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

Ms. Amy Bricker, Senior Vice President, Supply Chain, Express Scripts

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?**

   Consumer directed health plans (CDHPs) have become increasingly common since Congress created health savings accounts (HSAs) in 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act.

   It is estimated that more than 9 out of 10 employers are offering a CDHP to their employees this year. Also known as high-deductible health plans, CDHPs can be designed in a variety of forms. Typically, a CDHP offers a high-deductible health plan with a spending account for out-of-pocket costs, such as a health savings account (HSA) or health reimbursement arrangement (HRA). Most employers still offer a CDHP as a choice alongside a traditional PPO or HMO.

   Plan sponsors are turning to CDHPs as a way to lower premiums and incentivize consumers with the belief that patients will take a more proactive approach to purchasing health care and make the most informed choices possible as they bear more out-of-pocket expenses.

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?**

   One of the key ways CDHP members receive support is though a Preventive Medications program. This helps improve member adherence to medications, reducing the risk of worsening conditions and lowering overall healthcare costs.

   Our standard set of preventive medication lists may include the following:

   - Asthma/COPD medications

- Blood pressure lowering medications
- Blood thinners
- Cavity prevention agents
- Certain vitamins and fluoride supplements
- Cholesterol lowering medications
- Colonoscopy preparation agents
- Diabetic medication and supplies
- Migraine prevention
- Miscellaneous antivirals
- Osteoporosis prevention agents
- Respiratory syncytial virus prevention agents
- Smoking cessation agents
- Vaccines
- Weight loss agents

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?**

   Express Scripts takes a holistic approach to supporting CDHP members. We work to ensure that members who have greater financial responsibility for managing their care are able to do so effectively in terms of making better decisions that deliver healthier outcomes. Express Scripts' 2018 Drug Trend Report shows that out-of-pocket costs for patients with diabetes in high-deductible plans were cut in half when insulin is included on the 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?**

   As noted above, diabetic medication and supplies, including insulin, are part of our standard set of preventive medication lists.

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

Diabetic medication and supplies, including insulin, have been part of our standard set of preventive medication lists for more than a dozen years.

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?

An analysis in Express Scripts' 2018 Drug Trend Report showed that 64% of high-deductible plans used a preventive drug that included first-dollar coverage of insulin.

iv. How many covered lives does that translate to?

Approximately 3 million.

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

Plan sponsors, based on their own unique situation, determine the scope of their coverage, applicability of coverage criteria, and cost sharing that is most appropriate for their members. They make these decisions based on the needs of their covered individuals, including factors that may affect the cost of coverage, such as preventive lists.

The Honorable Brett Guthrie (R-KY)

1. What factors does Express Scripts consider when deciding whether to include an authorized generic on its formulary?

Recently, we introduced a novel formulary option to provide employers and health plans an opportunity to leverage changing dynamics to help lower their members' out-of-pocket costs. The Express Scripts' National Preferred Flex Formulary, which became available January 1, 2019, provides a way for plans to cover lower list price products, such as new authorized alternatives that drug makers are bringing to the market. Specifically:

- When a manufacturer launches a lower-cost authorized alternative to a branded medication currently on the market, Express Scripts will evaluate the product for placement on the National Preferred Flex Formulary.

- If appropriate, the authorized alternative product will be added to the Flex formulary with preferred or possibly non-preferred status. The innovator brand-name product, and potentially other products in the therapy class, then will be excluded from coverage.

- Members enrolled in the Flex formulary who have a high-deductible or co-insurance plan design can have access to the lower-priced authorized alternative medication.

Branded innovator products will remain preferred or non-preferred on other formularies, including Express Scripts' standard National Preferred Formulary, while the authorized alternative product may be excluded.

a. In Express Script's testimony, Express Scripts said that the company is in discussions with Eli Lilly about the authorized generic version of Humalog, and if the net cost is lower, Express Scripts will add the authorized generic to the company's Flex Formulary. In Express Script'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?

On March 4, 2019, Eli Lilly announced the introduction of a lower list price authorized alternative for its highly prescribed short-acting insulin, Humalog. The authorized alternative version will be added to the National Preferred Flex Formulary with an effective date of July 1, 2019, and the brand will be excluded. In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

b. If Express Scripts does get a lower net price on the authorized generic and put it on the Flex Formulary, will Express Scripts keep the branded product on the company's formulary as well? Why?

As noted above, the brand will be excluded from the National Preferred Flex Formulary effective July 1, 2019. The brand product will remain on the other Express Scripts formularies. In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

c. Has Express Scripts ever gotten a lower net price on an authorized generic and put it on formulary and kept the branded product on formulary as well?

In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

2. 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 Pharmacy Benefit Managers (PBMs), including Express Scripts, 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 Express Scripts is offered a rebate of 50 percent, thereby making the final price to Express Script's client $50. Product B has a list price of $50, and Express Scripts is not offered any rebates for the product.

