

## PRESCRIPTION MEDICINE PRICING: OUR PRINCIPLES AND PERSPECTIVES

At Sanofi, we work passionately to prevent, treat and cure illness and disease, understand and solve health care needs of people across the world, and transform the practice of medicine. Our focus spans a number of therapeutic areas in specialty care and general medicines, including immunology, oncology, rare diseases, rare blood disorders, diabetes and cardiovascular diseases, as well as vaccines. Sanofi has a longstanding commitment to promote health care systems that make our treatments accessible and affordable to patients in need.

Countries are increasingly seeking to achieve better value in health care spending. Sanofi understands and shares concerns about the affordability of medicines for patients while also recognizing that we are only one of many stakeholders in the health care system. In the United States, medicines are a small share – about 14% – of total health care spending.<sup>1</sup> In order to maintain an environment that will continue to bring new health care solutions to patients, we must encourage a transition to a value-driven health care system that provides incentives for the highest-quality care. This evolution will enable both affordable access to treatment and continued investment in medical innovation.

Sanofi is committed to helping address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are controlled by other stakeholders in the health care system, we believe we have a responsibility to be a leader in solving issues of patient access and system viability. For our part, we price our medicines according to their value, while contributing to broader solutions that improve patient outcomes and support affordability within the U.S. health care system.



## OUR PRICING PRINCIPLES: ADVANCING RESPONSIBLE LEADERSHIP

Pharmaceutical innovation brings value to our patients, our society and our health care systems. Given the growing concerns over rising health care costs, our approach to pricing reflects our commitment to patient access while minimizing our contribution to health care inflation. We therefore commit to continued transparency in how we price our prescription medicines and to limit any increase in prices in the United States to no more than the projected National Health Expenditure (NHE) growth rate.

### THE PRICING PRINCIPLES WE PUT FORTH FOCUS ON THREE PILLARS:



#### **CLEAR RATIONALE FOR PRICING**

at the time of launch of a  
new medicine



#### **LIMITED U.S. PRICE INCREASES**

on our medicines over time



#### **CONTINUED TRANSPARENCY IN THE U.S.**

around our pricing decisions



## CLEAR RATIONALE FOR PRICING

**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 the following factors:**

**A holistic assessment of value**, including 1) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; 2) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and 3) 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) and other analyses that help define or quantify value and include patient perspectives and priorities.

**Similar treatment options** available or anticipated at the time of launch, in order to understand the landscape within the disease areas in which the medicine may be used.

**Affordability**, including the steps we must take to promote access for patients and contribute to a more sustainable system for payors and health care systems.

**Unique factors** specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials to reinforce the value of our medicines (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.



## LIMITED U.S. PRICE INCREASES

**We acknowledge our role in preserving the sustainability of our health care system and in limiting our contribution to U.S. health care spending growth. Should we take a list price increase on one of our medicines, our guiding principle is to limit the total annual increase during our fiscal year (Jan. 1 to Dec. 31) to a level at or below the projected growth rate for National Health Expenditures for said year.**

**Our benchmark, the projected U.S. National Health Expenditure (NHE) growth rate**, is estimated and published annually by the Centers for Medicare & Medicaid Services (CMS). The NHE projection provides a critical forward-looking view needed for business planning. NHE measures spending across all health care goods and services and reflects payments made by both public and private payors.

Once the NHE projection is updated each year, we will adjust any future planned pricing actions to reflect the projection. Given the need for business planning, we will adopt the updated standard by April 1 each year.<sup>2</sup> More information about the NHE growth rate can be found [here](#).<sup>3</sup>

**Should we take a price increase above the NHE growth rate for a given medicine** that results in a list price increase greater than \$15 for a full course of treatment per year, we will provide our rationale, highlighting clinical value, real-world evidence, regulatory change, new data or other circumstances that support our decision.

<sup>2</sup> As measured by National Health Expenditures, published annually by the Centers for Medicare & Medicaid Services.

