

Sanofi-Aventis: reimbursement integrity and the meaning of insulin affordability

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1. Executive assessment: three different affordability questions

Sanofi-Aventis is a historical corporate name. The company announced the Sanofi US identity in June 2011 following the parent's change to Sanofi.¹ This report preserves the familiar historical label while identifying the relevant subsidiaries in enforcement matters and using Sanofi for the current business. A further boundary changed in April 2025, when the company sold a controlling stake in consumer-health business Opella and retained a 48.2% interest.⁴ Current prescription-medicine pricing should not be confused with the entire former consumer-health portfolio.

The evidence reviewed raises three distinct questions. First, are discounts accurately reflected in prices reported to public programs? A 2012 Hyalgan settlement resolved allegations involving free units and average sales price reporting. Second, does charitable assistance allocate support independently? A 2020 Lemtrada settlement addressed alleged coordination with a charitable foundation. Third, do lower list prices and savings programs reduce the costs patients actually face? Sanofi's insulin announcements and current program terms provide useful but incomplete evidence.^{2,3,5,6}

These questions should not be reduced to one company-wide accusation. The Hyalgan and Lemtrada matters were civil settlements of allegations, not criminal convictions in the cited records. Conversely, a current affordability initiative does not invalidate the significance of an earlier reimbursement-integrity case. The report examines the mechanism, disposition, and limits of each source separately.

Sanofi announced a 78% U.S. list-price reduction for Lantus and a 70% reduction for Apidra, effective January 1, 2024.⁵ Its current insulin savings terms describe different arrangements for commercially insured users and people paying without insurance, with eligibility conditions and program maximums.⁶ A statement that “all insulin costs \$35” would lose material information about the product, coverage route, supply period, and conditions.

The newest company transparency report adds another layer: Sanofi reported a 3.4% decline in its average aggregate U.S. net price during 2025, alongside a 2.8% average aggregate list-price increase.⁷ Those portfolio measures can move differently and neither directly measures every patient's cost. They are company-reported aggregates, not an independently audited dataset assembled for this report.

The central finding is therefore about price transmission and accountability. Information is most useful when it shows who receives a discount, how it affects a reimbursement benchmark, and whether it reaches a patient. A large discount or a favorable average cannot answer all three questions by itself.

2. Historical record: free units, reported prices, and assistance

The December 2012 resolution involved Sanofi-Aventis U.S. Inc. and Sanofi-Aventis U.S. LLC. DOJ said the companies agreed to pay \$109 million to settle False Claims Act allegations concerning Hyalgan, an injection used for knee conditions. The government alleged that free units were provided to induce purchases and prescriptions and that reported average sales prices failed to account for units contingent on purchases.² The alleged reporting problem matters because an invoice price can differ from a purchaser's effective acquisition cost.

DOJ described examples in which physician practices allegedly received additional units alongside paid purchases. It argued that the practice could increase the margin between acquisition cost and reimbursement while avoiding an overt reduction in the invoiced price. The public release described the allegations and negotiated resolution; it did not establish an adjudicated damages figure for all affected claims.² The \$109 million settlement must therefore be labeled as a settlement amount, not as an independently calculated total of patient overcharges.

The later Lemtrada matter involved a different pathway. In February 2020, the U.S. Attorney's Office announced an \$11.85 million settlement with Sanofi-Aventis U.S., LLC over alleged Medicare kickbacks through The Assistance Fund. The allegations concerned 2015-2016 donations, coordination through a reimbursement hub, and the allocation of grants when a multiple-sclerosis fund reopened.³ The date is 2020, not 2019; preserving the original announcement date avoids a common error from undated secondary summaries.

Date	Event	Evidence category
June 2011	Sanofi US identity announced	Company identity disclosure
December 2012	\$109 million Hyalgan resolution	Civil settlement of allegations
February 2020	\$11.85 million Lemtrada assistance resolution	Civil settlement and integrity agreement
March 2023	Insulin price cuts announced for January 2024	Prospective manufacturer action
April 2025	Controlling Opella stake sold	Corporate scope change
2026	Updated pricing and savings disclosures	Current company terms and data

The two enforcement matters are connected by financial incentives but not by the same mechanism. Hyalgan concerned provider acquisition economics and reimbursement reporting. Lemtrada concerned assistance timing and alleged preferential access to grants. Treating them as identical “price fixing” cases would be inaccurate. Neither cited announcement describes an agreement among competitors to fix a drug price.

These distinctions also help identify useful evidence for further work. Invoice and free-unit records matter for one case; donation dates, grant rules, and referral practices matter for the other. A credible transparency project should select its dataset to match the actual concern rather than collect a list of large settlements without explaining them.