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

We are not aware of this hypothetical scenario happening within classes of therapeutically equivalent insulin products. However, the process Express Scripts uses to develop formularies has been constructed to ensure that clinical considerations are paramount and fully taken into account *before* cost considerations. Formulary management is a highly effective strategy that pharmacy plan sponsors can implement to maintain a safe, affordable and meaningful benefit for patients. Our formulary development approach for the products you describe would follow this rigorous process, which is described in more detail below. For reasons outlined in the responses below, Express Scripts would likely include both products A and B on the formulary. The goal of the Express Scripts National Preferred Formulary is to provide broad access to products that will meet the clinical and financial needs of our clients and their members. Ultimately, plan sponsors choose the formulary design based on the unique needs of their members and make the decision to include or exclude products.

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

Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process.

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

While "net price" may be defined various ways, the net price plan sponsors or insurers pay for a drug is generally a function of the list price less any applicable discounts.

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

Express Scripts develops formularies through a four-step process involving the work of distinct committees: the Therapeutic Assessment Committee, National Pharmacy & Therapeutics Committee, Value Assessment Committee, and an annual formulary review by the National Pharmacy & Therapeutics Committee.

The Therapeutic Assessment Committee (TAC) is an internal clinical review body, consisting of clinical pharmacists and physicians who are employed by Express Scripts. From a formulary development perspective, the committee is tasked to review specific medications following approval by the Food and Drug Administration. Before discussing

a new drug at TAC, Express Scripts' clinical team conducts a search of the medical literature, evaluates published data from clinical trials, and develops comprehensive drug evaluation summary documents. The drug evaluation documents include, at a minimum: a summary of the pharmacology, safety, efficacy, dosage, mode of administration, and the relative place in therapy of the medication under review compared to other pharmacologic alternatives. Following a review of the drug evaluation summary document, TAC ultimately provides a formulary placement recommendation that is shared with the Express Scripts' National Pharmacy and Therapeutics (P&T) Committee. TAC formulary recommendations are merely a suggestion and cannot be formally implemented without the approval of the P&T Committee.

Express Scripts' P&T Committee is a group of independent, actively practicing physicians and pharmacists who are not employed by Express Scripts. The P&T Committee is tasked to review medications from a purely clinical perspective. The Committee does not have access to, nor does it consider, any information regarding Express Scripts' rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The Committee does not use price, in any way, to make formulary placement decisions.

The P&T Committee can establish one of the following three formulary placement designations: *include*, *exclude*, or *optional* from a formulary. Drugs with a designation of **include** are recommended for placement on all formularies. Drugs may be given an include designation for one or more of the following clinical reasons: unique indication for use addressing a clinically significant unmet treatment need; efficacy superior to that of existing therapy alternatives; a safety profile superior to that of existing therapy alternatives; a unique place in therapy; and/or drugs which treat medical conditions that necessitate individualized therapy and for which there are multiple treatment options. Drugs with an **exclude** designation are not recommended for formulary inclusion. Drugs may be given an exclude designation for one or more of the following clinical reasons: efficacy inferior to that of existing therapy alternatives; a safety profile inferior to that of existing therapy alternatives; and/or insufficient data to evaluate the drug. Medications recalled from the market for safety reasons take an automatic exclude status, and are formally reviewed at the next P&T Committee meeting. Drugs may also be designated as **optional** on a formulary. Drugs may be given an optional designation based on the conclusion that they are clinically similar to other currently available drug alternatives.

Optional medications are forwarded to the Value Assessment Committee (VAC) for further analysis, which considers the value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications. VAC consists of Express Scripts employees from various areas. No member of VAC can serve in any capacity on TAC (and vice-versa). VAC reviews drugs designated as optional by the P&T Committee, and develops a formulary placement recommendation.

Finally, on an annual basis, the National P&T Committee will review the final formulary recommendations, by drug class, for the upcoming plan year. The Committee utilizes this opportunity to ensure adherence to previously established formulary placement recommendations, and to recommend any additional changes to ensure that the formulary is clinically appropriate. The Committee also ensures that all Express Scripts national

formularies cover a broad distribution of therapeutic classes and categories, and that the formularies neither discourage enrollment by any group of enrollees nor discriminate against certain patient populations.

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

As noted above, the process Express Scripts uses to develop formularies has been constructed to ensure that clinical considerations are paramount and fully taken into account before cost considerations. Many insulins are considered easily interchangeable from a clinical perspective. We then evaluate the lowest net cost of the drug. Express Scripts is not aware of two therapeutically equivalent insulin products having the same list price. Additionally, we generally do not see multiple insulin manufacturers offering the same rebate discount. As noted in the hypothetical scenario above, if the net cost for two products are the same, both may be included on 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 Express Scripts exceeded the level of rebates that it guaranteed to its clients? How much did Express Scripts retain as a result?

Our clients, which are sophisticated entities and are often represented by benefit consultants and advisors, negotiate the overall pricing arrangement they believe best suits their pharmacy benefit needs. Terms vary across clients and contracts. Express Scripts' contractual terms with its clients are confidential and based on those confidentiality obligations, Express Scripts cannot disclose the individual financial performance of any specific contract.

Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates.

