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

Mr. Doug Langa, Executive Vice President, North America Operations, President, Novo Nordisk Inc.

The Honorable Joseph P. Kennedy III (D-MA)

1. At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.

   Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

   a. Where can patients find information on eligibility and criteria for the programs?

Answer: There are many ways patients can access details on Novo Nordisk's patient assistance programs in order to increase the likelihood that they can obtain the information they need in a timely manner. Information about Novo Nordisk's Diabetes Patient Assistance Program (Diabetes PAP) can be found on the Novo Nordisk Patient Affordability and Access Support website-www.NovoCare.com, as well as Novomedlink (found at www.Novomedlink.com), which is directed towards healthcare providers. The NovoCare® site is also linked to Novo Nordisk U.S. diabetes branded and unbranded sites directed at healthcare providers and patients. In addition, multiple key consumer and patient-advocacy maintained sites, and related mobile applications, connect to NovoCare®, including the American Diabetes Association (ADA), American Association of Diabetes Educators (AADE), Needymeds, Inc., medicineassistancetool.org (managed by PhRMA), and Drugs.com. Patients may also gather information through their medical providers, or by calling the Novo Nordisk Customer Care Line (at 1-800-727-6500), or the Novo Nordisk Reimbursement Hotline (at 1-855-253-2414).

   b. What are the eligibility criteria for the programs?

Answer: The eligibility requirements for the Diabetes PAP are as follows: The patient must be a U.S. citizen or legal resident, and must be uninsured and ineligible for Department of Veterans Affairs prescription benefits, or any federal, state, or local program such as Medicare or Medicaid. There is an exception for patients with Medicare Part D coverage who meet the threshold out-of-

pocket spend on prescription medication, which is currently $1,000; patients who are Medicare eligible and do not have Medicare Part D coverage and have applied for and been denied the Extra Help/Low Income Subsidy (LIS); and patients who are Medicaid eligible and have applied for and been denied Medicaid. Finally, patients need to demonstrate that their income is at or below 400% of the federal poverty level—about $103,000 for a family of four and $49,960 for an individual. Although these criteria govern eligibility for the Diabetes PAP, Novo Nordisk also considers patients who exceed the income threshold in certain situations—for example, job loss or sudden financial hardship—on a case-by-case basis.

c. What information and documents must patients submit in order to qualify for the programs?

Answer: Patients must fill out one page of the Diabetes PAP application that seeks basic identifying information such as their name, address, and social security number, as well as information about their prescription drug coverage. Patients can provide proof of income by submitting copies of any of the following: two most current paycheck stubs or earning statements for all working members of the household; a federal income tax return from the prior year; Social Security, pension, or other income statements; W-2 or 1099 forms; or unemployment benefit statements. If applicable, patients must provide a Medicaid eligibility form or, for Medicare Part D patients, documentation (such as a letter from a provider, a statement or explanation of benefits, or a pharmacy printout) showing that the patient has spent $1,000 on prescription medicine for the relevant benefit year. It ordinarily takes seven to ten days from the time Novo Nordisk receives a completed application until products are sent to the patient's healthcare provider. In many cases, medicine is sent to patients in less time.

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

Answer: For the Diabetes PAP, Novo Nordisk received 74,713 applications in 2018 for 105,220 products, as some applications requested multiple products. 16,477 (16%) of these product applications were either withdrawn or incomplete. Among the 88,743 completed product applications, 65,077 (73%), were approved while 23,666 (27%) were denied.

e. What are the ten most common reasons your company denies a patient's application?

Answer: Eligibility for Novo Nordisk's Diabetes PAP is governed by the criteria described above. If a patient does not meet those criteria, her application will not be approved. (As noted above, however, Novo Nordisk does make exceptions to the income criteria in certain situations decided on a case-by-case basis). In addition, if a patient does not complete the application process, including by verifying income eligibility, her application will not be approved.

