



**Testimony of Olivier Brandicourt, M.D.  
Chief Executive Officer  
Sanofi**

**Before the Senate Committee on Finance  
February 26, 2019**

Chairman Grassley, Ranking Member Wyden, and Members of the Committee, thank you for the opportunity to appear before the Senate Committee on Finance to discuss pharmaceutical pricing, affordability, and patient access in the United States. I am Dr. Olivier Brandicourt, the Chief Executive Officer of Sanofi.

At Sanofi, we work passionately every day to understand and address the health care needs of patients around the world. We are dedicated to solving patients' most serious health challenges in numerous therapeutic areas, including diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis (MS), rare diseases, and rare blood disorders. We are also devoted to preventing diseases through the research, development, and delivery of vaccines. And we contribute to improving the health of people around the world through our broad portfolio of consumer health products.

Sanofi's U.S. subsidiaries have a rich history in the United States dating back over 100 years. We currently employ more than 13,000 professionals across the United States in a broad range of critical roles, including business operations, research and development, and manufacturing, with our most significant presence in Massachusetts, where we are the largest employer in the life sciences industry, and major centers of operation in New Jersey, Pennsylvania, and Tennessee.

Last year, Sanofi spent almost \$7 billion on research and development, an increase of approximately 7 percent from 2017, which reflects our commitment to bringing better therapies to patients. Sanofi plans to maintain this level of R&D investment through 2021, and our R&D pipeline now contains 81 projects, including 33 new molecular entities in clinical development, and 35 projects that are in Phase III or have been submitted to regulatory authorities. This investment means that Sanofi potentially will seek approval for nine new medications in the next three years, primarily in therapeutic areas where Sanofi sees the greatest nexus between our expertise and patient need: diabetes, vaccines, oncology, immunology, rare diseases, and rare blood disorders.

Our work in R&D includes more than a dozen compounds for the treatment of various kinds of cancers, and we are employing cutting-edge approaches in an effort to make significant advances for patients. Our research includes potential treatments to help the body's own immune system fight cancer, and antibody drug conjugates that we believe can deliver cytotoxic drugs to tumors while sparing normal tissue. Earlier this month, we announced successful results with one such candidate in a mid-stage trial in lung cancer, and we intend to initiate a pivotal study later this year.

## I. Rising Costs for Patients

While the research and development landscape has fundamentally changed, the landscape in which patients access medications has also fundamentally changed, and not for the better. Affordability of medicines is a real and growing challenge for too many Americans. We understand the anger of patients who cannot afford the medicines they or their loved ones need due to rising out-of-pocket drug costs.

There is no single root cause to the problem of rising patient out-of-pocket costs, and in order to develop meaningful solutions for patients, it is critical to take a comprehensive look at what is driving rising costs for patients. Given the number of factors that contribute to determining out-of-pocket costs for patients, every part of the supply chain, including manufacturers, has a role to play in solving this problem.

