FRANK PALLONE, JR., NEW JERSEY
CHAIRMAN

GREG WALDEN, OREGON
RANKING MEMBER

ONE HUNDRED SIXTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6115
Majority (202) 225–2927
Minority (202) 225–3641

May 10, 2019

Dr. Sumit Dutta
Senior Vice President and Chief Medical Officer
OptumRx
11000 Optum Circle
Eden Prairie, MN 55344

Dear Dr. Dutta:

Thank you for appearing before the Subcommittee on Oversight and Investigations on Wednesday, April 10, 2019, at the hearing entitled "Priced out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin." We appreciate the time and effort you gave as a witness before the Subcommittee on Oversight and Investigations.

Pursuant to Rule 3 of the Committee on Energy and Commerce, members are permitted to submit additional questions to the witnesses for their responses, which will be included in the hearing record. Attached are questions directed to you from members of the Committee. In preparing your answers to these questions, please address your responses to the member who has submitted the questions using the Word document provided with this letter.

To facilitate the publication of the hearing record, please submit your responses to these questions by no later than the close of business on Friday, May 24, 2019. As previously noted, this transmittal letter and your responses, as well as the responses from the other witnesses appearing at the hearing, will all be included in the hearing record. Your responses should be transmitted by e-mail in the Word document provided with this letter to Jourdan Lewis, Policy Analyst with the Committee, at jourdan.lewis@mail.house.gov. You do not need to send a paper copy of your responses to the Committee. Using the Word document provided for submitting your responses will also help maintain the proper format for incorporating your answers into the hearing record.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Ms. Lewis at (202) 225-2927.

Sincerely,

Frank Pallone, Jr.
Chairman

Attachments

cc: Hon. Greg Walden, Ranking Member
Committee on Energy and Commerce

Hon. Diana DeGette, Chair
Subcommittee on Oversight and Investigations

Hon. Brett Guthrie, Ranking Member
Subcommittee on Oversight and Investigations

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?

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?

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?

    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?

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

        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?

iv. How many covered lives does that translate to?

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

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

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?

    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?

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

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.

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

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

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

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?

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?

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

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?

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

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?

The Honorable Jeff Duncan (R-SC)

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?

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?

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?

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

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?