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. Kathleen Tregoning, Executive Vice President for External Affairs, Sanofi

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.

Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability of insulin for patients. We have developed some of the most forward-leaning programs to help patients afford Sanofi's insulin products. We have three primary patient support programs that are designed to improve patient access to, and affordability of, Sanofi insulins.[1] In addition, Sanofi has various other patient support programs that provide patient access and assistance for our non-insulin products. We have developed these programs to address affordability challenges patients face due to the different circumstances they face, including insurance status, formulary design, and the increased prevalence of high deductible health plans. Each program is tailored to a specific population and designed to help address a different problem. Despite the many challenges and perverse incentives that exist in our health care system, Sanofi's commitment to patient affordability means that, today, approximately 75 percent of all patients taking Sanofi insulin pay less than $50 per month.

[1] Additionally, Sanofi offers the eVoucherRX Program to patients who manage their diabetes with Apidra/Apidra SoloSTAR, Lantus/Lantus SoloSTAR, Toujeo SoloSTAR/Toujeo Max Solostar, or Soliqua 100/33. The purpose of the eVoucherRX Program is to provide commercially insured patients with financial support through pharmacies participating in the program. The program is a co-pay assistance program applied automatically at the pharmacy counter without any enrollment process. The program reduces these patients' out-of-pocket costs to $0 with a maximum benefit of $1500 per year. The third-party vendor that administers the program screens claim submissions to mitigate the risk that the program could be used by federal health care program beneficiaries, consistent with OIG guidance.

Federal beneficiaries, including beneficiaries enrolled in Medicare and Medicaid, do not have access to some of our patient assistance programs. We support changing the law to allow co-pay assistance to be provided to federal program beneficiaries.

Our patient support programs for insulins and other products are described below.

- **Sanofi Co-pay Assistance Programs:** Sanofi has co-pay assistance programs for insulins and for other Sanofi products. Sanofi co-pay assistance programs aim to lower out-of-pocket costs for commercially insured patients regardless of income level.

  Patients are able to register and download electronic co-pay cards from a Sanofi website, or may contact our call center at (855) 984-6302 to request an actual co-pay card. Patients also may receive actual co-pay cards from their healthcare providers. Consistent with prior OIG guidance regarding the application of the federal Anti-Kickback Statute to coupon programs for federal beneficiaries,[2] Sanofi does not make its co-pay card programs available to patients covered by federal healthcare programs. In addition, and also consistent with OIG recommendations, Sanofi co-pay cards must be activated prior to use through an online activation process or by calling a call center number specified on the card. Patients who apply for Sanofi co-pay assistance may be approved that same day.

- **Insulins Val*you* Savings Program:** In early 2018, Sanofi launched the Insulins Val*you* Savings Program to provide financial relief to uninsured and cash paying patients. The program enabled eligible patients to access Sanofi insulins for $99 per 10 mL vial or $149 for a pack of SoloSTAR pens, which was approximately a 60% discount below the list price; this could result in savings of up to $3,000 per year.[3]

  In April, Sanofi announced an expansion of the **Val*you*** Savings program. Effective June 8, we will transition the program to a monthly 'Netflix'-like subscription model so that uninsured patients exposed to high out-of-pocket costs at the pharmacy counter will be able to access any combination of Sanofi insulin (with the exception of Soliqua) for a fixed price of $99/month for up to 10 vials or packs of SoloSTAR pens. Under the

[2] *See* https://www.oig.hhs.gov/compliance/alerts/bulletins/index.asp (May 2014).

[3] Patients with type 1 diabetes require insulin replacement with both background (basal) and mealtime (bolus) insulin. An average adult with type 1 diabetes who weighs 70 kg (155 pounds) should be taking anywhere from 0.5-1 u/kg/ day - depending upon activity levels, and meal choices. If a higher daily dose of 1 u/kg/day is used, the patient would need a total of 70 units/day of insulin, of which ~ half should be mealtime bolus insulin and half should be background basal insulin. That would mean the patient could possibly manage her disease with one vial of long acting and one vial of short acting or a pen pack for basal and bolus each month. For the average patient with type 1 diabetes, under the Val*you* program, the patient would meet the monthly insulin requirement with two payments of $99.

For patients with type 2 diabetes, many require background (basal) insulin only. Our internal data show that the average daily dose is roughly 45 units per day which results in a monthly requirement of 1350 units of basal insulin per month. The Lantus SoloSTAR pack contains 1500 units of insulin (5 pens x 300 units per pen) and the Toujeo SoloSTAR pack contains 1350 units of insulin (3 pens x 450 units per pen). For the average patient with type 2 diabetes, under the Val*you* program, the patient would meet the monthly insulin requirement with one payment of $149. Patients on lower doses of Lantus per month could opt for the 10ml vial, which is $99 per vial.

Val***you*** Savings Program, prices are guaranteed for 12 consecutive monthly fills. The program is available through all U.S. pharmacies and there are **no income** requirements.

Patients are able to register and download an electronic savings card from a Sanofi website (https://www.admelog.com/insulins-valyou-savings-program/), or may contact Sanofi's call center at (855) 984-6302 to request the savings card. Patients also may receive savings cards from their healthcare providers. Consistent with the analysis contained in an OIG advisory opinion on programs that allow patients to access drugs outside of their insurance at a cash price,[4] Sanofi does not make the Val*you* Savings Program available to federal healthcare program beneficiaries. In addition, consistent with OIG recommendations, patients must activate the savings cards prior to use through an online process or by calling a call center number specified on the card. Patients who meet eligibility criteria are immediately approved for the Insulins Val***you*** Savings Program and may be used the same day.

