers have implemented OptumRx's template HDHP preventive drug list, which includes insulin. In addition, OptumRx has other customers, including UnitedHealthcare, that have developed their own HDHP preventive drug lists that include insulin.

      iv. **How many covered lives does that translate to?**

RESPONSE: Approximately 2.8 million lives are covered by the OptumRx template HDHP preventive drug list or UHC's preventive drug lists that include insulin.

4. What are some of the reasons why a client wouldn't use a preventive list and include insulin on that list?

RESPONSE: The decision to add a drug to a preventive drug list is a complex, multi-faceted decision that balances clinical effectiveness, cost, and application of relevant rules and regulations. OptumRx has determined that insulin products are appropriate for inclusion on its template HDHP preventive drug list, which an individual customer can adopt as is. Individual customers can also ask us to implement a customized preventive drug list of their own choosing. We cannot speak to individual customers' reasons for using a preventive drug list, or including or not including a particular drug on that preventive drug list.

The Honorable Brett Guthrie (R-KY)

1. The press has reported on letters that OptumRx sent to pharmaceutical manufacturers requesting that manufacturers provide the Pharmacy Benefit Manager (PBM) with notice if the manufacturer decided to lower the list price of the medicine. During a briefing with Committee staff, OptumRx explained that they requested advance notice of price changes because of the long timeline for the Part D bid process and because the company wants to ensure greater transparency and predictability for plan sponsors.

a. If a pharmaceutical manufacturer does not provide OptumRx with sufficient notice that the manufacturer will decrease the list price of a medicine, what will the manufacturer's rebate liability be for the product in each market (*e.g.*, commercial, Medicare Part D, etc.)?

RESPONSE: Our customers who are Part D plan sponsors consider contracted-for discounts when setting their premiums. Those premiums must be submitted with their bids to the Centers for Medicare and Medicaid Services (CMS) six months before each plan year starts. CMS holds plan sponsors to those premiums for the duration of their contracts. We believe it is important for plans to be able to calculate premiums with confidence. For this reason, OptumRx proposed a Part D contract amendment requesting either advance notice from a drug manufacturer of list price decreases in the middle of a plan year or, in the absence of advance notice, a commitment by the manufacturer to honor its contracted-for discounts for the entire plan year.

If a manufacturer agreed to the terms of the proposed amendment, and then failed to provide the requested notice, it would be expected to maintain its contracted-for discounts for the duration of the plan year for which the discounts were negotiated to provide premium continuity and stability in the Part D market.

b. Have any manufacturers reduced the list price of insulin without giving OptumRx sufficient notice and triggered this provision?

RESPONSE: We are not aware of a single insulin manufacturer lowering the list price of brand insulin. In fact, as we noted in written testimony we submitted to the Committee, 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.[2] The Journal of the American Medical Association (JAMA) published research that found insulin prices went up 197% between 2003 and 2013.[3] Some manufacturers have introduced so-called "authorized generics" at a list price lower than that of the corresponding brand product; we address that circumstance below.

2. What factors does OptumRx consider when deciding whether to include an authorized generic on the company's formulary?

a. In OptumRx's experience, how many manufacturers making an authorized generic refuse to provide a rebate that would make the net price of the authorized generic less than the brand drug?

RESPONSE: OptumRx promotes the use of clinically effective, lowest net-cost prescription drugs. 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 evidence-based way. 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 equivalent.

If there is more than one drug in a particular class, OptumRx negotiates preferred formulary status among clinically equivalent alternatives, including so-called "authorized generics," based in part on the lowest net price. Whether a manufacturer could achieve the lowest net price by discounting their list price on a particular drug depends, therefore, on the circumstances, and in particular on the pricing of competitor drugs.