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

It would depend on the individual contract.

3. There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer

decides to lower the list price of a medicine. Has Express Scripts sent a similar letter to pharmaceutical manufacturers and/or does Express Scripts require that manufacturers provide the company with advance notice of a list price decrease? If yes:

No. Express Scripts welcomes manufacturers lowering their list prices so that patients can have greater access to medications. Nothing in our agreements prohibits any manufacturer from decreasing the list price of a drug.

a. Please describe the terms of this requirement and when Express Scripts established this requirement.

N/A

b. If a pharmaceutical manufacturer does not provide Express Scripts 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.)?

N/A

c. Have any manufacturers reduced the list price of insulin without giving Express Scripts sufficient notice and triggered this provision?

N/A

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?

Percentage-based fees are used throughout the pharmaceutical supply chain. However, the use of such fees has no impact on list prices set by manufacturers.

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

As noted above, the use of percentage-based fees has no impact on list prices. We welcome the opportunity to work with policymakers on initiatives that could increase competition and lead to lower list prices, providing greater access and affordability for plans and patients.

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?

As an initial matter, we note that rebates do not cause increases in list prices. Moreover, our formulary development approach for all medications prioritizes clinical considerations first and foremost before evaluating net cost to clients. Express Scripts has maintained a clear, unwavering position that achieving the lowest net cost for a clinically appropriate prescription medication is our mission for our clients and their members, whether that is through a negotiated rebate or reduction in list price.

Since 2014, Express Scripts has continued to evaluate the financial opportunities that clinically-appropriate exclusions represent for our clients, and our approach to driving savings would not change if manufacturers lowered their list prices. As noted above, our focus is on net cost, whether through a negotiated rebate or reduction in list price. We also offer an option for plans not implementing exclusions to utilize step therapies requiring the trial of a clinically appropriate preferred product before the patient can try a non-preferred drug. A medical exception process is always available for the prescribing physician to pursue if a patient's unique health situation requires a non-preferred product to be the only option. Like formularies, step therapies and other elements of benefit design are ultimately determined by our clients.

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?

Over the last several years, the list prices for insulin products have steadily increased. We have seen rates of growth in list prices of widely-used insulins increase more than 50 percent—and in some cases even higher—over the last five years. While there is limited innovation in the insulin market, Express Scripts is concerned that price increases are often the result of arbitrary increases and market manipulation rather than recovering the cost of insulin innovation.

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?

   Yes, there are. Express Scripts is concerned about practices such as so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. We applaud the Committee's recent unanimous passage of legislation that would block these anti-competitive agreements, removing barriers to competition and expanding the availability of lower-cost generics and biosimilars. According to a Federal Trade Commission (FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.

   We also support preserving the ability of the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office to invalidate patents that do not represent true innovation. Legislative and regulatory efforts to weaken this process will extend patent monopolies for pharmaceutical and biological products, resulting in higher prices for patients.

   In our 2018 Public Policy Analysis, Express Scripts identified an increasing number of patent settlements between biologic and biosimilar manufacturers as a trend that lawmakers need to resolve. Brand and generic drugmakers have been required since 2003 to file patent settlement agreements with the FTC, which evaluates the information and decides whether to take any legal action challenging the settlement. That requirement previously did not extend to biosimilar settlements, potentially delaying the market introduction of these lower cost biological treatments.

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?

Express Scripts remains concerned about competition-limiting practices such as patent "evergreening," whereby drug manufacturers can extend a brand drug's patent or exclusivity by the development of new formulations. These concerns apply to both insulin and insulin delivery devices, but are more widespread on the 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?**

Although patents are long-expired for some insulin brands, no biosimilar/follow-on versions were approved until recently due to the complexity of insulin production and, until recently, a lack of FDA guidelines for manufacturers. Basaglar (insulin glargine), the first follow-on insulin approved in the U.S., launched in December 2016. In fact, FDA tentatively approved Basaglar in August 2014, but due to litigation and the terms of a confidential settlement, the product was not launched in the United States until December 2016.

Although approved, FDA has not deemed the follow-on version A-rated (or interchangeable) with brand Lantus. For a drug/delivery device combination to receive interchangeability status with the brand (A-rated), it must have the same look and feel as the innovator (brand) product. This is where the device patents can delay in interchangeable competition (e.g. generics to EpiPen). Express Scripts looks forward to working with the Committee to identify policy solutions to address these barriers and speed generic and biosimilar entry.

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?**

Insulin is a complicated compound created in bacteria using recombinant DNA technology. The FDA will be transitioning from New Drug Applications (NDA's) -- or small molecule drugs -- to Biologic License Applications (BLA's) -- biologic drugs-- in March of 2020 for insulin products. After this date, manufacturers will have to receive FDA approval for a biosimilar to an insulin moving forward.

The number of patents for drug delivery devices has increased significantly in recent years, which has resulted in extending the patent and exclusivity period for certain brand drugs that otherwise could have lower cost generic versions. Express Scripts looks forward to working with the Committee to identify policy solutions to address these barriers and speed generic and biosimilar entry.