sanofi

June 23, 2025

Via Electronic Mail
Deidre S. Gifford, MD, MPH
Commissioner, Office of Health Strategy
450 Capitol Avenue, 1st Floor
Hartford, CT 06106

Re: June 23, 2025 Public Hearing

Dear Commissioner Gifford,

Sanofi is in receipt of the Office of Health Strategy (OHS) letter dated April 29, 2025 regarding Connecticut's healthcare cost growth benchmark initiative and public hearing on June 23, 2025. This letter constitutes our full response.

Sanofi is an R&D driven, AI-powered biopharma company committed to improving people's lives and creating compelling growth. We apply our deep understanding of the immune system to invent medicines and vaccines that treat and protect millions of people around the world, with an innovative pipeline that could benefit millions more. Our team is guided by one purpose: we chase the miracles of science to improve people's lives; this inspires us to drive progress and deliver positive impact for our people and the communities we serve, by addressing the most urgent healthcare, environmental, and societal challenges of our time.

We share Connecticut's goals of promoting affordability, transparency, and responsible pricing throughout the healthcare system. Each year since 2017, we have published a Pricing Principles Report, offering a clear rationale for our pricing decisions.[1] This report outlines our value-based approach to pricing -- ensuring that our medicines reflect their clinical and societal benefit while supporting the long-term sustainability of the U.S. healthcare system and helping to contain overall spending growth.

Your letter concerns our medication, Dupixent, which Sanofi commercializes with our partner, Regeneron. Dupixent is a first-in-class biologic medication that inhibits the signalling of two key sources of Type 2 inflammation (IL-4 and IL-13). Its broad therapeutic value is reflected in its current FDA-approved indications across eight different conditions: eczema/atopic dermatitis; asthma; nasal polyps; eosinophilic esophagitis (EoE); prurigo nodularis, chronic obstructive pulmonary disease (COPD), chronic spontaneous urticaria (CSU), and bullous pemphigoid

[1] *See* Sanofi, *2025 Pricing Principles Report: Advancing Responsible Leadership* (2025), https://www.sanofi.us/assets/dot-us/pages/images/our-company/Social-impact/responsible-business-values/pricing-principles/Sanofi-2025-Pricing-Principles-Report.pdf [hereinafter *2025 Pricing Principles*].

(BP).[2] Dupixent has received multiple FDA Breakthrough Therapy designations and was the first advanced therapeutic approved to treat six of its eight indications. For most of its indications, Dupixent addressed a significant unmet medical need in disease areas where only steroids or other generic treatments were the standard of care. The medication remains the only biologic approved for use in children as young as six months for atopic dermatitis and one year for EoE, and the only targeted medicine approved to treat BP.

Overall, Dupixent represents a transformative scientific innovation that has significantly improved the standard of care for patients with a wide range of chronic, often debilitating conditions—many of whom previously had limited or no effective treatment options. Its broad therapeutic impact underscores the value it brings to both patients and the healthcare system. As outlined below, we believe Dupixent's pricing reflects this clinical value, given its proven ability to improve patient outcomes and reduce reliance on other costly intervention. Moreover, we believe Dupixent's potential is still not fully realized. Sanofi remains deeply committed—and devotes significant resources — to exploring additional disease areas and patient populations that could benefit from the therapy, and we are actively conducting clinical trials to pursue further indications, with the goal of extending Dupixent's benefits to even more patients living with serious and conditions with unmet need.

OHS's Spending Data Does Not Accurately Reflect Dupixent's True Costs to the System

OHS states that "Dupixent… was ranked 5th in total 2023 commercial spending with an amount of $79,768,153 representing a 40.7% increase in annual spending growth. This medication also exhibited a 10.2% annual change in payment per 30-day supply."

As a preliminary matter, we are unable independently to verify these claims by reference to Connecticut's All-Payer Claims Database (the "Database"). For example, while the April 29 letter states that Dupixent ranked fifth in 2023 commercial spending, the medication does not appear among the top five drugs listed in the "Highest Spending" tab for 2023 for the commercial market — or any other year on record.[3] Additionally, the reported 10.2% increase in payment per 30-day supply appears inconsistent with Dupixent's 2023 list price increase of 6%, which remained below the price increases taken by other therapies in the

[2] *See* Dupixent Prescribing Information, https://www.regeneron.com/downloads/dupixent_fpi.pdf.
[3] *See* Connecticut Health Strategy, CT Retail Pharmacy Dashboard Glossary and Guide: Definitions (Apr. 2025), https://app.powerbigov.us/view?r=eyJrIjoiMDZiY2Y5ODEtZjFhNS00Y2Y2LTgxZjEtNmUyOWNkZmM1ZDJhIiwidCI6IjExOGI3Y2ZhLWEzZGQtNDhiOS1iMDI2LTMxZmY2OWJiNzM4YiJ9 (describing the "Highest Spending" report view as capturing "total spending for the five drugs with the most spending in the selected market").

therapeutic class that year. If that calculation is accurate, it must reflect pricing actions taken by other entities in the healthcare system, such as pharmacy benefit managers ("PBMs"), payors, and pharmacies, which establish reimbursement rates independently of pharmaceutical manufacturers.

