sanofi

May 10, 2024

Maryland Prescription Drug Affordability Board
16900 Science Drive, Suite 112-114
Bowie, MD 20715

Re: Drugs Referred to the Stakeholder Council

Dear Members of the Maryland Prescription Drug Affordability Board,

Sanofi appreciates the opportunity to submit comments to the Maryland Prescription Drug Affordability Board ("Board") on the list of drugs referred to the Stakeholder Council. For the reasons listed below, **we respectfully ask that the Board decide not to conduct any drug cost review at this time and at minimum decide not to conduct any cost review of Dupixent®.**

Dupixent, which Sanofi commercializes with its partner, Regeneron, is a biologic medication that blocks the signaling of two key sources of Type 2 inflammation (IL-4 and IL-13) and is currently indicated in the treatment of five conditions: eczema/atopic dermatitis; asthma; nasal polyps; eosinophilic esophagitis; and prurigo nodularis. Given these five indications, Dupixent's utilization is higher than if five separate drugs were developed to treat these conditions – evidence of the value it provides to the healthcare system and to patients. Dupixent was also the first advanced therapeutic approved to treat four of its five indications and remains the only approved advanced therapy down to six months of age in atopic dermatitis and one year of age in eosinophilic esophagitis, representing transformative scientific breakthroughs for patients suffering from those diseases and further demonstrating the value and innovation it brings to patients and the healthcare system.

I. Dupixent is affordable for Maryland patients

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a. Dupixent has already undergone a review by a nationally recognized, independent nonprofit healthcare research institute and was deemed cost effective

Dupixent was evaluated as part of the drug class used to treat atopic dermatitis by the Institute for Clinical and Economic Review ("ICER") at its initial launch in 2017. ICER is "an independent non-profit research organization that evaluates medical evidence and convenes public deliberative bodies to help stakeholders interpret and apply evidence to improve patient outcomes and control costs."[1] And ICER serves as a "non-partisan, independent, go-to resource for objective evidence about the value of health care in the US."[2] In 2017 when Dupixent launched in the market, ICER reviewed its clinical effectiveness and value. At that time, ICER "found the price of dupilimab [i.e., Dupixent] to be in line with its value."[3] ICER's Chief Medical Officer, Dr. David Rind, MD, MSc stated "Our analyses showed that dupilumab [i.e., Dupixent] offers important clinical benefit for patients with moderate-to-severe atopic dermatitis. Moreover, the drug was priced in a way that aligns well with the benefit it provides to patients."[4]

In the years following Dupixent's initial approval for atopic dermatitis, its value to the healthcare system has only increased with the approvals of four additional indications, and more indications are being studied in our research pipeline. At the same time, Sanofi has acted in line with our Pricing Principles,[5] taking reasonable price increases in the years since its launch. In fact, Sanofi has never had a product, including Dupixent, included in ICER's annual "Unsupported Price Increase Report." This determination of cost effectiveness at launch, coupled with our

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[1] *See* Institute for Clinical and Economic Review. What is ICER? *at* https://icer.org/what-is-icer/.
[2] Id. As of 2019, twenty state Medicaid agencies reportedly used ICER data in their Medicaid drug reviews. *See* Use of Comparative Effectiveness Reviews in Medicaid Drug Reviews, *at* https://www.kff.org/other/state-indicator/use-of-comparative-effectiveness-reviews-in-medicaid-drug-reviews/?currentTimeframe=0&selectedDistributions=state-incorporates-comparative-effectiveness-review-cer-information-in-drug-coverage-reviews--cer-info-sources&sortModel=%7B%22colId%22:%22CER%20Info%20Sources%22,%22sort%22:%22asc%22%7D.
[3] Institute for Clinical and Economic Review. (2017). Atopic Dermatitis: Final Evidence Report. Retrieved from https://icer.org/wp-content/uploads/2020/10/MWCEPAC_ATOPIC_FINAL_EVIDENCE_REPORT_060717.pdf
[4] Id.
[5] *See* Sanofi 2024 Pricing Principles Report *at* https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/diversity-equity-and-inclusion/employee-resource-groups/Employee-Resource-Groups/pricing-principles/Sanofi-2024-Pricing-Principles-Report.pdf (also attached in Appendix)

commitment to responsible price increases, leads to a conclusion that Dupixent remains a good value to patients and to the system and that it would be inappropriate for the Board to focus on Dupixent for a drug cost review, let alone its first drug cost review.

b. Sanofi's Copay Assistance and Patient Assistance Program are utilized by a significant percentage of Maryland patients

We understand that affordability to most patients is not about list price, but rather the price paid by the patient at the pharmacy counter. Pharmaceutical manufacturers do not control a patient's copay – that cost is determined by their health plan. Recognizing this, manufacturers do provide assistance to patients to help offset high copays that result from insurers' benefit design. Sanofi is committed to addressing this challenge and offers a copay card program for Dupixent patients in Maryland and nationwide to help ensure affordable access to this innovative treatment.[6]

In 2022, 72% of commercially insured patients in Maryland received copay assistance from Sanofi. With the Dupixent MyWay® Copay Card, which subsidizes commercially insured patients' out-of-pocket drugs costs, these patients may pay as little as $0* copay per fill of Dupixent.[7] According to our data, in 2022 the average out of pocket cost after manufacturer assistance was $38.53 per one month supply of Dupixent[8] for commercially insured patients in Maryland. All commercially insured patients are eligible for our copay card, and the enrollment process is quick and easy – as simple as filling out a form on our website.[9]

Additionally, through the Dupixent MyWay® Patient Assistance Program, qualified patients with incomes significantly above the Federal Poverty Level, up to $100,000 in income, who are uninsured or whose insurance does not cover Dupixent receive their medication at no cost.[10] The Dupixent MyWay® Support Team is available by phone 24/7 to help

[6] *Eligibility requirements and amount of assistance are subject to change. *See* Dupixent MyWay® Copay Card, *at* https://www.dupixent.com/support-savings/copay-card.
[7] *See* Dupixent Copay Card Enrollment, *at* https://www.dupixent.com/support-savings/copay-card-enrollment.
[8] Some indications may require different dosing.
[9] Id.
[10] *See* Dupixent MyWay® Program, *at* https://www.dupixent.com/support-savings/dupixent-my-way.

patients and healthcare providers to access the program.[11] 1,280 Maryland patients qualified for and received their Dupixent prescriptions at no cost through our Patient Assistance Program in 2023.