<sup>3</sup> To read the full data, please visit <https://go.cms.gov/39rnzgf>.



## CONTINUED TRANSPARENCY IN THE UNITED STATES

**We recognize calls for continued transparency in our pricing practices. Our principles reflect a desire to help our stakeholders better understand our pricing decisions.**

Our principles reflect both a desire to help our stakeholders better understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines. To continue this dialogue and provide greater insights about this topic, we will disclose annually our average aggregate U.S. list and net price changes from the prior calendar year. These data may help illustrate how pricing changes accrue to manufacturers versus others in the value chain, highlighting our discrete role in the broader U.S. health care environment and enabling a better-informed discussion on solutions to improve patient access and affordability.

While list prices often receive the most attention, they reflect only the initial prices set for our medicines and are not the prices typically paid by the insurers, employers or pharmacy benefit managers who purchase our medicines on behalf of patients in their respective health plans. We negotiate discounts and rebates with these payors, which are designed to offer the health care system lower prices in exchange for greater access and affordability for patients with insurance. List prices also fail to capture the substantial mandated discounts and rebates, sometimes required by law, provided to government programs, including those provided in Medicare Part D, Medicaid and the 340B drug pricing programs.

The net price is what Sanofi receives after discounts, rebates and fees paid to health plans and other parts of the health care system.

While our efforts focus on securing affordable coverage of our medicines for patients, it is important to note that patient cost-sharing and coverage decisions are ultimately made by payors and employers, not manufacturers of the medicines.

Simply put, patients' out-of-pocket costs depend on how the plan is structured and the extent to which it passes negotiated discounts to patients.



**These principles demonstrate Sanofi's commitment to patient access and affordability, a sustainable health care system and greater transparency in our pricing actions. Moreover, our position supports an environment that will enable us to continue to advance scientific knowledge and bring innovative treatments to patients worldwide.**



# **SANOFI 2022 PRICING PRINCIPLES REPORT: ADVANCING RESPONSIBLE LEADERSHIP**

In May 2017, Sanofi expanded on its commitment to tackle rising health care costs with the introduction of our Pricing Principles, which remain the most comprehensive assessment of corporate pricing decisions in the pharmaceutical industry. Our goal is to promote a culture of transparency that is adopted not only in our industry, but across health care – including hospitals and payors – where transparency is often sorely lacking.

Our pricing policy is a reflection of our unwavering dedication to providing patients innovative and life-changing treatments while limiting costs and minimizing our contribution to health care spending growth. The following report outlines our 2021 pricing decisions.

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## CLEAR RATIONALE FOR PRICING

### Nexviazyme® (avalglucosidase alfa-ngpt)

Sanofi introduced Nexviazyme in the United States in August 2021 for the treatment of patients 1-year-of-age and older with late-onset Pompe disease, a debilitating rare muscle disorder that impairs a person's ability to move and breathe and impacts an estimated 3,500 people in the United States.

Nexviazyme is an enzyme replacement therapy designed to specifically target the mannose-6-phosphate (M6P) receptor, the key pathway for cellular uptake of enzyme replacement therapy in Pompe disease. Nexviazyme has been shown in clinical trials to provide patients with improvements in respiratory function and walking distance compared to baseline.

At launch, Sanofi set the list price for Nexviazyme at \$1,714.90 per 100-mg vial, which, on a per-milligram basis, was on parity with the only other FDA-approved therapy for late-onset Pompe disease. The estimated annual list price, also referred to as the wholesale acquisition cost (WAC), varies by the weight of patients.

The price of Nexviazyme reflects a careful assessment of several unique factors including disease burden, unmet medical need and available alternative therapies, as well as the treatment's safety and efficacy profile, and feedback from health care professionals and payors. Given the size of the patient population, and in keeping with pricing of other rare disease therapies, the price of Nexviazyme also reflects the need to incentivize development of medicines for small groups of patients.

