

Amgen: biologic competition, patient assistance and negotiated prices

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1. Executive assessment: several distinct access questions

Amgen is a biotechnology company whose current portfolio spans general medicine, inflammatory disease, cancer and rare conditions. Its August 2026 financial release includes established products such as Enbrel, newer medicines and products brought into the company through Horizon Therapeutics. It also reports sales of biosimilars, including Amjevita/Amgevita and Pavblu. This combination makes a single description of Amgen as either an incumbent or a challenger inadequate: its commercial position depends on the medicine and market being examined.¹

This report addresses three separate mechanisms relevant to drug access. The first concerns promotion and reimbursement integrity, illustrated by the 2012 Aranesp criminal case and accompanying civil resolution. The second concerns the independence of charitable assistance, examined through the 2019 settlement over Sensipar and Kyprolis. The third concerns competition and purchasing power, including the conditions imposed on the Horizon acquisition and the first Medicare negotiated price for Enbrel. These mechanisms operate at different points between manufacturer, insurer, clinician and patient.

The strongest established misconduct in the selected record is Amgen's accepted guilty plea in the Aranesp matter. The broader civil allegations settled alongside it should not be described as additional convictions. Similarly, the 2019 assistance settlement resolved disputed allegations without a determination of liability. The Horizon order imposed prospective restrictions while expressly preserving the companies' denial of substantive wrongdoing.^{2,3,6}

The access question is consequently more precise than whether a company has paid a large settlement. Promotional incentives can affect reimbursed utilization. Assistance can reduce a patient's immediate expense while leaving the underlying payer expenditure intact. Contracting across a portfolio can affect whether a competing product reaches covered patients. A negotiated manufacturer price can change Medicare economics without becoming a universal cash price. Each deserves its own evidence and outcome measure.

The report's main assessment is that meaningful transparency requires connecting legal events to the relevant payment channel. It does not estimate a total amount of patient harm, attribute every medicine's price to the historical cases, or evaluate whether any individual should receive a particular treatment. Current company disclosures provide useful evidence of changing net revenue, but they do not reveal every payer contract or household's costs. That limitation is central to interpreting the findings, rather than a reason to overlook the documented events.

2. Timeline: promotion, assistance and portfolio expansion

In December 2012, a federal judge accepted Amgen's guilty plea for introducing misbranded Aranesp into interstate commerce. The combined resolution totaled \$762 million: \$136 million in criminal fines, \$14 million in criminal forfeiture and \$612 million to resolve civil False Claims Act allegations. The criminal conduct involved intended uses and dosing that FDA had not approved. The civil component covered additional promotion, kickback and price-reporting allegations involving several products.²

The distinction between marketing and prescribing matters. This was a case about the manufacturer's conduct and the legal conditions for marketing and reimbursement. It is not a finding that every use outside a label is unlawful, that every prescription was medically inappropriate, or that the medicine lacked approved uses. Collapsing these issues would obscure what the government actually established.

In August 2016, FDA approved Sandoz's Erelzi, a biosimilar referencing Enbrel. FDA's current Purple Book identifies the original approval date as 30 August 2016 and lists the reviewed presentations with a discontinued marketing status. The database establishes regulatory identity and status; it does not itself establish a launch date, transaction price or the reason for commercial availability limitations.¹⁰

In April 2019, Amgen agreed to pay \$24.75 million to resolve allegations concerning donations connected with Sensipar and Kyprolis assistance. DOJ attributed some Kyprolis conduct to Onyx, which Amgen acquired in 2013, and some subsequent donations to Amgen. Amgen disputed the government's characterization and stated that the agreement contained no admission of liability.^{3,4}

The Horizon acquisition produced a different kind of intervention in 2023. The FTC challenged the possibility that a larger portfolio would enable contractual exclusion of future rivals to Tepezza and Krystexxa. A proposed settlement was announced in September; the Commission issued its final order on 13 December 2023. The FTC case record now lists the matter as closed and records appointment of a monitor.^{5,6,7}

Finally, Enbrel was included in the first Medicare negotiation cycle, with an agreed price applicable from January 2026. The August 2026 earnings release reports a decline in Enbrel's net selling price and attributes it partly to that policy and partly to a change in 340B program mix.^{1,9} The sequence shows why a dated report is necessary: a historical price or market description cannot simply be carried forward into the present.