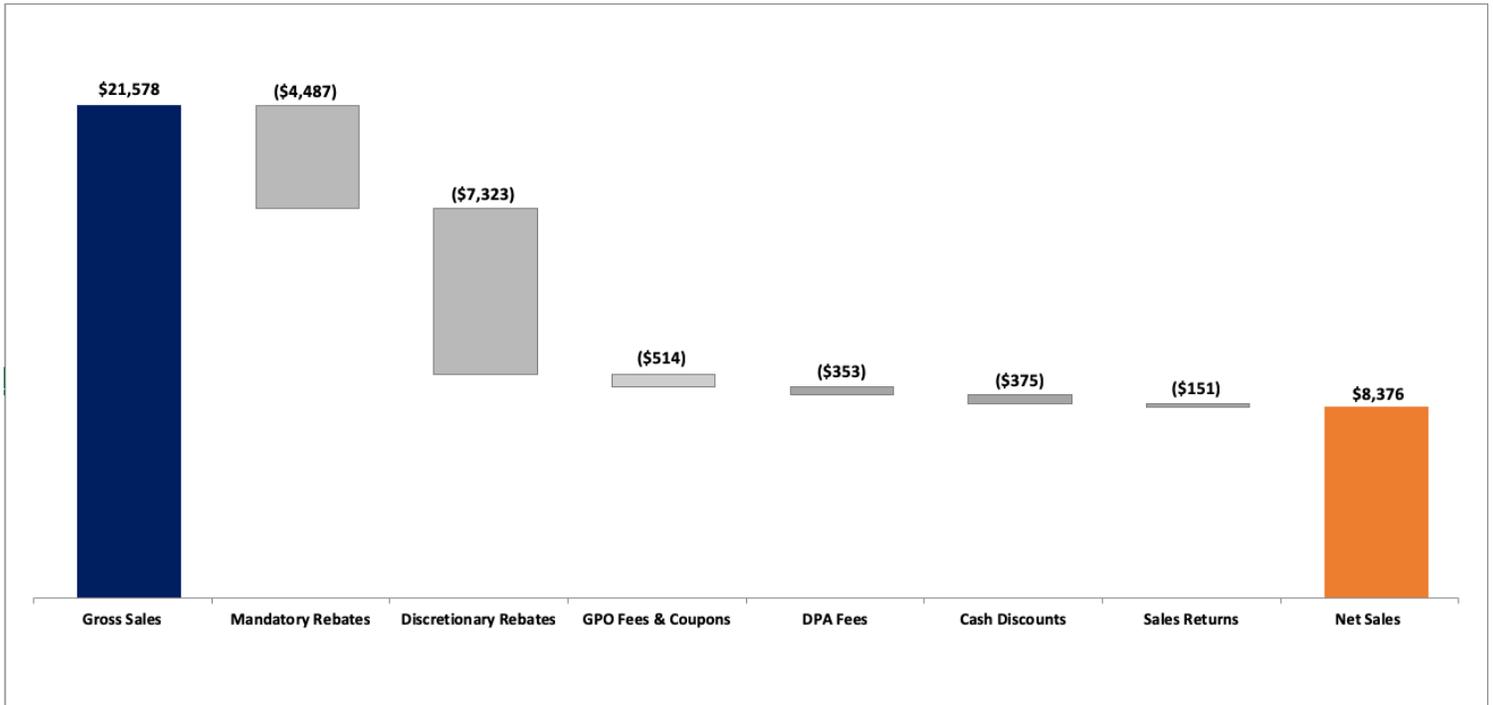
We want everyone – including patients, providers, payers, pharmacy benefit managers (PBMs), policy makers, and regulators – to understand why we set prices as we do, and to reaffirm our commitment to our core principles of access, affordability and innovation. An important component of pricing includes the intersection between the list prices of our medicines, the net prices we actually receive after accounting for all rebates and other discounts, and out-of-pocket costs.

While list prices often receive the most attention, they reflect the initial price we set for our medicines. They are not the amount Sanofi receives nor the prices typically paid by government and commercial insurers, employers, or PBMs. Under the current system, players within the supply chain – including PBMs, plans, wholesalers, distributors, and group purchasing organizations – receive either rebates and/or fees based on a percentage of the list price. Their economic incentives are therefore directly linked to the list price. And as long as the net price grows at a predictable rate, the greater the list price, the greater the economic returns for many players in the supply chain. Manufacturers, in turn, must account for anticipated rebates and other discounts when setting their list price.

Thus, list price is the starting point for negotiations with payers, and it is often the basis for patient out-of-pocket costs. But focusing solely on the list price does not tell the whole story. In the current system, manufacturers pay significant rebates as a percentage of the list price to both government and private payers, as well as other intermediaries, in an effort to improve access for patients. In 2018, 55 percent of Sanofi's gross sales were given back to payers as

rebates, including \$4.5 billion in mandatory rebates to government payers and \$7.3 billion in discretionary rebates. As described later in my testimony, due to these rebates, the average aggregate net price of our products, including our insulin products, actually has declined over the last number of years.

