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United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

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February 22, 2019

VIA ELECTRONIC TRANSMISSION

Mr. Olivier Brandicourt
Chief Executive Officer
Sanofi

Dear Mr. Brandicourt,

The Centers for Disease Control and Prevention has estimated that more than 30 million Americans have diabetes, equaling roughly 10 percent of the population, and the American Diabetes Association has estimated that 1.5 million people will receive new diagnoses each year.¹ For some with diabetes, particularly Type 1, patients require daily insulin injections or an insulin pump to manage blood sugar levels. Even though insulin has been used to treat diabetes for almost one hundred years, its price has continued to increase, putting stress on patients and taxpayers alike. For example, the price for Lantus increased from \$244 to \$431 between 2013 and 2019, an approximately 77% increase.²

The substantial increase in the price of insulin has caused significant concern among patients and Congress. On January 29, 2019, the Senate Finance Committee held a hearing to discuss increased drug prices, including insulin.³ At that hearing, Kathy Sego testified that her son was diagnosed with Type 1 diabetes at the age of seven. Years later, when her son started college, he picked up his monthly insulin supply at a cost of \$1,700 – with insurance. Worried about the financial burden to his parents, her son began to ration his insulin at the sacrifice of his health. Back home in Iowa and Oregon, our own constituents tell us they have faced similar financial hardships that have caused them to ration their insulin, and health care providers share concern over the number of patients who are unable to afford insulin or who spend a significant amount of their income to purchase it.⁴ And news reports have noted that some Americans have

¹ Centers for Disease Control and Prevention, *New CDC report: More than 100 million Americans have diabetes or prediabetes*, (July 18, 2017), <https://www.cdc.gov/media/releases/2017/p0718-diabetes-report.html>; American Diabetes Association, *Statistics About Diabetes*, <http://www.diabetes.org/diabetes-basics/statistics/> (Last edited March 22, 2018).

² Insulin, GoodRx.com, <https://www.goodrx.com/insulins> (last accessed Feb. 21, 2019).

³ Senate Committee on Finance, *Drug Pricing in America: A Prescription for Change, Part I*, (Jan. 29, 2019), <https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-i>.

⁴ Dr. Naomi Kaplan, *Costs of lifesaving drugs rising faster than inflation: Study*, ABC News (Jan. 12, 2019), <https://abcnews.go.com/beta-story-container/Health/costs-lifesaving-drugs-rising-faster-inflation-study/story?id=60338388>; Des Moines Register, *Iowa man loses job, health insurance, access to insulin and his life, When will Congress act?*, (Feb. 6, 2019), <https://www.desmoinesregister.com/story/opinion/editorials/2019/02/06/editorial-iowa-jesse-lutgen-loses-job-insurance-insulin-life/2748651002/>; Des Moines Register Editorial, *Every month, I worry about being able to stretch my insulin to my next paycheck*, (Feb. 6, 2019), <https://www.desmoinesregister.com/story/opinion/editorials/2019/02/06/struggling-drug-costs-quickly-learned-ration-my-insulin/2772054002/>; Nigel Jaquiss, *Oregonians Pay Way More Than They Should for Insulin, One*

even traveled to Mexico to purchase insulin because of its high cost in the United States.⁵ These hardships can lead to serious medical complications that are entirely preventable and completely unacceptable for the world's wealthiest country.

In addition, the increased price of insulin has caused federal programs to pay more for diabetes care. For example, in 2012, Medicare Part D spending for just one insulin product, Lantus, was approximately \$1.1 billion in 2012 and gross Medicaid spending was approximately \$314 million. In 2016, just four years later, Medicare Part D spending increased to approximately \$1.7 billion and gross Medicaid spending more than doubled to approximately \$785 million.⁶

When one insulin product costs the taxpayer more than \$1 billion in one year, the American people ought to know how the company prices its product. We are concerned that the substantial increases in the price of insulin over the past several years will continue their upward drive and pose increasingly severe hardships not only on patients that require access to the drug in order to stay alive but also on the taxpayer.