Of the applications for the Diabetes PAP that are denied, about 70% are denied because the patient has insurance. A far less common reason is that the patient exceeds the income threshold, which occurs in 7%-20% of denials (varies by product). Other reasons include failure to meet the requirements for qualification with Medicare coverage (such as providing proof of out-of-pocket expenses) or failure to provide identifying information requested in the application (such as social

security number or healthcare provider information). If a patient appears to be eligible for Medicaid, Novo Nordisk requires that the patient apply for Medicaid before approving their PAP application.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

Answer: For uninsured patients, an approved application is valid for 12 months. For Medicare Part D patients, an approved application is valid for the calendar year in which they applied. Patients may be reapproved annually for as long as they meet the eligibility criteria.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018?

Answer: Novo Nordisk invests in website design features that offer information about affordability options, including the Diabetes PAP, and has worked to improve those features each year. In addition, Novo Nordisk telephone representatives are equipped to answer questions about the Diabetes PAP when patients call the customer care line. Novo Nordisk sales representatives also educate physicians on the Diabetes PAP so that they may in turn educate patients needing assistance. Novo Nordisk works with patient organizations, such as the American Diabetes Association, to ensure that patients are aware of the affordability options available to them, including the Diabetes PAP. Because these efforts are adjunct to Novo Nordisk's general product promotion activities, it is not possible to quantify the dollars spent specifically on public awareness for the Diabetes PAP.

i. How much did your company spend on advertising for insulin in 2018?

Answer: Novo Nordisk spent $91.6 million on print and television advertising, as well as other consumer-facing marketing activities, for insulin medicines in 2018.

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.

a. Where can patients find information on eligibility and criteria for the programs?

Answer: In addition to the Diabetes PAP, Novo Nordisk operates Patient Assistance Programs for growth hormone disorders (Growth Hormone Patient Access Program or Growth Hormone PAP), Hemophilia (Hemophilia Product Assistance Program or Hemophilia PAP), and hormone therapy (Hormone Therapy Patient Assistance Program or Hormone Therapy PAP). Information about those programs can be found on Novo Nordisk's website Novonordisk.us, as well as other web sources, and through health care providers.

b. What are the eligibility criteria for the programs?

Answer: For the Growth Hormone Patient Access Program, the following eligibility criteria apply: The patient must be a U.S. citizen or legal resident and must have a diagnosis that is an FDA-

approved indication for Norditropin®; the patient's total household income must be at or below 350% of the federal poverty level after inclusion of Norditropin® estimated cost deduction; and the patient cannot have or qualify for government insurance, including any federal, state, or local program such as Medicare or Medicaid. Patients who are eligible for Medicaid or VA prescription benefits must have been denied enrollment, including exhaustion of all appeals, in order to be eligible for the PAP. If the patient is Medicare eligible but does not have Medicare Part D coverage, the patient must have applied for and been denied the LIS.

For the Hemophilia Product Assistance Program, the following eligibility criteria apply: The Patient must be a U.S. citizen or legal resident and must be prescribed a Novo Nordisk factor product for an indicated condition; the patient must not have prescription coverage; and the patient's total household income must be at or below 400% of the federal poverty level. The patient cannot have or qualify for government insurance, including any federal, state, or local program, such as Medicare or Medicaid, and patients who are eligible for Medicaid or VA prescription benefits must have been denied enrollment, including exhaustion of all appeals, in order to be eligible for the PAP. If the patient is Medicare eligible but does not have Medicare Part D coverage, the patient must have applied for and been denied the LIS.

For the Hormone Therapy PAP, the following eligibility criteria apply: The patient must be a U.S. citizen or legal resident; the patient must not have private prescription coverage or state, federal, or local prescription coverage, such as Medicare, Medicaid, or VA benefits; and the patient's total household income must be at or below 200% of the federal poverty level. If approved, a 90-day supply is sent to the patient's health care provider.

c. What information and documents must patients submit in order to qualify for the programs?

Answer: For the Growth Hormone Therapy PAP and the Hemophilia PAP, patients must fill out the application form and provide certain documentation. For proof of income, they may provide any of the following: the two most current paycheck stubs or earning statements for all working members of the household; a copy of last year's federal income tax return (1040); a copy of Social Security income, pension, and other income statements, including interest or dividend statements; a copy of last year's (or most current) W-2 or 1099 form; or a copy of an unemployment benefits statement. Some patients must also provide a Medicaid, VA, or Extra Help/LIS denial letter (dated within 1 year of applying for the PAP). For the Growth Hormone Therapy PAP, some patients must provide a copy of their medical and pharmacy insurance cards. For the Hemophilia PAP, patients must provide their prescription with exact quantity and assay limits.