**Sanofi and Sanofi Genzyme U.S. Gross to Net 2018 Breakdown\***



\* Below are the summarized categories (by type) for various transactions:

**Mandatory Rebates:** Medicaid, VA-DOD, Tricare, 340B, Medicare Coverage Gap

**Discretionary Rebates:** Commercial, Medicare, Managed Medicaid, Medicaid Supplemental, GPO, Institutional Discounts

**Government Purchasing Organization (GPO) Fees & Coupons:** Fees paid for administration of Sanofi’s agreements with Group Purchasing Organizations on behalf of their members and various copay assistance programs

**DPA Fees:** Performance based fees earned by wholesalers for providing complete sales information and maintaining targeting inventory rates

**Cash Discounts:** Trade discounts offered to wholesalers for prompt payment of invoices

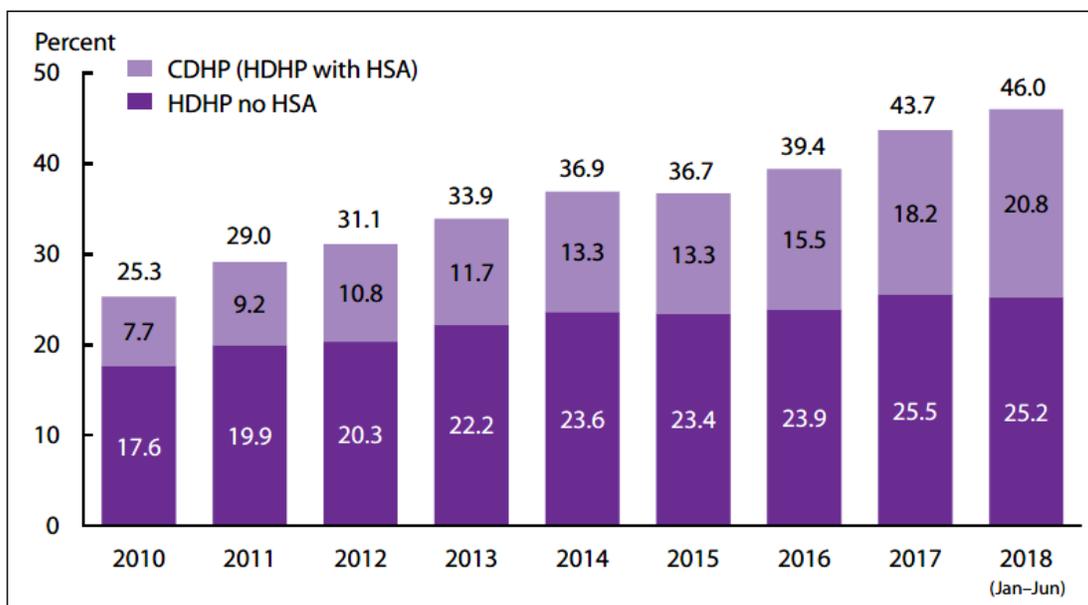
**Sales Returns:** Netted with Clawback, Other Corrections / Credit Memos

Sanofi provides rebates to PBMs and health plans to improve patient access to, and affordability for, Sanofi medicines. We want these rebates, which lower net prices, to benefit patients. Unfortunately, under the current system, savings from rebates are not consistently passed through to patients in the form of lower deductibles, co-payments or coinsurance amounts.

For some patients, out-of-pocket costs are calculated based on a medicine’s list price. However, based on variability in plan design, the list price alone does not explain patients’ increasing affordability issues.

For instance, in some cases, affordability issues are the result of changes in health plan designs, such as the increase in the number of high deductible health plans. Among those with private health insurance, enrollment in high deductible health plans (HDHPs) has generally increased since 2010. The design of these plans generally requires patients to pay the full list price of medicines during the deductible phase of the program, rather than the negotiated drug price available when the insurance portion kicks in.

**Percentage of persons under age 65 enrolled in a high-deductible health plan or in a consumer-directed health plan, among those with private health insurance coverage: United States, 2010–June 2018\***



NOTES: CDHP is consumer-directed health plan, which is a high-deductible health plan (HDHP) with a health savings account (HSA). HDHP no HSA is a high-deductible health plan without an HSA. The individual components of HDHPs may not add up to the total due to rounding. Data are based on household interviews of a sample of the civilian noninstitutionalized population. SOURCE: NCHS, National Health Interview Survey, 2010–2018, Family Core component.