- **Sanofi Patient Connection (SPC)**: The purpose of Sanofi Patient Connection (http://www.sanofipatientconnection.com/) is to administer Sanofi's patient assistance program, which provides financially needy patients who meet eligibility criteria with free medicine. The Sanofi Patient Connection application is available online[5] or by calling Sanofi Patient Connection and Patients who apply for Sanofi Patient Connection are approved, on average, within two to five business days.

- **Additional Sanofi Patient Assistance Programs:** In addition to the SPC, Sanofi provides other medicines within its portfolio free of charge to eligible patients through other patient assistance programs. The purpose of all Sanofi free drug patient assistance programs is to provide financially needy patients who meet the eligibility criteria with free medications.

In addition to the programs outlined above, Sanofi continues to work with policy-makers on initiatives that would remove the existing barriers to patient access and affordability, including removing the restrictions on providing co-pay assistance to Medicare Part D beneficiaries.

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

Sanofi makes information about its co-pay assistance programs, Insulins Val***you*** Savings Program, and SPC — including eligibility criteria — readily accessible to, and easily understandable for, patients. Sanofi publishes information about its patient support programs in a variety of forums, including on the Internet, through social media, through direct outreach to physicians, pharmacies and advocacy organizations (including those focused on diabetes awareness and education), in direct-to-consumer advertising, and over the phone to patients who contact the Sanofi patient support call centers.

[4] See OIG Advisory Opinion No. 14-05.
[5] *See* http://www.sanofipatientconnection.com/media/pdf/SPC_Application.pdf.

With respect to information on the Internet, patients can access information about Sanofi's patient support programs, including eligibility criteria for those programs, through: (1) program-specific Sanofi websites,[6] (2) the Teaming Up For Diabetes website (http://www.teamingupfordiabetes.com), the Sanofi US website, which provides a link to each program-specific website, and (3) on Medication Assistance Tool (https://mat.org/), a publicly available website maintained by the Pharmaceutical Research and Manufacturers of America (PhRMA), which provides a dedicated search engine to help patients search for financial assistance resources.

b. What are the eligibility criteria for the programs?

Outlined below are the eligibility criteria for each of the three Sanofi patient support program described above.

I. Sanofi Co-pay Assistance Programs for Insulin Products

Commercially insured patients, regardless of income level, are eligible to participate in Sanofi's co-pay assistance programs. To help Sanofi determine a patient's eligibility, the patient must answer the following questions:

- Are you a current resident of the United States, Puerto Rico, Guam, or the US Virgin Islands?
- Are you a patient or caregiver over 18 years old?
- Do you have private commercial health insurance?
- Do you currently receive Medicaid?
- Are you currently serving in the US military?
- Do you qualify for Medicare?

Based on the answers to these questions, Sanofi's vendor determines eligibility.

The Sanofi co-pay cards may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or other federal or state programs, including any state pharmaceutical reimbursement program. This restriction is in place to comply with OIG guidance relating to the Anti-Kickback Statute — namely that pharmaceutical manufacturers may not offer co-pay assistance to federal program beneficiaries.

[6] For eligibility and criteria information relating to Sanofi's Rx Savings Program for Lantus, patients can visit https://www.lantus.com/sign-up/savings-and-support. For eligibility and criteria information relating to Sanofi's Rx Savings Program for Toujeo, patients can visit https://www.toujeo.com/toujeo-savings-card-coupon-and-support. For eligibility and criteria information relating to Sanofi's Apidra $0 Co-Pay Program, patients can visit https://www.apidra.com/apidra/saving.aspx. For eligibility and criteria information relating to Sanofi's Soliqua 100/33 Savings Card, a patient can visit https://www.soliqua100-33.com/savings-andsupport. For eligibility and criteria information relating to the Sanofi Val*you* Savings Program, patients can visit https://www.admelog.com/insulins-valyou-savings-program/. For eligibility and criteria information relating to Sanofi's provision of free medicines through Sanofi Patient Connection, patients can visit Sanofi Patient Connection, http://www.sanofipatientconnection.com/patient-assistance-connection.

Sanofi supports policy reforms that would remove these restrictions, which would help to make insulins and other products more accessible and affordable to patients in federal programs.

II. Sanofi Insulins Val***you*** Savings Program

Uninsured and cash paying patients, regardless of income level, are eligible to participate in the Insulins Val***you*** Savings Program. Similar to the Sanofi co-pay assistance programs, to help determine a patient's eligibility for the Sanofi Insulins Val***you*** Savings Program, the patient must answer the following questions:

- Are you a current resident of the United States, Puerto Rico, Guam, or the US Virgin Islands?
- Are you a patient or caregiver over 18 years old?
- Do you have private commercial health insurance?
- Do you currently receive Medicaid?
- Are you currently serving in the US military?
- Do you qualify for Medicare?

Based on the answers to these questions, Sanofi's vendor determines eligibility.

Consistent with the OIG guidance explained above, as well as an advisory opinion from OIG concerning direct-to-patient cash price programs,[7] the Insulins Val***you*** Savings Program is not available to federal program beneficiaries, such as Medicare patients. Sanofi supports policy reforms that would remove these restrictions, so that we could extend the Val***you*** Savings Program to Medicare and other federally insured patients.

III. Sanofi Patient Connection

To be eligible for our patient assistance program through Sanofi Patient Connection, a patient must meet the following criteria:

- The patient must be a U.S. citizen or resident and be under the care of a licensed healthcare provider authorized to prescribe, dispense and administer medicine in the U.S.;

- The patient must also have:

    - No insurance coverage or access to the prescribed product or treatment via their insurance; or

    - Medicare Part D coverage and 1) not have coverage for a generic equivalent product and 2) have spent at least 5% of their annual household income on prescription medications covered through their Part D plan in the current year; and

[7] See OIG Advisory Opinion No. 14-05.