For the Hormone Replacement Therapy PAP, patients may demonstrate their income eligibility by providing their most recent federal tax return (1040), or Social Security income, Pensions, Interest, Retirement, and Child Support documentation.

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

Answer: In 2018, for the Growth Hormone Therapy PAP, Novo Nordisk received 994 applications and approved 687. Of the applications that were not approved, 221 were withdrawn or incomplete. For the Hemophilia PAP (again, in 2018), Novo Nordisk received 28 applications and approved 7. Of the remaining applications, 6 were withdrawn or incomplete. For the Hormone Therapy PAP (also in 2018), Novo Nordisk received 63 applications and approved 39.

e. What are the ten most common reasons your company denies a patient's application?

Answer: As described above, each of Novo Nordisk's PAPs have eligibility criteria. If patients do not meet the eligibility criteria, including by verifying income, their applications may be denied. However, Novo Nordisk evaluates certain atypical financial situations on a case-by-case basis.

The most common reason that patients are denied approval for the Growth Hormone, Hormone Therapy, and Hemophilia PAPs is that their income exceeds the eligibility threshold. Other reasons include failing to meet other criteria or providing incomplete information or documentation.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

Answer: Approvals must be renewed annually. Patients may reapply as long as they remain eligible.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018?

Answer: As explained in response to question 1, it is not possible to quantify the amount spent on public awareness campaigns for the Patient Assistance Programs because those efforts are adjunct to other corporate communications and product promotion activities.

h. How much did your company spend on advertising for medication in 2018?

Answer: In 2018, Novo Nordisk spent $274 million on print and television advertising, as well as other consumer-facing marketing activities, across all of its products.

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

Answer: All of Novo Nordisk's medicines that are currently marketed are available through Novo Nordisk's PAPs, with one exception. Saxenda®, which is used to treat obesity, is not available. Novo Nordisk considers obesity to be a separate disease space from diabetes and does not currently have an Obesity PAP.

4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When

your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.

Answer: Novo Nordisk does not use a private foundation to operate the Patient Assistance Programs described above. The company does not take a charitable tax deduction for the products it provides to patients through its PAPs, or for costs of administering the programs. NovoCare® is not a private foundation—it is an arm of Novo Nordisk dedicated to patient access and affordability support in the U.S.

The Honorable Brett Guthrie (R-KY)

1. 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 the medicine. Has Novo Nordisk received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Novo Nordisk lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Novo Nordisk and describe the requirements set forth in the letter.

Answer: Novo Nordisk received the letter from OptumRx requesting notice of any decision to lower list prices. Novo Nordisk did not agree to provide that information. Novo Nordisk is not aware of receiving similar letters from any other PBM.

   a. Does Novo Nordisk have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.

Answer: No. As described above, OptumRx sought to include such obligations in its contracts with Novo Nordisk, but Novo Nordisk declined.

   b. Has Novo Nordisk provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.

Answer: No, it has not.

   c. What happens to Novo Nordisk's rebate obligations with PBMs if Novo Nordisk lowers the list price of insulin or any other medicine?

Answer: Novo Nordisk's contracts with PBMs hold the company to a certain rebate amount. That amount is expressed as a percentage of list price. Because rebates are a function of list price, if Novo Nordisk lowers list prices for its medicines, the amount of the rebate paid to the PBM will decrease. As such, PBMs will earn less in rebates for products where the list price is lowered.

d. Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Novo Nordisk's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.

Answer: Although Novo Nordisk did not agree to OptumRx's request, the letter indicates the importance of rebates to the PBMs, payers, and plan sponsors. Rebates are critically important to PBMs and other payers and can represent millions of dollars for a single contract in a single year. The role and importance of rebates to payers' business models is, of course, a consideration in pricing. Novo Nordisk always considers the entire market when setting list prices, including the rebate percentages and dollars that are required to secure and maintain formulary access.

2. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Novo Nordisk's testimony, Novo Nordisk said that the net prices for its insulins have declined year-over-year from 2015 through 2018—the net price of the NovoLog® declined by 21 percent from 2003 to 2018 while the list price of the product increased by 310 percent during the same period. 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 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. Please explain.

Answer: As outlined above, rebates are critically important to PBMs and other payers and can represent millions of dollars for a single contract in a single year. Novo Nordisk has had discussions with payers about the possibility of eliminating rebates and focusing instead on net price—in other words, lowering list price to the amount the company actually receives from payers. In those discussions, PBMs and other payers have expressed concern about the consequences of such a systemic change and have been unwilling to offer assurances that Novo Nordisk would maintain its formulary positions if it no longer offered rebates.[1]

Formulary access is crucial to ensuring that Novo Nordisk's products reach the patients who rely on them. Having products available on formulary is the way that the vast majority of patients can access Novo Nordisk products at reasonable co-pays. If Novo Nordisk products were excluded from formularies, patients would either have to pay much higher prices for their medicine or switch to another product that might not work as well for them. No two diabetes patients are alike, which is why it is so important that patients not lose access to the medicines that work for them.

Because of consolidation, the three PBMs who testified at the April 10th hearing manage the pharmacy benefit for over 80% of the patients in the United States. Accordingly, losing access to any of their formularies would materially impact Novo Nordisk's business and market share,

[1] The question correctly notes that there has been a decline in the net price of NovoLog® since 2003. It is important to recognize that the 21% decline reflects adjustments for inflation.

as well as Novo Nordisk's ability to deliver its medicines to patients. For these reasons, in the current system, Novo Nordisk must proceed cautiously with respect to reducing or eliminating rebates. Complicating matters, rebate pressures have been increasing year over year. Across all products and channels, Novo Nordisk paid 68% in rebates and other discounts and fees last year—up 40% from 2014. As long as this persists, Novo Nordisk must offset growing rebate demands with list price increases in order to remain a sustainable business capable of delivering its medicine to patients and continuing to invest in innovation to ultimately defeat diabetes.

Novo Nordisk supports the proposed rule from the Department of Health and Human Services, *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* (the Rebate Rule). Novo Nordisk believes that the Rebate Rule will benefit patients and supports its expansion to the commercial market. However, Novo Nordisk believes that the wholesale conversion of both markets simultaneously could cause confusion in the marketplace and disrupt patient access to medications. There are many new operational and system requirements necessary to ensure that the appropriate discount is applied at the pharmacy counter, that patient cost-sharing responsibilities are correctly calculated, and that pharmacies are fully compensated. Previous changes of this magnitude have been afforded years for implementation, and were themselves not without challenges at the outset. Therefore, Novo Nordisk supports a focus on ensuring a successful implementation in the Part D market before moving on to other channels.

Novo Nordisk also supports other legislative or regulatory changes that would ensure that the rebates pharmaceutical manufacturers pay to secure and maintain formulary access are passed on to the patients who use those medicines.

3. Are any of Novo Nordisk's insulin drug substances currently protected by patents or are all of the current patent protections on Novo Nordisk's insulin products for the delivery systems? Please describe how a patent on the delivery system limits the ability of a competitor to make a generic version of the product.

Answer: Several of Novo Nordisk's insulin drug substances are protected by patents, while several are not. Novo Nordisk also manufacturers devices, which are the result of significant innovation and are also protected by patents. These devices allow for more accurate and convenient delivery of insulin, allowing patients to dose themselves more easily and with less pain. They also allow patients who may struggle with fine motor skills to self-dose, thereby obviating the need for medical assistance and permitting patients—particularly elderly patients—to maintain their independence.

Patents on Novo Nordisk's innovative devices do not impede the ability of generic competitors to produce the underlying medication. A generic competitor may produce the unpatented substance and market it in their own delivery device, or for use with a traditional vial and syringe.

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?

Answer: The disadvantage of a system in which administrative fees are paid as a percentage of list price is that there is increased pressure to keep list prices high because various actors in the supply chain benefit from the higher prices. This is an example of misaligned incentives in the current system.