It is important to understand that "authorized generics" are not true generics. The marketing and production of "authorized generics" is exclusively controlled and directed by the 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 so-called "authorized generics" can result in net prices higher than the brand drugs they replace. In fact, we have found that drug manufacturers often seek to introduce so-called "authorized generics" at a list price that is lower than the original brand's list price, but higher than the net price that has been negotiated for the original brand. OptumRx proactively pursues discounts off the so-called "authorized generic" list price to achieve lower net prices, but is not always able to achieve such discounts for all of its plans.

Finally, OptumRx develops template formularies that its customers can adopt as their own. Those formularies reflect the independent clinical judgment of OptumRx's P&T Committee. Customers can also choose to develop their own drug formularies, and indeed many of our customers (generally large employers and health plans) have their own P&T Committees to make those judgments.

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[2] 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).

[3] 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).

b. If OptumRx does get a lower net price on the authorized generic and put it on formulary, will OptumRx keep the branded product on formulary as well? Why?

RESPONSE: OptumRx supports strategies that lower the overall net cost to our customers for a therapeutic category. Achieving that goal requires analysis. OptumRx performs customer-specific analysis and consults with customers to help drive to the lowest costs for them and their employees. Ultimately, the decision about which drugs to include on a formulary is one made by the customer. Depending on the circumstances, it may be advantageous for our customers to cover the "authorized generic," the original brand, or both.

c. Has Optum Rx ever gotten a lower net price on an authorized generic and put it on the company's formulary and kept the branded product on formulary as well? If so, why?

RESPONSE: As noted above, OptumRx seeks to negotiate even lower net pricing on so-called "authorized generics". As a result, there have been occasions where both products are covered on a customer's formulary.

3. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs, including OptumRx, that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price.

To help us better understand the role of rebates, there is a hypothetical question below.

There are two therapeutically equivalent insulin products, product A and product B. Product A has a list price of $100 and OptumRx is offered a rebate of 50 percent, thereby making the final price to OptumRx's client $50. Product B has a list price of $50, and OptumRx is not offered any rebates for the product.

a. Is there any reason OptumRx would prefer Product A, the product with the higher list price and rebate, over Product B? If so, please describe.

RESPONSE: Net price is one consideration among several factors OptumRx considers in making formulary recommendations. Other factors include improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees. While it is not possible for OptumRx to answer this hypothetical question with certainty without additional factual context, it is likely OptumRx would recommend coverage of Product B to its customers under the circumstances described above.

b. Which drug would be more profitable for OptumRx to include on the formulary?

RESPONSE: If we recommended covering Product B, we would seek to negotiate adjustments to our customer contracts as needed to ensure our customers and their members get the benefit of lower prices. As a practical matter, our customers expect us to drive costs lower and to the extent we make decisions and recommendations at odds with those interests, we would have difficulty retaining those customers.

c. How does OptumRx determine the "net price" of the medicine?

RESPONSE: Net price is the manufacturer list price of a drug minus the discount associated with that drug.

d. How would OptumRx decide which product to include on formulary or would OptumRx include both products on its formulary?

RESPONSE: See answer to 3(a), above.

e. Has OptumRx ever been offered two therapeutically equivalent insulin products at the same price? Is there a threshold OptumRx uses if the prices are substantially similar when deciding whether to include both products on the formulary?

RESPONSE: If two therapeutically equivalent insulins are offered at substantially the same list price (as are Humulog and Novolog, for example), we negotiate with manufacturers to drive to the lowest net cost for the customer. That may result in exclusivity of one brand or parity for both, depending on the price concessions offered by each manufacturer, their application to various formulary options, and other factors including those referenced in 3(a), above.

f. My understanding is that pharmacy benefit managers (PBMs) have generally provided their clients with guaranteed levels of rebates, and in some instances, if the PBM exceeds the guarantee level, they may keep all or some of those rebates.

i. During the last 5 years, how many times has OptumRx exceeded the level of rebates that it guaranteed to its clients? How much did OptumRx retain as a result?

