

Mallinckrodt: Acthar Pricing, Public Rebates, and Accountability After Restructuring

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1. Executive assessment and the current corporate boundary

The historical Mallinckrodt name now requires an explanation. Mallinckrodt and Endo combined in July 2025; the combined generics and sterile-injectables businesses were separated as Par Health in November 2025. The remaining branded-therapeutics business became Keenova Therapeutics. Its current financial disclosures distinguish continuing branded operations from the separated business.^{1,2} This report retains “Mallinckrodt” in the title because that is the name in the historical Acthar enforcement record, while identifying the contemporary organization accurately.

The central medicine in this review is H.P. Acthar Gel, or repository corticotropin injection. The record raises three distinct access questions: whether acquiring development rights to a potential rival preserved market power; whether Medicaid received the inflation-related rebates it was owed; and whether manufacturer-funded patient assistance improperly supported reimbursed purchases. These questions involve competition, public financing, and conflicts in assistance design respectively. They should not be reduced to one claim that the medicine's entire price was illegal.

In 2017, a stipulated court order resolved FTC and state charges concerning Questcor's acquisition of Synacthen rights. The order required monetary relief and a development sublicense but expressly stated that it was not an admission of liability or wrongdoing and resolved the matter without trial.³ In 2022, a separate \$260 million settlement addressed Medicaid rebate and copay-assistance allegations. The company admitted a specific fact about Acthar's historical marketing date and agreed to correct the rebate baseline; the broader claims remained allegations without a determination of liability.⁵

Financial restructuring adds another layer. Mallinckrodt's 2023 filing distinguishes revised opioid settlement obligations from the Acthar settlement and integrity agreement, which were treated as unimpaired.⁷ It would therefore be inaccurate to say bankruptcy eliminated every obligation or, conversely, that every earlier opioid payment promise continued unchanged.

Assessment. The strongest public-interest conclusion is that access depends on the integrity of several systems at once: competitive entry, accurate rebate reporting, genuinely independent assistance, and enforceable remedies. This report documents how those systems intersected in the Acthar record and identifies the limits of the available evidence. It does not estimate an individual patient's appropriate treatment, attribute all historical conduct to today's portfolio, or present a settlement amount as a precise measurement of total patient harm.

2. Historical context: Questcor, Acthar, and the sequence of cases

The 2017 FTC complaint describes Questcor's acquisition and subsequent pricing of Acthar, followed by its acquisition of U.S. rights to develop Synacthen, a potentially competing synthetic ACTH product. The FTC alleged that controlling those rights obstructed another company's route to developing a competing medicine.⁴ The complaint is the government's theory of the conduct, and its allegations must be distinguished from the later consent remedy.

Mallinckrodt acquired Questcor in 2014, according to the stipulated order's corporate definitions. The order identifies Questcor under its later Mallinckrodt ARD name, which provides the entity link between the earlier conduct and the 2017 defendants.³ This distinction matters for historical precision: the product's history predates both the acquisition and the current Keenova identity.

Date	Documented development	Why it matters
2013	Questcor obtains Synacthen rights	Basis of later competition allegations
2014	Mallinckrodt acquires Questcor	Establishes historical corporate relationship
January 2017	Stipulated FTC/state order entered	Monetary relief and licensing remedy
March 2022	Federal Acthar settlement approved	Rebate correction and integrity obligations
2023	Further financial restructuring	Different treatment of opioid and Acthar obligations
July-November 2025	Endo combination and Par Health separation	Current branded business becomes Keenova

Sources: court order, FTC complaint, DOJ, and company filings.^{1,3,4,5,7}

The FTC case and the Medicaid case concerned different mechanisms. The first focused on a potential competitor's development rights. The second concerned the calculation of government rebates and related assistance arrangements. A company can face scrutiny under both systems, but a remedy in one does not automatically settle the other. That is why separate case identifiers and instruments matter more than a cumulative list of negative headlines.

The chronology also cautions against treating a license as an immediately available treatment alternative. A development-rights remedy creates an opportunity and imposes obligations; it does not itself establish FDA approval, commercial stock, insurer coverage, or patient uptake. Likewise, a bankruptcy plan's approval changes obligations under specified terms, but does not show how every recipient ultimately used the resulting funds. This report records those legal and corporate milestones while leaving unsupported outcome claims out of the narrative. Each later update should identify the exact event that changed, rather than silently moving an old allegation into the present tense.