*\*Chart reproduced from ME Martinez et al., National Center for Health Statistics, Health Insurance Coverage: Early Release of Estimates from the National Health Interview Survey, January - June 2018 (November 2018).*

In other cases, affordability issues are caused by changes in insurance design which increasingly ask patients to pay higher cost-sharing for their medicines, even when the price of those medicines has stayed relatively flat or has declined for the health plan. For example, as noted later in my testimony, the average net price of Lantus, our most prescribed insulin, 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. In this case, not only are discounts apparently not being passed on to patients, but

patients are in fact being asked to pay more when PBMs and health plans are paying less for the medicine. This situation defies logic and should not happen.

Increasing out-of-pocket costs also can result from changes to prescription drug formularies, which have a significant impact on the amount of out-of-pocket costs a patient will be asked to pay. A recent opinion piece in the New York Times<sup>1</sup> powerfully highlights how changes to prescription drug formularies not only can create confusion and frustration for providers and patients, but also ultimately increase costs for patients when the medicines they need are not covered on a formulary's preferred tier.

The impact of the role each of these factors plays in out-of-pocket costs for any individual patient is highly variable, thus compounding the complexity of this issue. Out-of-pocket costs for a medicine for any particular patient depend on a number of factors in addition to list price, including: (1) what portion, if any, of a manufacturer's rebates a PBM or payer passes through to the patient, (2) the benefit design of the patient's health plan, and (3) the level of reimbursement negotiated between the patient's plan and the particular pharmacy. Each of these factors varies significantly among plans and pharmacies – even within the same health insurance company or PBM receiving the same manufacturer rebate – creating confusion and frustration for patients.

Given the complexity in the system and number of factors that impact out-of-pocket costs, every part of the health care system has an obligation to work to solve this problem. I am grateful that this Committee – and others – are taking a holistic approach to collecting information both on what is causing the problem for patients, and also on solutions to address patient access and affordability without undermining the incentives and rewards for scientific risk-taking and discovery that are the hallmark of the United States ecosystem and economy.

I am here today to share Sanofi's story, the actions we have taken to improve patient access and affordability, and our ideas about what more can be done.

## II. Sanofi Actions to Improve Patient Access & Affordability

As a global health care leader, Sanofi has a long-standing commitment to promoting health care systems and policies that make our treatments accessible and affordable to patients in need. We believe we can play an important role in the development of constructive solutions that will benefit both patients and the healthcare system as a whole. I will address some of our ongoing initiatives and recommendations for solutions in my testimony.

Sanofi's ultimate goal, detailed below, is to encourage a transition to a value-driven health care system that provides incentives for continued improvements in patient care while increasing access and affordability. Given the complexities of the current system, changes must be approached thoughtfully, with a focus on establishing processes that will both enable

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<sup>1</sup> See <https://www.nytimes.com/2019/01/18/opinion/cost-insurance-diabetes-insulin.html>.

affordable access to treatment and protect innovation in an era of potentially transformative scientific advancements.

Sanofi is – and will continue to be – an industry leader in helping to address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are influenced or controlled by others in the health care system, including other manufacturers, we recognize that there are actions we can take to help improve access and affordability for patients. For our part, we recognize that we must price our medicines transparently and according to their value, while at the same time contributing to broader solutions that improve patient outcomes and the financial sustainability of the U.S. health care system.

Policy changes are required across the entire health care system. But we are not waiting for systemic change to arrive before taking action. Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability for patients. Whether it has been launching new medicines in multiple sclerosis and rheumatoid arthritis at disruptively low prices, limiting price increases to an external benchmark of overall medical spending, or lowering the net price of a medicine, Sanofi has approached the challenge of access and affordability not with words, but with actions.

### III. Sanofi Pricing Principles and Actions

Two years ago, Sanofi announced our 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.<sup>2</sup>

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 pricing decision 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. Across our entire portfolio of medicines, the average aggregate list price increase was 4.6 percent while the average aggregate net price – that is, the actual price paid to Sanofi – declined by 8.0 percent.