RESPONSE: OptumRx has exceeded the level of rebates guaranteed to its customers in some instances, and has fallen short of those guarantees in others. In either instance, OptumRx honors its commitments to its customers, which vary depending on the terms of those customer agreements. Overall, OptumRx passes on to its customers approximately 98% of the discounts it negotiates with manufacturers.

ii. What happens if OptumRx does not achieve this guaranteed level of rebates?

RESPONSE: How discount guarantees are negotiated varies from customer-to-customer, but it is predicated in substantial part on an analysis of trends in the marketplace and predictions about where the market for insulin pricing – and who the potential new entrants, if any, to the market – will be 2-5 years in the future, when contracts being negotiated today will be in effect. Our predictions are imperfect, however, because manufacturers continue to have unfettered

control over the setting and raising of list prices, and because they alone decide whether, when, and by how much to raise prices.

As we noted above, we are not aware of any list price reductions for brand insulins. Some manufacturers have introduced so-called "authorized generics" at a list price lower than that of the corresponding brand product. In those cases, OptumRx proactively pursues discounts off the so-called "authorized generic" list price to achieve lower net prices, but is not always able to achieve such discounts for all of its plans. In addition, with insulin, unlike some other therapeutic categories, there have been fewer new market entrants to lower costs, and as a result we have been unable to factor future increased competitive dynamics into our forecasting. OptumRx must balance this market uncertainty in an intensely competitive marketplace for pharmacy benefit management services. In some instances, market forces shift in ways that were not predicted, and manufacturer discounts are less than were anticipated during negotiations with the plan customer. As in all its dealings with customers, OptumRx honors its agreements and ensures that our customers receive the benefit promised, whether or not the market acts as OptumRx predicted.

4. **During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

    a. **What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

RESPONSE: OptumRx does not collect an administrative fee from manufacturers for Medicare or Medicaid plans, or with respect to drugs for which manufacturers provide no discount. The drugs in this latter category – the majority of which are generics – constitute approximately 90% of all prescriptions processed by OptumRx.

OptumRx supports moving to a fair market value fee not based on list price. For that small minority of drugs for which OptumRx currently charges manufacturers a fee to administer the discount program, consistent with market practice and current regulations, OptumRx has based those fees on a percentage of list price.

    b. **Does your company support moving to a system where administrative fees are based on a flat fee instead?**

RESPONSE: Yes. OptumRx supports moving to a system where all payments by pharmaceutical manufacturers for services provided by third parties are set in advance, fixed, and based on fair market value.

5. **During the hearing, pharmaceutical manufacturers testified that one reason pharmaceutical companies have increased their list prices is because the companies had to provide larger rebates to have their product included on formularies and maintain formulary access and access to patients. If manufacturers lowered the list price of their medicines and therefore provided lower rebates to PBMs, would your company continue to offer the same formulary access that you are offering to pharmaceutical manufacturers at higher list prices? In your opinion, if insulin products had lower list prices and lower rebates as a result, would the use of exclusive formularies increase or decrease?**

RESPONSE: OptumRx promotes the use of clinically effective, lowest net-cost prescription drugs. This work starts with an independent, clinically based formulary design process. OptumRx's 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 evidence-based way. 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 negotiates preferred formulary status among clinically equivalent alternatives based in part on the lowest net price. Whether a manufacturer could achieve the lowest net price by discounting its list price on a particular drug depends, therefore, on the circumstances, and in particular on the pricing of competitor drugs. Whether a customer chooses to prefer or exclude certain products from its formulary would likewise depend on multiple factors, including the negotiated net price of the various clinically equivalent products and the customer's prescription drug benefit philosophy.

While we would welcome the lowering of list prices of insulin, history tells us that manufacturers will not lower list prices without true generic competition. That is why we support Congress taking action to:

- Eliminate "pay-for-delay" agreements that delay the market entry of lower cost alternatives;

- Eliminate manipulation and abuses of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generics;

- Prevent "evergreening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, which extends the patent exclusivity period, preventing lower-cost alternatives from reaching patients;

- Reduce the exclusivity period for brand and specialty drugs; and

- Continue Food and Drug Administration (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.