- In each instance, an annual household income of ≤250% of the current Federal Poverty Level (for example, in 2019, $64,375 for a family of 4).

Patients potentially eligible for Medicaid are required to provide documentation of a Medicaid denial before they may be eligible for patient assistance through Sanofi Patient Connection.

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

The product and program-specific websites referenced in footnote 6 above outline the documents and information that patients must submit to qualify for a Sanofi patient support program.[8] A more general description follows for ease of reference.

I. Sanofi Co-pay Assistance Programs for Insulin Products and Insulins Val***you*** Savings Program

To qualify for Sanofi's insulin co-pay assistance programs and Insulins Val***you*** Savings Program, a patient must provide his or her name, email address, and date of birth on the enrollment form. The patient also must certify that he or she meets all eligibility criteria. If the patient meets the criteria, the patient may access the program.

II. Sanofi Patient Connection

To qualify for free medicine through Sanofi Patient Connection, a patient and/or the patient's physician must complete an application, which can be submitted online, by fax, or through U.S. mail. The application requires, in part: the patient's HIPAA authorization for the release of the patient's identification and insurance information to Sanofi and their agents and representatives for benefit verification; information relating to the patient's prescription, including dosage and the diagnosis code; the state license number and signature of the prescriber; the patient's household income verification and authorization to run a soft credit inquiry/background check; and the patient's signature. The patient must also provide his or her own identifying information, including name, address, date of birth, social security number, and health insurance information, and identifying information for the prescriber.

[8] *See infra* Footnote 6.

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

The chart below outlines the estimated[9] number of patients that applied for, were approved, and were denied for Sanofi's insulin-related patient support programs during the 2018 calendar year:

Program	**Applications Received**	**Applications Approved**[10]	**Applications Denied**
Insulin-Related Co-Pay Assistance Programs and Insulins Val*you* Savings Program	382,000	250,841	56,000
Sanofi Patient Connection for Insulin Products	84,164	61,095	23,069

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

As a business practice, Sanofi tracks the top three reasons for denials of patient support program applications for insulin products. Those three reasons for 2018 are provided below for each of the three programs.

I. Sanofi Co-pay Assistance Programs for Insulin Products

The top three reasons for denial of a patient's application for an insulin co-pay assistance program are:

1) the patient has health care coverage for the insulin product under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs;
2) the patient is not a resident of the US; and
3) the patient does have commercial insurance and has been prescribed Admelog (in which case the patient is invited to apply for the Insulins Val***you*** Savings Program).

These three reasons represent 100% of the total application denials for Sanofi's Insulin Co-pay Assistance Programs.

[9] Sanofi does not track or maintain data regarding the total number of applications received and denied for insulin co-pay assistance programs and the Insulins Val***you*** Savings Program. The information provided regarding the total number of applications received and denied are estimates.
[10] The number of applications approved for Insulin-Related Co-Pay Assistance Programs and the Insulins Val*you* Savings Program reflects total unique patients approved for enrollment, rather than number of applications approved.

II. Insulins Val***you*** Savings Program

The top three reasons for denial of a patient's application for the Insulins Val***you*** Savings program are:

1) the patient has health care coverage for the insulin product under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs;
2) the patient is not a resident of the US; and
3) the patient has commercial insurance and utilizing one of our co-pay programs would allow the patient to access their insulin at a lower out-of-pocket cost.

These three reasons represent 100% of the total application denials for the Insulins Val***you*** Savings Program.

III. Sanofi Patient Connection

The top three reasons for denial of a patient's application for SPC are:

1) the patient has insurance coverage for the product;
2) financial eligibility for the program has not been met; and
3) an off-label diagnosis code was provided.

The first two reasons mentioned above represent 94% of the total application denials. If a patient is denied, the patient is offered the opportunity to apply for the Insulins Val***you*** Savings Program.

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

The reapplication process for Sanofi's insulin-related patient support programs varies by program and is designed to comply with OIG guidance.

I. Sanofi Co-pay Assistance Programs for Insulin Products and Insulins Val***you*** Savings Program

With respect to the insulin-related co-pay assistance programs and the Insulins Val***you*** Savings Program, patients must reapply for approval after the patient has used the co-pay card 12 times. Sanofi requires patients to reapply for approval under a co-pay assistance program or the Insulins Val***you*** Savings Program to help ensure that all enrolled patients continue to meet the eligibility criteria, including eligibility criteria relating to compliance with the Anti-Kickback Statute.

II. Sanofi Patient Connection

Patients eligible for Medicare Part D must reapply for the free drug through Sanofi Patient Connection at the end of every calendar year, which aligns with OIG guidance that patient

assistance must be available for the Medicare Part D plan year.[11] All other patients must reapply for approval for free drug through Sanofi Patient Connection every 12 months. Sanofi requires that patients reapply for approval every 12 months to ensure that patients' insurance status has not changed from the prior year and that they continue to meet eligibility requirements.

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

In 2018, Sanofi spent approximately $414.87 million on advertising for insulin products, which includes direct-to-consumer advertising, direct-to-physician advertising, and promotion of co-pay assistance programs for insulin and the Insulins Val***you*** Savings Program through the Internet, social media, direct outreach to physicians, pharmacies and advocacy organizations (including those focused on diabetes awareness and education), and over the phone to patients who contact the Sanofi patient support call centers.

