



**Testimony of Kathleen W. Tregoning
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**Before the House Energy and Commerce Subcommittee on
Oversight and Investigations
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Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy and Commerce Subcommittee on Oversight and Investigations to discuss issues related to pricing, affordability, and patient access to insulin in the United States.

I am Kathleen Tregoning, Executive Vice President, External Affairs, at Sanofi. I am here today to have an open discussion about the current system for pricing and accessing insulin in the U.S., the actions we have taken to improve patient access and affordability to insulin, and our ideas about what more can be done.

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 has 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. Our most significant U.S. presence is in Massachusetts, where we are the largest employer in the life sciences industry, and New Jersey, home to our U.S. headquarters. We also have major business, manufacturing and R&D operations in Pennsylvania and Tennessee.

Last year, Sanofi spent almost \$7 billion globally 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. Just last 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. Evolution of Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and 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 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.

The discovery and development of glargine changed all of that. 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 once-daily administration of glargine also provided a significant boon to patient lifestyles. The FDA first approved insulin glargine under the tradename Lantus® in 2000. Since its launch, Lantus has been studied in more than 90 million patient lives. Sanofi went above and beyond the regulatory authorities' approval requirements and conducted the first large Cardiovascular Outcome trial (CVOT - (ORIGIN)), to demonstrate the cardiovascular effects of an antidiabetic drug. Sanofi sponsored over 200 clinical trials, with more than 200,000 patients treated, resulting in over 2000 peer reviewed publications.

Since its discovery of insulin glargine, Sanofi has developed a new glargine formulation and a combination product to meet individual patient needs. While Lantus® provides significant

improvement for long acting (basal) insulin, for some patients, Lantus does not provide sufficient 24-hour basal insulin coverage. For other patients using higher doses, Lantus has a peak of action, which could lead to hypoglycemia. In order to more closely mimic endogenous basal insulin secretion, and to help type 2 diabetes patients meet their glycemic goals, Sanofi developed a next generation basal insulin, Toujeo®. Approved by the FDA in 2015, Toujeo provides an improved therapeutic effect at a higher concentration of glargine and exhibits a different and longer-acting profile than Lantus®.

Recognizing that approximately half of patients treated with basal insulin were still not achieving their blood glucose (HbA1c) targets, Sanofi launched Soliqua 100/33® in 2017. Intended for adults whose Type 2 diabetes is inadequately controlled on basal insulin or an oral antidiabetic medicine, Soliqua is 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 (GI) side effects. Soliqua has demonstrated reduction in average and overall glucose levels and reduction in GI side effects, with similar rates of hypoglycemia – thus allowing balance of lowered glucose levels without more hypoglycemia. Moreover, Soliqua has been found to have a beneficial effect on body weight, addressing one of the unwanted side effects of insulin.

These three products are among five insulin products currently manufactured by Sanofi.

In 2000, Lantus launched in a vial, so patients needed to inject the product with a syringe. Since that time, we have developed several more convenient injection devices for administering insulin. Our latest pen delivery system, SoloSTAR®, 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 that has improved the lifestyle and medication compliance of millions 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 couples and decouples complex internal mechanisms from each other 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, and it very quickly became the gold standard for pre-filled, disposable injection pens. It has won awards for its novel design.

Sanofi developed Toujeo SoloStar with several 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 pen delivery system easier to use. Additionally, Sanofi developed SoloStar Max®, which holds more units in the reservoir (900 vs 450) and gives

the patient the ability to dose up to 180 units in one injection vs the 80 units in the SoloSTAR pen, allowing for fewer injections and potentially for fewer refills and related copays.

We continue to study the safety and efficacy of our products for higher risk patient populations who would benefit from the more stable pharmacokinetic and pharmacodynamic profile, such as children and geriatric patients with diabetes. Sanofi understands that randomized clinical trials do not always provide a full picture of patient outcomes, so we have launched one of the most comprehensive real world evidence studies for a diabetes medication in the United States. We are studying Toujeo in diverse settings, ranging from a randomized, pragmatic prospective trial to predictive analytics and machine learning applied to large patient datasets. We believe that studying our medications in real world settings will continue to help drive needed innovation in diabetes treatment.