Most importantly, it appears that the figures reflected in the Database do not account for the substantial discounts and rebates Sanofi pays on Dupixent.[4] As you may know, a medication's "list price" represents the initial price established for a product. However, this price point does not reflect the significant discounts, rebates, and fees that Sanofi pays across the healthcare value chain, including to PBMs and payors, to make our medicines accessible to patients. Instead, a medication's "net price" more accurately represents its true cost, as it reflects the actual amount Sanofi receives after considering these price concessions. For example, as detailed in our 2024 Pricing Principles Report, in 2023 Sanofi paid 46% of our gross sales across our products to PBMs and payors as rebates. These substantial price concessions resulted in an average aggregate net price decline across our U.S. portfolio of 15.7% compared to net prices in 2022. Sanofi pays these significant rebates and discounts to PBMs and payors with the intention of improving the affordability and access of our medications for patients. However, Sanofi does not control whether or how PBMs and payors ultimately choose to apply the rebates we pay to the costs patients are charged to access our treatments. As a result, the pricing data relied upon by OHS does not reflect the true costs of Dupixent and is an unreliable benchmark for the committee's analysis.

Similarly, the Database does not capture the impact of Sanofi's patient assistance program and copayment assistance supporting Dupixent. Specifically, through Dupixent MyWay®, patients may access financial assistance, including free treatment for eligible financially-needy patients, as well as copayment assistance for commercially-insured patients that may lower a patient's copayment to as little as $0 per fill. In 2023, over 750 Connecticut patients received free Dupixent through our patient assistance program. Additionally, 3980 commercially insured Connecticut patients received copay assistance for their Dupixent in 2023.

High Utilization Reflects High Value to Patients and the Healthcare System

While Sanofi has not been able independently to verify the specific figures cited in OHS's April 29 letter, we believe the observed increase in spending may largely be attributed to increased utilization of Dupixent. Nationally, Dupixent experienced a significant increase in use in 2023. We believe this growth directly reflects the number of new indications, populations, and diseases for which Dupixent has been approved since its first approval in 2017. It also reflects increased awareness by

[4] *See id.* (defining "spending" as "The total amount paid for a prescription claim, including insurance payments and consumer out-of-pocket payments. Manufacturer rebates are not included[.]").

healthcare professional and patients regarding the clinical value of Dupixent to improve symptoms, reduce disease burden, and help prevent or mitigate negative health outcomes. Particularly in the chronic and underserved conditions Dupixent is approved to treat, increased uptake underscores that the medication continues to meet critical patient needs and is a strong indicator of trust among the medical community in the treatment's value. Simply put, when more patients and providers choose a medication, it is often because it delivers meaningful clinical benefits and fills critical care gaps. Dupixent's growing utilization is a result of the significant post-approval investment in science made by Sanofi and its partner, Regeneron, to identify underserved patient populations and diseases with high unmet medical needs for which Dupixent holds the potential to transform the practice of medicine.

Dupixent is Responsibly Priced

Dupixent, like all Sanofi medicines, is priced based on a rigorous assessment of its value—reflecting our commitment to patient access while minimizing our contribution to overall healthcare system spending.[5] Sanofi evaluates each treatment's value through a comprehensive framework that considers clinical value and outcomes, economic value, and broader societal benefits.[6] Our pricing strategy also prioritizes system-wide affordability, including taking steps to enhance patient access and support the long-term sustainability for payors and healthcare systems.[7]

Consistent with these pricing principles, the price of Dupixent reflects its substantial clinical value and its proven ability to improve disease control across multiple chronic conditions, including atopic dermatitis, asthma, EoE, and COPD. In multiple studies, Dupixent consistently demonstrates strong cost-effectiveness by reducing hospitalizations and healthcare utilization,[8] delivering better clinical outcomes at a lower cost per responder,[9] improving long-term quality of life and

[5] *See 2025 Pricing Principles* at 2.

[6] *See id.* at 3.

[7] *See id.*

[8] *See*, *e.g.*, Silverberg et al., *Dupilumab Treatment Reduces Hospitalizations in Adults with Moderate-to-Severe Atopic Dermatitis*, J Allergy Clin Immunol Pract (2022) ("Patients who received dupilumab had a 62% lower risk of all-cause hospitalizations and 79% lower risk of atopic dermatitis–related hospitalizations compared with controls. . . . Dupilumab significantly reduced hospitalizations and shortened the duration of atopic dermatitis–related hospital stays compared with control."); Tavi et al., *Economic Value of Preventing and Treating Comorbid Asthma With Dupilumab in Pediatric Patients With Atopic Dermatitis: A Cost-Offset Model From the US Payer Perspective* (2025) (demonstrating lower 5-year cumulative healthcare costs with Dupixent versus conventional therapy).