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?

As with its patient support programs for insulin products, Sanofi publishes information about its patient support programs for all products in a variety of forums, including on the Internet, through social media, through direct outreach to physicians, pharmacies, and advocacy organizations, in direct-to-consumer advertising, and over the phone to patients who contact the Sanofi patient support call centers at (855) 984-6302.

b. What are the eligibility criteria for the programs?

I. Sanofi Co-Pay Assistance Programs

In addition to the co-pay assistance programs for insulin products described above, Sanofi has developed and maintains co-pay assistance programs for Aubagio, Lemtrada, Dupixent, Kevzara, Libtayo, Alprolix, Eloctate, Aldurazyme, Cerdelga, Cerezyme, Fabrazyme, Lumizyme, and Thyrogen, and Praluent. The eligibility criteria and other terms for each of the programs are outlined on the websites that describe each program.[12] Generally, there are two predominant

[11] 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005).

[12] Eligibility criteria for the Aubagio $0 Co-Pay Program can be found at https://www.aubagiohcp.com/support-resources?s_mcid=ps-AGH-google-Branded-Information-Co-Pay. Eligibility criteria for the Lemtrada Co-Pay Program can be found at https://www.lemtradahcp.com/patient-support. Eligibility criteria for the Dupixent MyWay Co-Pay Card Program can be found at https://www.dupixenthcp.com/atopicdermatitis/access-support/dupixent-myway. Eligibility Criteria for the Kevzara Connect Copay Card can be found at https://www.kevzarahcp.com/kevzara-connect. Eligibility criteria for the Libtayo Surround Commercial Co-Pay Program can be found at https://www.libtayohcp.com/accessinglibtayo/patientaccessandreimbursementsupport. Eligibility criteria for the Alprolix Co-Pay Program can be found at https://www.alprolix.com/resources/financial-

eligibility criteria that are consistent across all Sanofi co-pay assistance programs: 1) commercially insured patients can participate in Sanofi's co-pay assistance programs regardless of income level; and 2) consistent with OIG guidance relating to the Anti-Kickback Statute, Sanofi co-pay assistance may not be used in connection with prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical program.

II. Sanofi Free Drug Patient Assistance Programs

The predominant eligibility criteria for SPC described above in response to Question 1(b) generally apply to all of Sanofi's free drug patient assistance programs, with minor differences in eligibility criteria among the various programs.

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

I. Sanofi Co-Pay Assistance Programs

The information and enrollment forms a patient must submit to qualify for Sanofi's co-pay assistance programs for its other products are similar to the information and enrollment forms described in Question 1(c) above for insulin-related co-pay assistance programs.

II. Sanofi Free Drug Patient Assistance Programs

The information requirements and enrollment process outlined in response to Question 1(c) for SPC (including for insulin products) is similar to and generally consistent with the information requirements and enrollment process applicable to the other Sanofi free drug patient assistance programs.

assistance.aspx. Eligibility criteria for the Eloctate Co-Pay Assistance Program can be found at https://www.eloctate.com/resources/downloads.aspx?gclid=CjwKCAjw27jnBRBuEiwAdjQXDCWEfWNfC78ioeULgVejHZLwutiy9X7t4VrYvQSugdVZrI6UDx2iMxoCkBQQAvD_BwE&gclsrc=aw.ds. Eligibility criteria for the Aldurazyme Co-Pay Assistance Program can be found at https://www.aldurazyme.com/patients/patient-services/sanofi-genzyme-co-pay-assistance-program.aspx. Eligibility criteria for the Cerdelga Co-Pay Assistance Program can be found at http://cerdelga.com/co-pay.html. Eligibility criteria for the Cerezyme Co-Pay Assistance Program can be found at https://www.cerezyme.com/patients/patient_services/cerezyme_co-pay_assistance_program.aspx. Eligibility criteria for the Fabrazyme Co-Pay Assistance Program can be found at https://www.fabrazyme.com/patients/Patient-Services/co-pay-assistance-program.aspx. Eligibility criteria for the Lumizyme Co-Pay Assistance Program can be found at https://www.lumizyme.com/patients/patient_services/co-pay_assistance_program_prequalifier.aspx. Eligibility criteria for the Thyrogen Co-Pay Assistance Program can be found at https://www.thyrogen.com/patients/Financial-Assistance/Financial-Assistance-Programs.aspx.

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

Across its patient support programs in 2018, Sanofi approved a large number of applications that resulted in thousands of patients having access to Sanofi products at more affordable prices. Sanofi received 106,477 applications for free drug product provided through SPC. Of those applications, Sanofi approved 67,216 applications and denied 26,652 applications (12,609 applications were cancelled by the patient or the patient's provider prior to approval or denial). Sanofi is committed to helping patients access its products.

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

Please see the response to Question 1(e) above for information responsive to this question with respect to products provided through Sanofi Patient Connection. Sanofi Patient Connection includes insulins and certain other Sanofi product, but does not include certain other Sanofi products that are available through other patient assistance programs.

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

Please see the response to Question 1(f) above for information responsive to this question with respect to products provided through Sanofi Patient Connection. Sanofi Patient Connection includes insulins and certain other Sanofi product, but does not include certain other Sanofi products that are available through other patient assistance programs.

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

In 2018, Sanofi spent approximately $4.5 billion on advertising and marketing for all of its products.[13] Such spending is inclusive of public awareness campaigns to promote Sanofi patient support programs.

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.

Through the Val***you*** Savings Program, Sanofi helps to lower out-of-pocket costs for patients who manage their diabetes with the following products:

- Lantus
- Lantus SoloSTAR
- Admelog

[13] "Advertising and marketing" includes global spending on promotion and marketing management.