The Board should consider the breadth of these Sanofi programs, which lower or eliminate Maryland patients' out-of-pocket costs, in evaluating Dupixent's affordability. Based on the above data, Dupixent is affordable to Maryland patients, so the Board should not review this product and certainly not prioritize its review.

II. Dupixent represents exactly the type of innovation that public policy should protect

a. Dupixent has an orphan designation

Additionally, Sanofi asks the Board to consider that Dupixent's indication for eosinophilic esophagitis ("EoE") was approved as an orphan drug designation. According to the American Partnership for Eosinophilic Disorders ("APFED"), "EoE is a chronic, allergic inflammatory disease of the esophagus (the tube connecting the mouth to the stomach). It occurs when a type of white blood cell, the eosinophil, accumulates in the esophagus. The elevated number of eosinophils cause injury and inflammation to the esophagus. This damage may make eating difficult or uncomfortable, potentially resulting in poor growth, chronic pain, and/or difficulty swallowing."[12] Dupixent is the first FDA-approved therapy to treat patients with EoE. Dupixent is also currently being studied in patients with bullous pemphigoid, a rare autoimmune disease that causes painful skin blisters and many patients' disease is not adequately controlled with currently approved therapies.[13]

Medicines approved to treat rare diseases are exempt from certain laws and regulations, as a recognition that patients suffering from rare diseases can benefit only when companies are willing to assume the risks involved in orphan drug development. Other state Prescription Drug Affordability

[11] Contact 1-844-DUPIXENT (1-844-387-4936) to speak to a DUPIXENT MyWay Case Manager or representative.
[12] *See* APFED "What Are EGIDS? – About EoE" *at* https://apfed.org/about-ead/egids/eoe/.
[13] Zhao L, Wang Q, Liang G, et al. Evaluation of Dupilumab in Patients With Bullous Pemphigoid. *JAMA Dermatol.* 2023;159(9):953–960. doi:10.1001/jamadermatol.2023.2428.

Boards, such as Oregon's,[14] exempt drugs with orphan indications. The Board should follow Oregon's example in this regard and omit Dupixent and other orphan drugs from review. Any untested tampering with the economics of an orphan drug may discourage manufacturers like Sanofi from taking the financial risks necessary for orphan drug development.

b. Dupixent is still being studied in other indications that have no currently approved advanced therapies

Sanofi remains committed – and devotes significant resources – to exploring other potential disease states and patient populations that could benefit from Dupixent. A recent clinical trial showed positive results in some patients with chronic obstructive pulmonary disease ("COPD") who were treated with Dupixent.[15] There are currently no biologic products approved to treat COPD, and many COPD patients' symptoms are not well controlled with currently approved therapies.

We believe that Dupixent may also benefit patients in other indications, and strongly encourage the Board to consider the potential chilling effect that a price control could have on this type of innovation. In fact, Dupixent represents precisely the type of innovation and approach to pricing that should be encouraged in our industry – pursuing first-in-class or best-in-class medicines that have the potential to transform the practice of medicine for patients, and pricing those medicines in a manner that reflects the value they provide to patients and society.

III. The Board has provided insufficient data for a complete response and has failed to follow a reasonable process

The Board recently posted to its website incomplete data on the eight selected drugs that is simply described as a "sample database that includes non-proprietary data and data that has been approved for public display".[16] The provided chart does not address the Board's methodology, list its sources for the data it includes, describe how the Board identified the eight

[14] Or. Rev. Stat. § 646A.694 (2021).
[15] Bhatt, Surya P., et. al. (2023). Dupilumab for COPD with Type 2 Inflammation Indicated by Eosinophil Counts. *New England Journal of Medicine*, 389, 205-214. DOI: 10.1056/NEJMoa2303951
[16] *See* Cost Review Study Process Updates, *at* https://pdab.maryland.gov/cost_review_process.html.

drugs it referred to the Stakeholder Council, nor show the data for any drug reviewed but not referred to the Stakeholder Council. Thus, Sanofi remains concerned that the methodology, data sources, and criteria used by the Board to identify drugs for inclusion in this list was not made available to the public and may not accurately prioritize drugs that pose actual affordability challenges for patients. For example, we note that the Board's chart includes out-of-date information, such as the Medicare patient out-of-pocket cost and spending data from 2020, which predates the Inflation Reduction Act's Medicare rebates that cap drug price increases to economy-wide inflation for that program and reduce and cap patient out-of-pocket costs. The Board should halt any consideration of a cost review until these data issues are resolved, lest the Board arbitrarily and unnecessarily pull inappropriate drugs, like Dupixent, into its cost review process.

The Board also must adequately explain why it is treating these eight drugs differently than the thousands of other drugs that were eligible for a Stakeholder Council referral. Without such an adequate explanation, the decision to refer these eight drugs for Stakeholder Council discussion was, and any decision to conduct a cost review on them would be, inherently arbitrary and unreasonable and would raise serious concerns under State and Federal law. (Sanofi recognizes that there was brief discussion of the eight drugs at the March 25, 2024 Board meeting, but this discussion did not address the factors applied or evidence considered by the Board in deciding to refer these drugs to the Stakeholder Council. Moreover, this discussion was particularly insufficient because the Board has not publicly released recordings or transcripts of this and other recent Board meetings.)

The Board has likewise failed to articulate standards for selecting drugs for cost review and has not yet established an "action plan" for determining upper payment limits ("UPLs") and/or applying UPLs in practice. Likewise, the Maryland Prescription Drug Affordability Board statute and regulations do not define key cost review terms such as "affordability challenge" or "high out-of-pocket costs," and while these authorities describe numerous factors for the Board to consider when identifying drugs for a cost review, they do not describe how to weigh them. Plus, neither the Maryland statute nor regulations articulate a standard for what would be an appropriate UPL. The Board cannot implement a reasonable and compliant cost review process without first filling these major gaps, so the Board should delay its cost review until it has done so.

Finally, the Board has given itself too little time to consider public comments in advance of the May 20, 2024 Board meeting – only 10 days to review comments regarding the eight drugs referred to the Stakeholder Council and only seven days to review comments regarding the therapeutic alternatives lists – given that meeting's agenda to select drugs for cost review and to approve lists of therapeutic alternatives. As Sanofi will note in detail in its forthcoming comments on the therapeutic alternatives identified for Dupixent, determining appropriate therapeutic alternatives requires a nuanced and complex analysis, especially for products such as Dupixent that have five approved indications. To ensure that the selected alternatives are reasonable and genuinely meet patient therapeutic needs, each potential alternative must be analyzed under many factors, including but not limited to, each drug's safety, efficacy, pharmacology, and cost-effectiveness. Even where therapeutic alternatives are available, whether and how patients respond to them will vary significantly. We do not see how the comprehensive data regarding the dozens of potential therapeutic alternatives to the eight referred drugs can reasonably be reviewed by the Board in so little time. Therefore, the Board should not vote to approve any drug for cost review or any therapeutic alternative during its meeting on the May 20, 2024.