As part of our commitment to ensure treatment access and affordability for innovative therapies, Sanofi's CareConnectPSS program provides personalized support, including financial assistance, for eligible patients and their families impacted by Pompe disease. More information about Pompe disease can be found [here](#).<sup>4</sup>

### Vaxelis® (Diphtheria and Tetanus Toxoids and Acellular Pertussis, Inactivated Poliovirus, Haemophilus b Conjugate and Hepatitis B Vaccine)

Vaxelis is the first and only hexavalent (six-in-one) combination vaccine available in the United States for active immunization in children from six weeks through 4-years-of-age against diseases caused by six invasive agents – diphtheria, tetanus, pertussis, poliovirus, *Haemophilus influenzae* type b (Hib) and hepatitis B.

In June 2021, Vaxelis launched in the United States with a list price of \$128.27 per dose. When determining the price, multiple factors were considered, such as immunogenicity, clinical attributes, value to patients, accessibility and affordability.

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Most patients with commercial insurance will have no out-of-pocket costs for Vaxelis or its administration. There may be a copay associated with the office visit. The federally funded Vaccines for Children program provides vaccines at no cost to children who are enrolled in Medicaid, uninsured, underinsured or an American Indian or Alaska Native through age 18.

Vaxelis was developed as part of a U.S.-based partnership between Merck and Sanofi Pasteur, now known as the MSP Vaccine Company.

### MenQuadfi® Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

MenQuadfi is approved in the United States for the prevention of invasive meningococcal disease in persons 2-years-of-age and older. MenQuadfi is given as a single dose across all four serogroups and is the only MenACYW vaccine with an expanded age group for all individuals 2-years-of-age and older, including patients older than 55-years-of-age. MenQuadfi is also approved for use as a booster dose for patients 15-years-of-age or older who are at continued risk of meningococcal disease – even if the patient was primed with another licensed MenACYW vaccine – so long as at least four years have elapsed since the prior dose. MenQuadfi does not prevent N. meningitidis serogroup B disease.

MenQuadfi launched in 2021 with a list price of \$703.40 per unit of five 0.5 mL single-dose vials, which, after promotional discounts for prebooking doses, is at parity with Sanofi's Menactra® (Meningococcal [Groups A, C, Y and W-135] Polysaccharide Diphtheria Toxoid Conjugate Vaccine), for all contract customers.

Sanofi considered feedback from various stakeholders including payors to determine an appropriate price for MenQuadfi. Sanofi also took steps to ensure access for eligible patients by securing a new and unique Current Procedural Terminology code from the American Medical Association for MenQuadfi based on its clinical differentiation compared to other MenACYW vaccines. MenQuadfi is available through the Vaccines for Children program at no cost to enrolled health care providers.<sup>5</sup>

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<sup>5</sup> Centers for Disease Control and Prevention, Vaccines for Children Program (VFC), 2016.



## LIMITED U.S. PRICE INCREASES

The Centers for Medicare & Medicaid Services' most recent estimate of the U.S. National Health Expenditure projected growth rate for 2021 was 5.1%.<sup>6</sup>

In 2021, Sanofi increased the list price of 50 of our 81 prescription medicines. All increases were within our Pricing Principles guidelines, which is the only policy in the industry that limits price increases on all individual medicines to a measure of health spending growth.

Sanofi also took two price decreases, lowering the list prices of Lovenox Premier by 74% in April 2021 and sevelamer carbonate by 46% in May 2021.



## CONTINUED TRANSPARENCY IN THE UNITED STATES

<sup>6</sup> Centers for Medicare & Medicaid Services, 2019.  
<sup>7</sup> Aggregated across Sanofi's prescription portfolio.  
<sup>8</sup> Price increases or reductions that are taken mid-year may have an impact in two calendar years. In our 2019 pricing report, Sanofi announced that it took a price reduction on Admelog<sup>®</sup> (insulin lispro injection) 100 units/mL in July 2019. The 2020 carryover impact of that change is not included in the 2020 Average Aggregate List Price above. If included, the 2020 Average Aggregate List Price change vs. 2019 would have been effectively 0%, and the Average Aggregate Net Price would decrease by 8.0%.