- Admelog SoloSTAR
- Apidra
- Apidra SoloSTAR
- Toujeo
- Toujeo SoloSTAR

Through Sanofi co-pay assistance programs, Sanofi helps to lower the out-of-pocket costs for patients who are prescribed the following products:

- Aldurazyme
- Alprolix
- Apidra
- Apidra SoloSTAR
- Aubagio
- Cablivi
- Caprelsa
- Cerdelga
- Cerezyme
- Dupixent
- Eloctate
- Fabrazyme
- Kevzara
- Lantus
- Lantus SoloSTAR
- Lemtrada
- Libtayo
- Lumizyme
- Multaq
- Praluent
- Soliqua 100/33
- Thyrogen
- Toujeo
- Toujeo SoloSTAR
- Toujeo Max SoloSTAR

Sanofi provides free medicine through patient assistance programs for the following products:

- Adacel
- Admelog
- Adlyxin
- Aldurazyme
- Alprolix
- Apidra
- Aubagio

- Cablivi
- Caprelsa
- Cerdelga
- Cerezyme
- Dupixent
- Elitek
- Eloctate
- Fabrazyme
- Imogam
- Imovax
- Jevtana
- Kevzara
- Lantus
- Lemtrada
- Libtayo
- Lovenox
- Lumizyme
- Menactra
- Mozobil
- Multaq
- Pentacel
- Praluent
- Priftin
- Soliqua 100/33
- Tenivac
- Thymoglobulin
- Thyrogen
- Toujeo
- Zaltrap[14]

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.

Sanofi's "Sanofi Cares North America" and "Genzyme Charitable Foundation, Inc" are 501(c)(3) organizations through which Sanofi makes its medications available free of charge to financially eligible uninsured and under-insured patients. Sanofi Cares North America provides

[14] Sanofi does not provide patient support for the following products: Ambien, Arava, Avalide, Avapro, Clolar, Eloxatin, Ferrlecit, Hectorol, Seprafilm, Synvisc, and Taxotere.

Sanofi products free of charge to eligible financially needy uninsured and underinsured patients through Sanofi Patient Connection. Sanofi Cares North America also donates product to five non-governmental organization partners—Americares, DirectRelief, Heart to Heart International, MAP International, and Project Hope—and to approximately one hundred summer camps with 501(c)(3) status for children with diabetes.

Under the US Internal Revenue Code, a corporation can claim a deduction for charitable contributions to qualifying organizations. The deduction is limited to 10% of the corporation's taxable income. The product donations described above qualify for that deduction and therefore reduce Sanofi's federal taxable income, subject to the limitations in the tax code. Sanofi also makes cash donations that qualify as tax deductible charitable contributions. As there is no ordering rule to distinguish between cash and product donations, it is not possible to determine exactly how much of the 2018 charitable deduction is attributable to product donations as compared to cash donations. Consistent with IRS requirements, Sanofi determines the amount of the charitable tax deduction for donations to foundations by calculating the lower of: (i) two times the cost of the drug (where cost is measured based on an adjusted WAC that subtracts certain discounts and fees); or (ii) cost plus half the product margin. This calculation is performed on a product-by-product basis.

Because Sanofi's 2018 tax return is not due until October 2019, Sanofi's 2018 deductible product donation amounts have not yet been finalized. At this point, and subject to change prior to filing, Sanofi estimates that product donations will result in a 2018 tax deduction of between $23 and $32 million.

The Honorable Nanette Díaz Barragán (D-CA)

1. **Sanofi has filed 74 patent applications on Lantus, and more than 90 percent of these were filed after the drug was already approved and on the market. I'm concerned that these patents are not related to innovative improvements to the drug, but are part of Sanofi's strategy to further delay competition and retain control of this market.**

   Please explain the innovative nature of these patents filed after the approval of Lantus, and why they merit additional exclusivity to the detriment of diabetes patients?

There are currently twenty-one patents listed in the FDA Orange Book for Lantus and Lantus SoloSTAR. Each patent granted on a Sanofi product, including the patents for Lantus and Lantus SoloSTAR, represents the US Patent and Trademark Office's (PTO) determination that the particular product innovation is worthy of patent protection. The PTO grants a patent only after conducting a lengthy examination process that tests whether the new invention meets all of the legal requirements for patentability, including that the invention is new, not obvious, and useful. Although many of the patents listed in the Orange Book were granted after FDA initially approved Lantus in 2000, FDA approval of a medicine does not foreclose future innovation with respect to that product. To the contrary, the PTO's patent process encourages ongoing innovation that further helps patients long after products are FDA-approved. Additionally, we note that patents granted after FDA approval do not limit competition in general, and have not limited competition in the diabetes market in particular. With respect to insulin, for example,

Lantus faces competition from a follow-on biologic insulin glargine that launched shortly after the loss of patent exclusivity for the Lantus compound, despite the twenty-one patents currently listed.

By way of background, the patents granted for Lantus reflect that Sanofi's initial discovery of insulin glargine and subsequent development of an improved insulin glargine formulation and a more convenient, easy-to-use injection pen to deliver the insulin glargine have enhanced the lives of millions of patients living with diabetes in the United States and worldwide. The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and to wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma, or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The initial discovery and development of insulin glargine were therefore significant. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The FDA approved insulin glargine under the tradename Lantus in 2000. But there was more to do to enhance the lives of patients with diabetes.