[9] *See*, *e.g.*, Tavi et al., *Number Needed to Treat and Cost per Additional Responder of Biologic Therapies in Adults with Moderate-to-Severe Atopic Dermatitis* (2025) ("Dupilumab was $17,760 and $158,657 less expensive per additional responder than tralokinumab and lebrikizumab, respectively.").

productivity,[10] and offsetting future costs by preventing disease progression.[11] By mitigating disease advancement and associated complications, Dupixent lowers long-term costs for payors and health systems by reducing the need for other high-cost interventions.

Dupixent has been widely recognized as a therapy priced in alignment with the value it delivers. At the time of its initial approval for atopic dermatitis, the Institute for Clinical and Economic Review (ICER)[12] as well as payors deemed Dupixent's launch price "cost effective," reflecting both its clinical benefits and the healthcare costs it helps avoid. ICER concluded that Dupixent was priced "in line with its value,"[13] with its Chief Medical Officer concluding that "the drug was priced in a way that aligns well with the benefit it provides to patients."[14] In a subsequent 2021 review that was last updated in 2023, ICER reaffirmed that Dupixent remains more cost effective than alternatives in treating atopic dermatitis.[15]

In the years following Dupixent's initial approval, Sanofi has adopted reasonable annual price increases at or below the growth rate for National Health Expenditures, an index produced by the Centers for Medicare & Medicaid Services representing the total amount spent on healthcare in the United States. These price increases have been similar to or lower than those of other specialty drugs

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[10] *See*, *e.g.*, Wang et al., *Dupilumab Improves Health-Related Quality of Life and Work Productivity Among Adults With Moderate-to-Severe Atopic Dermatitis in Clinical Practice: 5-Year Follow-up Results From the RELIEVE-AD Study* (2025) ("Dupilumab treatment resulted in rapid improvements in health-related quality of life and working productivity, sustained over 5 years.").

[11] *See*, *e.g.*, Tavi et al., *Economic Value of Preventing and Treating Comorbid Asthma With Dupilumab in Pediatric Patients With Atopic Dermatitis: A Cost-Offset Model From the US Payer Perspective* (2025) ("Cumulative 5-year prevalent asthma-related costs and future incident asthma costs from onset were 23% and 35% lower, respectively, for dupilumab vs conventional therapies.").

[12] 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." ICER, *What is ICER?*, https://icer.org/what-is-icer/.

[13] ICER, *Dupilumab and Crisaborole for Atopic Dermatitis: Effectiveness and Value* (Jun. 8, 2017), https://icer.org/wp-content/uploads/2020/10/MWCEPAC_ATOPIC_FINAL_EVIDENCE_REPORT_060717.pdf.

[14] ICER, *Institute for Clinical and Economic Review's final report on treatments for atopic dermatitis provides policy recommendations to support appropriate patient access to dupilumab* (Jun. 8, 2017), https://icer.org/news-insights/press-releases/institute-for-clinical-and-economic-reviews-final-report-on-treatments-for-atopic-dermatitis-provides-policy-recommendations-to-support-appropriate-patient-access-to-dupilumab/.

[15] ICER, *JAK Inhibitors and Monoclonal Antibodies for the Treatment of Atopic Dermatitis: Effectiveness and Value* 47 (Aug 17, 2021, *updated* Feb. 27, 2023), https://icer.org/wp-content/uploads/2023/02/Atopic-Dermatitis_Final-Evidence-Report_Unmasked_02272023.pdf ("Compared to dupilumab, baricitinib and tralokinumab were found to be less costly and less effective whereas abrocitinib (using a placeholder price) and upadacitinib did not meet commonly cited cost-effectiveness thresholds.")

in the therapeutic class. In fact, the increase in Dupixent's net price has been negative in some years and the average annual net price increase has been minimal in the years since its launch.

This determination of cost effectiveness at launch, coupled with our commitment to responsible price increases, reinforces that Dupixent continues to deliver exceptional value to both patients and the broader healthcare system.

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Dupixent exemplifies the kind of innovation and value-based pricing that should be expected from our industry—delivering first-in-class or best-in-class therapies that have the potential to transform patient outcomes, while ensuring that pricing reflects the meaningful benefits these therapies bring to patients, healthcare systems, and society as a whole.

If there are further inquiries, I can be reached at kathryn.lavriha@sanofi.com or (301) 908-3367.

Sincerely,

Kathryn Lavriha
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