3. What the enforcement evidence establishes

The 2012 criminal and civil proceedings should be separated even though they were announced together. The accepted Aranesp plea provides a firmer basis for describing proven conduct than the civil allegations. DOJ also alleged inaccurate reporting of Average Sales Prices, Best Prices and Average Manufacturer Prices. Those are program-specific reporting concepts, not interchangeable labels for a pharmacy's price. The settlement addressed government claims associated with those practices; it did not publish a patient-level overcharge ledger.²

This distinction has practical analytical consequences. A reimbursement-reporting problem can affect a public program's payment calculation even when an individual prescription's copayment is fixed. Improper promotion can increase spending through additional utilization or dosing rather than a change in the posted unit price. A pricing report that looks only for annual list-price increases would miss both pathways. Conversely, the existence of these pathways does not establish their magnitude without transaction and utilization data.

The 2019 assistance allegations illustrate another pathway. DOJ alleged that a Sensipar fund was designed to cover only that medicine for a period, and that Kyprolis-related support included travel assistance and information used to tailor donations. The resolution required a five-year corporate integrity agreement with measures intended to protect assistance-program independence. DOJ expressly stated that the settled claims were allegations only and that liability had not been determined.³

Amgen's response is material to the record. The company said it disagreed with the government's factual and legal view and characterized the donations as support for patients obtaining their medicines.⁴ Neither this position nor the settlement amount resolves how much assistance benefited particular patients. The immediate patient benefit and the financing arrangement's legality are separate questions. A patient receiving help is not, by that fact, responsible for a donor's alleged conduct.

The Horizon matter was prospective merger enforcement. The FTC's theory was that rebates on established Amgen medicines could be tied to favorable treatment of Tepezza or Krystexxa and thereby disadvantage emerging competitors. The consent framework prohibits specified bundling and conditional rebate practices and requires monitoring.⁵ Its final text records denial of the charges and no admission of substantive allegations.⁶

Analytically, the order identifies a risk that can exist before a rival loses a sale. It is not evidence that the feared conduct occurred after closing. Nor does an order directed at two products establish that every Amgen rebate is exclusionary. Evaluating compliance would require the relevant contracts and monitor findings, which this public-source review has not obtained.

4. Enbrel: interpreting the numbers without overstating savings

CMS's first-cycle publication provides a defined comparison for Enbrel: an agreed 2026 price of \$2,355 for a 30-day equivalent supply against a 2023 list-price measure of \$7,106. CMS reports a 67% discount in that comparison. The source identifies the list-price measure as wholesale acquisition cost, standardized using prescription-fill information; it is not the amount every purchaser previously paid. CMS also reports approximately 48,000 Part D enrollees using Enbrel and about \$2.95 billion in gross covered drug costs during 2023.⁹

Measure	Amount	Meaning
2023 Enbrel list-price comparator	\$7,106	CMS 30-day standardized WAC measure
Agreed price applicable in 2026	\$2,355	Medicare negotiated 30-day equivalent price
CMS-reported comparison	67%	Discount from the specified 2023 list comparator
2023 Part D users	About 48,000	Historical Medicare population, not all users

These published figures are reproduced without creating a new estimate. Multiplying the difference between the two prices by every historical fill would not establish realized savings. The older comparator excludes the confidential rebates that reduce net spending, utilization can change, and the applicable population has limits. The comparison is meaningful only within these definitions.

The earnings data answer a different question. For the second quarter of 2026, Amgen reported Enbrel sales of \$580 million, down 4% year over year. It attributed a 22% reduction in net selling price to Medicare negotiation and increased 340B mix, while favorable changes in estimated sales deductions partly offset the revenue effect.¹ This is company-reported accounting information covering the product's commercial results; it is not a controlled estimate of the policy's effect.

The public evidence is consistent with a material change in manufacturer realization, but it does not isolate the contribution of each cause. Payer mix and adjustments to earlier sales estimates can change reported net price without matching a contemporaneous sticker-price change. An analysis that equates the 22% net-price movement with a 22% reduction in every patient's bill would be incorrect.

For access monitoring, the next useful measurements would be the proportion of eligible prescriptions successfully filled, patient payment distributions, prior-authorization outcomes and treatment interruptions. These should be stratified by insurance type and period. The present sources do not supply that linked dataset, so this report stops at the observed policy terms and disclosed financial effects. It does not promise a particular out-of-pocket amount to readers.