IV. Over-emphasizing a medicine's list price will not necessarily improve patient affordability, and will likely impede patient access

The list price of a drug is not the price that most patients pay at the pharmacy counter. As noted above, a patient's copay is set by their health plan, not the manufacturer. Further, commercially insured patients' out-of-pocket costs are reduced by the drug manufacturer copayment support programs noted above, and many patients pay nothing for their drugs through patient assistance. Over-emphasizing the list price of a medicine in Maryland's cost review is unreasonable and will fail to adequately address patient access and affordability challenges. A price control will likely also have unintended consequences such as impairing patient access to their medicines and undercutting pharmaceutical innovation. We encourage the Board to consider recommendations for broader reforms that will truly make the health care system work better for all patients.

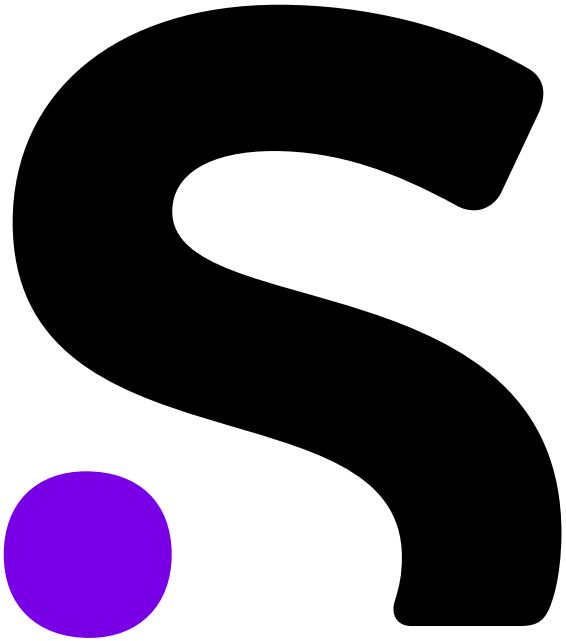
Thank you for the opportunity to provide comments and for considering our concerns. We hope that after considering this information, **the Board will decide not to conduct any drug cost review at this time, and at minimum decide not to conduct any cost review of Dupixent.**

Please feel free to contact me at deanne.calvert@sanofi.com with any questions.

Sincerely,

Deanne Calvert
Head, State Government Relations, Sanofi

APPENDIX



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2024 Pricing Principles Report

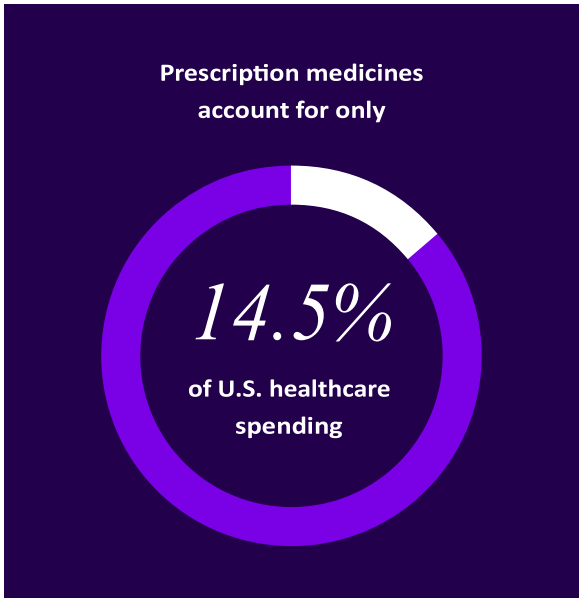
Advancing Responsible Leadership

Prescription Medicine Pricing: Our Principles and Perspectives

At Sanofi, we work passionately to help prevent, treat, and cure illness and disease, understand and solve healthcare needs of people across the world, and transform the practice of medicine.

Our focus spans a number of therapeutic areas, including:

Immunology *Rare diseases* *Rare blood disorders* *Vaccines* *RSV* *Diabetes* *Cardiovascular diseases* *Neurology* *Oncology* *Transplant*



Sanofi has a longstanding commitment to promote healthcare systems that make our treatments accessible and affordable to those in need. We understand and share concerns about the affordability of medicines for patients while also recognizing that we are only one of many stakeholders involved in healthcare delivery. In the United States, medicines are a small share – about 14.5%[1] – of total healthcare spending.

To maintain an environment that will continue to bring new healthcare solutions to patients, **we must encourage a transition to a value-driven healthcare system that provides incentives for the highestquality care.** This evolution will enable both affordable access to treatments 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 U.S. healthcare delivery continuum, **we believe we have a responsibility to be a leader in addressing issues of patient access and system sustainability.** For our part, we price our medicines according to their value, while advancing broader solutions that improve patient outcomes and support affordability within the U.S. healthcare system.

1. The Altarum Institute. Projections of the Prescription Drug Share of National Health Expenditures Including Non-Retail. July 2022.

Our Pricing Principles:

Advancing Responsible Leadership in Access & Affordability

Pharmaceutical innovation brings value to patients, society, and healthcare systems. Given ongoing concerns over rising healthcare costs, our approach to pricing reflects our commitment to patient access while minimizing our contribution to overall healthcare system spending.

We, therefore, commit to both continued transparency in how we price our prescription medicines and to limit increases in prices in the United States.

The Pricing Principles we put forth focus on three pillars:

1. ***Clear rationale for pricing*** *at the time of launch of a new medicine*
2. ***Reporting of U.S. pricing actions*** *on our medicines over time*
3. ***Continued transparency in the United States*** *around our pricing decisions*

"

Responsible pricing is not just a policy; it's a promise to our patients that we will hold ourselves accountable for the life-saving medicines and vaccines we discover, develop, and bring to market.

Adam Gluck
Head, U.S. and Specialty Care
Corporate Affairs, Sanofi

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 of care
2. **Economic value**, or how the medicine reduces the need for — and therefore spend on — other healthcare interventions
3. **Social value**, or how the medicine contributes to quality of life and productivity standard

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.

Comparable treatments available or anticipated

We review similar current or future treatment options at the time of launch to understand the landscape within the disease areas in which our medicines or vaccines may be used.