**U.S. Portfolio Annual Aggregate Price Change from Prior Year<sup>7</sup>**

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
2019	2.9% INCREASE	11.1% DECREASE
2020 <sup>8</sup>	0.2% INCREASE	7.8% DECREASE
2021	1.5% INCREASE	1.3% DECREASE

## GROSS SALES GIVEN BACK TO PAYORS AS REBATES

In 2021, 49% of Sanofi's gross sales were given back to payors as rebates, including \$5.8 billion in mandatory rebates to government payors and \$8.3 billion in discretionary rebates.



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## HOW REBATES, DISCOUNTS AND FEES IMPACT OUT-OF-POCKET COSTS

Too many Americans struggle to pay for the medicines and treatments they need due to high and rising out-of-pocket drug costs imposed by insurance companies. This is unacceptable.

**Sanofi recognizes the urgent need to eliminate these cost burdens, which fuels our continued efforts to break down the barriers standing between patients, their medicines and healthier lives. Unfortunately, in many cases, factors beyond Sanofi's control, dictated by other players in the health system, prevent us from lowering out-of-pocket costs for patients.**

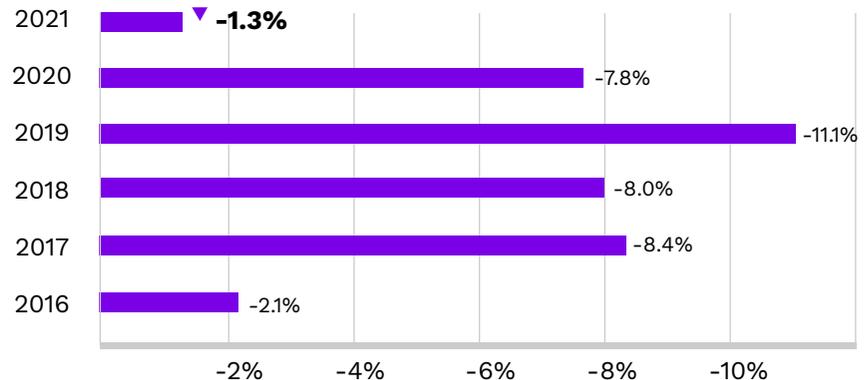
**All prescription medicines have both a list price and a net price.** The “list price” of a medicine often receives the most attention, but it does not reflect the amount Sanofi receives, nor does it reflect the price patients pay at the pharmacy counter every time our medicines are purchased.

It is important to note that manufacturers, including Sanofi, pay significant discounts, rebates and fees – often as a percentage of the list price – to different stakeholders across the health care system to make sure our medicines are available to patients. Payors, including pharmacy benefit managers (PBMs) and government and private insurance plans, decide which medicines to make available to patients through their plans in part based on the discounts and rebates we give them for each of our medicines.

Sanofi chooses to pay these discounts, rebates and fees, which increase each year, to make sure our medicines are covered by PBMs and insurance plans, and therefore readily available to patients – it is one way we provide access to patients. Many government programs also require us to pay discounts, rebates and fees to make our medicines available to patients covered under those specific programs.

The “net price” of a medicine factors in the various discounts and rebates paid, and most accurately reflects the amount Sanofi receives for its medicines.

In 2021, the average aggregate net price of our medicines declined by 1.3%, the sixth consecutive year our net prices have declined.



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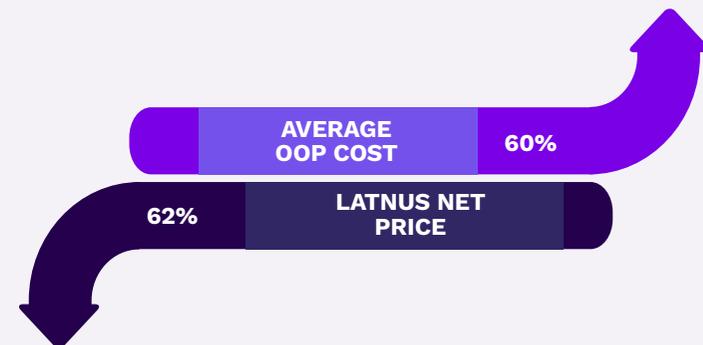
ENCOURAGING PATIENT-FOCUSED POLICY SOLUTIONS

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When looking at insulin, the impact of net prices is even more pronounced. Despite the rhetoric about skyrocketing insulin prices, the net price of insulin has fallen for seven consecutive years, making our insulins significantly less expensive for insurance plans.