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<sup>2</sup> See [https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription\\_Medicine\\_Pricing\\_2019.pdf](https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf)

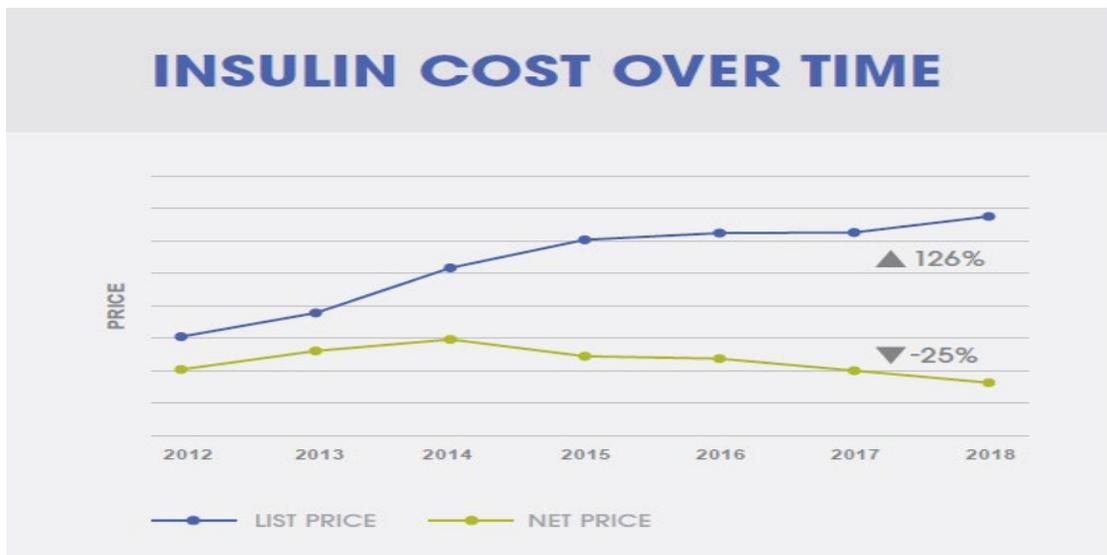
The declining average aggregate net price in 2018 represents the third consecutive year the amount that health plans and PBMs pay Sanofi for our medicines has declined.

**U.S. Portfolio Annual Average Aggregate Price Changes\***

Year	Average Aggregate List Price	Average Aggregate Net Price
2016	4.0% Increase	2.1% Decrease
2017	1.6% Increase	8.4% Decrease
2018	4.6% Increase	8.0% Decrease

\* Average aggregate across Sanofi's prescription product portfolio

Specific to insulin, the average aggregate net price across all Sanofi insulin products has declined over the past four years. **For our entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.**<sup>3</sup>



In addition to our pledge to limit price increases in the U.S., Sanofi's pricing policy includes a commitment to transparency in how we price new medicines coming to the market for the first time. When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers four factors:

<sup>3</sup> Based on internal review of pricing actions and payer contracting.

- 1) A holistic assessment of value, including (a) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; (b) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and (c) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA) approaches and other analyses that help define or quantify value and include patient perspectives and priorities.
- 2) Similar treatment options available or anticipated at the time of launch in order to understand the competitive landscape within the disease areas in which the medicine may be used.
- 3) Affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payers and health care delivery systems.
- 4) Unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to provide additional critical information on the value of the product (e.g., longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care.

Using this approach, Sanofi has launched a number of highly innovative products at prices well below the competition, some even before our principles were officially adopted.

- In 2012, Sanofi launched Aubagio<sup>®</sup>, a medicine used to treat relapsing forms of MS, at a list price more than 25 percent below the other approved oral MS medication on the market at the time.
- In 2017, we launched Kevzara<sup>®</sup>, a second line medication used to treat certain types of rheumatoid arthritis (RA), at a list price 30 percent below other leading treatments for RA. After completing a head to head study against the market-leading anti-TNF, Kevzara was found superior in RA patients.
- In 2017, we launched Dupixent<sup>®</sup>, the first drug of its kind for moderate to severe atopic dermatitis, specifically within the cost-effectiveness range provided by the Institute for Clinical and Economic Review (ICER) of \$37,000, compelling the Chief Medical Officer for a leading PBM to say “this is how pricing should work.” While we have concerns about ICER’s methodology in many of their drug reviews, our willingness to work with ICER is further demonstration to our commitment to price our medicines based on the value they provide with consideration of input from a third-party analysis.
- In 2018, we launched Admelog<sup>®</sup> at the lowest list price of any mealtime insulin.

