

Endo: generic entry, opioid marketing and corporate succession

Research checked: 9 September 2026. Publication date: 9 September 2026. New research edition.

1. Executive assessment: identifying the business before assessing it

“Endo” now identifies a complicated corporate history rather than one unchanged operating company. The current Endo website states that Endo and Mallinckrodt merged on 31 July 2025, then separated the generics and sterile-injectables business as Par Health in November 2025. The remaining specialty business became Keenova Therapeutics. The site describes Keenova and Par Health as separate companies.¹ This account uses the historical name while distinguishing old misconduct, present product ownership and current corporate responsibility.

An additional transaction occurred during 2026. Keenova's SEC filing confirms that its Percocet and Endocet businesses were sold to Par Health on 31 July 2026. The filing says Keenova will cease marketing, manufacturing and distributing opioids after related transition services are completed.² The qualification matters: closing a sale and completing every operational handoff are distinct events. Neither event, by itself, determines the fate of historical liabilities.

The selected record presents two major access issues. One concerns generic competition, including the Endo-Impax agreement over Opana ER. The other concerns truthful promotion and the public-health consequences of marketing reformulated Opana ER with unsupported abuse-deterrence claims. A separate Lidoderm marketing resolution illustrates how promotion can affect reimbursement without changing a medicine's posted price.

The most definitive recent outcome is the 2024 criminal conviction and sentence of Endo Health Solutions Inc., or EHSI. DOJ reported an accepted misdemeanor guilty plea and a \$1.536 billion criminal fine-and-forfeiture judgment. Crucially, the sentencing announcement also explained that EHSI would not emerge from bankruptcy and that payment was governed by the broader bankruptcy resolution.³ The judgment should not be presented as \$1.536 billion newly paid in cash by today's Keenova or Par Health.

This report treats affordable access and safe, evidence-based access as complementary concerns. Earlier generic availability can reduce commercial barriers, while unsupported safety claims can distort the decisions that create demand. These mechanisms should be examined together without assuming that wider use of any particular opioid is itself a desirable outcome. The analysis concerns company conduct, competition and financing; it provides no individual treatment recommendation.

The main conclusion is that Endo's history requires both a clear legal timeline and a precise corporate map. Without them, a report can attach the right allegation to the wrong entity or confuse a settlement's face value with money available to affected communities.

2. Timeline: from Lidoderm promotion to the Opana resolution

In February 2014, DOJ announced a \$192.7 million Lidoderm resolution involving Endo Health Solutions and Endo Pharmaceuticals. It included a deferred prosecution agreement with \$20.8 million in monetary penalties and forfeiture, plus \$171.9 million in civil settlements. The criminal information concerned marketing during 2002-2006 for uses beyond the approved post-herpetic-neuralgia indication. DOJ distinguished conduct admitted through the deferred prosecution agreement from the remaining civil allegations, for which liability was not determined.⁴

The procedural label is important. A deferred prosecution agreement is not the same disposition as the 2024 guilty plea. Combining the two under a generic heading such as “convictions” would misstate the earlier matter. The Lidoderm marketing resolution also differs from antitrust litigation about generic Lidoderm: the same product name does not mean the same conduct, period or cause of action.

For Opana ER competition, the relevant agreement dates to 2010. The FTC record says Endo settled its charges through a federal stipulated order, while the administrative case continued against Impax. The Commission concluded in 2019 that the agreement violated competition law; the Fifth Circuit upheld that result in April 2021. The Supreme Court denied Impax's petition for review in December 2021.^{5,6,7}

The product's safety history followed a separate track. FDA's official timeline records a request on 8 June 2017 that Endo remove reformulated Opana ER because its benefits might no longer outweigh its risks. Endo announced voluntary withdrawal on 6 July. The company maintained its position that the medicine had a favorable benefit-risk profile when used as intended, while agreeing to coordinate removal.^{8,9}

Bankruptcy later shaped the monetary response to opioid claims. DOJ's February 2024 announcement described a proposed settlement of federal criminal, civil, healthcare-cost and tax claims within the restructuring. By the May sentencing announcement, the bankruptcy plan had been confirmed and operating affiliates had emerged, while EHSI itself would cease operating in its existing form.^{3,10}

Endo's own February 2024 statement distinguished the proposed misdemeanor plea from the civil settlement, which it said contained no admission of liability. It also described strengthened compliance procedures and a voluntary operating injunction continuing through August 2030.¹¹ This is the company's account of its response, not an independent assessment that its compliance systems succeeded.