<u>The Honorable Jeff Duncan (R-SC)</u>

1. **One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.**

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

So, which is it? Is there innovation in the insulin market or not?

RESPONSE: Insulin has been used to treat diabetes for nearly 100 years, and manufacturers have not introduced any significant new innovations to the drug itself to improve clinical efficacy in decades. To the extent there have been advancements, they have been primarily in the area of delivery devices, which are heavily patented and create significant hurdles to the introduction of generic alternatives.

2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."**

   Yet, OptumRx's testimony states that "[f]or 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. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?

RESPONSE: Insulin manufacturers are exploiting the patent system to stifle competition. As an example, I-MAK's Report *Overpatented, Overpriced Special Edition: Lantus* notes that "the wall of patents" one insulin manufacturer built around its insulin product "continues to keep competitors' biosimilar products to treat diabetes out of the market in the U.S."[4]

3. **As follow-up to that, we have specifically heard concerns about patent "evergreening," which is when brand-name companies patent a slight modification of an older drug. Some say that evergreening does not significantly improve the therapeutic nature of the drug, but rather it provides the company that made the drug an economic advantage by avoiding more competition entering the market.**

   In your opinion, do these patent "evergreening" concerns apply to the insulin products themselves or does it more so have to do with the newer delivery devices?

RESPONSE: While we believe patent "evergreening" applies to both products and delivery devices, it appears to be easier for drug manufacturers to continue to maintain their exclusivity through slight modifications in their delivery devices.

   a. **If a company wants to create a generic alternative or biosimilar version of an insulin pen product, what are the existing regulatory barriers that make it**

[4] I-MAK Report, October 30, 2018, *Overpatented, Overpriced Special Edition: Lantus (insulin glargine)*, available at https://www.i-mak.org/lantus/.

difficult for them to create the generic alternative if there are only patents remaining on the delivery device?

RESPONSE: As mentioned above, we believe this problem applies to both products and delivery devices. For drug/device combination products, like many insulins, FDA requires not only bioequivalence of the drug; it also requires essentially equivalent use of the device. When a delivery device is on patent, it is difficult for a generic manufacturer to provide sufficient data to show the FDA that a user's experience with the generic device is sufficiently similar to the brand.

Drug device combination products are becoming increasingly common. And the term of many device patents last years beyond the primary patents on the drug itself. The brand-name insulin companies have built a significant patent portfolio surrounding the devices that accompany many of the insulin products. For example, according to Novo Nordisk's website, patents covering Novo Nordisk's NovoPen®, do not expire until 2032.[5] There has also been extensive coverage of the patent portfolio Sanofi has built around its Lantus product. According to the FDA Orange Book, Sanofi has 26 active patents across 4 insulin products, only 5 of which are for insulin medications. One study of insulin pens published in 2015, found that the number of patents listed with the FDA on insulin combination products more than doubled between 2004 and 2014.[6]

As companies begin to seek approval for biosimilar versions of insulin, it is possible that patent "evergreening" or other life-cycle extension strategies will become a concern for the product, as well. These can include "product hopping" strategies whereby the brand makes minor changes in the product and switches doctors and patients to the new product before the generic comes to market, thereby eliminating the existing market for the current version of the drug without obtaining additional patent exclusivity.

b. **If the delivery device is the only part of the product that is patented, why aren't we at least seeing generic versions of insulin vials?**

RESPONSE: We address some of these issues in our response to Question 3(a), above. Broadly speaking, we believe there are several reasons why there is a lack of true generic competition in the insulin market, including abuse of the patent system by drug manufacturers and a complex and burdensome regulatory approval process (which is not helped in the short term due to the upcoming reclassification of insulin as a biologic product as that could delay the approval of generic insulins existing in the pipeline).

[5] https://www.novonordisk-us.com/products/product-patents.html.
[6] Luo, J. & Kesselheim, *A.S. Lancet Diabetes Endocrinol*. 3, 835–837 (2015).