Accordingly, in order to more fully understand how Sanofi sets prices for its insulin products, please answer the following questions no later than March 8, 2019:

1. Please provide a list of every insulin product sold in the United States since January 1, 2014, including any variations in formulation, delivery method, or dosing size that would require a product to have a unique National Drug Code (NDC) label. For each product, please provide the following information in an Excel Workbook and in hard copy form:
 - a. A brief description of the product, its dosage size, the volume sold in the United States for each year since January 1, 2014, revenue generated in the United States for each year since January 1, 2014, and gross margin for each year since January 1, 2014.
 - b. Every list price (i.e., the Wholesale Acquisition Cost or WAC) since January 1, 2014, including the date when each list price was set, changed and went into effect. Please provide these prices on the basis of dosage units, i.e. the form in which they are marketed and sold. Please also specify how you are reporting the price, e.g. per box, per bottle or per milliliter.
 - c. Every net price that was in effect at any time since January 1, 2014, for Part D plans, and all pharmacy benefit managers ("PBM") or other entities that represented or negotiated on behalf of a Part D plan, as well as your company's

Couple is Fighting to Change That, Willamette Week (Nov. 14, 2018), <https://www.wweek.com/news/2018/11/14/oregonians-pay-way-more-than-they-should-for-insulin-one-couple-is-fighting-to-change-that/>.

⁵ NBC Nightly News, *Why some diabetics are going to Mexico for insulin*, (Jan. 22, 2019), <https://www.nbcnews.com/nightly-news/video/why-some-diabetics-are-going-to-mexico-for-insulin-1430028355710>.

⁶ Centers for Medicare and Medicaid Services, *Medicare Part D Drug Spending Dashboard and Data*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html> (last accessed Feb 21, 2018); Centers for Medicare and Medicaid Services, *Medicaid Drug Spending Dashboard*, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/Medicaid.html> (last accessed February 21, 2018).

10 largest commercial plans, as defined by the number of covered lives. For each net price, please include the date on which the price went into effect. Please provide these prices on the basis of dosage units, i.e. the form in which they are marketed and sold. These prices should be reported on the same basis as the response to Question 1(b).

- d. Every formulary placement since January 1, 2014, for any Part D plan, and all PBMs or other entities that represented or negotiated on behalf of a Part D plan, and your company's 10 largest commercial plans, as defined by the number of covered lives.
2. For each product line, please describe all changes to the formulation, delivery method or dosing size that have been made since January 1, 2014. For each product line, please also answer:
- a. How did the change(s) associated with a new NDC add value to patients?
 - b. What were the research and development costs related to the changes described in Question 2(a)? How did the changes described in Question 2(a) affect manufacturing costs?
 - c. Please explain the relationship between the changes in formulation, delivery method and/or dosing size, and any changes in list (WAC) or net dosage unit prices.
 - d. Note any instance in which your company sought and/or received a new patent since January 1, 2014. Please provide all patent applications and approvals. Please also note any NDCs with which the patents are associated.
 - e. The gross and per-unit manufacturing costs for each insulin product with an NDC.
3. For each PBM that has been provided a rebate, discount, or other price concession for one or more of your company's insulin products, please provide:
- a. The amount of the rebate, discount, or other price concession for coverage of the product and the dates the concession was in effect;
 - b. A description of how the rebate or other price concession impacted the product's formulary placement; and
 - c. A description of any other terms or contract conditions that were agreed to as part of the rebate or other price concession negotiation that would affect patient access, including but not limited to, elimination of prior authorization, step

therapies, volume targets, revenue targets, and other utilization management methods. Please include the dates such concessions remained in effect.