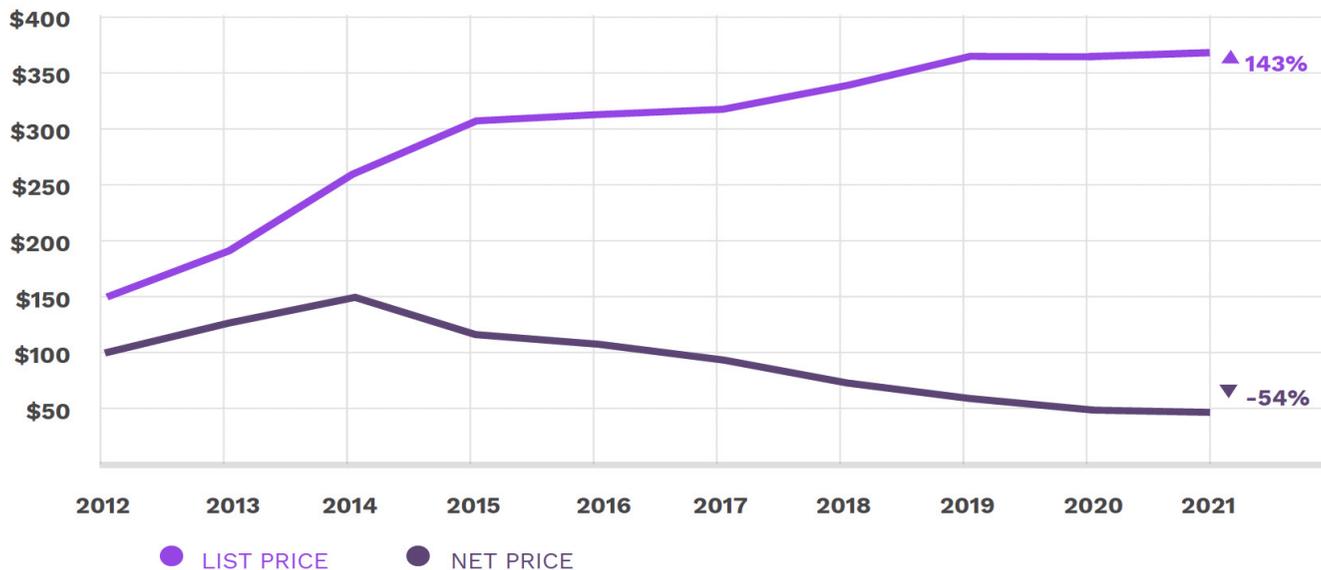
Since 2012, the net price of Sanofi insulins has declined by 54%. Over the same period, the net price in commercial and Medicare Part D plans of our most prescribed insulin, Lantus® (insulin glargine injection) 100 units/mL, has fallen 62%.<sup>9</sup> However, in contrast, average out-of-pocket costs for Lantus patients with commercial insurance and Medicare have risen approximately 60%. Health plans and others continue to put the spotlight on list prices, but the average net price of Lantus today is lower than it was in 2004.

Since 2012, for people taking Lantus® (insulin glargine injection) 100 units/mL on commercial and Medicare Part D plans:



**And even with a consistent decline in net insulin prices, out-of-pocket costs are on the rise, creating an unsustainable situation for many patients.** Patients are being asked to pay more, while PBMs and health plans are paying less thanks to the increasing discounts and rebates they receive from manufacturers like Sanofi. Health plans in particular are placing more of the cost burden onto patients through high deductibles, co-insurance and multiple cost-sharing tiers. If health plans and PBMs are not paying list prices, then why are consumers?