- In February 2019, Sanofi and Regeneron announced that Praluent® will be made available at a new reduced U.S. list price. Beginning in early March, new U.S. National Drug Code (NDC) option will be available at approximately 60 percent less than the original list price for the drug. This action follows our earlier announcement in March 2018, when Sanofi and Regeneron committed to lowering the U.S. net price for payers in return for reducing burdensome access barriers for appropriate patients.<sup>4</sup> Sanofi and Regeneron took the additional step of announcing a new NDC to further assist patients, particularly in Part D, who still face cost-sharing linked to the list price, and who were thus not helped by the earlier net price reduction. With the new lower-priced Praluent, most Medicare Part D patients are expected to save as much as \$345 per month, depending on their insurance plan.

With the right incentives in the system, our approach to setting launch prices for these new medicines would have had the effect of ensuring affordable access for patients. Unfortunately, because of the way the U.S. health care system is currently constructed, our experience has shown that pricing medicines at lower list prices has failed to result in adequate access or affordability for most patients. For instance, since Dupixent was launched, rebates have been required in most cases to secure access for patients. Despite the responsible list price and subsequent rebates, 8 commercial and 2 Medicaid plans nevertheless implemented a step edit requiring patients to try immunosuppressant therapy first before using Dupixent. They implemented this step edit notwithstanding the fact that immunosuppressant therapy is not FDA approved for use in atopic dermatitis and is referenced as a worst-case scenario for patients in practice guidelines due to its questionable benefit-risk profile.

#### IV. Sanofi's Insulin Products: A Case Study

We feel a special obligation to address the pressing issues around access and affordability of insulin products. In my time as CEO, Sanofi has made a concerted effort to improve both system sustainability and patient affordability in our approach to our portfolio of insulin products, which includes six different products to meet individualized patient needs. And it is important to note the evolution and innovation of insulin, as we are often asked if anything has changed in the last 100 years that warrants pricing action.

Sanofi's groundbreaking discovery of insulin glargine, and its development of a novel pre-filled disposable injection pen to deliver insulin glargine, have profoundly improved the lives of millions of patients living with diabetes in the United States and worldwide. Sanofi's insulin glargine drug products are sold under the tradenames Lantus®, Lantus SoloSTAR®, Toujeo SoloSTAR®, and Toujeo Max SoloSTAR®, each of which represents a significant leap forward in the treatment of diabetes. Sanofi has been awarded patents for its innovative technologies on each of these products.

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<sup>4</sup> See <http://www.news.sanofi.us/2018-03-10-Sanofi-and-Regeneron-announce-plans-to-make-Praluent-R-more-accessible-and-affordable-for-patients-with-the-greatest-health-risk-and-unmet-need>.

These novel drug products began with Sanofi's discovery of insulin glargine. Despite having "insulin" in its name, Sanofi's insulin glargine is markedly different from prior insulin products, which had a relatively short duration of action and required patients to inject themselves multiple times a day and wake up at night for injections in order to control blood glucose levels. Each injection of prior insulin products 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 over the last century 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.

Glargine changed all of that. Sanofi scientists, in a remarkable feat of protein engineering, 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 once-daily administration of glargine also proved a significant boon to patient lifestyles.

Insulin is also an excellent example of list prices not reflecting the actual prices paid by insurance companies, and out-of-pocket costs that continue to rise despite lower net prices. The net price of our insulin product Lantus<sup>®</sup>, for example, has fallen over 30 percent since 2012; yet, over this same period, average out-of-pocket costs for patients with commercial insurance and Medicare – before the benefit of any Sanofi financial assistance program – has risen 60 percent.

#### V. Sanofi's Financial Assistance Programs

Our commitment to affordability for patients extends beyond responsible launch pricing, limited price increases, and transparency. We offer a suite of traditional and innovative patient assistance programs to enable appropriate patient access and to help patients afford the Sanofi medicines prescribed to them. We publicize our programs in a number of ways to ensure patients and providers are aware of our offerings, including through advertising online, on television, as well as in provider office settings and at pharmacies.

As noted previously in my testimony, rising out-of-pocket costs for patients is a complex problem with many causes. In some cases, access issues are linked to lack of insurance. But having insurance is no longer a guarantee of affordable care, and Sanofi believes it is also critical to address the needs of patients who may be exposed to excessive cost-sharing based on insurance plan design or other deficiencies in the system.