The 2025 merger, subsequent separation and 2026 product sale complete the current corporate timeline. They distinguish the historical Endo record from the businesses responsible for current products and assistance information.

3. Principal findings: what was established, and against whom

The Opana criminal case establishes a specific marketing failure. EHSI admitted that certain sales representatives promoted purported abuse-deterrent, tamper-resistant or crush-resistant properties between April 2012 and May 2013 without clinical data supporting those claims. DOJ reported that managers knew about these representations and that demonstrations with nonmedicated samples conveyed the claimed resistance. EHSI pleaded guilty on 18 April 2024; the sentence followed on 3 May.³

The admitted facts concern the representation of risk, not merely the medicine's chemical composition. For access analysis, this matters because a claimed safety advantage can influence prescribing and willingness to pay. The record supports scrutiny of that mechanism; it does not quantify how many prescriptions resulted from each sales interaction. A causal estimate would require evidence beyond the criminal resolution, including clinician behavior and an appropriate comparison group.

The civil allegations were broader. DOJ described marketing to high-volume prescribers and alleged that concerns about diversion or inappropriate prescribing were minimized. Those allegations were resolved without a determination of liability except insofar as the criminal admissions applied.¹⁰ The report therefore does not convert the full civil narrative into admitted facts. Doing so would exaggerate the reach of the conviction.

The competition evidence has a different procedural foundation. In the Impax appeal, the Fifth Circuit upheld the Commission's determination under the rule of reason. The opinion describes a delayed generic launch, an agreement not to introduce an authorized generic during Impax's initial exclusivity period, and credits that protected Impax if the original branded market contracted. The court found substantial evidence supporting the competition analysis and the availability of a less restrictive settlement alternative.⁶

An authorized generic is a generic version marketed under the brand's existing approval. An agreement to withhold that competitor can transfer economic value even without a single upfront check. This is why reviewing only cash payments would be incomplete. The value can lie in protection from competition during the first generic's most commercially significant period.

The finding was made in the proceeding against Impax; Endo had separately settled. The FTC record makes that distinction explicit.⁵ The result is meaningful evidence about the agreement, but it is not a new criminal conviction of Endo. Nor does it establish that all patent settlements violate antitrust law. The court's reasoning examines the challenged exchange and its competitive justification, rather than treating settlement itself as misconduct. Preserving that level of specificity makes the report useful for understanding policy rather than merely collecting adverse headlines.

4. Pricing and recovery: do not add unlike dollar amounts

The public record supplies large figures, but few are retail drug prices. They describe forfeiture, civil claims, bankruptcy recoveries, transaction consideration or product revenue. These categories should not be added together into a company “overcharging” total. A fine is a sanction; a damages claim is an asserted entitlement; a bankruptcy distribution reflects available assets and legal priorities. None automatically measures what a patient paid above a competitive price.

Figure	Date and context	Correct interpretation
\$192.7 million	2014 Lidoderm resolution	Combined criminal monetary and civil settlement amounts
\$1.086 billion	2024 Opana sentence	Criminal fine imposed on EHSI
\$450 million	2024 Opana sentence	Criminal forfeiture, with specified trust-payment credits
\$364.9 million plus contingent payment	2024 federal bankruptcy agreement	Scheduled recovery structure across multiple federal claims

The first figure comes from the Lidoderm announcement; the criminal figures come from the later sentencing announcement.^{3,4} They concern different matters and retain their individual labels here.

The federal bankruptcy agreement illustrates the gap between face-value liabilities and recoveries. DOJ described \$364.9 million payable over ten years, with an option to prepay \$200 million at the plan's effective date, plus up to \$100 million dependent on the new business's performance. That structure resolved several categories of government claims. Separately, the government agreed to credit qualifying state, local and tribal opioid-abatement payments against criminal forfeiture.¹⁰ The report has not audited actual receipts or determined which optional payment route was ultimately used.

Accordingly, the criminal forfeiture and credited trust payments must not be counted twice. The word “up to” also cannot disappear from a contingent recovery. Presenting the maximum as guaranteed money received would overstate available funding and mislead readers interested in community access to treatment and prevention resources.

The historical product data are different again. Endo reported Opana ER net sales of \$158.9 million in 2016 and \$35.7 million in the first quarter of 2017 when announcing withdrawal.⁹ Revenue is not a unit price or profit estimate. It depends on volume, product mix and deductions, and it cannot be used alone to infer household affordability.