System-wide affordability

We consider the steps we must take to promote access for patients and contribute to a more sustainable system for payors and healthcare systems.

Unique launch factors

There may be factors specific to a medicine or vaccine 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.

Reporting of U.S. Pricing Actions

We acknowledge our role in preserving the sustainability of our healthcare system and in limiting our contribution to U.S. healthcare spending growth.

On January 1, 2023, with the passage of the Inflation Reduction Act and the presence of other evolving market dynamics, Sanofi revised the “Limited U.S. Price Increases” policy we first established in 2017. As of 2023, our approach to pricing our medicines responsibly balances:

Our ambition to chase the miracles of science to improve people's lives and

"

Every decision we make is done with the patient in mind, ensuring that we remain a driving force for both innovation and affordability in healthcare.

Deborah Glasser
Head, Specialty Care
North America and
U.S. Country Lead

ensure patients have access to the medicines they need now and in the future;

Government policies; and

Evolving trends in the marketplace.

For any list price actions taken by Sanofi during the fiscal year 2023 on any of our medicines, the guiding principle was to adhere to a level that is consistent with our approach on responsible pricing.

Sanofi will annually disclose additional background if price actions trigger a prescription drug mandatory supplemental rebate under the Inflation Reduction Act of 2022.

Continued Transparency in the United States

To maintain an open dialogue and recognize calls for continued transparency in our pricing actions, **we will annually disclose our average aggregate U.S. list and net price changes from the prior calendar year.** These data illustrate how the U.S. healthcare system impacts the way pricing changes accrue to manufacturers versus others in the healthcare delivery continuum. The data also highlight our discrete role in the U.S. healthcare system, i.e., what we as a maker of medicines can control. We believe this information contributes to better-informed discussions to improve patient access and affordability.

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 their healthcare insurance coverage is structured and the extent to which their health plan passes negotiated discounts to patients.

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.

While list prices often receive the most public attention, they do not reflect the price patients pay at the pharmacy counter, nor do they typically reflect the price Sanofi is paid for our medicines.

List prices...

our

...are not the prices typically paid by the insurers, employers, or pharmacy benefit managers who purchase medicines on behalf of patients in their respective health plans. We negotiate discounts and rebates with payors, designed to offer the healthcare system lower prices in exchange for greater access and affordability for patients with insurance.

...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.

Net prices...

fees

...are what Sanofi receives after discounts, rebates, and paid to health plans and other parts of the healthcare system.

...take into account copay expenses that help reduce patients' prescription medicine costs.

Clear Rationale for Pricing

ALTUVIIIO® [Antihemophilic Factor (Recombinant), Fc-VWF-XTEN Fusion Protein-ehtl]

Sanofi introduced ALTUVIIIO in the United States in March 2023 for routine prophylaxis and on-demand treatment to control bleeding episodes and perioperative (surgery) management of bleeding in adults and children with hemophilia A. ALTUVIIIO is the first and only once-weekly hemophilia A treatment that delivers factor activity levels in the normal to near-normal range (over 40%) for most of the week.

Hemophilia A is a rare, lifelong condition in which the ability of a person's blood to clot properly is impaired, leading to excessive and spontaneous bleeds into joints that can result in joint damage and chronic pain, and potentially impact quality of life. The severity of hemophilia is determined by the level of clotting factor activity in a person's blood, and there is a negative correlation between risk of bleeding and factor activity levels.

A Look Back: 2023 Report Card

In May 2017, Sanofi expanded on its commitment to tackle rising healthcare costs with the introduction of our Pricing Principles. Our goal – then and now – is to promote a culture of transparency that would be adopted not only in our industry, but across healthcare – including hospitals and payors – where transparency is often sorely lacking.

Our Pricing Principles are a reflection of our unwavering dedication to providing patients with innovative and life-changing treatments while limiting costs and minimizing our contribution to healthcare spending growth.

The following report outlines our 2023 pricing decisions.

At launch, Sanofi set the U.S. list price of ALTUVIIIO at $5.11 per international unit (IU). As a weight-based dosing regimen, costs per course of ALTUVIIIO treatment will vary by patient. ALTUVIIIO is priced at parity to the annual cost of treating a Hemophilia A patient prophylactically on ELOCTATE® [Antihemophilic Factor (Recombinant), Fc Fusion Protein], another recombinant factor VIII from Sanofi, to ensure that patients have access to the improved bleed protection provided by ALTUVIIIO. Actual costs to patients, payors, and health systems are anticipated to be lower as list pricing does not reflect discounts, rebates, or patient assistance programs.

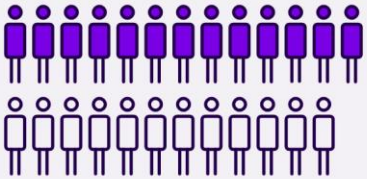
The pricing of ALTUVIIIO reflects Sanofi's commitment to responsible pricing to help ensure all appropriate patients have access to ALTUVIIIO. To set the list price of ALTUVIIIO, Sanofi considered input from payors, pharmacists, and physicians while also recognizing the experience of patients living with hemophilia A. And Sanofi is committed to demonstrating the cost-effectiveness of ALTUVIIIO via real world analyses in published posters and ongoing research.

Sanofi Patient Support Services for ALTUVIIIO is committed to helping eligible U.S. patients access the support they need. Assistance includes disease and medication education, electronic enrollment, financial support, insurance investigation paired with ePrescribing technology, and ongoing help to address barriers throughout the treatment journey.

Beyfortus® (nirsevimab-alip) 50 mg and 100 mg Injection

Sanofi, in partnership with AstraZeneca, introduced Beyfortus 50mg and 100mg Injection in the United States in September 2023. Beyfortus is the first and only long-acting monoclonal antibody indicated for the prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in newborns and infants born during or entering their first RSV season, and for children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.

At launch, Sanofi set the U.S. list price of Beyfortus at $495 per dose. The 50mg and 100mg formulations carry the same price to simplify access. For those infants who remain vulnerable through their second RSV season, they are administered 200mg (2 x 100mg injections).



Currently, there are an **estimated 25,000 patients in the United States with hemophilia A** across all severity levels, of which approximately **13,000 are treated.**

= ~1,000 patients = patients treated

Sanofi priced Beyfortus in accordance with the public health value and innovation it delivers to infants and their families, health systems, and society. The price was determined by considering a range of factors, including the prevention of RSV in infants and the cost burden of RSV-related complications and hospitalizations. As presented in economic models shared during the June 22, 2023, Advisory Committee on Immunization Practices (ACIP) meeting, Beyfortus was shown to be a cost-effective immunization over the long term. As part of the ACIP review process, vaccines undergo a rigorous cost-effectiveness analysis. Both Sanofi and the Centers for Disease Control and Prevention (CDC) conducted these analyses based on the 50mg dose, and they were disclosed and discussed in a public ACIP meeting.