Because patient situations are different, we have carefully tailored our assistance programs for insulin products to meet a variety of patient needs:

- **Commercially insured patients qualify for our co-pay assistance program**, which reduces the financial burden for insulin products. Through this program, over 90 percent of participating commercially insured patients pay either \$10 or \$0 per month for their Sanofi-manufactured insulin products. Last year, our co-pay assistance programs for commercially insured patients provided more than 400,000 eligible patients with \$342 million in patient savings.
- **For diabetes patients who do not qualify for one of our co-pay assistance programs**, we created the Insulins ValYOU Savings Program in 2018. The purpose of this program is to provide relief for those patients who currently pay high variable retail prices for insulin and do not qualify for other assistance programs. Through this program, eligible individuals can access all Sanofi insulins for \$99 per 10 mL vial or \$149 for a pack of SoloStar pens, approximately a one-month supply of insulin,<sup>5</sup> at a discount of up to 60 percent discount below the list price, resulting in potential savings of up to \$3,000 per year. There are no income requirements and the program is available at U.S. pharmacies. Last year (its first year), the program resulted in \$6.2 million in patient savings.
- **For eligible low-income patients**, Sanofi offers many of our medicines, including our insulin products, at no charge through its Sanofi Patient Connection patient assistance program. We are proud that, in 2018, more than 93,000 patients participated in the Sanofi Patient Connection program, receiving free medicine valued at \$508 million.

While Sanofi alone cannot eliminate the issue of patient affordability, no matter how comprehensive or innovative our patient assistance programs, we believe that our efforts can make a meaningful difference for many patients. We are committed to maintaining these programs and raising awareness of these options to the patients who need them.

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<sup>5</sup> Patients with type 1 diabetes require insulin replacement with both long-acting (basal) and mealtime (bolus) insulin. An average adult with type 1 diabetes who weighs 70 kg (155 pounds) should be taking anywhere from 0.5-1.0 u/kg/ day - depending upon activity levels, and meal choices. Using the higher daily dose of 1.0 u/kg/day, this patient would need a total of 70 units/day of insulin, of which approximately half should be mealtime (bolus) insulin and half should be long-acting (basal) insulin. For this average patient, one vial of long-acting (basal) and one vial of mealtime (bolus) insulin could provide a monthly supply of insulin.

Many patients with type 2 diabetes require long-acting (basal) insulin only. Our internal data shows the average daily dose is approximately 45 units per day, resulting in a monthly requirement of 1350 units of long-acting (basal) insulin per month. Lantus SoloSTAR<sup>®</sup> pack contains 1500 units of insulin (5 pens x 300 units per pen) and Toujeo SoloSTAR<sup>®</sup> pack contains 1350 units of insulin (3 pens x 450 units per pen). For the average patient with type 2 diabetes, the ValYOU Savings Program would meet the monthly insulin requirement with one payment of \$149. Patients on lower doses of Lantus may opt for the 10ml vial, which would meet the monthly insulin requirement with one payment of \$99.

## VI. Policy Proposals

Over the past few years, we have led by example and made decisions to help improve access and affordability for patients. I am here today to tell you that I know our actions, while well-intentioned, have not been enough. I hope we can all agree on market-based policy solutions that will incentivize a high-value, sustainable health care system that improves the affordability of innovative medicines in the U.S.

Based on our experience, targeting list price controls alone will not be sufficient to address patient access and affordability. That is why the solution to drug pricing must include protections for patients, tying responsible pricing to both access and affordability for patients.

There are obviously a variety of ways to accomplish this, and Sanofi could support any number of options that align to our core principles:

- 1) The U.S. should continue to maintain a strong ecosystem for innovation. As such, any policy proposals should strictly avoid directly and artificially controlling the price of medicines, either through price controls set by the federal government, or worse, outsourcing that decision to foreign governments. Policy proposals that we believe would fundamentally undermine the unique innovation ecosystem of the United States include reference pricing, importation, or price controls set by CMS. Based on our experience, these approaches may be effective at controlling budgets for central payers but come at a steep cost for patients – namely limiting access to innovative treatments. Additionally, given that the U.S. is the world’s leader in science and innovation – and the jobs that come with it – these approaches pose additional risks to the U.S. economy and future scientific discovery. Finally, and most importantly, given the differences between systems, these approaches may do little to improve access and affordability for patients.