The antitrust record supports concern about lost competition, but this review does not reconstruct a transaction-level counterfactual price series. No defensible percentage overcharge or patient savings total is calculated here. A future study would need formulation-specific prices, generic entry dates, prescription volumes and payer categories, with the safety-related withdrawal analyzed separately from ordinary competitive entry.

5. Outcomes, company response and the present operating picture

Endo's 2017 withdrawal statement maintained that Opana ER was safe and effective when used as intended and said the company would work with FDA to minimize disruption. It also acknowledged the withdrawal decision and associated accounting effects.⁹ FDA's timeline independently confirms the request and subsequent announcement.⁸ These sources can coexist: one records the regulator's public-health action, the other the company's interpretation and response. The company's position does not negate the later admitted marketing conduct.

In 2024, Endo said it had stopped direct promotion of Opana ER to U.S. healthcare providers in 2016 and stopped selling the product in 2017. It characterized the criminal count as a strict-liability misdemeanor and emphasized that the civil agreement contained no admission. Its statement also described compliance changes and the operating injunction.¹¹ These are relevant procedural and response details, but this review has not tested the effectiveness of the claimed reforms.

The sentencing record confirms that the resolution included operating restrictions and document-publication requirements for the emerging affiliates. It also states that EHSI itself would not emerge.³ That is more precise than saying either that “Endo disappeared” or that the original defendant simply continued under a different name. Assets, operating businesses, creditors and legal entities can follow different paths in a restructuring.

Current public-facing ownership has changed again. Keenova and Par Health are now separate companies following the merger and spin-off.¹ The 2026 sale of Percocet and Endocet is a transfer of business ownership, not evidence that these medicines were withdrawn from the market. Keenova's filing puts the expected total consideration at approximately \$250 million, including \$25 million upfront and future payments related to gross profit, with transition services still relevant to its operational exit.² That expected transaction value should not be mistaken for an opioid settlement or a guaranteed cash receipt.

The report retains “Endo” as its recognizable historical title while explaining the successor businesses near the beginning. Current product and assistance information depends on the present owner, while historical documents retain the legal names used when issued. These distinctions preserve both historical accountability and an accurate understanding of the present businesses.

The available evidence establishes important completed outcomes: a criminal plea and sentence, withdrawal of reformulated Opana ER, an upheld competition decision in the Impax proceeding, and subsequent corporate transactions. It does not establish that every settlement dollar has reached its ultimate beneficiary, that every compliance obligation has been completed, or that current access to all successor-company medicines is adequate.

6. Implications, research method and limits

Endo's history offers a concrete lesson for access research: the route from medicine to patient depends on accurate information, competition and institutional accountability. Unsupported safety claims can alter demand. Delayed generic competition can affect the alternatives available to purchasers. Bankruptcy can determine whether an imposed financial obligation becomes a usable resource for treatment or prevention. These are connected policy issues, but each requires a different measure of success.

A rigorous follow-up would keep three linked records. A product record would distinguish original and reformulated Opana ER, Lidoderm and later transferred products. A legal record would identify the defendant, alleged conduct, disposition, admissions and continuing obligations. A payment record would separate judgments, allowed claims, scheduled distributions, credited payments and confirmed receipts. This proposed structure is an analytical framework derived from the ambiguities in the reviewed evidence; it is not a claim that such a complete dataset was assembled for this report.

For competition, the most valuable additional data would concern actual generic availability and transaction prices by formulation and period. For the opioid resolutions, the next questions concern delivery of abatement funding, documented program uses and outcomes. For present-day navigation, the immediate question is whether patients and researchers are directed to the correct current company. These workstreams should not be collapsed into a single numerical score.

This report reviewed DOJ announcements, an appellate opinion, the Supreme Court docket, the FTC case record, FDA's historical timeline, Endo's direct statements and a current SEC filing. A fresh search checked the 2026 successor-company transactions. The latest corporate filing is especially important because earlier Endo or Mallinckrodt pages can describe a business configuration that no longer exists.

The review did not obtain complete bankruptcy distribution records, confidential contracts, individual medical records or every relevant patent docket. It does not determine individual causation, prescribe treatment, or assess a patient's entitlement to compensation. No aggregate calculation is made by summing the disparate amounts reported above. The references identify the original sources so that narrower questions can be investigated without treating this narrative as the underlying evidence.

The defensible conclusion is that historical Endo conduct includes established misbranding and a consequential agreement examined in an upheld antitrust proceeding, alongside civil allegations resolved without broader admissions. Corporate restructuring has changed the operating map but has not made the history irrelevant. Reporting the history accurately, while directing current readers to the right business and preserving the limits of the payment evidence, is the most useful contribution this report can make.

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