The list price of Beyfortus was based on the cost-effectiveness analyses of Beyfortus for infants at the 50mg dose. This ensures that the price is reflective of the clinical benefit of Beyfortus to all infants as well as the healthcare system. As the clinical benefit is the same for both the 50mg and 100mg doses, we chose to price both equally.

Additionally, the recommendation from ACIP to include Beyfortus in the CDC's Child and Adolescent Immunization Schedule means the cost of Beyfortus is covered by private insurance plans without a co-pay in accordance with the Affordable Care Act. Moreover, Beyfortus was included in the Vaccines for Children's (VFC) program at discounted pricing of $395 per dose. This federally funded program provides vaccines at no cost to children who might not otherwise be vaccinated because of inability to pay. Because of its inclusion in the VFC program, Beyfortus will be provided at no cost to many eligible babies, supporting the goal of more equitable access. Thus, Beyfortus is available at no out-of-pocket cost to families through their insurance plans or through the VFC program. Currently coverage is in place for nearly 100% of infant lives in the United States.

[2]Leader, S., & Kohlhase, K., 2003.
[3]Zhou H., et al., 2012.
[4]Rainisch G., et al. 2020.

Reporting of U.S. Pricing Actions

In 2023, Sanofi increased the price of 48 of its 80 prescription medicines in line with our pricing principles.

Of these, we increased the list price of Enjaymo® (sutimlimab-jome) by 4.44% in January 2023. This increase resulted in a nominal penalty under the new mandatory rebate program created by the Inflation Reduction Act for the period between July 1 – September 30, 2023, the first quarter the program was in place. Triggering the nominal penalty was due to a difference between Sanofi's forecasted inflation estimate and the final calculation of the annual rate of inflation during the CMS lookback period.

In 2023, Sanofi announced significant price reductions for two of its insulin products in the United States.

The list price of Lantus® (insulin glargine injection) 100 Units/mL, our most prescribed insulin by

▼ *78%*

Similarly, the price of our short-acting insulin, Apidra® (insulin glulisine injection) 100 Units/mL by

▼ *70%*

These changes took effect January 1, 2024.

Sanofi also took six price decreases, lowering the list prices of the following vaccines in 2023 compared to December 2022:

- Tenivac® (Tetanus and Diphtheria Toxoids Adsorbed) by ▼*6.9%*
- Imovax® (Rabies Vaccine) by ▼*1.8%*
- Daptacel DTAP® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) by ▼*19.2%*
- Adacel TDAP® (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed) by ▼*9.1%*
- Acthib® [Haemophilus b Conjugate Vaccine (Tetanus Toxoid Conjugate)] by ▼*33.1%*
- Tubersol® (Tuberculin, Purified Protein Derivative) by ▼*2.6%*

Continued Transparency in the United States

U. . Portfolio Annual Aggregate Price Change from Prior Year[17]

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[18]	0.2% Increase	7.8% Decrease

17 Aggregated across Sanofi's prescription portfolio.

18 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 (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 Aggregated List Price change vs. 2019 would have been effectively 0%, and the Average Aggregate Net Price would decrease by 8.0%.

Gross sales paid as rebates in 2023

Sanofi paid

46%

of our gross sales to payors as rebates

$5.8 Billion

in mandatory rebates to government payors as required by federal law

$9.2 Billion

in rebates negotiated with health plans and PBMs and their related fees

2021	1.5% Increase	1.3% Decrease
2022	2.6% Increase	0.4% Decrease
2023	4.3% Increase	15.7% Decrease

Sanofi's annual net price change is influenced by a number of factors, including the level of discounts, rebates, and fees paid to ensure access to our medicines, the makeup of our product portfolio, the type of health plan or program through which the medicine is dispensed (especially those with both negotiated and government-mandated rebates and discounts), and the extent of patient assistance we provide to improve the affordability of our medications.

In 2023, we experienced a 15.7% decrease in our average aggregated net price, the most significant decrease compared to any previous year since we began reporting these data. This decline was the result of a combination of the above factors, including dynamics within our insulin portfolio and heightened demand for rebates and fees from health plans and PBMs who continue to assert control over drug pricing and patient out-of-pocket costs.

The Relationship Between Prescription Drug List and Net Prices

All prescription medicines have both a list price and a net price.

The **"list price"** of a medicine often receives the most attention in public discussions, but it does not reflect the price patients pay at the pharmacy counter, nor does it reflect the amount health insurance companies pay (or that Sanofi receives).

A Look Back: Our Commitment to Patient Affordability in 2023

In too many cases Americans continue to struggle to afford their medicines due to rising out-of-pocket drug costs. Despite the policy and regulatory fervor around drug pricing, very little action has been taken to address what patients pay at the pharmacy counter – which is dictated by health plans and pharmacy benefit managers.

As part of Sanofi's commitment to enabling affordable access, we continue to invest in innovative and industry-leading savings programs that directly lower out-of-pocket costs for patients. We take responsible actions in areas where patients face the greatest need, such as access to insulin.

Sanofi provides significant discounts, rebates, and fees to different stakeholders across the healthcare value chain to ensure our medicines are accessible to patients. The **"net price"** accounts for these various discounts, rebates, and fees, accurately resulting in the amount Sanofi receives for its medicines.

List Price	—	*Discounts, Rebates, and Fees*	=	*Net Price*
(set by Sanofi using our Pricing Principles)		(provided by Sanofi to its customers, including insurers and distributors, to obtain access)		(the amount Sanofi receives for its medicines)

Payors, including pharmacy benefit managers (PBMs) and government and private insurers, ultimately decide which medicines to cover on their plans' drug formularies. Their coverage decisions are based in part on the discounts and rebates Sanofi provides for each of our medicines. Sanofi's rebates – which help to secure formulary placement on prescription coverage plans – should guarantee that patients can access and afford necessary medicines. But this is often not the case. Unfortunately, **there is no way for a pharmaceutical manufacturer like Sanofi to ensure that rebates are passed on to patients** in the form of lower copays and cost-sharing for the patient.