3. Principal evidence: where an affordability benefit can be redirected

The Hyalgan allegations illustrate why the word “free” can be misleading without specifying the recipient and transaction. DOJ alleged that samples tied to purchases lowered physicians' effective acquisition costs and made the product attractive because reimbursement did not fall correspondingly. It also alleged inaccurate average sales price reporting.² The issue was not that every sample is unlawful. It was the particular alleged link between additional units, prescribing incentives, and public reimbursement.

The economic mechanism can be expressed without inventing a drug price: when a buyer receives additional usable units for the same total payment, the average payment per unit decreases. Whether reimbursement should reflect that change depends on the applicable rules and transaction facts. This report does not reconstruct an ASP submission or determine which units were legally reportable; it explains the government's stated concern and the settlement resolving it.

The Lemtrada case shows a different possible redirection. DOJ alleged that The Assistance Fund's multiple-sclerosis fund did not maintain a waiting list while closed and that Sanofi's reimbursement hub quickly referred Lemtrada patients after donations reopened the fund. The government said those patients consequently received a disproportionate share of grants compared with people using other multiple-sclerosis medicines.³ That is an allegation in the settlement record, not a finding that all assistance recipients acted improperly.

The relevant distinction is between relieving financial distress and determining who gets that relief. Patients can benefit immediately from copayment support while the allocation process still warrants scrutiny. Independence requires more than a charitable name: timing, information sharing, disease-fund design, and selection procedures can affect whether support follows need or a manufacturer's commercial interest. This is an analytical implication of the described case, not a claim that all manufacturer-supported charities use the same practices.

The 2020 announcement also reported a corporate integrity agreement requiring measures concerning third-party assistance programs, independent review, and certifications by executives and board members.³ Such obligations are a documented response, but their existence alone does not prove subsequent compliance. This review did not obtain ongoing monitoring reports or conduct an audit of the agreement.

For public reporting, the strongest formulation is specific: the companies settled allegations about identified conduct involving Hyalgan and Lemtrada, and the Lemtrada resolution included an integrity framework. The evidence does not justify labeling every discount, donation, or patient-support program as a kickback. It also does not justify treating a reduction in a patient's immediate copayment as sufficient proof that the wider reimbursement arrangement is fair. Both the benefit and the incentive structure need examination.

4. Quantitative context: list price, net price, and the \$35 programs

Sanofi's March 2023 announcement specified Lantus insulin glargine 100 units/mL and Apidra insulin glulisine 100 units/mL. The respective announced U.S. list-price reductions were 78% and 70%, with January 2024 implementation.⁵ These percentages describe changes to manufacturer list prices for the specified products. They should not be applied to all Sanofi products, all countries, or every individual's total diabetes spending.

Current insulin savings terms state that eligible commercially insured individuals using insurance pay no more than \$35 per 30-day supply of each covered product. Eligible people without insurance, or paying without using it, can pay no more than \$35 in total for one or multiple participating Sanofi insulins filled together each month. Maximums and other conditions apply. The program is not insurance and excludes prescriptions submitted for reimbursement to specified government programs.⁶

Figure	Period and unit	Appropriate interpretation
Lantus list-price reduction	78%; announced for January 2024, U.S.	Product-specific list-price change
Apidra list-price reduction	70%; announced for January 2024, U.S.	Separate product-specific change
Commercial savings offer	Up to \$35 per 30-day supply, each covered product	Conditional patient payment
Cash/non-insurance offer	Up to \$35 per 30-day supply, participating insulins filled together	Conditional combined offer
Aggregate net-price change	Down 3.4% in 2025, U.S. portfolio	Manufacturer-reported average
Aggregate list-price change	Up 2.8% in 2025, U.S. portfolio	Different measure from net price

The portfolio measures come from Sanofi's 2026 transparency document.⁷ Their divergence is informative but not paradoxical: discounts, rebates, fees, portfolio composition, and payment channels influence the amount received after a list price is set. An average decrease does not establish that every medicine's net price fell or that any specific patient's prescription became cheaper. No patient-level claims data were analyzed here.

Medicare's insulin protection is a separate route. Medicare states that each covered insulin product costs no more than \$35 for a one-month supply, without an insulin deductible, while other costs can apply.⁹ A manufacturer savings card and a statutory insurance benefit should be shown separately in an access guide. They have different eligibility rules, administration, and permanence.

An affordability evaluation should therefore record the actual benefit pathway before comparing payments. It should also include supplies, appointments, and other treatment costs when asking about total burden. The cited savings program covers medication costs, not every expense associated with living with diabetes.⁶ This report documents published terms; it does not guarantee a transaction or establish individual eligibility.