Lantus initially received FDA approval for, and launched, a vial; patients were required to inject the product with a syringe. Since that time, Sanofi has developed, received FDA approval for, and launched, several improved injection devices for administering glargine. Sanofi also reformulated the original Lantus vial formulation to solve the unexpected and unknown problem of potential cloudiness in prior Lantus vials and to make it more stable. The PTO awarded Sanofi two patents on this new formulation, both of which are listed in the Orange Book. Sanofi began selling its reformulated Lantus vial product in the U.S. in 2006, after the initial approval of Lantus.

Sanofi's latest pen delivery system, SoloSTAR, similarly has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with premier design firms to develop this pre-filled, disposable injection pen for self-administration, which in turn has improved the lifestyle and medication compliance of diabetes patients. The SoloSTAR contains numerous features specifically designed to address the needs of people with diabetes, who often have health complications such as impaired vision and reduced dexterity. The pen's

features include a clutch that can reversibly lock the complex device components in rotation to allow patients to "dial up" a dose for injection; dose dial stops that prevent patients from setting an excessive dose; a rotating dial that can easily correct an over-dialed dose; and a specially designed injection button that is easy for people with diabetes to depress and receive a highly accurate delivery of the set dose. All of the pen's complex mechanical features and parts were seamlessly incorporated into the SoloSTAR's design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007. It has subsequently won awards for its novel design. The patents currently listed in the Orange Book for Lantus SoloSTAR relate to the SoloSTAR pen injector dosage form.

The PTO granted Sanofi patents for each of these innovations, reflecting that each met the PTO's rigorous standards for patentability. Those patents protected Sanofi's innovations; they have not served to inhibit competition.

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

On December 14, 2018, Sanofi received a draft amendment to its Medicare Part D rebate agreement with OptumRx, Inc. (Optum). In the communication from Optum, Optum reported that a similar amendment would be forthcoming for the Sanofi-Optum commercial rebate agreement. The draft amendment requested that Sanofi provide advance written notice to Optum by March 1 of each calendar year if the following were to occur in that calendar year: 1) reduction of the WAC of any existing NDC; or 2) introduction or authorization of a lower priced authorized generic or a lower priced brand version of an existing NDC. Under the terms of the amendment, if Sanofi were to fail to notify Optum of a price reduction or launch of a lower list price alternative with the required advance notice, Optum would earn an "Effective Rebate Amount per Unit," calculated as a dollar amount, per unit, based on the original WAC, for a set period of time. Sanofi has not signed the proposed amendment.

   a. **Does Sanofi 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.**

With respect to insulins and most other Sanofi products, Sanofi is not party to any contractual requirements to provide supply chain partners, including health plans, PBMs, and wholesalers, with notice before lowering list price. Sanofi is currently party to contractual relationships with

specialty distributors for certain rare disease products that require advance notification of price changes.

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

No, Sanofi has not provided any of its supply chain partners with notice of a list price decrease.

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

Because PBM rebates are currently set as a percentage of a product's list price, absent agreement to the contrary with the PBM, a lower list price would result in lower aggregate rebates per unit to the PBM. As noted above, one PBM has asked for advance written notice of such list price reductions. Other PBMs are currently evaluating and proposing various options to address the issue of lower list prices.

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

Sanofi makes pricing changes based on its own independent assessment of the value proposition of the product, the competitive environment, patient access considerations, and investment in further product development or needs to reinvest in R&D more generally. Nevertheless, certain decisions by PBMs and wholesalers may affect a patient's ability to access Sanofi medicines. Because patient access considerations play a role in Sanofi's pricing decisions, actions by PBMs and wholesalers could have a future effect on those decisions.

2. In Sanofi's testimony, Sanofi notes that the average net price of Sanofi's most prescribed insulin, Lantus, has declined by over 30 percent since 2012 while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 60 percent over that same period. Which factor described in Sanofi's testimony (*e.g.*, list price, increase in number of high deductible health plans, changes in insurance design, changes to drug formularies, etc.) has had the greatest impact on the out-of-pocket burden for patients using insulin?

The formulary design for health plans and PBMs is determined independently by the health plan or its PBM. Sanofi does not have visibility into that decision-making process and therefore believes that this question is best addressed to the health plans, or PBMs that represent or negotiate on behalf of health plans. However, we can confirm that Sanofi offers significant rebates on certain of our products in a highly competitive marketplace, including for Lantus. These negotiations have resulted in net prices that are well below the product's list price. While we do not have insight into PBM relationships with their clients, or their clients' relationships with pharmacies and patients, we do know that Lantus' average net price since 2012 has declined by more than 30% while the average out-of-pocket burden for commercially insured and Medicare patients has increased by approximately 60% over the same time period.

3. According to a November 2018 I-MAK report on Lantus, 74 patent applications have been filed on Lantus and 95 percent of the patent applications on Lantus were filed after the drug was first approved and on the market in 2000.[15] Is this correct, and if so, why did Sanofi file these patent applications after the drug was first approved and on the market?

Sanofi does not know the basis for the statement in the I-MAK report and is therefore unable to confirm the information in it. That said, there are currently twenty-one patents listed in the FDA Orange Book for Lantus or Lantus SoloSTAR. The patents currently listed in the Orange Book for Lantus SoloSTAR relate to the SoloSTAR pen injector dosage form. Those patents, granted by the PTO, protect Sanofi's innovations. Sanofi files patent applications when it believes that there has been meaningful innovation worthy of patent protection, but it is the PTO that ultimately decides when it is appropriate to grant a patent, based on its assessment of patentability. Innovation does not cease simply because a product has been approved by FDA. As described above, FDA's approval of Lantus did not halt innovation on Lantus or curtail competition. Sanofi filed new patent applications after Lantus's initial approval to protect new innovations with regard to the Lantus formulation as well as with the SoloSTAR pen device.

a. How many of the patents relating to Lantus are on the insulin drug substance and how many are on the delivery device?