Looking to the future, our scientists are working on ways to potentially transform diabetes care by treating the underlying disease. To this end, Sanofi has a multi-pronged approach, through which we seek to prevent the progression of diabetes to insulin-dependence or restore insulin-producing cells through stem cell technologies. In addition, we recognize that the greatest contributor to the current diabetes epidemic is obesity. Our researchers are exploring the molecular mechanisms by which obesity leads to diabetes, and working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. This type of research, and the development of these new technologies, takes many years, and we continue to invest in these projects with the hope that we can eventually transform the lives of these patients.

II. Rising Costs of Insulin for Patients

While the treatment of diabetes has been transformed by medical innovations, including multiple new discoveries to improve the quality and delivery of insulin, the landscape in which patients access medications has also fundamentally changed, and not for the better. We understand the anger of patients who cannot afford the insulin they need due to rising out-of-pocket drug costs.

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 actor 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 we want to reaffirm our commitment to our core principles of access, affordability and innovation.

While list prices of medicines often receive the most attention, they reflect the initial price we set for our medicines. The list price is not the amount Sanofi receives or the price 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. As long as the net price grows at a predictable rate or even decreases, the greater the list price, the greater the economic returns for many players in the supply chain.

List price is the starting point for negotiations with payers and sometimes impacts 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 government and private payers, as well as other intermediaries, in an effort to improve access for patients. As described later in my testimony, due to these rebates, the average aggregate net price of our products, including our insulin products, has declined over the last several years.

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 (HDHPs). Among those with private health insurance, enrollment in HDHPs has 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 in the insurance portion of the plan.

In other cases, affordability issues are caused by changes in insurance design, which increasingly require patients to pay higher cost-sharing amounts for their medicines, even when the prices of those medicines have stayed relatively flat or declined for the health plan. For example, 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.

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 Times¹ highlights how changes to prescription drug formularies can not only 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.

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

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

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 appreciate that this Subcommittee is taking a holistic approach to collecting information on what is causing the problem for patients. As we consider solutions to address patient access and affordability, it is essential that we not undermine the incentives and rewards for scientific risk-taking and discovery that are the hallmark of the United States ecosystem and economy.

III. 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 insulins 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.

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, 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. That is why in May 2017 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.²

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.

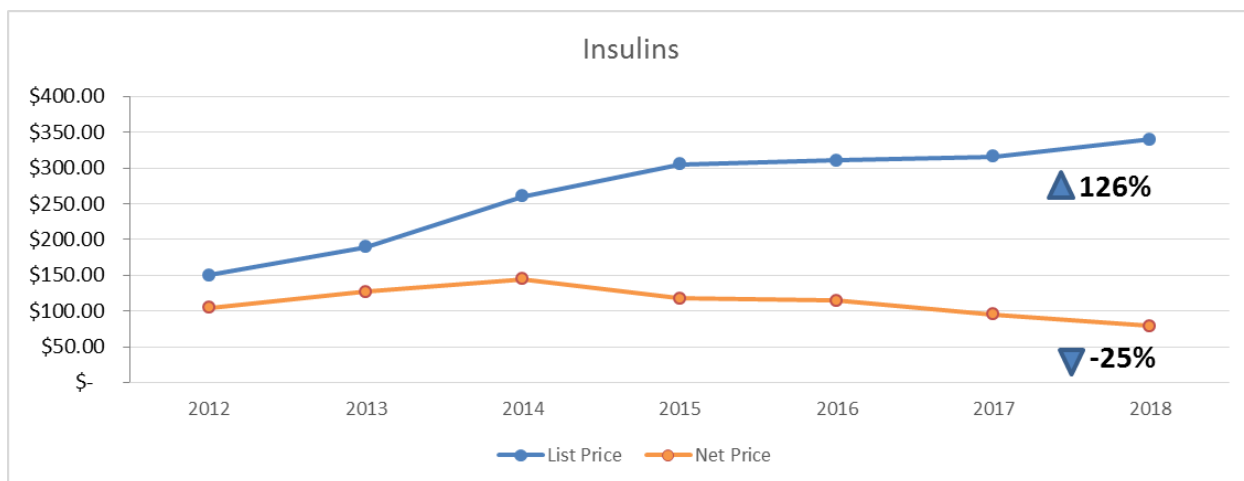
In 2018, all of our price increases were consistent with our principles, as are all pricing actions we have taken in 2019. Across our entire portfolio of medicines, the average aggregate list price increase was 4.6 percent while the average aggregate net price – that is, the actual price paid to Sanofi – declined by 8.0 percent.