5. Company positions and the status of competition in 2026

Amgen said in September 2023 that it had no reason, ability or intention to bundle Tepezza or Krystexxa with its other products, and that formalizing this assurance would not affect its business. That statement explains the company's rationale for accepting the Horizon settlement; it is not independent verification of all subsequent contracting.⁸ The final order lasts 15 years from issuance, subject to its terms, while the FTC docket's closed status refers to the proceeding rather than the disappearance of compliance obligations.^{6,7}

The outcome was a merger permitted under conditions. Calling it a blocked merger would ignore consummation of the business combination reflected in current operations. Describing the company as cleared of all concerns would erase the binding restrictions. A consent outcome can preserve a transaction and impose meaningful obligations without a trial verdict resolving the underlying economic theory.

The same care applies to patient assistance. The 2019 government announcement specified a five-year integrity agreement. This review has not independently established a formal closeout determination or the outcome of every monitoring obligation. It therefore describes the agreement historically and does not label Amgen as currently under that particular agreement simply by extending an old press release into 2026. Nor does it assume that passage of the stated term proves every requirement was satisfied.³

Biosimilar status also needs more than an approval headline. Erelzi's FDA listing establishes that a biosimilar was approved and supplies the current marketing-status field reviewed for this report.¹⁰ It does not support a claim that inexpensive Erelzi prescriptions are available at every American pharmacy. Patent litigation, commercial strategy, manufacturing and coverage can each affect entry, but this report has not reconstructed the complete etanercept patent docket and does not assign a cause from the database alone.

Amgen itself sells biosimilars in other markets, as reflected in its current product results.¹ That is relevant because competition policy should assess conduct and market conditions, rather than assign an enduring moral category to a manufacturer. A company can seek access against an incumbent for one molecule and defend an established franchise for another.

As of the research cutoff, the selected current sources establish an operating Amgen portfolio that includes former Horizon products, a binding historical merger remedy and financial effects associated with the first year of Enbrel negotiation. They do not establish universal affordability, a current violation of the merger order, or a comprehensive verdict on the company's access practices.

6. Implications and method: follow the payment channel

The evidence supports three priorities for a transparency organization. First, preserve the legal status of each event. A criminal plea, a disputed civil settlement and a prospective merger order have different legal meanings. Otherwise, a summary can become materially misleading even when every dollar figure is individually correct. The source register accompanying this edition records those differences.

Second, present assistance and affordability as related but distinct measurements. A sound public dataset would record who funds an assistance program, how independently eligibility is determined, which medicines qualify and what share of applicants receives support. A separate dataset would examine the insurer's net spending and the patient's own payment. Combining them into a single “savings” figure could conceal whether expenditure was reduced or shifted between parties. This is an analytical recommendation, not a conclusion that every manufacturer-supported program has the problems alleged in the 2019 case.

Third, connect competition claims to observable access outcomes. A product's regulatory approval, legal ability to launch, actual commercial availability, formulary position and patient uptake are successive stages. Evidence at one stage should not substitute for evidence at the next. The Erelzi record is especially useful for teaching this distinction because a dated approval and a current marketing-status field can coexist without providing a complete explanation of commercial history.

This report used primary government records, FDA product information, CMS price documentation and direct company statements. Recent searches were followed by review of the August 2026 earnings release and the FTC's case record. Source selection was directed toward promotion, assistance, competition and negotiated prices; it was not an exhaustive review of every Amgen product, lawsuit or clinical study. The analysis makes no independent judgment about individual treatment selection.

No confidential net-price contracts, claims-level patient records or monitor reports were obtained. Consequently, no causal estimate of household savings or aggregate historical harm is offered. The financial amounts have their original dates, currencies, units and procedural meanings. Settlement payments are not treated as profits or automatically converted into patient losses. Published percentages are attributed rather than recalculated from rounded inputs.

The most defensible conclusion is that Amgen's record contains documented enforcement, disputed assistance claims and important current changes in purchasing arrangements. Clear reporting can explain those developments without confusing corporate revenue with patient affordability. Realized access data and evidence about the continuing operation of remedies could strengthen the outcome assessment beyond the history documented here.

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