4. Please provide all contracts, including but not limited to, supply agreements, pricing agreements, rebate agreements, and other pricing concession agreements involving insulin products that were agreed to with Part D plans, PBMs or any other entities, such as specialty pharmacies, that represented or negotiated on behalf of a Part D plan, and your company's 10 largest commercial plans, as defined by the number of covered lives, that involved insulin products. Please provide all contracts that were in effect at any time on or after January 1, 2014.
5. Please describe the Research and Development program for each of your insulin product lines and what items are included in this cost category. For each fiscal year since January 1, 2014, please provide an itemized accounting of your R&D costs that breaks out costs by activity (e.g., basic research, clinical trials for marketing approval, post-marketing research and surveillance, etc.). Please explain how each activity directly supports R&D for insulin products.
6. Please describe your Marketing and Advertising program for each of your insulin product lines. For each fiscal year since January 1, 2014, please provide an itemized accounting of costs, including but not limited to your costs attributable to your sales force, market research, product samples, third party vendors, and medical conference sponsorships. Separately, for the same timeframe, please provide an itemized accounting of the cost of marketing activities targeting prescribers, and direct-to-consumer advertising.
7. With respect to your company's process for pricing insulin, please answer the following:
 - a. Please describe your company's process for making pricing and market access decisions related to its insulin products, including how account managers, brand managers, pricing committees, outside consultants and other entities contribute to decisions regarding price, the steps that are involved in determining prices, any internal approval processes, and how prices are communicated to wholesalers, payers and other outside entities.
 - b. Please provide the names and titles of all company officials that have final pricing authority for your company's insulin products.
 - c. Please provide all written and electronic communications records that were sent, received, or otherwise provided to your company's senior leadership related to proposed pricing changes for insulin products since January 1, 2014. Please include any marketing studies that were used in connection with pricing decisions.

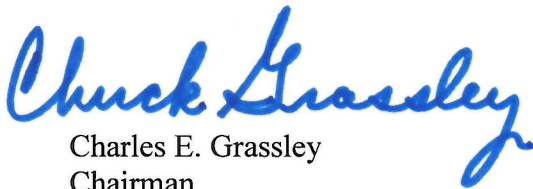
8. Please provide a list all internal and external programs that your company has used and funded since January 1, 2014, to financially assist patients purchasing insulin or obtaining free insulin. For each program, please list:
 - a. What type of program it is, for example, a coupon program, an internal patient assistance program, an external patient assistance program, a charity care program, or some other type of program. In each case, please describe how these programs were administered, through an electronic system, debit cards, physical coupons, vouchers, or some other method, and who administered them.
 - b. Eligibility requirements and eligibility exclusions.
 - c. How much money the company has spent on the program for each fiscal year since January 1, 2014. In your answer, please describe how your company calculates its spending on such programs. In other words, when your company accounts for free or discounted products, is it using a product's manufacturing price, retail price, list price, or some other method?
 - d. The number of patients in the United States who were served by the program for each fiscal year since January 1, 2014.
 - e. What percentage of total patients who used your company's insulin products did the program cover each year?
 - f. The amount of revenue and net income each program generated.
 - g. What was the abandonment rate of patients who were unable to fill their prescriptions at the pharmacy? Did your company or the entities it funded make any effort to follow up with patients who dropped out of these programs?
9. Please describe how the costs of the assistance programs are accounted for within your company's financial statements. Please also describe the types of market information, such as prescribing and use patterns, that your company collects from different types of patient assistance programs and patient hub services.
10. Please provide a list of all contributions since January 1, 2014, that your company has made to any tax exempt organizations working on issues related to diabetes, including but not limited to patient groups, disease awareness groups, medical or professional societies, universities or hospitals, industry associations or leagues. For each contribution, please provide the name of the organization that received the donation, the date the donation was made, the amount of the donation, and a description of the purpose of the contribution (i.e., was the contribution for the general fund, a specific purpose to a specific program, or continuing medical education). Please also note whether the contribution was unrestricted or restricted; if it was restricted, please explain all

restrictions. Finally, if your company maintains a foundation or other separate charitable arm, please provide the name of all such entities, and list all diabetes-related donations made from that entity or entities.

11. If the proposed rule from the Department of Health and Human Resources and its Inspector General, *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*,⁷ is implemented, please describe how it will impact the pricing of your company's insulin products.

Should you have questions, please contact Josh Flynn-Brown of Chairman Grassley's Committee staff and Peter Gartrell of Ranking Member Wyden's Committee staff at 202-224-4515.

Sincerely,



Charles E. Grassley
Chairman
Senate Finance Committee



Ron Wyden
Ranking Member
Senate Finance Committee

⁷ Proposed Rule, *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*, 84 F.R. 2340, (Feb. 6, 2019), 3<https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals>.