Insulin has long been in the spotlight as an area where the out-of-pocket burden on people with diabetes is unacceptable. This phenomenon persists in part because scrutiny has been directed toward list prices rather than ensuring that rebates, discounts, and fees are used to make insulin more affordable for patients.

The amount that Sanofi pays in discounts, rebates, and fees for our insulin products has continued to grow. In fact, the net price of insulin has fallen for nine consecutive years, making our insulins significantly less expensive for insurance plans.

The out-of-pocket burden on people with diabetes has lessened in recent years as a result of policy and other solutions that deliver direct savings to patients, which Sanofi has long championed and played a meaningful role. These solutions include Centers for Medicare & Medicaid Services' Senior Savings Model and state caps on monthly insulin copays for people enrolled in state-regulated insurance plans.

Still, too many patients struggle to pay for their insulins despite growing discounts and rebates paid by Sanofi, demonstrating the misalignment between discounts paid to payors and patients' out-of-pocket costs.

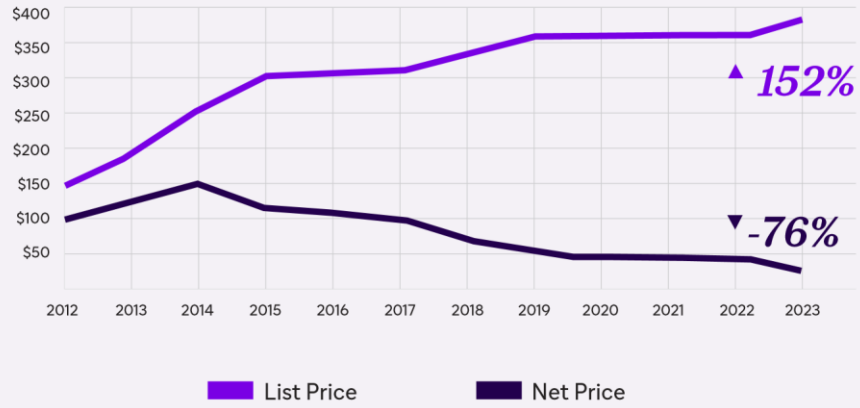
Given these affordability challenges patients face, **Sanofi has taken direct action to improve access and affordability for millions.** For example, we launched an unbranded biologic for Lantus® at 60% less than the Lantus list price in June 2022. However, despite this pioneering low-price approach, patients did not realize the full cost savings because incentives within the health system lead health plans and middlemen to favor high list prices and larger rebates. Lack of interest from health plans to include Sanofi's lower list price option on their formularies led, in part, to its discontinuation.

To further our commitment to support patients directly at the pharmacy counter and accelerate the transformation of the U.S. insulin market, Sanofi announced in March 2023 a list price reduction of Lantus (insulin glargine injection) 100 Units/mL, our most widely prescribed insulin in the United States, by 78% as well as the list price of our short-acting Apidra® (insulin glulisine injection) 100 Units/mL by 70%, both of which took effect in January 2024.

Sanofi's historic list price reduction and continued partnership with stakeholders across the drug supply chain underscore our longstanding commitment to offering affordable access to medicines.

Change in Insulin Costs Over Time

Since 2012, the net price of Sanofi insulins has declined by 76%. Despite this, health plans and others continue to spotlight changes in list prices. However, our insulins are less expensive for insurance plans year over year because of the deep discounts and higher fees we pay.



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

▼ Lantus Net Price Decreased 58%
(lower today than it was at launch in 2004)

▲ Average OOP Costs Increased 24%

Insulin Affordability in Action

2018

Launched Admelog® (insulin lispro injection) 100 Units/mL at a list price that was 15% lower than the reference product, which was the lowest list price of any mealtime insulin.

Introduced of Insulins Val***you*** Savings Program, allowing all who are uninsured to have access to Sanofi insulins at a single, low monthly cost.

2019

Reduced the list price of Admelog by 44% to ensure the medicine retained the lowest list price for mealtime insulin in the United States.

Expanded of Insulins Val***you*** Savings Program so all uninsured patients, regardless of income level, can access one or multiple Sanofi insulins for a fixed price of $99 per 30-day supply (for up to 10 boxes of pens and/or 10mL vials per 30-day supply).

2020

Introduced temporary changes to Sanofi Patient Connection to help those who experienced unexpected loss of income and health insurance during the COVID-19 pandemic. This included providing eligible people with immediate access to a 30-day supply of their medicines, early reordering of prescriptions, expansion of acceptable documentation for proof of income, and extension of its Temporary Patient Assistance Program.

2021

Began voluntary participation in the CMS Senior Savings Model, which gave patients who enrolled in a participating Part D plan access to Sanofi insulins for a $35-or-less copay for each 30-day prescription.

2022

Reduced the list price of Admelog by an additional 25%.

Initiated a new collaboration with Direct Relief to donate insulin and combination diabetes medicines at no cost to people living with diabetes in underserved communities.

Launched Insulin Glargine Injection 100 Units/mL (U-100) at a price 60% less than the 2022 list price of Lantus (insulin glargine injection) 100 Units/mL.

Updated our Insulins Val***you*** Savings Program to allow uninsured patients with a valid prescription to buy any combination and amount of Sanofi insulins for $35 per 30-day supply.

2023

Announced the planned list price reduction of Lantus (insulin glargine injection) 100 Units/mL by 78%, as well as the list price of Apidra (insulin glulisine injection) 100 Units/mL by 70%.

Began collaborations with GoodRx and Amazon Pharmacy to cap the cost of some Sanofi insulins at $35 a month for commercially insured patients. These collaborations, along with other third party partnerships, **led to patient savings amounting to $4.6 million in 2023.**

Bridging the Affordability Gap: Our Patient Support Programs

Sanofi takes pride in developing new life-saving medicines and ensuring access for the patients who need them most. We have developed a suite of innovative, patientinformed programs to help reduce prescription medicine costs — regardless of a person's insurance status or income level.

Each of Sanofi's programs is tailored to a specific population, and we are continually listening to patients, advocates, and caregivers to better understand additional actions we could take to address ongoing or emerging challenges. Sanofi informs patients and providers about the availability of these programs through several mediums, and we continue to seek new ways to educate the public about their availability.

"Over the years, Sanofi has taken proactive steps to address the cost of insulin, implementing innovative solutions to support the lowest out-of-pocket expenses for patients. We are proud to continue to support this community, prioritizing patient access and helping to create a more affordable health system for patients.