² See 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.

Specific to insulin, the average aggregate net price across all Sanofi insulin products has declined for the past four years, and based on existing contracts, will fall again in 2019. **For our entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.**³

Sanofi Insulins List vs. Net Price Changes⁴ Between 2012-2018



When considering the patient access and affordability challenges of insulin, it is important to not only look at list price changes over time, but also net price changes. For example, Lantus, our oldest and most prescribed insulin, is frequently cited in stories about increasing insulin prices. While the list price of Lantus has increased significantly since it was approved, the net price – the amount Sanofi receives after discounts and rebates – has been declining for several years. In fact, the net price of Lantus today is lower than it was in 2006.

Unfortunately, competition among various diabetes treatments, and the resulting insulin net price declines, has not resulted in lower out-of-pocket costs for patients. As noted previously in my testimony, while the net price of Lantus has declined by over 30% since 2012, out-of-pocket costs for patients with commercial insurance and Medicare Part D have increased by approximately 60% over that same period of time.

In addition to our pledge to limit price increases in the U.S., Sanofi’s pricing principles include a commitment to transparency in how we price new medicines coming to the market for the first time.

³ Based on internal review of pricing actions and payer contracting.

⁴ List Prices are calculated by dividing Gross Sales (sales at List Prices before discounts and rebates) by total trade units sold. Net prices calculated by dividing Net Sales (sales after discounts and rebates) by total trade units sold.

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:

- 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 (including 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.

Applying these methodologies, Sanofi has launched a number of innovative products at prices well below the competition. In the insulin space, we launched, and are committed to maintaining, Admelog[®], a biosimilar of insulin lispro, at the lowest list price of any mealtime insulin.

With the right incentives in the system, our approach to setting launch prices for these new medicines coupled with our limit on list price increases should have had the effect of ensuring affordable access for patients.

Sanofi Patient Support Programs

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.

Commercially insured patients qualify for our co-pay assistance program, regardless of income, which reduces the financial burden for insulin products. Through this program, over 90% of participating patients pay either \$10 or \$0 per month for their Sanofi insulin. While current regulations prohibit us from offering this type of program to patients insured under Medicare

or similar federal or state programs, Sanofi supports efforts that would expand this access program to all those who might benefit.

Additionally, we created the Insulin **Valyou** Savings Program in 2018. The intent of the Insulin **Valyou** Savings Program is to provide relief for those who currently pay high variable retail prices for their 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 – roughly a one-month supply – at a discount of up to 60 percent below the list price, resulting in savings of up to \$3,000 per year. There are no income requirements, and the program is available at U.S. pharmacies. Since it was launched last April, the program has resulted in approximately \$10 million in patient savings.

For eligible uninsured and underinsured low-income patients, including Medicare 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.

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. We believe many others may be eligible for one of these programs to reduce their costs, and we continue to promote these programs to raise awareness about the support that is available.

Last week, Sanofi joined other insulin manufacturers to fund a program that limits insulin co-pays to \$25 for patients covered under ESI and Cigna plans. While this out-of-pocket maximum is greater than patients may pay if they enroll directly in Sanofi's co-pay assistance program, which may reduce a commercially insured patient's out-of-pocket burden to as low as \$0, we believe this new initiative launched by ESI and Cigna will unquestionably lower out-of-pocket costs for some patients.

IV. Solutions

I am proud of Sanofi's leadership to help improve access and affordability to insulin products for patients. However, despite the actions we have taken, on behalf of everyone at Sanofi, I know more needs to be done. My testimony today is intended to provide a more transparent and open picture into the system surrounding access to insulin therapies in order to enable this Subcommittee to consider a common set of facts and design solutions to meet urgent patient needs. I hope we can all agree on market-based policy solutions that will incentivize a high-value, highly competitive, and sustainable health care system that improves the affordability of innovative medicines in the U.S.