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.

- 2) Changes to the pricing system must be holistic, and the majority of benefits should accrue to patients. As noted previously, simply enacting price controls – either set by a state, federal, or foreign government – will not solve the problem of access and affordability for patients. We believe system incentives need to change to encourage smaller list price increases, or even list price reductions, by requiring health plans to cover those medicines that meet these standards at an affordable co-pay level and only allow access restrictions consistent with the label and accepted evidence-based best clinical practice.

If policies are enacted that solely target the list price of medicines without these common-sense patient protections, our shared goal of lowering drug costs – for both government and patients while maintaining the engine of innovation in the United States to bring new innovative medicines to patients will not be fully achieved. To appropriately accomplish this objective, Sanofi is willing to trade price for access and affordability and share accountability for offsetting the financial impact on the Medicare programs.

Sanofi supports and recommends several policy solutions to incentivize responsible pricing behavior. To ensure that these changes do not create a windfall for manufacturers or health plans and PBMs, Sanofi recommends applying these policies only to medicines that satisfy certain limits on price increases. This approach will shift the current incentives in the system to reward “good” behavior in a manner that truly helps patients. Several of the solutions outlined below are also priorities for Chairman Grassley, Ranking Member Wyden and other Members of this Committee and I look forward to the opportunity to work with you on advancing these and other policy initiatives:

First, reducing out-of-pocket costs for patients is our top priority. As we have experienced, limiting list price of medicines alone is not sufficient to fully solve this problem. Sanofi has identified a number of ways to effectively reduce out-of-pocket costs for consumers and broadly supports tradeoffs between price and access to help patients, including:

- Implementation of the Anti-Kickback Safe Harbor rebate proposed rule in a manner that directly lowers out-of-pocket costs for patients without creating loopholes that would undermine the proposed rule’s intent.
- Requiring a portion of the discounts and rebates paid by manufacturers to reduce costs for patients at the pharmacy counter.
- Changing government price reporting rules and the Anti-Kickback statute in a manner that would promote value-based contracting.
- Implementing an annual out-of-pocket cap for Medicare beneficiaries.
- Allowing manufacturers to offer co-pay assistance to Medicare beneficiaries.
- Changing or clarifying government price reporting rules to make it easier to reduce list prices on medicines that have been on the market for a long time – namely by (1) making clear that the government pricing metrics for the new, lower list price drug do not have to be averaged with the metrics for older, higher list price drug and (2) permitting a company to treat the new lower price drug as a new product for purposes of Medicaid rebate calculations, which will help to link the rebate liability for the new drug to the new drug’s lower price as opposed to the higher price for the old drug.

Second, Sanofi supports policies that cultivate a highly competitive free market system and rewards the type of entrepreneurial risk-taking necessary to the discovery and development of

life-saving new medicines. A key element of that system is a strong and predictable intellectual property system. However, after a reasonable period of time – which I believe is already reflected in U.S. law – generic and biosimilar medicines should quickly enter the market to offer long-term access at lower costs. To help accomplish these goals, Sanofi supports:

- Legislation that promotes competition, such as the CREATES Act, and prohibitions on “reverse payment” agreements. While some changes may be needed to avoid unintended consequences, we support moving forward with policies that limit manufacturers’ ability to unfairly avoid competition. At Sanofi, we make product supply available to generic and biosimilar manufacturers developing data necessary for FDA applications for their products. We do this in a timely manner and on reasonable terms.
- Increased system-wide transparency, which would improve competition across health care by making relevant information available to patients and policymakers. Providing more information about what is driving costs in the system and how money is flowing through the system will allow for increased competition and better-informed decision making. Policies like the SPIKE Act, which appropriately include a threshold for reporting to incentivize responsible pricing behavior and the C-THRU Act, are potential approaches.

## VII. Conclusion

I look forward to having a productive conversation about the complexities of the current prescription drug pricing system and proposals to improve affordable patient access to high quality, innovative medications to drive optimal health outcomes.

Thank you for the invitation to speak with you today and I look forward to working with you.