Olivier Bogillot
Head, North America
General Medicines, Sanofi

We remain committed to addressing pressing issues around insulin access and affordability. 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. And now, our innovative and patientcentric savings programs help most people reduce the cost of our insulin medicines (Admelog, Apidra, Lantus, Toujeo, and Insulin Glargine U-300) to a price of $35 or less for a 30-day supply, regardless of income or insurance status.

We also provide free medications to qualified low- and middle-income patients as part of a number of Patient Assistance Programs across our therapuetic areas including Sanofi Patient Connection.

We continue to review and evolve our programs to better serve and improve affordability for patients.

Every patient has unique circumstances, and Sanofi has live support specialists who can be reached at *(855) 984-6302* to answer individual patient questions and navigate their unique situation to find the best resources and programs to help lower their out-of-pocket costs.

2023 Patient Support: By the Numbers

3.6 Million+
# of redemptions of assistance card

128,609
# of times Insulins a Sanofi copay Val***you*** Savings Program was used

127,369
# of patients who use of copay through patient assistance programs

$1.48 Billion+
patient savings from received free medicine assistance programs

$61.9 Million+
patient savings from use Val***you*** Savings Program

$ 1.71 Billion+
value of medicine of Insulins provided via patient assistance programs

A Look Forward: Our Position on System Transformation

Sanofi supports policy solutions that can help transform healthcare delivery to achieve lower costs and wider access for patients taking prescription medicines. Driving system savings through better, more efficient health outcomes and not blunt cost-cutting measures will require change across the healthcare continuum – including substantial reforms to benefit design in commercial and government coverage.

Broader System Reforms Are Needed to Improve Patient Outcomes & Affordability

History has shown that the **most effective changes in health policy are solutions that directly address the cost barriers patients face.**

This is especially true of major prescription drug reforms, such as the passage of the Medicare Part D drug program in 2003. Two decades later, 50.5 million Americans on Medicare now receive direct coverage for their outpatient prescriptions.

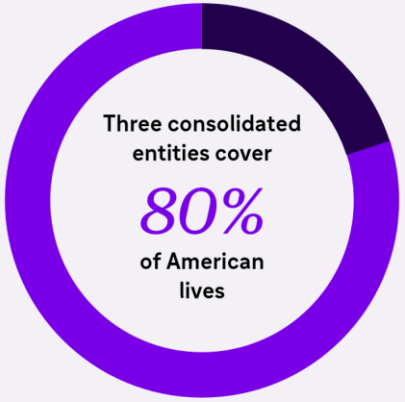
To continue delivering the shared goals of better health outcomes and ongoing treatment innovation, it is essential for policies to directly address patient cost and access barriers. This means **shifting our narrow focus on list prices to the development of solutions that can improve benefit design and balance system incentives** across many stages of prescription drug delivery.

Central to the process of medicines reaching patients are the players in the middle of drug delivery: pharmacy benefit managers (PBMs), insurers, wholesalers, specialty and retail pharmacies, and group purchasing organizations.

The U.S. health system has seen significant consolidation among these groups, which are now often owned by the same parent corporations, cycling patients between different divisions within the same company for care and reimbursement. This is especially true for specialty medicines, where PBMs steer patients toward their own specialty pharmacies.

Due to the concentration of market power among these three consolidated companies, Sanofi has had to agree to more rebates, discounts, and fees during the negotiation process to try to ensure patients are able to access our medicines. In 2023, we had a 15% increase in fees – or service charges – paid on top of negotiated rebates to PBMs and health plans in Managed Care, Medicare Part D, and Managed Medicaid agreements. In total, we paid about $1.4

Impact of Vertical Integration



Manufacturers pay significant rebates, fees and discounts to try to secure access for patients on these plans.

Yet, patients still struggle with out-of-pocket costs at the pharmacy counter.

billion more in negotiated rebates and fees than in 2022 – almost an 18% increase year-over-year.

The increased scale of these negotiated payments, on top of the substantial mandated discounts provided to government programs (e.g., Medicare Part D, Medicaid, and the 340B drug pricing programs), greatly contributed to a 15.7% decrease in our portfolio net price in 2023, the largest decrease in any previous year since we began reporting.

Additionally, insurers are more frequently applying restrictions or diversion tactics to the robust copay assistance programs provided by Sanofi and other manufacturers that are intended to help patients afford their medicines. These revenue strategies, known as **copay accumulators and maximizers or alternative funding programs, funnel manufacturer patient assistance funds into the payor's bottom lines, rather than applying them toward a patient's deductible or out-of-pocket maximum.**

These business tactics negatively impact patients as the extensive rebates and fees we pay are not translating into medication access for too many people enrolled in insurance plans. Insurers are avoiding their appropriate financial responsibility to cover their beneficiaries' medicines by shifting those costs back to patients in the form of significant out-of-pocket costs.

If policies are enacted to add oversight and accountability to protect patient interests, we can address the barriers patients face and support broader coverage and access to the medicines they need. Therefore, **Sanofi supports policies that would correct these market distortions**, including:

1. Mandating that service fees levied across the pharmaceutical supply chain (e.g., administration fees, data fees, formulary fees, etc.) are flat rather than charged as a percentage of the list price of a medicine.
2. Requiring that manufacturer rebates and discounts paid to PBMs and insurers benefit patients by lowering out-of-pocket costs at the pharmacy counter.
3. Preventing PBMs from capturing manufacturer copay assistance through diversion of funds intended to reduce patient cost-sharing or denial of coverage for their medicine.
4. Allowing patients in federal health insurance programs, such as Medicare, to access manufacturer copay assistance programs when there's no generic or biosimilar alternative available.