INSULIN COST OVER TIME<sup>10</sup>



<sup>9</sup> For clarification, the decline in the net price of Lantus® (insulin glargine injection) 100 units/mL since 2012 in 2020 was 61% versus 44.9% reported in the 2021 Pricing Principles Report due to a calculation error.

<sup>10</sup> Sanofi took no price increase on insulin products in 2021. The change in average list price is a reflection of the change in product sales mix.



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For those on employer-sponsored health plans, average patient spending on deductibles has increased by 68% from 2011 to 2021.<sup>11</sup> Such high cost-sharing, particularly for high-value and highly rebated therapies such as insulin, creates a stark financial barrier for patients, making it difficult to obtain essential treatments and potentially forcing some to ration their insulin.

**Sanofi has delivered lower aggregate net prices for six consecutive years**, which should have made it easier for patients to get the medicines they need, but the complex design behind insurance policies continues to pose a challenge for patients. It is clear that focusing solely on lowering the list price of medicines does not guarantee that patients will see the benefits they deserve, including a lessened financial burden.

**The growing amount manufacturers pay in discounts and rebates every year to PBMs and health plans should guarantee that patients pay less out of pocket every time they fill a prescription**, but ultimately this is beyond Sanofi's control. Insurers and employers set the benefits that determine out-of-pocket costs and overall health care coverage for patients. There is little visibility into whether or how PBMs and health plans pass our discounts and rebates on to patients at the pharmacy counter. Without a commitment to affordability from insurers and their partners, drugmakers alone cannot solve the cost-sharing challenges harming millions of Americans.

Collective action across the health system is the only way we can honor our industry's obligation to the health and well-being of all Americans. We must be willing to put forward bold policy solutions that address the many disparate parts of the equation that determines what patients pay for medicines. Policies that solely target the list price of medicines – without system-wide accountability and compliance, or common-sense patient protections – fail to address the issue and prevent us from achieving the shared goal of lowering out-of-pocket costs for patients.

### When policy solutions target out-of-pocket costs, patients benefit.

For example, patients' out-of-pocket spending on Lantus rose 82% between 2012 and 2020, placing more pressure on patients even as we dramatically lowered our net price. But in 2021, out-of-pocket spending on Lantus actually fell by 12% compared to 2020.

Why? In 2021, we began our voluntary participation in the CMS Senior Savings Model, which gives patients an additional lower cost option for Sanofi insulins, allowing patients who enroll in a participating Part D plan to pay a \$35-or-less copay for each 30-day prescription of a Sanofi insulin throughout the year.

Sanofi has advocated and continues to advocate for programs and initiatives like the CMS Senior Savings Model that directly lower out-of-pocket costs for patients.

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<sup>11</sup>Kaiser Family Foundation, 2021.

# ENCOURAGING PATIENT-FOCUSED POLICY SOLUTIONS

We believe that any policy solution aimed at lowering prescription drug costs should include contributions from across the entire health care system – including substantial reforms of rules governing benefit design in government and commercial coverage – to ensure that the patient truly benefits.

## SANOFI BELIEVES IN POLICIES THAT MAKE REDUCING PATIENT OUT-OF-POCKET COSTS A TOP PRIORITY...

- Requiring manufacturer rebates and discounts directly benefit patients receiving those medicines.
- Minimizing deductibles and requiring that patients are not charged more than a health plan's net cost for medicines.
- Delinking supply chain payments from list prices.
- Prohibiting PBMs and insurers from confiscating the value of manufacturer-provided patient coupons and requiring such coupons to count towards deductibles and out-of-pocket limits.
- Implementing out-of-pocket caps in states and for Medicare Part D beneficiaries and establishing payment plan policies to limit out-of-pocket variability at the pharmacy counter throughout the year.
- Encouraging Medicare, state entities, and health care exchanges to provide information to patients about the availability of patient assistance programs from manufacturers and other sources, such as state pharmaceutical assistance programs (SPAPs) and nonprofit charities.