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

Answer: Novo Nordisk supports moving to a flat fee system, provided that the fees are based on the fair market value of the service rendered. Novo Nordisk agrees with the position taken in the proposed Rebate Rule that such fees cannot be determined based on additional business that is provided to the PBM or health plan by manufacturers.

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?

Answer: The suggestion that insulin has not changed in 100 years is incorrect. In fact, there has been significant innovation over the last several decades with continued research and development in the insulin space occurring even in these most recent years.

During the mid-20th century, advances in insulin purification and stability allowed many patients to dose insulin more safely and accurately. In the 1980s, advances in the use of recombinant DNA

technology meant that patients requiring insulin would no longer have to depend on bovine or porcine sources in order to control their glucose levels. Human insulin revolutionized the treatment of diabetes because it could be produced in a purer form, and it reduced the occurrence of allergic reactions.

The development of analog insulins in 2000 represented another significant change in diabetes therapies. Novo Nordisk's analog insulin, sold under the name NovoLog®, is a modified form of human insulin in which the amino acid structure of the insulin molecule has been altered at specific sites to change the onset and duration. For patients, this provides better control of mealtime blood glucose levels by more closely matching the body's natural insulin action. In doing so, the medication allows for a more flexible lifestyle, as injections can be taken immediately before, or even just after, meals. This flexibility offers a meaningful improvement in quality of life for patients as well as improvements in their glucose levels immediately following a meal.

In just the last five years, Novo Nordisk has introduced other new products that materially improve patients' lives. In 2015, Novo Nordisk introduced Tresiba®, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients.[2] This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba® is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Even more recently, in 2017, Novo Nordisk introduced Fiasp®, a new short-acting insulin that offers quicker onset when compared to other current analog insulins. These two recent advances, Tresiba® and Fiasp®, have allowed people who are insulin-dependent to safely and effectively control their diabetes around mealtimes, when blood sugar rises quickly after eating, as well as overnight and in-between meals. For patients, better nighttime control may mean the difference between getting a good night's sleep and waking for a productive day ahead, and experiencing the very frightening and often times dangerous sleep interruptions caused by fluctuations in glucose levels through the night.

Today, Novo Nordisk is the largest private funder of diabetes research and development in the world. Novo Nordisk has also formed research collaborations to further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop a capsule device that contains compressed insulin, which is injected into the patient after the capsule reaches the stomach. This capsule could potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. Novo Nordisk is also conducting research into stem cell therapies to treat diabetes in collaboration with the University of California, San Francisco, as well as other chronic diseases.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving patients' lives through new medications and delivery systems. Novo Nordisk will continue to innovate to address the needs of patients and to meet the goal of defeating diabetes.

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[2] At the hearing, Chair DeGette suggested in a closing statement that Tresiba® is not an insulin, but is a product that is used to improve insulin absorption in patients with type 2 diabetes. *See* Tr. at 140. It is important to clarify that this is incorrect – Tresiba® is an insulin medicine and is FDA approved for patients with both type 1 and type 2 diabetes.

The assertion that there is no competition in the insulin market is also incorrect. As a single company, Novo Nordisk pays approximately 10% of all rebates across the entire pharmaceutical industry, much of that within the insulin space. This is a result of the fierce competition between the insulin manufacturers, in the current system, to secure and maintain formulary access. In 2018 alone, Novo Nordisk invested approximately $18 billion in rebates, discounts, and other fees. The company makes this investment to ensure that patients who rely on Novo Nordisk's medicines can continue to access them at reasonable co-pays.

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?

Answer: As outlined above, there is significant competition in the insulin market, as evidenced by the degree to which rebates to secure formulary access grow each year.

With respect to generic alternatives, Novo Nordisk cannot speak to the reasons why a generic competitor has not brought a product to market. This could be because insulin products, as large peptide biologics, are more difficult to produce than some other prescription medicines for a variety of reasons. Nonetheless, Novo Nordisk supports competition in the insulin market. Several of Novo Nordisk's medicines are no longer covered by patents and, if a generic competitor attempted to produce a generic alternative to those products, Novo Nordisk would not prevent them from doing so (assuming the product met applicable FDA requirements).