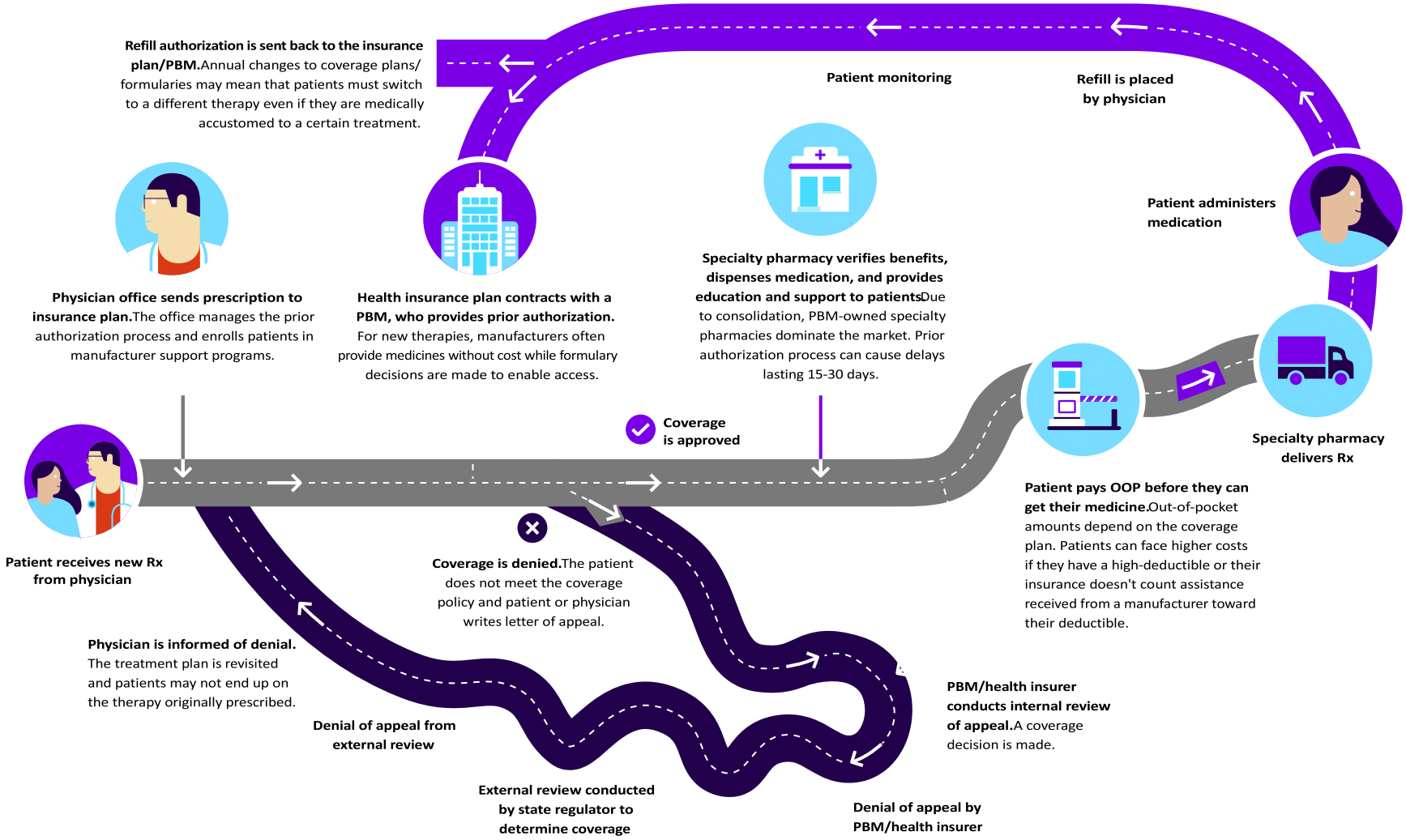
"By establishing policies that align incentives so the value driven by competition accrues to patients, we can accomplish our shared goal of lowering drug prices and patient costs, while also protecting and cultivating the entrepreneurial risk-taking necessary for pharmaceutical manufacturers to continue to discover, develop, and bring to market life-saving new medicines.

Paul Hudson
CEO, Sanofi

The Road to Access: Understanding Specialty Pharmacy Barriers

Specialty medicines – typically defined as those used to treat rare, complex or chronic conditions – require extra patient education, ongoing monitoring, adherence support, and specialized handling, such as unique medication storage or shipment requirements. As a result, these medications are not available directly over the pharmacy counter and have their own reimbursement and distribution processes.

Patients prescribed specialty medicines experience more frequent coverage restrictions despite the billions in rebates and fees that manufacturers pay to insurers



and PBMs to ensure access to medications. Implementing policies that aim to remove these barriers can help widen and accelerate access to the medicines patients need.

Health Policy Solutions That Protect Innovation While Delivering Out-of-Pocket Relief for Patients

The U.S. pharmaceutical industry has delivered unprecedented scientific breakthroughs that have changed the way we treat and prevent diseases, spanning a wide range of therapeutic areas. **Sanofi supports policy solutions that preserve drug discovery and development** while ensuring broad and affordable patient access to life-changing medicines.

While Sanofi supports the modest affordability improvements included in the Inflation Reduction Act (IRA), unfortunately, in only the first couple of years since enactment, we are already seeing the earliest signs of the negative impact the IRA may have on innovation and science.

The IRA's "negotiation" process, as written, is essentially government price setting, which will artificially influence research and development (R&D) investment decisions. This can significantly impact drug candidates that can target multiple disease areas, as the IRA's pre-price control window limits a company's ability to conduct clinical trials for regulatory approval in different indications. This could lead to as many as 139 fewer drugs developed over the next decade alone. As science is iterative, the long-term consequences could be even more dramatic, contradicting the government's other healthcare goals, including advancements in oncology treatments. If the IRA continues down this path and curtails U.S. innovation in medicines, the lack of novel treatments could lead to higher medical costs and increased hospital stays – areas of the system where both costs are high and patient burdens significant.

Without changes, **the IRA's price controls will place a thumb on the scale of science** in ways that will significantly limit scientific research, **and too many seniors will continue struggle to afford their medicines.** Sanofi supports changes to the IRA's drug pricing policies to minimize the harms to innovation and make the system work better for patients, including:

> "
>
> The IRA barely impacts patients' out-of-pocket expenses and does nothing to address other parts of the health system that limit patient access. The next phase of health reform should reverse the approach – improve the remaining 85% of the healthcare industry outside pharmaceuticals – to better address patient affordability before further impacting science and innovation.
>
> ***Adam Gluck***
> ***Head, U.S. and Specialty Care Corporate Affairs, Sanofi***

1

Modifying the current law's unscientific distinction between small molecule drugs and biologics, which will discourage the development of medicines that typically come in pill or capsule form. Small molecule drugs, which are often preferred by patients, receive four fewer years of protection before price controls compared to other forms of prescription drugs.

2

Reducing the disincentives that constrain investment in multiple indications for a drug candidate. For example, exemptions for orphan medicines should be expanded to those that treat more than one rare disease.

Accounting for value as it relates to both patients and the health system. For example, value should properly reflect the ability to lead a productive life mostly free of disease, the impact of the side effects, the cost of physician monitoring, and other clinical outcomes valued by patients and their families.

3

4

Monitoring formulary decisions by health plans to protect patient access to new medicines through frequent, adequate updates of oversight plans. Medicare should contribute to a future where providers and patients have an array of clinical choices so that the best and most appropriate innovations are available to treat patients needing such advances.