3. Principal evidence: competition, rebates, and assistance

The FTC settlement record is unusually useful because the actual court order is available. It resolves the action without final adjudication and establishes a sublicense framework covering development and commercialization in specified fields. Its definitions include manufacturing technology, regulatory information, and other assets necessary to support development.³ That detail shows why effective entry may require more than a bare patent license: a prospective competitor may also need technical and regulatory material. The order is evidence of the agreed remedy, not a guarantee of its eventual commercial success.

The FTC case summary identifies the agreed \$100 million payment and explains the agency's concern about the acquisition of a potential rival to Acthar. Its timeline records court entry of the order and subsequent sublicense-related action.⁸ Those procedural milestones are more precise than presenting the initial announcement as an unresolved proposal or calling the payment a criminal fine.

DOJ's 2022 Acthar announcement describes alleged rebate underpayments from 2013 through 2020. It says the company treated the medicine as newly marketed in 2013 for baseline purposes, excluding earlier price increases from the calculation. In the settlement, Mallinckrodt acknowledged that Acthar was not new in 2013 and had been marketed before 1990, and agreed to correct the baseline. The announcement also describes allegations involving a charitable foundation and copay subsidies.⁵

The related integrity agreement separately defines government-pricing, promotional, and assistance functions and specifies compliance oversight. These categories are important because a charitable contribution, a price submission, and a sales communication can each affect public spending through different pathways. The agreement's principal compliance term is five years, and the OIG's current listing estimates completion in March 2027.^{6,9}

New analysis. The rebate issue demonstrates why transparency about a current price is incomplete without the historical inputs used in reimbursement formulas. A published price can be visible while the baseline determining public rebates is wrong. The assistance issue raises a different concern: relief at the pharmacy counter can coexist with increased program spending if assistance steers purchases toward a particular product. These are mechanisms to investigate, not evidence that all assistance is improper. A fair account asks who controls eligibility and funding, which products qualify, and what the arrangement does to purchasing incentives. It does not equate the mere existence of financial help with misconduct.

4. Pricing and access: the numbers and their limits

The FTC complaint alleged that Acthar's per-vial price rose from approximately \$40 in 2001 to more than \$34,000 by the period of the 2017 case. It also described a course of treatment requiring multiple vials.⁴ These are historical figures attributed to the complaint. They are not a current 2026 pharmacy quotation, a manufacturer's present net receipt, or a universal out-of-pocket cost. This report does not turn the rounded endpoints into an exact new percentage calculation.

The difference between price levels and financial remedies is equally important. The \$100 million competition settlement and \$260 million federal Acthar agreement address different claims.^{5,8} They cannot be interpreted as the total revenue generated by the medicine or the exact amount patients overpaid. A settlement can reflect litigation risk, financial capacity, allocation rules, and negotiated releases. Those factors make the headline amount unsuitable as a substitute for an economic damages model.

The Medicaid dispute shows why the price concept must be named. The base-date average manufacturer price is an input to a statutory rebate calculation; it is not simply a consumer's retail bill. The government alleged that resetting the historical baseline reduced inflation-related rebates owed to Medicaid.⁵ A public-program financial consequence can therefore occur even when the patient's immediate copayment is unchanged. Conversely, a patient may experience affordability barriers not visible in the manufacturer's rebate obligation.

Keenova's August 2026 release reports Acthar second-quarter net sales of approximately \$205 million, up 17% from the prior-year quarter, and attributes the change to demand, payer mix, product-device uptake, and execution.¹⁰ Net sales are a company revenue measure. Dividing that amount by an assumed course price would not produce a reliable patient count, because treatment patterns, concessions, timing, and presentation mix are not specified in such a calculation.

New analysis. A useful follow-up access study would separately measure coverage decisions, time to prescription fulfillment, quantities dispensed, and patient payments for a defined indication and setting. It would compare equivalent product presentations and disclose how rebates were handled. If the study examined the effect of a competing product, it would need an explicit market-entry date and an appropriate comparison period. The existing legal documents justify asking these questions; they do not provide the patient-level dataset needed to answer them. The report therefore uses historical figures to establish context while avoiding an invented contemporary affordability estimate.