## ...WHILE CONTINUING TO CULTIVATE A COMPETITIVE, FREE MARKET SYSTEM.

To facilitate affordable access to innovative treatments, Congress and the states should enact policies that encourage competition while rewarding the risk-taking necessary to discover and develop life-saving medicines. After a reasonable period, generic and biosimilar medicines should be able to enter the market to offer patients long-term access at lower costs. To achieve these goals, Sanofi supports:

- **Reimbursement that fosters investment and risk-taking to create new innovations**, and competition among medicines to drive value. Although innovations can serve patients for generations, we expect at some point such inventions will be copied and manufacturers should not unfairly limit such competition.
- **Increasing system-wide transparency by encouraging more information be available to patients and policymakers.** Providing greater transparency around what is driving costs in the system, including the role of PBMs and others and why discounts are not reaching patients at the pharmacy counter, will enable increased competition across health care and better-informed decision-making.
- **Ensuring adequate system incentives exist around quality and outcomes for the benefit of all patients.** Such incentives should help to thwart formulary benefit design that is skewed too narrowly with a bias toward pharmacy cost. The extremes of benefit design tools such as higher out-of-pocket costs and utilization management should be better checked so that clinical care and outcomes are not compromised, health equity gaps do not go unaddressed, and other health care system expenditures do not increase.

## PRIORITIZING PATIENT AFFORDABILITY

Our duty to put life-saving medicines in the hands of patients goes well beyond responsible launch pricing and limited list price increases. We have built a suite of novel and comprehensive patient programs to eliminate cost barriers for patients.

As part of our commitment to society, we have a special obligation to address the pressing financial issues that can prevent patients from getting the medicines they need. That's why Sanofi continues to invest in our innovative and industry-leading savings programs that directly lower out-of-pocket costs for patients.

Sanofi was the first company to introduce a program through which uninsured patients could access one or more of our medicines at a set price: our Insulins **Valyou** Savings Program allows uninsured patients to buy one or multiple Sanofi insulins at a fixed price of \$99 per month for up to 10 boxes of SoloStar pens and/or 10mL vials, or five boxes of Toujeo® (insulin glargine injection) 300 units/mL Max SoloStar pens. Additionally, the Soliqua® (insulin glargine & lixisenatide injection) 100 units/mL and 33 mcg/mL cash offer allows uninsured patients to pay \$99 per box of pens, for up to two boxes of pens for a 30-day supply. Sanofi's copay assistance programs for commercially insured patients limit out-of-pocket expenses for a majority of participating patients between \$0 to \$10 per month for their diabetes medicines, regardless of the patient's income level.

In addition, we provide free medications to qualified low- and middle-income patients with a demonstrated financial need through a number of patient assistance programs, including through Sanofi Patient Connection. Some people facing an unexpected financial hardship may be eligible for a one-time, immediate month's supply of their Sanofi medicine as they wait for their application to process. As a result of COVID-19, we also made temporary changes to our patient assistance programs, including permitting early reorder of prescriptions and extending our Temporary Patient Assistance Program from 90 to 180 days.

Every patient has unique circumstances, and no one should have to forego the medication they need because they can't afford it. Sanofi has live support specialists at (800) 633-1610 to answer patients' questions and help navigate their individual situations to find the best resources and programs to help lower their out-of-pocket costs.

### 2021 PATIENT SUPPORT: BY THE NUMBERS

**2 MILLION**

# of times a Sanofi copay  
assistance card was used

**97,010**

# of times Insulins **Valyou**  
Savings Program was used

**99,337**

# of patients who received  
free product through patient  
assistance programs

**\$800 MILLION**

patient savings from copay  
assistance programs

**\$37 MILLION**

patient savings from use of  
Insulins **Valyou** Savings Program

**\$1.25 BILLION+**

value of medicine provided  
via patient assistance  
programs