5. Company position and September 2026 status

Sanofi's current global principles describe launch pricing as considering clinical and economic value, alternatives, country affordability, and medicine-specific circumstances. The policy uses country-level indicators of wealth, healthcare spending, and household contribution to care when assessing flexibility.⁸ This is the company's stated framework. The publication of principles is useful evidence of policy, but it does not reveal every negotiated price or prove that every patient can afford treatment.

The 2026 U.S. transparency report argues that insurers and pharmacy benefit managers determine benefit design and that manufacturer rebates do not necessarily reach patients. Its aggregate data show the distinction between list and net pricing.⁷ These statements provide Sanofi's position in the policy debate. This report does not adopt broader claims about intermediary conduct without separate evidence, nor does it use those claims to remove manufacturer pricing decisions from scrutiny.

The company's 2023 insulin announcement similarly said lower list prices needed broader system changes to translate into pharmacy-counter savings.⁵ That observation is consistent with the need to identify the coverage pathway. It does not establish that a particular plan, pharmacy, or intermediary caused an individual access problem. Product-specific formulary and transaction records would be needed to evaluate such a claim.

Current corporate context also matters. Sanofi's April 2025 Opella transaction announcement said CD&R acquired a 50.0% controlling stake, Sanofi retained 48.2%, and Bpifrance would hold 1.8%.⁴ The report consequently treats the current biopharmaceutical business separately from an independently controlled consumer-health business. Ownership percentages describe governance and investment; they do not allocate a prescription drug's price among those shareholders or resolve historical subsidiary liabilities.

The fresh review also checked Sanofi's July 30, 2026 second-quarter results page, which confirms continuing corporate reporting under the Sanofi identity.¹⁰ Current savings terms, carrying a June 2026 version marker, were opened rather than relying solely on the broad language of a 2023 press release.⁶ Those terms can change; the cited eligibility information describes the version checked for this edition.

The historical enforcement releases remain records of settled civil allegations. This review found no basis in the selected materials to recast either proceeding as a criminal conviction. It did not conduct an exhaustive review of every Sanofi lawsuit or verify the completion of all integrity-agreement obligations. The current assessment is intentionally bounded: documented historical reimbursement concerns, concrete published affordability measures, and unresolved questions about actual patient experience. Neither a settlement total nor a savings-program headline can substitute for that fuller picture.

6. Implications, methods, and a practical evidence agenda

A useful Pharma Foundation follow-up would build two complementary datasets. One would compare exact insulin products and payment routes over time, using dated list-price sources alongside independently observed patient costs where permission and privacy safeguards allow. The other would record assistance-program terms, including eligibility, quantity limits, renewal requirements, government-coverage restrictions, and whether multiple products must be filled together. These are proposed projects, not datasets represented as completed in this report.

For the historical cases, the most valuable additional records would be the actual settlement agreements, underlying reimbursement calculations, and any public integrity-monitoring outcomes. The DOJ releases identify the allegations and announced remedies, but they do not supply a complete transaction-level record. Those gaps do not permit an assumption that the settlement equals total harm, total revenue, or the number of affected patients.

A comparison of assistance programs should also examine access to information. A program can exist without being easy to use. Relevant questions include whether a patient can find the correct enrollment route, understand the benefit without reading contradictory summaries, and obtain help when an application fails. This review read published webpages and terms; it did not enroll a patient, submit personal data, test a pharmacy claim, or measure processing delays. Those unperformed steps should not be described as validated access outcomes.

Research used primary government announcements, official company transaction statements, current program terms, a company pricing report, and Medicare guidance. Sources were read for dates and definitions. Civil allegations remain attributed. Manufacturer claims remain labeled as company disclosures. A fresh search located 2026 materials and the 2025 corporate change so the analysis would not present an old press release as the whole current picture.

The principal limitations are missing net transaction prices, no patient interviews, no causal evaluation of list-price cuts, and no comprehensive litigation or compliance audit. Portfolio averages are not product-level observations. Global principles are not country-specific price schedules. U.S. assistance terms do not apply automatically elsewhere. The report neither recommends treatment changes nor claims that an advertised program will suit a particular person's coverage.

This is a new research edition, not a recovered historical publication or independent evidence of past Pharma Foundation impact. Its substantive contribution is to make the chain of accountability visible: a price or subsidy begins with one actor, passes through a reimbursement or assistance arrangement, and may affect another actor differently. Reporting each step accurately is more useful than treating every low price as successful access or every financial transfer as misconduct. Future updates can strengthen the account by adding observed outcomes while preserving the distinctions already established by the public record.

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