5. Outcomes, restructuring, and the company's current position

The 2023 annual filing records that remaining opioid-related deferred settlement obligations were replaced under specified restructuring terms, including a \$250 million payment and contingent value rights. It separately states that the Acthar settlement and associated integrity agreement were unimpaired, and that nonmonetary opioid-related obligations were generally preserved.⁷ This is a concrete example of why “bankruptcy canceled the settlement” is too broad. The relevant question is which obligation, owed by which entity, changed under which instrument.

Those contingent rights subsequently changed again. Keenova's 2025 annual report records their cancellation on 10 November 2025 under an agreement providing a \$35 million payment to the Opioid Disbursement Trust II.¹ The 2023 contingent-rights arrangement therefore should not be presented as still outstanding in September 2026. This later transaction is separate from the continuing Acthar integrity obligations.

For the 2017 competition matter, the company's legal position is contained in the order itself: the settlement was not an admission of liability or wrongdoing.³ For the 2022 matter, the specific baseline acknowledgment should be retained alongside DOJ's statement that there was no determination of liability on the broader claims.⁵ Presenting either a blanket denial or a blanket adjudication would lose that distinction.

Keenova's first-quarter 2026 release described improved patient access as contributing to Acthar growth beginning in the second quarter of 2025.¹¹ This is a company-reported explanation, not an independently validated access study. It is relevant and should be included with attribution. A critical report need not ignore favorable company information; it should apply the same questions about definitions and measurement that it applies to adverse claims.

The August 2026 release reports plans for an NYSE listing in 2027.¹⁰ A contemporaneous SEC filing confirms that the Percocet and Endocet sale to Par Health closed on 31 July 2026, while complete cessation of opioid marketing, manufacturing and distribution follows completion of related transition services.¹² That listing plan supersedes an earlier intention to seek a 2026 listing. It is a plan rather than a completed listing, and leaving it out of a historical report would be preferable to describing it as accomplished. The current operating identity remains Keenova, with the separated Par Health business outside its continuing branded results.^{1,2}

As of September 2026, the most relevant remaining uncertainties concern performance rather than existence of obligations: compliance with the Acthar integrity agreement, payment status under the surviving settlement, and observable patient-access effects. This report does not certify those outcomes. OIG's March 2027 estimated completion date establishes a monitoring horizon, not an endorsement of every current practice.⁹ The corporate name change likewise does not establish that historical remedies vanished. The report preserves both continuity of the public record and the changed perimeter of the current business.

6. Implications, methodology, and limitations

This is new research prepared for Pharma Foundation in September 2026. It is not a recovered historical company report and does not establish earlier student or volunteer contributions. The source set was selected to connect original allegations, the entered competition order, the federal settlement announcement, the integrity agreement, historical restructuring disclosures, and current company reporting. Each source is used for the specific claim it can establish.

The analysis separates legal outcomes from economic outcomes. A consent order establishes duties; it does not prove every disputed allegation. A factual acknowledgment about a rebate baseline has a narrower scope than an admission to all alleged misconduct. A financial filing describes accounting and legal obligations but does not independently measure patient experience. A company statement about improved access is relevant evidence of its position, while the underlying definition and data remain necessary for validation.

The report's principal limitation is the absence of transaction-level and patient-level data. It does not measure net acquisition prices across payers, denied claims, unmet need, or clinical outcomes. Nor does it independently review the entire developmental history of Synacthen or every contemporary ACTH product. Consequently, it makes no claim that the 2017 remedy achieved a specified price reduction, that a particular alternative is clinically preferable, or that all historical spending was unnecessary.

A focused next study could reconstruct one public program's Acthar coverage and spending over a defined interval, with clear treatment of rebates and product quantities. Another could examine the implementation of the development-rights remedy, distinguishing licensing, clinical development, approval, and commercial availability. Those are different research projects with different evidence requirements. Combining them into a single unsupported figure would conceal rather than resolve uncertainty.

The practical lesson for drug-pricing transparency is that visible prices, hidden calculation inputs, market structure, and financing arrangements belong in the same inquiry but must remain separate measurements. Mallinckrodt's history shows why both the front end of access - whether a medicine can be obtained - and the back end - who pays and under what rules - matter. The current Keenova identity and intervening restructuring make careful attribution even more important. A credible nonprofit account can describe the concerns directly, include company positions, identify the actual remedies, and leave a clear trail for updating claims when new public evidence becomes available.

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