Of the twenty-one patents listed in the FDA Orange Book for Lantus or Lantus SoloSTAR, nineteen relate to the Lantus SoloSTAR injectable pen product and two relate to the Lantus vial product. The insulin glargine compound patents previously listed in the Orange Book for Lantus and SoloSTAR expired in 2009 and late 2014 and thus are no longer listed in the Orange Book. We note that, in addition to the patents, the FDA grants regulatory exclusivity to new molecular entities that meet statutory standards. Those exclusivities for Lantus did not expire until February 2015.

b. How many potentially competing products for Lantus has Sanofi challenged because of the existing patents on Lantus?

Sanofi has initiated five patent infringement lawsuits against competitors to protect its innovations relating to Lantus.

In two lawsuits against Eli Lilly (one relating to the company's application to market and sell a vial product and another relating to its application for a pen product), Sanofi asserted infringement of certain formulation and device patents that were listed in the FDA Orange Book for Lantus or Lantus SoloSTAR. Eli Lilly and Sanofi entered into a settlement agreement to resolve one of the lawsuits in September 2015. Under the settlement, Eli Lilly was permitted to market Basaglar, a follow-on biologic to Lantus SoloSTAR, in December 2016, more than seven years before the last expiration date of the patents asserted in the Eli Lilly lawsuit. Basaglar is

[15] I-MAK, Overpatented, Overpriced: Lantus (Nov. 1, 2018), *available at* https://www.i-mak.org/lantus/.

currently on the market and competing against Lantus. The court dismissed the other lawsuit against Eli Lilly after the company decided against commercializing the product at issue.

In a September 2016 lawsuit against Merck following Merck's application for a follow-on biologic for Lantus and Lantus SoloSTAR, Sanofi asserted infringement of several drug and device patents listed in the FDA Orange Book for Lantus and Lantus SoloSTAR. Sanofi also filed a separate lawsuit against Merck in August 2017 alleging infringement of two other Orange Book-listed patents. Those lawsuits were both dismissed voluntarily at Merck's request, as Merck unilaterally decided not to commercialize follow-on versions of Lantus or Lantus SoloSTAR.

A lawsuit against Mylan and its development partner Biocon is ongoing, and involves claims that Mylan and Biocon have infringed certain formulation and device patents that are listed in the FDA Orange Book for Lantus or Lantus SoloSTAR.

c. What impact, if any, did these patent applications have on the launch of Basaglar?

Patent applications do not affect competition. Thus, Sanofi's patent applications have not impeded the launch of Basaglar, which occurred in 2016 -- more than seven years before the last expiration date of the patents asserted in the Eli Lilly lawsuit and not long after the expiration of the Lantus compound patent. Basaglar is currently on the market and competing against Lantus.

4. Eli Lilly launched a follow-on insulin product—Basaglar—in 2016 to compete with Lantus. What impact, if any, has the launch of Basaglar had on the list price and net price of Lantus?

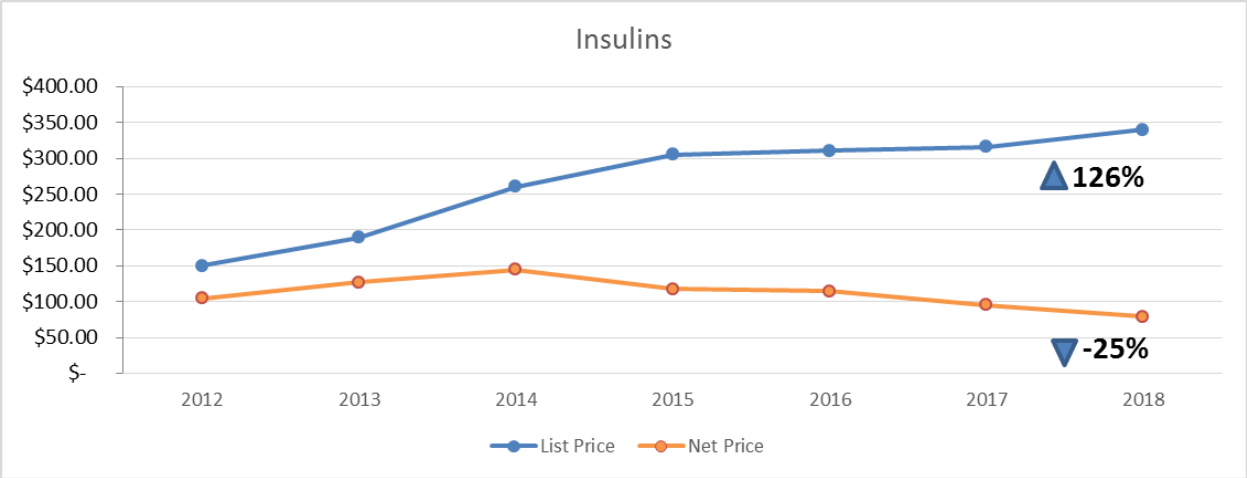
The competition between Lantus and Basaglar has led to Sanofi substantially lowering the Lantus net price, as compared to prior years. Sanofi hopes that those price reductions will benefit patients but, as explained in our testimony and in the below chart, that does not appear to have been the case to date. As with all other Sanofi pricing decisions, any increase in the list price for Lantus since the launch of Basaglar has been consistent with Sanofi's progressive pricing policy, which includes a commitment to keep annual list price increases at or below the projected U.S. National Health Expenditure growth rate.

5. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Sanofi's testimony, Sanofi said that, between 2012 and 2018, the average aggregate net price across all Sanofi insulin products has declined by 25 percent while the list price has increased by 126 percent. 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.

As shown in the below chart, between 2012 and 2018, the average aggregate net price across all Sanofi insulin products has declined by 25 percent while the list price across all Sanofi insulin products has increased by 126 percent.

Sanofi Insulins List vs. Net Price Changes Between 2012-2018



In May 2017, Sanofi announced its progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines.[16] These principles include a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. These principles apply to all of our prescription medicines if a price increase results in more than a $15 annual increase in the price of the medication. In addition, we committed to making both our average aggregate list and net price changes across our portfolio transparent to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain. In 2018, all of our price increases were consistent with our policy, as are all pricing actions we have taken in 2019.

With respect to PBMs interests, as HHS and HHS OIG have observed in their recent proposed Medicare Part D rebate rule, rebate payments and other forms of payment to PBMs are often based on a percentage of list price. Whether this causes PBMs to favor higher list price products over lower cost products is a question best directed to them, but it is clear that payments based on a percentage of list price result in a higher margin for the higher list price product than for the lower list price product. To illustrate this point, consider Sanofi's experience with Admelog, a biosimilar of insulin lispro. When it launched in 2017, Admelog was the lowest list price

[16] *See* https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf.

mealtime insulin product, yet it was not, and still is not, covered by any Medicare Part D or commercial plans. At the committee hearing, PBM witnesses testified that this was due to another product having a lower net price and a higher list price.[17] As we have experienced, within the current system, declining prices for payers or new treatments priced at responsibly lower list prices are no guarantee that those actions will translate to affordability or access for patients.

6. 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?

The payment of administrative fees that are a percentage of product list prices is a standard industry practice. The Anti-Kickback Statute safe harbor for GPO administrative fees protects percentage of list price-based administrative fees up to 3% of list price, and further protects percentage of list price-based fees above 3% if the fee amount is disclosed to the members of the GPO. In 2003, the OIG extended this safe harbor to PBM administrative fees.[18] Nevertheless, because percentage of list price payments could potentially create incentives for manufacturers to maintain high list prices, Sanofi supports reform of the current system to ensure that administrative fees are fixed and reflect fair market value for bona fide services performed for Sanofi.[19]

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

Yes, Sanofi supports a shift toward flat fees throughout the supply chain. Specifically, Sanofi supports the recent HHS OIG Proposed Rulemaking regarding the creation of a new safe harbor for PBM fees, and Sanofi has submitted comments on those proposals.

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**

[17] Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. on Oversight and Investigations, 116 Cong. 51 (2019) (Statement of Amy Bricker, Senior Vice President, Supply Chain, Express Scripts).
[18] Notice, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).
[19] *Id.*

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?

There is substantial innovation in the diabetes marketplace, including for insulin products. Diabetes continues to be a critical area of focus of Sanofi's research and development efforts. Since Sanofi's discovery and development of Lantus, Sanofi has continued to invent new formulations to meet individualized patient needs. For example, Toujeo, approved by the FDA in 2015, more closely mimics endogenous basal insulin secretion and provides an improved therapeutic effect at a higher concentration of glargine than Lantus; Toujeo exhibits a different and longer-acting profile. In 2017, Sanofi launched Soliqua 100/33, a fixed-ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal side effects. Soliqua 100/33 has demonstrated reduction in average and overall glucose levels while also reducing the gastrointestinal side effects related to GLP-1s.

There has also been significant innovation related to insulin delivery mechanisms. As noted above, the launch of Lantus SoloSTAR has enhanced the lifestyles and medication compliance rates of millions of diabetes patients throughout the US and around the world. Sanofi has also developed Toujeo SoloSTAR, a pre-filled disposable injection pen that includes innovative design features and attributes, ranging from the length of time it can be held without overheating the contents to other ergonomic features designed to make the device easier to use.

Sanofi's scientists are working every day on ways to transform the future of diabetes care by addressing the underlying disease. Sanofi has initiated multi-pronged research efforts aimed at preventing progression of the disease, reducing insulin-dependence, and restoring insulin-producing cells though stem cell technologies. Sanofi researchers are also exploring the molecular mechanisms by which obesity leads to diabetes, and they are working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. Sanofi is committed to continued investment so that we can bring better and more convenient breakthrough treatments to diabetes patients.

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?

Patents are not preventing innovation and competition. To the contrary, there is robust competition among diabetes drug manufacturers. This competition only continues to intensify with the introduction of additional generic and biosimilar medicines. As with any technology, this a reflection of the number of problems that had to be solved with novel and innovative solutions to bring the technology to the market. Sanofi's patents reflect novel inventions, as evidenced by PTO's grant of those patents. US patents are granted only after a comprehensive examination process by the PTO that tests whether the invention meets all the legal requirements of patentability including that the invention be new, not obvious, and useful.

Sanofi invests billions of dollars in the pursuit of new treatments for patients and our patents serve to protect our innovative discoveries. From 2012 through 2018, Sanofi's total research and development (R&D) investment in diabetes was approximately $4.5 billion. In 2018 alone, Sanofi's total research and development investment in diabetes was approximately $800 million. Sanofi plans to maintain this level of research and development investment through 2021. From a life sciences perspective, the patent system serves to attract the risk-taking, entrepreneurial spirit, and the capital needed to engage the brightest minds in science to solve some of the world's greatest health challenges—in short, the patent system encourages innovation.