It is my belief that targeting list price alone will not be sufficient to address patient access and affordability. Just lowering list prices, without guarantees that those lower-priced medicines would be included on formularies at affordable, low co-pay tiers may not solve the problem for

most patients. Sanofi's Insulin Valyou savings program offers significantly less expensive access to all of our insulin products even when compared to recent actions by others to lower list prices. The solution to insulin access and affordability must include protections for patients, tying responsible pricing to both access and affordability.

There are a variety of ways to accomplish this goal, 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 other 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 in other countries, 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 benefits should accrue to patients. As noted previously, simply enacting price controls 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 list price reductions, by requiring health plans to cover those medicines that meet these standards at affordable co-pay levels and only allow access restrictions consistent with the product label and accepted evidence-based best clinical practice.

If policies solely target the list price of medicines without these common-sense patient protections, our shared goal of lowering insulin costs – for both government and patients – while maintaining the engine of innovation in the United States to bring innovative medicines to patients will not be fully achieved. To appropriately accomplish our shared objective of greater access and affordability for patients, Sanofi is willing to contribute our fair share to offset any financial impact to the health care system as long as patient access and affordability are improved for all patients.

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 Members of this subcommittee 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. 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 the following:

- Whether through legislation, implementation of the Anti-Kickback Safe Harbor rebate proposed rule, or changes in market dynamics, link lower list prices to improved access and affordability for patients.
- All payments in the supply chain should be de-linked from list price, which would remove the perverse incentive that sometimes feeds the cycle of higher list prices paired with higher rebates.
- Require a substantial portion of the discounts and rebates paid by manufacturers to reduce costs for patients at the pharmacy counter.
- Change government price reporting rules and the Anti-Kickback statute in a manner that would promote value-based contracting.
- Implement an annual out-of-pocket cap for Medicare beneficiaries.
- Allow Medicare beneficiaries to access manufacturer co-pay assistance programs.
- Change or clarify 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 further cultivate a highly competitive free market system and reward the type of entrepreneurial risk-taking necessary to the discovery and development of life-saving new medicines. A key element of that system is strong and predictable intellectual property protection. 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:

- Increasing competition among medicines. Whether through prohibiting “reverse payment” patent settlements, requiring timely access to samples for generic or biosimilar manufacturers, establishing a clear patent listing of biologics through a “Purple Book”, or further encouraging the development of biosimilar insulin products, Sanofi supports robust competition to encourage continued development of life-saving medicines. 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 commercially reasonable terms. We support both the CREATES Act and the Purple Book Continuity Act as passed out of the full Committee last week.
- Increasing system-wide transparency, which would improve competition 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 that include price reporting requirements to incentivize responsible pricing behavior have the potential to change current practices, but they should be modified to protect confidential information and preempt similar state law policies in order to create a single set of requirements.
- Requiring health plans and PBMs to disclose an annual list of medicines for which the net price has decreased, as well as how the decrease (or value generated by it) was allocated among the health plans, PBMs, government payer, and patients.

Finally, Sanofi supports many of the recommendations made by the Congressional Diabetes Caucus in its whitepaper⁵ entitled: “Insulin: A lifesaving drug too often out of reach,” including the following:

- Encourage the development and use of value-based contracts between insulin makers and PBMs.
- Promote the use of payment arrangements between insulin makers and wholesalers that involve standardized fees instead of rebates.
- Require insulin makers, PBMs, and health insurers to disclose the value and volume of rebates that they receive and share with other entities in the insulin supply chain.
- Link patient out-of-pocket costs to negotiated prices instead of list prices.
- Allow generic manufacturers to produce older, off-patent insulin formulations.
- Require manufacturers to disclose their insulin’s list pricing process.

⁵ <https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf>

- Standardize the process for requesting exemptions or filing appeals from formulary changes.
- Standardize drug formulary disclosure of patient cost-sharing information.
- Limit the number of changes an insurer is permitted to make to a formulary each year.
- Cap out-of-pocket expenses for prescription drugs that are needed for chronic conditions.

V. 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 life-saving medications such as insulin to drive optimal health outcomes.

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